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Summary of safety and clinical performance

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

Following this information there is a summary intended for patients.

The template of the SSCP is created according to the guidance MDCG 2019-9 rev. 1.

For the VENUS®- and VENUS®nano Spinal Fixation Systems which are class IIb implantable devices, it is hereby confirmed that the SSCP on the Homepage of HumanTech Spine and in Eudamed (if available) is in alignment with the current version of the Technical Documentation (TD).

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1. Device identification and general information

1.1. Device trade name(s)	VENUS® Spinal Fixation System and VENUS®nano Spinal Fixation System
1.2. Manufacturer's name and address	HumanTech Spine GmbH Gewerbestraße 5, D-71144 Steinenbronn
1.3. Manufacturer's single registration number (SRN)	SRN: DE-MF-000010596
1.4. Basic UDI-DI	See Appendix 1
1.5. Medical device nomenclature description / text	Spinal Screw Rod Fixation Devices
1.6. Class of device	Class IIb
1.7. Year when the first certificate (CE) was issued covering the device	2010 (VENUS) 2013 (VENUSnano)
1.8. Authorised representative if applicable; name and the SRN	Not applicable
1.9. NB's name (the NB that will validate the SSCP) and the NB's single identification number	DQS Medizinprodukte GmbH (0297) August-Schanz-Straße 21 60433 Frankfurt am Main Germany Tel: +49 (0)69 95427-0 Fax: +49 (0)69 95427-388 E-Mail: medical.devices@dqs.de

2. Intended use of the device

2.1. Intended Purpose

VENUS

The implants of the VENUS® Spinal Fixation System are intended for posterior mono- or multisegmental fixation, after prior correction if necessary, and immobilization during bony fusion to achieve stabilization of the thoracic, lumbar and iliosacral spine. The VENUS® Spinal Fixation System can be used in an open or a minimally invasive surgical approach. The implants are intended for long-term stand-alone use.

VENUS nano

The implants of the VENUS®nano Spinal Fixation System are intended for mono- or multisegmental fixation, after prior correction if necessary, and immobilization during bony fusion to achieve stabilization of the thoracic, lumbar and iliosacral spine. VENUS®nano is used in a posterior and VENUS®nano VDS in an anterior open surgical approach. Ventral derotation spondylodesis (VDS) with VENUS®nanoVDS can be performed with a minimized incision size. The implants are intended for long-term stand-alone use.

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2.2. Indication(s) and target population(s)

2.2.1. Indication(s)

VENUS and VENUSnano

A treatment of the following diseases and injuries with VENUS® and VENUS®nano Spinal Fixation Systems is only intended if surgical spondylodesis is indicated.

- instabilities
- degenerative disc disease
- (degenerative) spondylolisthesis
- (degenerative) stenosis (spinal canal stenosis, neuroforaminal stenosis)
- deformities as (idiopathic) scoliosis, kyphosis or lordosis
- pseudarthrosis
- spinal trauma
- tumours
- inflammation (spondylitis, spondylodiscitis)
- conditions requiring revision surgery

2.2.2. Target population(s)

VENUS:

There are no general limitations of the patient population in addition to the defined indications and contraindications. The patient's age may lead to restrictions, e.g. due to immature skeleton in pediatric patients or limited availability of implant sizes. This requires the consideration by an experienced surgeon to assess the suitability of the implant with respect to incomplete growth phase in pediatric patients or infants and other conditions as e.g. the expected activity of the individual patient. Age-related or other comorbidities may limit the surgical success, which requires careful risk-benefit weighting by the responsible surgeon.

VENUSnano:

There are no general limitations of the patient population in addition to the defined indications and contraindications. The patient's age may lead to restrictions, e.g. due to immature skeleton in pediatric patients or limited availability of implant sizes. This requires the consideration by an experienced surgeon to assess the suitability of the implant with respect to incomplete growth phase in pediatric patients or infants and other conditions as e.g. the expected activity of the individual patient. In elderly patients, e.g. comorbidities may limit the surgical success, which requires careful risk-benefit weighting by the responsible surgeon.

The implant sizes of VENUSnano are suitable for patients of small stature. As a Guideline: for patients weighing less than 45 kg at the time of surgery.

2.2.3. Contraindications

Contraindications may be either relative or absolute.

Absolute contraindications

- Suspected or documented allergy or intolerance to the materials used.

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- Medical or surgical condition which would preclude a potential benefit of spinal implant surgery, such as the presence of congenital abnormalities.
- Inadequate tissue coverage over the operative site.
- Inadequate bone stock or bone quality making implant anchoring impossible
- Anatomical structures expected to interfere with the usage of the implant (e.g. extreme anatomic abnormalities) or to impair the instrumentation
- If the implant is expected not being able to perform adequately after implantation.
- If the implant components selected for use would be too large or too small to achieve a successful result.

For minimally invasive/percutaneous procedures only:

- Severe neural deficits, which require canal decompression

Relative contraindications

Relative contraindications are conditions that may decrease the surgical success and its outcomes. The responsible physician has to weigh the risks and benefits of an implantation in each individual case. If the implantation is performed despite the presence of a relative contraindication, special care or procedures may be required.

- Fever or leucocytosis
- Acute or chronic infection
- Significant risk of infection (e.g. in case of immune deficiencies)
- Signs of local inflammation
- Open wounds
- Wound healing disorders
- Pregnancy: Operations on pregnant women must be avoided if possible. If they are nevertheless performed, they require special care or procedures.
- If the use of components other than the metals or alloys used in this system is required.
- Local bone tumors
- Concomitant diseases or conditions that could negatively affect the function and success of the implant, e.g.
 - advanced age
 - smoking
 - diabetes
 - osteoporosis, osteopenia, osteomalacia, joint disease, bone absorption
 - obesity
 - chronic kidney disease
 - depression or conditions of reduced mental health
 - neuromuscular diseases that would place excess strain on the implant during the healing period.
- If the patient is unwilling or not able to follow postoperative instructions.

For minimally invasive/percutaneous procedures only:

- All the situations causing difficulty in imaging such as rotational deformities, obesity and osteopenia
- Multilevel vertebral fractures
- Pedicle fractures
- Adjacent body fracture

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- Patient with significant kyphosis or sagittal malalignment

3. Device description

3.1. Description of the device

VENUS® Spinal Fixation System

The VENUS® Spinal Fixation System includes pedicle screws, rods, set screws, transverse connectors, rod connectors, and extension units to form appropriate spinal screw-rod constructs depending on the application.

The implant system is used for surgical stiffening of spinal segments by spondylodesis. The pedicle screws of the VENUS® Spinal Fixation System are placed in the left and right pedicles of the vertebrae and then connected to a rod on each side. The essential function of the resulting screw-rod construct is to offer a fixed scaffold that is able to take off strain of the vertebral bodies in the treated segment so that the natural process of bone fusion is as undisturbed as possible. Once the fusion is complete, the implants have no longer any active function but can remain in the body for the long-term. The use of the VENUS® Spinal Fixation System should lead to clinical benefit for the patient by improving its quality of life through pain reduction, clinically relevant improvement in function, and/or stabilization to support the natural curvature.

The VENUS® Spinal Fixation System is supplemented by several kits of additional implants and/or instruments for specific applications, e.g. the extension of an already implanted VENUS Spinal Fixation System (VENUS®Extension), minimally invasive surgery (VENUS®mini 2.0, VENUS®mini 2.0 Fracture), the treatment of complicate deformities as scoliosis (VENUS®Scoliosis), facilitated rod-to-screw approximation under difficult anatomic or surgical conditions by using long-head screws (VENUS®Reduction) or augmentation in cases of low bone quality (VENUS®Augmentation). For each application, refer to the corresponding brochure.

The pedicle screws of the VENUS® Spinal Fixation System includes polyaxial, monoaxial and iliac screws. The screw types are either solid, cannulated, or fenestrated and are available in various forms, different lengths, and diameters to meet the patients' individual pathologies. Polyaxial screws are further available in short and long-head configurations. Long-head screws (Reduction Screws) allow for facilitated approximation of the rods to the screws in difficult anatomic or surgical situations. Cannulated and fenestrated screws of the VENUS® are suitable for minimally invasive surgery with the integrated VENUS®mini set and can be placed via a guide wire. Fenestrated screws contain a series of fenestrations which allows bone cement (e.g. polymethylmethacrylate (PMMA)) to be injected into the treated site to increase screw fixation in cases of reduced bone quality (augmentation).

VENUS® rods are available in titanium alloy or cobalt chrome. Cobalt chrome offers higher strength than the titanium alloy. Titanium alloy rods are available in straight or pre-curved configurations and in various lengths. To extend an existing construction, Inline Rod Connectors, Domino Connectors, Parallel Connectors or Revisionsconnector Cap can be used. Lateral Connectors can be used for connecting an Ilium Screw or other offset constructions. Further, transverse connector hooks are available which are placed at a 90° angle to the rod construct in order to increase the rotational stability of the entire frame construct.

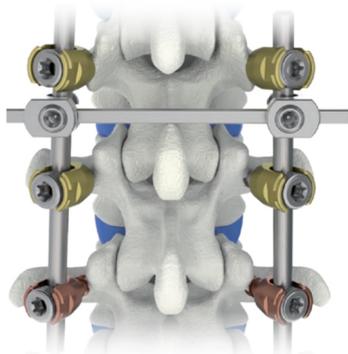
The VENUS® Spinal Fixation System can also be used as additional posterior support for interbody fusion systems (e.g. ADONIS® Lumbar Interbody Fusion System) or vertebral body replacement systems (e.g. SAMSON® Vertebral Body Replacement System).

The HumanTech instruments and accessories, intended for use with the implants of the VENUS® Spinal Fixation System, and the surgical techniques for the specific applications are described in the corresponding brochures and are mandatory for implantation.

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Source: Brochure VENUS® Fixation

VENUSnano

The VENUS®nano Spinal Fixation System consists of rods, pedicle screws, set screws, connector elements and washers.

The implant system is used for surgical stiffening of spinal segments by spondylodesis. The pedicle screws of the VENUS®nano system are placed in the left and right pedicles of the vertebrae and then connected to a rod on each side. The essential function of the resulting screw-rod construct is to offer a fixed scaffold that is able to take off strain of the vertebral bodies in the treated segment so that the natural process of bone fusion is as undisturbed as possible. Once the fusion is complete, the implants have no longer any active function but can remain in the body for the long-term. The use of the VENUS®nano system should lead to clinical benefit for the patient by improving its quality of life through pain reduction, clinically relevant improvement in function, and/or stabilization to support the natural curvature.

The implant sizes of VENUSnano are suitable for patients of small stature. As a Guideline: for patients weighing less than 45 kg at the time of surgery.

VENUS®nano system includes monoaxial, polyaxial and long-head Reduction Screws. Under difficult anatomic or surgical conditions, Reduction Screws can facilitate the rod-to-screw approximation during rod insertion or repositioning.

VENUS® nano rods are available in titanium alloy or cobalt chrome. Cobalt chrome offers higher strength than the titanium alloy. Titanium alloy rods are available in straight or pre-curved configurations and in various lengths. One transverse connector hook has to be placed on each of the rods of the construct. In addition, a transverse connector rod is placed between the rod and the transverse connector hook in 90° angle to the rod construct. To extend an existing construction, Inline Rod Connectors, Domino Connectors, Parallel Connectors or Revisionsconnector Cap can be used. Lateral Connectors can be used to connect an Ilium Screw or for other offset constructions.

The VENUS®nano VDS kit includes monoaxial screws, washers, rods and set screws for a ventral insertion using a double-rod treatment. A bicortical screw with a minimum diameter of 5 mm should be used for ventral treatment. The screws of the VENUS®nano VDS kit are screwed directly into the vertebral body. LP Washers are used to prevent screw loosening during lateral screw-rod fixation with two parallel 4.5 mm rods.

Various forms and sizes of the VENUS®nano and VENUS®nano VDS implants are available to meet the patients' individual pathologies.

The HumanTech instruments and accessories, intended for use with the implants of the VENUS®nano system, and the surgical techniques for the specific applications are described in the corresponding brochures and are mandatory for implantation.

Implants of the VENUS® and VENUS®nano Spinal Fixation System are intended for single use only and are available as sterile and non-sterile version. The sterile is sterilized by gamma irradiation.

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Materials in contact with patient tissues

All components of the VENUS® Spinal Fixation System and VENUS®nano Spinal Fixation System including all components of preassembled assemblies, but except CoCr rods, are made of titanium alloy Ti6Al4V according to DIN EN ISO 5832-3.

CoCr rods are manufactured of cobalt-chromium-alloy CoCr28Mo6 according to ISO 5832-12.

The materials are proven materials in implant technology and have been used in clinical practice for decades.

Information on specific substances

Devices of the VENUS® and VENUS®nano Spinal Fixation System do not incorporate, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8) of EU-Regulation 2017/745 (MDR). No further evaluation is therefore required in this regard.

Devices of the VENUS® and VENUS®nano Spinal Fixation System are not manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are covered by the EU-Regulation 2017/745 (MDR) in accordance with points (f) and (g) of Article 1(6). Furthermore devices of the VENUS® and VENUS®nano Spinal Fixation System do not incorporate, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by the EU-Regulation 2017/745 (MDR) in accordance with the first subparagraph of Article 1(10). No further evaluation is therefore required in this regard.

Devices of the VENUS® and VENUS®nano Spinal Fixation System are partially composed of substances or combinations of substances that are intended to be introduced into the human body but are not intended to be absorbed by or locally dispersed in the human body. No further evaluation is therefore required in this regard.

Devices of the VENUS® and VENUS®nano Spinal Fixation System are not containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I of the EU-Regulation 2017/745 (MDR) with exception of CoCr Rods.

3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences

3.2.1. Previous generations

No previous product generations exist.

3.2.2. Variants

No variants are available.

3.3. Description of any accessories which are intended to be used in combination with the device

Accessories of implants

- Surgical Sterilization container (including cover and sterilization filter elements)
- Sterilization fleece/sterilization paper
- Implant tray (including cover) of the VENUS®, VENUS®nano and VENUS®nano VDS system

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- Setscrew Box (including cover) of the VENUS® and VENUS®nano System
- Handles
- MIS Implantbox
- Implant Box

Accessories of VENUS

- Tray VENUS Screw Inlay / -Cover / -Frame
- Torque Drivers
- Rod Bender, Connector Bender
- Derotation Extension DT
- Key Deformity Tower
- MIS Multitool
- MIS Rod Compass
- MIS Assembling Tool

Accessories of instruments Ir / VENUSnano

- Torque Driver

3.4. Description of any other devices and products which are intended to be used in combination with the device

The VENUS® and VENUS®nano Spinal Fixation Systems can be used as an additional dorsal fixation system for the Lumbar Interbody Fusion System (ADONIS®) or the Vertebral Body Replacement System (SAMSON®).

Devices of the VENUS® and VENUS®nano system are not intended for a direct connection to the ADONIS® Lumbar Interbody Fusion System or SAMSON® Vertebral Body Replacement System. Components of the ADONIS® Lumbar Interbody Fusion System or SAMSON® Vertebral Body Replacement System are only intended as an additional lateral and/or anterior support of the complete instrumentation.

Components of the VENUS® and VENUS®nano System are not intended to be replaced by components/products from other systems from another source or from a different manufacturer. Furthermore, no direct connection of components / products of the system to components of other systems may be established. Instruments intended for direct or indirect combined use with VENUS® and VENUS®nano are part of a separate Technical Documentation for instruments including the consideration of the combinations of implants/instruments.

Devices of the VENUS® and VENUS®nano system are not intended to be used in combination with other devices which are not medical devices.

4. Risks and warnings

4.1. Residual risks and undesirable effects

According to the IFU and the Technical Documentation, the following residual risks and side effects are known so far:

The side effects and complications for VENUS® and VENUS®nano Spinal Fixation System listed are not only due to the implants, but often also to the surgical procedure and include, but are not limited to:

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Possibly related to implant:

- Delayed bone growth or no visible fusion and pseudarthrosis, delayed bone healing or lack of bone healing
- Modification of spinal curvature and stiffness of the vertebral column
- Partial loss of the degree of correction achieved during surgery.
- Reduction of bone density due to stress shielding
- Proximal Junctional Kyphosis (adjacent segment degeneration)
- Altered growth of the fused spine
- Fracture of a vertebra, the pedicle, and/or the sacrum, micro fracture, damage to or penetration of a vertebral body above or below the treated segment/s
- Vertebral joint degeneration due to altered biomechanics in the spine
- Allergic reaction to the implant material
- Persistent skin irritations
- Risk of infection or inflammation
- Autoimmune reaction
- Metallosis due to intra- or postoperative abrasion or corrosion with possible secondary chronic-inflammatory foreign body reactions as scar formation, local tissue necrosis, formation of neoplasia/tumours and/or osteolysis
- Breakage, deformation, loosening or migration of the implant
- Local pain, discomfort or abnormal sensitivity
- Pressure sores on the skin caused by components located in positions with insufficient tissue coverage over the implant, with potential penetration of the skin
- Revision surgery
- Stopped growth of the chest wall and lungs, with associated consequences.

Possible risks of augmentation:

- Allergic reaction to the bone cement used
- Cement leakage (possibly leading to neurological impairment, cement embolism, local pain and/or inflammation, revision surgery depending on the anatomical location of the cement flow)

Possibly related to surgical procedure

- Malposition of the implant
- Superficial infection (wound), deep site infection and inflammatory phenomena
- Neurological complications, e.g.
 - due to injury or irritation of the spinal cord, the root nerves (radiculopathy) or peripheral nerves, e.g. transient or permanent motor weakness, loss of motory or sensory functions or paralysis
 - Injury or lesion of the dura mater with risk of loss of cerebrospinal fluid (CSF) or CSF fistula
 - Urinary retention or loss of bladder control, or other types of impairment of the urological system, dysfunction of the rectum, genitourinary disorders, gastrointestinal disorders
 - Temporary or permanent retrograde ejaculation in men, damage to the reproductive system, sterility and sexual dysfunctions
- Injury or lesion of surrounding soft tissue, blood vessels (e.g. aorta abdominalis, vena cava inferior or other vessels) or lymphatic vessels (including potential lymph leakage)

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Possible general surgical risks:

- Delayed wound healing
- Superficial wound dehiscence
- Bleeding and/or haematomas
- Vascular disorders including thrombus, myocardial infarction or death
- Development of respiratory problems, including pulmonary embolism, atelectasis, bronchitis, pneumonia, pneumothorax, transient pleural effusion or death
- Inability to perform daily tasks

4.2. Warnings and precautions

Warnings and precautions, see IFU:

General

- When using X-ray equipment for diagnosis or control, the national limit values for the radiation dose must be observed
- VENUS® and VENUS®nano Systems consist of implants and instruments. VENUS® and VENUS®nano implants must only be used with the intended system-specific instruments and accessories described in the surgical techniques in the respective brochures

MR safety information

VENUS® implants have been examined in non-clinical-testings in accordance with ASTM norms and determined as “MR conditional”. Patients with VENUS® implants can be safely examined via MRI on following conditions:

- Static magnetic field of 1.5 T to 3 T
- Spatial gradient magnetic field up to max. 1100 Gauss/cm or 11 T/m
- Whole body specific absorption rate (SAR) up to max. 2 W/kg in normal operating mode and at max. 15 min continuous scan duration

VENUS® implants can heat up to 4,7 °C with continuous scanning time of 15 min. and under the scanning conditions defined above. Under these conditions, a patient can be examined at low risk. To keep the risks of warming low, the scan duration should be kept as short as possible and the SAR as low as possible.

The product has not been examined for artifacts in MR environment. MR image quality may be reduced if the examined area is in relative proximity to VENUS® implants.

A thorough risk-benefit assessment by the attending doctor must be carried out.

Preoperative

- The use of implants for implantation must be decided upon in accordance with the surgical and medical indications, the potential risks and restrictions associated with this type of surgical procedure, as well as in knowledge of the contraindications, side effects and defined precautions, and in awareness of both the nature and the physical, chemical and biological characteristics of the implant.
- A decision for an implantation must be made in agreement between the doctor and the patient taking into account the general health condition including comorbidities of the patient. The physician has to inform the patient about the consequences of the implantation, especially that the treatment results in segmental stiffness and that the use of the implant in the area of the thoracic spine in children or adolescents can stop the growth of the chest wall and lungs, with

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associated consequences. As a result, multiple operations must be performed during the growth period in order to adapt the structure to the spine as it grows.

- Moreover, the patient has to be informed, that adapting the structure to a spine that is fully grown can lead to a drastic reduction in the expected service life of the implant. It is therefore advisable to replace the rod and set screw.
- The patient has to be informed in detail about any possible side effects of the implants and the risks of the procedure, including any revisions that may be necessary.
- To exclude a suspected allergy against the implant materials, appropriate tests shall be carried out.
- For elderly patients, the responsible physician must carefully weigh the potentially benefits against the risks, taking into account the patient's general health condition, increased comorbidities such as e.g. osteoporosis, slower healing and an age-related higher risk of general surgical complications such as infections or cardiovascular problems.
- Polypharmacy, especially hyperpolypharmacy, can have a negative impact on the surgical outcome and the patient's health in elderly patients. The number and interactions of prescribed medications in this patient group should be considered prior to surgery.
- The activities / movement behaviour of the patient has a significant influence on the service life of the implant. The patient must be informed that any activity increases the risk of loss, bending or fracture of the implant components. It is crucial to inform the patient about restrictions in activities in the post-operative phase and to monitor the patient post-operatively in order to assess the development of the fusion and the condition of the implant. Even when bone fusion is completed, implant components may still bend, break or loosen. Therefore, the patient must be informed that implant components can also bend, break or loosen if the restrictions in activities are properly followed.
- Surgical therapy should only be considered after conservative treatment options have failed. The treating physician is responsible for the accurate diagnosis and decision-making for or against surgery as well as the appropriate planning and conductance of the surgery. This implies the patient-specific choice of size and design of the implants, taking into account the individual pathology and anatomy.
- The correct selection and placement of implants is crucial for the surgical success and has to be ensured or to be checked based on suitable pre-, intra- and postoperative diagnostic procedures.
- Errors in implant selection can lead to premature clinical implant failure. The number of segments to be treated is to be determined carefully. The surgeon has to ensure the availability of sufficient different implant sizes and required instruments for the surgical procedure.
- Improper preoperative planning can have a negative impact on the surgical result and the patient's health.
- HumanTech Spine accepts no liability for negative consequences resulting from incorrect diagnosis or indication, an inappropriate choice of implant, incorrect use of implant components and/or an improper surgical technique or asepsis.

Intraoperative

- The instructions in the surgical technique must be adhered to. You can download these online at www.humantech-spine.de or obtain them directly from your HumanTech representative. It is mandatory to use the instruments described in the surgical technique, which are intended to be used with the implant system. No liability can be assumed for the use of third-party instruments.
- Implants showing any signs of damage or contamination must not be implanted.

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- Components of the VENUS® and VENUS®-nano System must not be replaced by components / products from other systems from another source or from a different manufacturer. Furthermore, no direct connection of components / products of the system to components of other systems shall be established. If this is not observed or if the products are used improperly or otherwise than according to IFU and the mandatory surgical technique, HumanTech Spine GmbH assumes no responsibility.
- Bending of the rods / revision connector affect the biomechanical properties of the implant. Bending in the area of the fixation of the rod in the Poly- or Monoaxial Screw can have negative influences on the fixation of the rod – bending in this area has to be avoided.
- Breakage, slippage or incorrect use of the instruments or implants can result in an injury of the patient or the surgical personnel or result in an extension of the duration of the surgery.
- Care should be taken to maintain the integrity of the pedicle and vertebral body structures. Damage to the pedicle can lead to a loosening of the implants and to a loss of the stability of the fixation.
- The diameter of the screws should be selected in a sufficiently wide size in order to make use of the maximum compression in the pedicle area. This will ensure the greatest possible stability and counteract implant loosening. However, in order to avoid injury to the pedicle structures, the screw width should not fit too tight into the pedicle.
- The rod must be tightened correctly to pedicle screw with the corresponding setscrew.
- Careful inspection of the implants is recommended before and during surgery to ensure that the implants remain undamaged during insertion.
- Implantation of the implant must be performed under continuous x-ray control in order to avoid misplacement.
- Proceed with extreme caution in the area of the spinal cord and the nerve roots, as any damage to nerves can result in the negative impairment or loss of neurological functions.
- Extreme caution is required to avoid injuries of the aorta abdominalis or the vena cava inferior because this can be life-threatening.
- If an implant component or part of an instrument loosens or breaks in situ, all resulting residues – whether made of implant material or other materials – must be completely removed.
- Implants that have come into contact with a patient's body fluids or tissues or have been soiled must not be reused.
- The rods of the VENUS® Mini-System have marks. It is not allowed to use the area between the ends of the rod and the marks for the fixation of the pedicle screw. In this area the rods must also not be bent. The system stability can be increased with a ventral support. In the lumbar area, especially when the use of pedicle screws with a diameter of 5,5mm or smaller can't be avoided, a ventral support is strongly recommended
- Augmentation: The IFU provided by the manufacturer of the bone cement used as well as the IFU "Bone Filler" and the surgical technique of HumanTech Spine must be adhered to. The volumes of cement used for fenestrated / cannulated screws should ultimately be determined by the surgeon based on the individual patient anatomy. Especially in patients with severe heart or lung impairment, the quantity of applied cement must be chosen as low as possible. Bone cement application has to be monitored by suitable imaging to avoid cement leakage as far as possible.
- For the usage of guide wires in minimally invasive procedures, the instructions in the surgical techniques must be adhered to and all the cautions have to be observed strictly. The correct positioning of the guide wire must be monitored by suitable imaging during the whole surgical procedure to allow accurate screw insertion and to avoid vessel perforation or other tissue

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damage.

Postoperative

- The patient should be instructed to inform his treating physician immediately regarding any unusual changes in the surgical area.
- The patient should be monitored if a change in the area where the implant(s) is/are located is noticed. The treating physician should assess the possibility of clinical implant failure and discuss with the patient the actions required to achieve further healing.
- A prolonged healing phase, lack of bone fusion or subsequent bone resorption can lead to overloading of the implant, which may result in implant failure
- The implants are used for internal fixation and immediate immobilization of the treated segments during the bone healing process lasting a maximum of two years. Once the fusion is complete, the implants have no longer any active function. Removal of the implant is possible, but can cause damage to surrounding tissue and loss of stability and should only be performed after a careful risk-benefit consideration by a qualified surgeon and the patient.
- In case of complications, the surgeon has to decide whether a revision of the implant should be carried out, taking into account the patient's health condition and the possible risks involved
- Risk of further injuries due to postoperative trauma
- Never reuse the implants. Even if the implant appears to be intact after the revision, alterations within the implant or minute defects resulting from the loading and stressing to which the implant has been exposed can cause the implant to break.
- Handle removed implants in such a way that their reuse is not possible.

Warnings and precautions, see Processing Instructions:

These recommendations are for processing non-sterile HumanTech Spine implants.

The information provided applies to HumanTech Spine implants only.

Explanted implants must never be reprocessed and should be handled according to hospital protocol upon removal.

Details on disposal please refer to IFU.

Any implant that has not been used, but has become soiled, should be handled according to hospital protocols. Refer

to implant's product insert for any specific processing, cleaning, and sterilization instructions for that implant.

CAUTIONS

- The implants must be cleaned, disinfected and sterilised before use on the patient
- Effective cleaning and disinfection is an indispensable requirement for effective sterilisation
- We do not recommend processing used implants. A used implant is an implant that has come into direct contact with a patient, even though it has not been implanted
- Implants should not be lubricated
- Do not use implant if the surface has been damaged
- Do not use steel wool or abrasive cleaners on implants
- Implants are critical devices and must be terminally sterilized prior to use
- The sterilization parameters are only valid for devices that are adequately cleaned
- Do not disassemble unsterile pre-mounted implants for reprocessing

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Non-sterile delivered implants are delivered either in equipped trays within sterilisation containers or packaged individually. The individual packaging must be intact at the time of delivery. The sterilisation containers, trays and associated covers must not be damaged

- If implants are still in the original individual packaging, these are to be taken from the packaging before processing

LIMITS ON REPROCESSING

- Repeated processing cycles with mechanical or manual methods, as well as sterilization have minimal effects on implants
- Implants should be inspected for corrosion, damage such as scratches and notches, debris, discoloration or residue. Any implant with corrosion, scratches, notches, residue, or debris should be discarded

Warnings during Pregnancy

The use of the VENUS Spinal Fixation System during pregnancy is associated with increased risk of serious complications. Potential risks include implant displacement, nerve damage, infection, blood clots, and other pregnancy-related complications. Additionally, there is a risk that the implant may pose harm to the developing fetus.

Responsibilities of the Physician:

- **Information and Education:** The physician must thoroughly inform the pregnant patient about the risks and possible complications associated with the use of orthopedic implants.
- **Alternative Treatment Options:** The physician should discuss possible alternatives to implant treatment in order to find the best possible option for the patient.
- **Minimizing Blood Loss:** The physician should take measures to reduce blood loss during the operation. These measures include:
 - **Tourniquet:** The use of a tourniquet can block blood flow to the surgical area and thereby reduce blood loss.
 - **Hemostatic Agents:** Special agents, such as fibrin glue or oxidized cellulose, can be applied to bleeding areas as needed to stop the bleeding.
 - **Electrocautery:** Electrocautery can be used to coagulate bleeding vessels and reduce bleeding.
 - **Careful Surgical Technique:** The surgeon should work with great precision and carefully ligate blood vessels to avoid unnecessary blood loss.

Anesthesia and Pain Management in Pregnant Women:

Before surgery, a thorough examination and assessment of the patient are necessary:

- **Medical History:** The physician reviews the patient's medical history, including allergies, medications, and previous experiences with anesthesia.
- **Gestational Age:** The exact gestational age must be determined in order to choose the appropriate anesthesia technique.
- **Fetal Monitoring:** The physician must monitor the condition of the fetus, e.g., by using ultrasound.

Anesthesia Techniques:

- **Regional Anesthesia:** In most cases, regional anesthesia (such as epidural or spinal anesthesia) is preferred, as it reduces the risk of respiratory complications.
- **General Anesthesia:** In emergencies or if regional anesthesia is not possible, general anesthesia may be required.

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After Anesthesia:

- **Recovery:** The mother and fetus must be closely monitored after the surgery until both are stable.
- **Pain Management:** Pain medications must be chosen carefully, as some drugs could affect the fetus.

Special Considerations:

- **Pregnancy-induced Hypertension:** Special caution is required when selecting anesthetic agents in pregnant women with hypertension, as they may be more susceptible to complications.
- **Gestational Diabetes:** Blood sugar levels must be closely monitored in patients with gestational diabetes, as anesthetic agents can affect metabolism.
- **Multiple Pregnancies:** In cases of twins or multiple pregnancies, higher risks such as premature labor or fetal distress must be expected.

Radiation Protection During Surgery:

If the surgery is performed in an environment with radiation exposure, special attention must be paid to minimizing radiation exposure for both the pregnant patient and the fetus:

- **Risk Assessment:** The physician must assess radiation exposure for both mother and fetus before the operation.
- **Alternative Procedures:** If possible, alternative procedures without radiation exposure should be considered.
- **Patient Education:** The pregnant patient must be informed about the potential risks and benefits of radiation exposure prior to treatment.

Strategies to Reduce Radiation Exposure:

- **Lead Aprons:** A lead apron can be used to protect the abdominal area of the pregnant patient and minimize radiation.
- **Beam Collimation:** Limiting the radiation field to the necessary area only reduces exposure.
- **Low-Dose Protocols:** Low-dose protocols should be used for imaging procedures such as CT scans or fluoroscopy.
- **Pulsed Fluoroscopy:** Pulsed fluoroscopy can be used to reduce radiation exposure compared to continuous fluoroscopy.

After Surgery:

- **Radiation Exposure Monitoring:** After surgery, the radiation exposure of the pregnant patient and fetus should be evaluated.
- **Follow-up and Counseling:** It is important to inform the patient about possible effects of radiation exposure after surgery and to monitor her regularly.

Special Caution Regarding Radiation Exposure:

- **Fetal Age:** The age of the fetus should be considered when assessing the radiation risk, as the risk varies depending on the stage of pregnancy.
- **Radiation-Sensitive Tissues:** The physician must be especially careful to consider the sensitivity of tissues such as the fetal central nervous system.

Risks for Mother and Child:

The orthopedic surgeon must consider the physical changes during pregnancy and the potential risks for the fetus. Possible risks include preterm birth, premature placental abruption, abnormal fetal positioning, and even the risk to the mother's life.

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4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

VENUS®

From **453587** products sold during the last 5 years, 16 complaints comprising 26 implants were obtained from customers. Since product launch in 2010, only 14 incidents (of 83 complaints) with negligible or very mild effects on the patients and one serious incident occurred. The serious incident was reported to the BfArM. Based on the analysis, the serious incident was caused by an “expected or random component failure without any design or manufacturing issue” and therefore a recall or a Field Safety Notice (FSN) were not necessary. Since one failure could have led to a serious adverse event (in 2014), it was reported to the BfArM followed by the recall of the possibly concerned products and a Field Safety Notice (FSN). One FSN including recall was necessary due to material mix-up of titanium grade 4 and grade 5, but no other FSCA became necessary in the considered period (to date, Juni 2025, no adverse event has been reported):

BfArM Case -No. 8312_14 (2014-12-12):

Number of Field Safety Notice: 20140148, Article-No.: VL-PS2-5-6550, Description: Polyaxial Screw 6T 6,5x50mm, LOT: H1217HJ, Basic UDI-DI: 2505399046N7).

Description: As a result of an error in the further processing process, the above-mentioned pedicle screws have errors in the marking. The products were provided with an incorrect length specification. The marking of the product by means of laser marking and the associated product label indicates a length of 50mm, the actual length of the screw shaft is 55mm. Only the above-mentioned pedicle screws of lot no. H1217HJ are affected.

Material Mix-up BfArM Case -No. 20710/24

In June 2024, HumanTech Spine received the information of deviations in a raw material. A complaint has been sent to the supplier. Therefore, an FSN (Field Safety Notice) was prepared and a (preventive) recall of several VENUS batches was conducted. No adverse event has been reported so far subsequent to this non-conformity. The root cause analysis of the supplier has been completed and appropriate risk mitigation measures have been introduced. To ensure the long-term safety of the (wrong) implants of commercially pure titanium (cpTi) grade 4, biomechanical tests were performed and a finite element model was applied. Both analysis showed no significant difference between the influence of the two different rod materials, Titan Grad 5 (Ti6Al4V) and Titan Grade 4 on the range of motion of the lumbar spinal segments and dynamic stability.

Additionally, several rods for implantation made of cpTi (grade 4) are available on the market and used for more than a decade in clinical practice.

Based on the performed analyses, it could be concluded that there is no increased risk for patients with implanted Ti grade 4 rods.

All the risks described in the complaints have already been considered in the Risk Management File. The overall complaint rate of the considered period of 5 years is with 0,01% very low.

VENUS®nano

From **6593** products sold during the last 5 years, only no complaint was reported from customers. No incident or serious incident occurred. No product recall, FSN or other FSCA became necessary. All the risks described in the complaints have already been considered in the Risk Management File. The overall complaint rate is with 0,00% very low.

No incident occurred with VENUSnano.

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5. Summary of clinical evaluation and post market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable

According to MDR requirements, no equivalent device is available.

5.2. Summary of clinical data from conducted investigations of the device before CE marking, if applicable

No clinical investigation was conducted before CE marking. VENUS® and VENUS®nano are legacy devices. The devices were CE-certified under MDD on the basis of equivalence to equivalent devices. However, based on the new definition of equivalence under the MDR these devices are not equivalent anymore.

5.3. Summary of clinical data from other sources, if applicable

Clinical data regarding the safety and performance of VENUS® Spinal Fixation System and VENUS®nano Spinal Fixation System

High-Quality User Survey (HQUS) for VENUS and VENUS nano

Although a PMCF study for VENUS and VENUS nano was not deemed necessary as they are established legacy devices, four HQUS for VENUS and two for VENUSnano were conducted to collect long-term safety, performance, and efficacy data.

1.1. HQUS 1 for VENUS (Latvia)

This study included cumulative data from 30 patients treated with 144 VENUS screws in 2022. The average age of patients was 60.4 ± 12.7 years, with 53.3% male and 46.7% female. Primarily, two segments were treated (21 patients).

- Treated Indications (Most Common): Instabilities (29 patients), degenerative disc diseases (27 patients), degenerative stenoses (29 patients).
- Clinical Outcomes (after 3 ± 1 months follow-up):
 - Improvement in lordosis/kyphosis: 96.6% of patients showed partial or complete achievement of the goal.
 - Reduction of leg or back pain: 100% of patients showed partial or complete achievement of the goal.
 - Spinal stabilization: 100% of patients showed partial or complete achievement of the goal.
 - Functional improvement: 100% of patients showed partial or complete achievement of the goal.
 - Motor improvement: 100% of patients showed partial or complete achievement of the goal.
 - Sensory improvement: 100% of patients showed partial or complete achievement of the goal.
 - Stopping deformity progression: 93.3% of patients showed partial or complete achievement of the goal.
 - Correction of malalignment due to deformities: 100% of patients showed partial or complete achievement of the goal.
 - All but one patient achieved their respective surgical goals at least partially or completely after 3 (± 1) months.

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- **Complications:**
 - Abrasion: In 3 out of 30 patients (10%) within 12 (± 3) months.
 - Infection: In 1 out of 30 patients (3.3%) directly after surgery.

1.2. HQUS 2 for VENUS (Nürnberg)

This study included cumulative data from 30 patients treated with 181 pedicle screws in 2022. The average age was 69.8 ± 11.4 years, with 33.3% male and 66.67% female. All patients received combined treatment with VENUS and ADONIS.

- **Treated Indications (Most Common):** Degenerative disc diseases (28 patients), degenerative stenoses (28 patients), instabilities (23 patients).
- **Clinical Outcomes (after 3 ± 1 months follow-up in 24 patients):**
 - Improvement in lordosis/kyphosis: 90.0% of patients showed partial or complete achievement of the goal.
 - Reduction of leg or back pain: 95.8% of patients showed partial or complete achievement of the goal.
 - Spinal stabilization: 100% of patients showed partial or complete achievement of the goal.
 - Functional improvement: 100% of patients showed partial or complete achievement of the goal.
 - Motor improvement: 100% of patients showed partial or complete achievement of the goal.
 - Sensory improvement: 100% of patients showed partial or complete achievement of the goal.
 - Stopping deformity progression: 100% of patients showed partial or complete achievement of the goal.
- **Complications (up to 12 months follow-up):**
 - Implant loosening (screw, rod): 2 out of 30 patients (6.7%).
 - Non-fusion: 1 out of 30 patients (3.3%).
 - Instability: 3 out of 30 patients (10%).
 - Motoric dysfunction: 1 out of 30 patients (3.3%).
 - Superficial or deep infections/inflammations (e.g., discitis, sepsis): 2 out of 30 patients (3.3%) directly after surgery.
 - Wound infection: 2 out of 30 patients (3.3%) directly after surgery.
 - Neurological complications: 1 out of 30 patients (3.3%).
 - Adjacent segment disease: 2 out of 30 patients (3.3%).
 - Fracture of vertebra, pedicle, or sacrum: 1 out of 30 patients (3.3%).
 - In total, 4 patients suffered from the consequences of complications, including prolonged hospital stays and further surgeries. In 2 out of 4 cases, a connection to the implant was suspected.

1.3. HQUS 3 for ADONIS / VENUS (Mexico)

This HQUS included **48 patients** treated with VENUS and ADONIS between 2018 and 2023. The average age was 55 ± 14.9 years. All patients received an ADONIS TLIF PEEK in combination with a VENUS System for dorsal fixation.

- **Treated Indications:** Degenerative disc diseases (17 patients), Spondylolisthesis Grade I or II (18/20 patients), revision surgeries (11/15 patients).

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- **Clinical Outcomes (longer than 24 months follow-up in 22 patients):** Nearly all surgical goals were primarily partially or completely achieved. The complete success rates ranged from 81% to 100%, demonstrating good long-term clinical performance of up to 60 months.
- **Complications (ADONIS-related):** Out of 43 reported complications in 19 patients, 12 were implant-related.
 - Screw loosening: 3 patients.
 - Device breakage: 1 patient.
 - Cage migration: 3 patients.
 - Pseudoarthrosis: 1 patient.
 - Pain: 3 patients.
 - Neurological symptoms: 3 patients.
 - Infections: 2 patients.
 - Hematoma: 1 patient.
 - Nerve root entrapment: 1 patient.
 - Dural tear: 1 patient.
 - Implant fracture: 1 patient (the inserter broke during insertion and remained in the implant).

1.4. HQUS 4 for VENUS (Mexico, Dr. Villegas)

This HQUS reports cumulative data from

52 treatments using 900 pedicle screws between 2022 and 2023. The surgeon has 4-10 years of expertise in orthopedics and performs 6-10 surgeries at the thoracic, lumbar, or sacral spine per month. All 52 included patients underwent an open procedure. No minimally invasive procedures were performed. No patients suffered from osteoporosis or received augmented screws. No combinations with SAMSON or ADONIS were used, and VENUSnano VDS was not applied.

- **Complications:**
 - Implant breakage (screw/rod): 2 out of 52 patients (3.8%) after 24 months.
 - Implant loosening (screw/rod): 4 out of 52 patients (7.7%), with 3 patients until 12 months and 1 patient until 24 months.
 - Implant/Screw migration: 2 out of 52 patients (3.8%) until 12 months.
 - Detachment of components: 1 out of 52 patients (1.9%) directly after surgery.
 - Wound infection: 2 out of 52 patients (3.8%) directly after surgery.
 - 2 patients suffered consequences from complications, including prolonged hospital stays and further surgery (revision surgery). No patient died.

1.5. HQUS 1 for VENUS nano (Mexico)

This HQUS reports cumulative data from 30 treatments using 120 VENUS nano screws in 2022. The surgeon has more than 10 years of expertise in orthopedics and performs 6-10 surgeries at the thoracic, lumbar, or sacral spine per month. All 30 included patients underwent an open procedure. No minimally invasive procedures were performed.

- **Treated Indications (Most Common):** Degenerative disc disease (25 patients), degenerative stenosis (23 patients), spondylolisthesis (23 patients), trauma (12 patients).
- **Clinical Outcomes (after 3 ± 1 months follow-up):**
 - Improvement in lordosis/kyphosis: 96.6% of patients showed partial or complete achievement of the goal.
 - Reduction of leg or back pain: 100% of patients showed partial or complete achievement of the goal.

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- Spinal stabilization: 100% of patients showed partial or complete achievement of the goal.
- Functional improvement: 100% of patients showed partial or complete achievement of the goal.
- Motor improvement: 100% of patients showed partial or complete achievement of the goal.
- Sensory improvement: 100% of patients showed partial or complete achievement of the goal.
- Stopping deformity progression: 93.3% of patients showed partial or complete achievement of the goal.
- Correction of malalignment due to deformities: 100% of patients showed partial or complete achievement of the goal.

● **Complications:**

- Implant breakage (screw/rod): 2 out of 30 patients (6.7%) within 12 months.
- Implant loosening (screw/rod): 1 out of 30 patients (3.3%) within 12 months.
- Implant/Screw migration: 1 out of 30 patients (3.3%) within 12 months.
- Surgical site infection: 1 out of 30 patients (3.3%) directly after surgery.
- 2 patients suffered consequences from complications, including prolonged hospital stays and further surgery (revision surgery). No patient died.

1.6. HQUS 2 for VENUS nano (Germany)

This HQUS reports cumulative data from **30 treatments** using **146 VENUS nano screws** between 2022 and 2023. The surgeon has more than 10 years of expertise in orthopedics and performs more than 10 surgeries at the thoracic, lumbar, or sacral spine per month. All 30 included patients underwent an open procedure. No minimally invasive procedures were performed.

- **Treated Indications (Most Common):** Degenerative disc disease (28 patients), degenerative stenosis (26 patients), instabilities (23 patients).

● **Clinical Outcomes (after 3 ± 1 months follow-up):**

- Improvement in lordosis/kyphosis: 93.3% of patients showed partial or complete achievement of the goal.
- Reduction of leg or back pain: 93.3% of patients showed partial or complete achievement of the goal.
- Spinal stabilization: 100% of patients showed partial or complete achievement of the goal.
- Functional improvement: 100% of patients showed partial or complete achievement of the goal.
- Motor improvement: 100% of patients showed partial or complete achievement of the goal.
- Sensoric improvement: 100% of patients showed partial or complete achievement of the goal.
- Stopping deformity progression: 100% of patients showed partial or complete achievement of the goal.
- Correction of malalignment due to deformities: 100% of patients showed partial or complete achievement of the goal.

● **Complications:**

- Implant loosening (screw/rod): 2 out of 30 patients (6.7%) within 12 months.
- Non-union: 1 out of 30 patients (3.3%) within 12 months.

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- Adjacent segment disease: 1 out of 30 patients (3.3%) within 12 months.
- Surgical site infection: 1 out of 30 patients (3.3%) directly after surgery.
- 1 patient suffered consequences from complications, including prolonged hospital stays and further surgery (revision surgery). No patient died.

2. Observational Application / SAMSON

An observational study was performed with **33 patients** treated with SAMSON. **14 of these patients** (11x VENUS, 3x VENUSmini) were treated with VENUS/VENUSmini and SAMSON at 4 different hospitals in an observational application evaluating the safety, performance, and efficacy of the SAMSON device.

- In 7 out of 14 surgeries, there were **no complications**, and in 13 out of 14 surgeries, **no complications with VENUS** were reported.
- Slight loosening of screws was observed at 3 months follow-up in one patient (out of 33) treated with VENUS 6T.
- The remaining complications in the 6 VENUS/SAMSON treatments (e.g., subsidence in caudal base plate, intraoperative break-in in base plate during preparation, psoas irritation, loss of height due to loosening of locking screw of the SAMSON device) rather referred to the SAMSON implants or associated instrumentation.

3. Surgery reports

VENUS

Several surgery reports for the application of VENUS and VENUSnano were collected in the last years. In sum 370 surgery reports were collect in Germany as well as 385 in Mexico describing intraoperative data for 755 patients. These surgery reports confirm the intraoperative safety and performance of the VENUS in the intended indications for the intended patient group. VENUS was used in the following indications:

- Instabilities
- Degenerative Disc disease
- Degenerative Spondylolisthesis
- Degenerative Stenosis
- Deformities, e.g. Scoliosis and Kyphosis
- Pseudarthrosis
- Spinal Fractures
- Spondylitis, Spondylodiscitis
- Tumor
- Revision surgery

The patients treated were all older than 17 years, with an approximately equal ratio of males to females."

The occurred adverse events were not implant-related and no functional insufficiency of the implants could be identified. In sum 11 adverse events in 370 reports (3%) were reported. Mostly the adverse events resulted from use errors or the underlying patients' condition like osteoporosis.

The surgery reports reported the successful combined use of VENUS with the ADONIS Lumbar interbody fusion system in 233 surgeries and the SAMSON Vertebral Body Replacement System in 6 surgeries.

VENUSnano

For VENUSnano 29 surgery reports were collected describing the successful use of VENUSnano in 29 patients. The patients were between 6 and 64 years old (pediatric patients and patients of small stature). 22 of 29 patients treated with VENUSnano were <18 years old. The average age was 20,3 ±15,8 years (median:15 years). The age of one patient is unknown. 24 patients were female, 5 patients were male.

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In 18 cases, the VENUS®nano VDS system was used for ventral derotation spondylodesis (16 cases with double rod, 3 cases with single rod, see X-ray images); in 6 patients, autologous bone was used to achieve interbody fusion.

Duration of surgery: 1-8 h (2 exceptions: 15h10min and 14h30min)

Indications

Scoliosis
Kyphosis
Fracture
Tumour
Revision

Complications

One set screw could not be properly threaded, and the thread of the monoaxial screw was damaged, requiring replacement. (1 report in 29 surgeries, 3,4%)

5. Literature Review

During the literature review, no publications regarding the VENUS and VENUSnano were identified. However, since both systems are based on well-established technology, literature concerning similar devices can be used to prove the safety and performance of VENUS and VENUSnano.

In the identified publications the following performance parameters and clinical benefit was investigated.

Publication	Performance parameters studied and clinical benefit
Weise et al. 2008, [93]	<p>Sixty-seven consecutive thoracic and lumbar fusions. Pedicle screw (here: Xia Precision of Stryker which is a screw-rod fixation system) was used for posterior lumbar interbody fusion (PLIF), dorsal stabilization, fusion with laminectomy, fusion with debridement and/or tumor resection, and dorsoventral fusion. After a follow-up of 16 months, it was possible to conclude that the use of this cannulated screw system for the placement of pedicle screws in the thoracic and lumbar spine is accurate and safe.</p> <p>Combination of screw-rod fixation system with interbody fusion device: Screw system was used in 24/67 (35.8%) cases in combination with a posterior lumbar interbody fusion device (PLIF).</p> <p>The total medio-caudal pedicle wall perforation rate was 9.2% (30/326). In 19 of these 30 cases a cortical breakthrough of less than 2 mm occurred. The misplacement rate (defined as a perforation of 2 mm or more) was 3.37% (11/326). Three of these 11 screws needed surgical revision due to neurological symptoms or CSF leakage. There have been no screw breakages or dislocations over the follow up-period.</p>
Zotti et al. 2015, [94]	<p>The focus of this publication is the clinical benefit of implant removal:</p> <p>From 50 consecutive patients who underwent removal of posterolateral instrumentation for an index elective lumbar fusion for discogenic back pain, 34 patients were identified that met the criteria with a mean follow-up of 25 months (range, 18-36 months). The VAS and ODI improved in 22/34 (65%) of participants. The mean cohort VAS score was 6.6 pre-surgery and 4.3 post-surgery (P=0.04). Preoperative and postoperative mean Oswestry disability scores were 64 and 41, respectively (P=0.05). There was a statistically significant difference in the proportion of patients with poorer compared to satisfactory outcomes with regards to compensable status, preoperative grade II opioid use and shorter time between fusion and removal procedure. Complications were one postoperative hematoma and one superficial wound infection, both of which settled without re-operation.</p>

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Publication	Performance parameters studied and clinical benefit
	<p>Approximately two thirds of patients were satisfied with removal of instrumentation for treatment of residual low back pain (LBP) following elective lumbar fusion and recorded reduced VAS and grade II opioid use. this study suggests that removal of instrumentation is safe and provides modest benefit as a palliative procedure for a subset of patients with significant disability from chronic LBP without an underlying cause following lumbar fusion.</p>
Wimmer et al. 2008, [95]	<p>The pedicle screw-rod minimally invasive system was indicated for osteochondrosis of the lumbar and thoracic spine, spondylolisthesis grade I–III according to Meyerding. Instability after nucleotomy, fracures, spondylodiscitis and flexible scoliosis of the lumbar and thoracic spine.</p> <p>The average operating time for purely dorsal instrumentation was 65 min (55-125 min), the length of the skin incisions was of the skin incisions was 4.5 cm (4-8 cm). The average intraoperative blood loss was 75 ml (10-150 ml). Postoperatively, pain was reduced compared to the open procedures. At the last follow-up examination, 80% of the patients patients showed no pain in the area of the operated segment, 15% reported a significant improvement, and in 5% there was no change. No patient complained of a worsening of the preoperative preoperative findings. The clinical examination showed a significant improvement in the VAS from a preoperative average of 8 (7-10) to 2 (0-3) at the time of the last follow-up examination.</p> <p>The complication rate was low and there was a pain improvement after surgery. Therefore, the use of this system is effective and secured for this purpose.</p>
Oh et al. 2013, [96]	<p>Retrospective case series to compare the accuracy of percutaneous pedicle screw fixation (PPF) with that of open pedicle screw fixation (open PF) and to investigate the risk factors associated with pedicle wall penetration. Pedicle wall penetration occurred in 75 patients (13.4%) in the open PF group and 71 patients (14.3%) in the PPF group and was not significantly different between the groups.</p> <p>The rate of wall penetration between percutaneous pedicle screw and open technique was not statistically different. The penetration was severe in 5 cases, moderate in 13 cases and minor in 53 cases. The complication rate was low; thus the fixation system and percutaneous technique are considered secure.</p>
Barakat et al. 2019, [97]	<p>The fixation systems were used for treatment of spine fractures and followed with 1 year postoperative. There was significant improvement of pain with both fixation devices. There was no advantage regarding pain reduction and neurological outcome, despite USS in thoracolumbar fracture as a short-segment fixation led to a sustained near anatomical reduction when compared to the CDH Legacy system.</p> <p>From March 2015 to January 2016, 40 consecutive patients with unstable traumatic thoracolumbar fractures who met our inclusion criteria were treated with either the USS system or CDH Legacy system. Segmental kyphosis angle (SKA) and anterior body height (ABH) of fractured vertebrae, and ASIA Impairment Scale (AIS) were evaluated. Radiological fusion was confirmed with plain X-rays and when indicated with computerized tomography (CT). Results: The mean immediate kyphotic angle correction was 16.6 for the Schanz and 6.4 for the CDH Legacy system, and the immediate mean anterior vertebral body height correction was 0.92 cm for the Schanz and 0.51 cm for the CDH Legacy system. Our study shows a significant statistical difference between Schanz and CDH Legacy systems regarding postoperative segmental kyphosis and height correction immediately postoperatively, at 6 months and at one-year follow-up (p-value < 0.005). The degree of pain reduction and neurological improvement was not influenced by the screw system.</p>

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Publication	Performance parameters studied and clinical benefit
Schmidt et al. 2007, [98]	Forty-nine patients (64.5%) suffered from minor trauma (Injury Severity Score <16). Polytraumatized patients (n=27; 35.5%) had associated chest (n=20) and traumatic brain injuries (n=22). Patients of thoracolumbar fractures were stabilized by percutaneous dorsal stabilizations and evaluated 6 months after surgery. For mono- and bisegmental dorsal instrumentation the CD Horizon Sextant™ was used in 60 patients, whereas in 16 longer ranging instrumentations the (prototype) Longitude™ system was implanted. Operation time was substantially lower than in conventional approach at minimum 22.5 min for Sextant and 36.2 min for Longitude™, respectively. Geriatric patients with high perioperative risk according to ASA classification benefited from the less invasive approach and lack of approach-related complications including no substantial blood loss. The complication rate was low and the functional improvement reported by 76.3 % of patients. Therefore, the fixation system showed favorable outcomes, and can be considered safe and effective.
Ramo et al. 2012, [99]	Symptomatic implants (2.4%), curve progression (2%), and delayed infection (1.6%) continue to be the most common reasons for repeat operations. A 5-year review (2003–2007) of 452 patients with idiopathic scoliosis (older than 9 yr) who underwent definitive instrumentation/fusion at one institution had a significantly lower reoperation rate (7.5%) than a previously published cohort from the same institution (12.9%). This reflects a change in instrumentation systems to more rigid, lower profile implants and techniques
Smals et al. 2021, [100]	Ninety-one patients were submitted to surgical correction of scoliosis using pedicle screw system CD-Solera instrumentation between 2010 and 2016 at age 14.8 ± 1.6 years. On pre- and postoperative biplanar full spine radiographs Cobb angles of the primary and secondary curves and sagittal profile were measured before surgery, immediately postoperative, and at two-year follow-up. Medical records were reviewed for complications. Clinical outcome was analyzed using the SRS-22r questionnaire. The minimum follow-up was 2 years. The function was evaluated in 56 subjects. <i>Results:</i> In this study 77% of the patients had a structural thoracic curve (type Lenke 1 or 2), and 23% had a structural (thoraco-)lumbar curve (Lenke 3-6). A correction of 55.1% and 51.7% was achieved respectively immediately post-operative, and at last-year follow up for the primary curve. The mean loss of correction was 2°. Health related quality of life was 4.0 (good) on the SRS-22r-questionnaire. In total six revision operations were executed, of which one was related to the material (rod breakage). Other reasons for revision operation were not due to the material. No neurological problems were encountered. Complication rates are low and health related quality of life comparable to literature. The CD-Solera can be regarded as a safe and effective instrumentation in surgical treatment of AIS. In patients with AIS the initial correction and maintenance of correction as achieved by posterior spinal fusion using the CD-Solera instrumentation is comparable to other reported devices. Complication rates were low and health related quality of life was comparable to other literature.
Gazzeri 2020, [101]	Single-center prospective randomized controlled study. Informed consent with possibility to refuse participation Declaration of Helsinki. Fenestrated pedicle screws augmented with cement versus expandable pedicle screws in percutaneous vertebral fixation surgical procedures. Treatment of degenerative and traumatic spinal diseases in aging patients with osteoporosis. Indications: 24x vertebral fracture, 16x lumbar instabilities. A total of 40 patients were enrolled in the study, with 20 patients randomized to expandable screws and 20 patients randomized to fenestrated/augmented screws. The mean age was 72.4 years (range 60–82 years). An

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Publication	Performance parameters studied and clinical benefit
	<p>average shorter operative time was found in procedures in which expandable screws were used versus those in which cement-augmented screws were used ($p < 0.001$). No differences resulted in perioperative blood loss between the 2 groups. VAS and ODI scores were significantly improved in both groups after surgery. The ODI scores significantly decreased from a mean of 78.4% preoperatively to 23.8% in group I (expandable screws), and from 77.4% to 22.9% in group II (cement-augmented screws). There was no significant difference between the 2 groups with respect to baseline VAS or ODI scores. The satisfaction rate of both groups was more than 85% at 24 months follow-up. Radiographic outcomes also showed no significant difference in segment stability between the 2 groups. No major complications after surgery were seen. There were 4 cases (20%) of approach-related complications, all in fenestrated screw procedures in which asymptomatic cement extravasations were observed. In 1 case the authors detected a radiologically evident osteolysis around a cement-augmented screw 36 months after surgery. In another case, they identified a minor loosening of an expandable screw causing local back discomfort at the 3-year follow-up.</p> <p>Clinically significant improvements of VAS and ODI at 6, 12 and 24 months. No significant differences between the two groups. No patient had status deterioration or worsening scores in terms of functionality.</p> <p>Expandable pedicle screws and polymethylmethacrylate augmentation of fenestrated screws are both safe and effective techniques to increase the pull-out strength of screws placed in osteoporotic spine. In this series, clinical and radiological outcomes were equivalent between the 2 groups.</p>
Schlösser et al. 2024	<p>Retrospective multicenter review of all primary scoliosis cases (2018–2020) with > 1 year FU from three centers. Topic: axial rod slip (ARS). Aims of the study: Investigation of the occurrence and magnitude of ARS with the Mesa2 deformity system of Stryker. In a second step: comparison of the results to the alternative construct Reline of NuVasive.</p> <p>More than 500 patients treated with Mesa2/Stryker. ARS risk (with Mesa2/Stryker) was 27% (56/205) with slipping over a distance of 3.6 ± 2.2 mm. 42% occurred before 4 months, the rest before 1 year.</p> <p>205 patients were selected and analyzed 2–4 years after index surgery. 56 of 205 patients (27%) had an axial rod slip defined as > 1 mm change in residual distal rod length from the screw in the lowest instrumented vertebra (LIV) and assessed by two independent observers (interobserver reliability was high). A cohort of 56 patients was treated with Reline/NuVasive and was analyzed 1–3 years after surgery.</p> <p>Axial rod slip occurred in 56 of 205 cases (27%) with Mesa2/Stryker, at a remarkably different rate and magnitude between the centers: 31, 53, and 13%, respectively. In the Reline/NuVasive cohort including 56 patients, only one slip (1/56 patients, 2%) was observed after 1 year.</p> <p>Summary: ARS occurred in about 27% of cases, with an average slippage of 3.6 ± 2.2 mm with Mesa2/Stryker device (non-similar to VENUS). The screw density in the distal region (near the Lowest Instrumented Vertebra (LIV)) had no significant influence on the occurrence of ARS. The type of end screw was much more decisive: changing to a different screw design (Reline/NuVasive) reduced the risk of ARS (from 27 % to 2 %).</p>

In the identified publications the following complications were reported.

Publication	Complications in % occurrence
Zotti et al. 2015, [94]	There were two complications, one closed wound hematoma, which resolved with aspiration and without the need for reoperation, and one superficial infection that

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Publication	Complications in % occurrence
	resolved with a week of oral antibiotics Closed wound hematoma: 1/34 patients (2,9%) Superficial infection: 1/34 patients (2,9%)
Wimmer et al. 2008, [95]	Screw broken through pedicle wall: 2/72 (2,8%); Radicular pain in 1/72 cases (1,4%) Screws located laterally outside of the pedicle: 4/72 patients (5,6%) Other „errors, dangers and complications“ referred to handling issues of the devices.
Oh et al. 2013, [96]	Immediate revision surgeries: 3/111 patients (2,7%) Motor weakness: 3/111 patients (2,7%) (resolved after 3 months FU) Decreased sensation: 1/111 patients (0,9%) Radicular pain: 22/111 patients (19,8%) Persistent radicular pain: 8/111 patients (7,2%) (patients' complaints at 6 months after operation) Retaining mild radicular pain: 2/111 patients (1,8%) Severe pedicle wall penetration: 5/111 cases (4,5%), Moderate pedice wall penetration: 13/111 cases (11,7%) Minor pedice wall penetration: 53/111 cases (47,7%).
Barakat et al. 2019, [97]	Deep wound infection (Staph. aureus): 1/40 patients (2,5%) Three patients developed Urinary tract infection: 3/40 patients (7,5%) Fracture of pedicular screw due to de novo back trauma: 1/40 patients (2,5%) Transient paralytic ileus: 1/40 patients (2,5%) Deep venous thrombosis: 1/40 patients (2,5%) (patient had complete paraplegia)
Schmidt et al. 2007, [98]	Paravertebral hematoma: 1/60 patients (1,7%) Surgical revision: 1/60 patients (1,7%) (due to paravertebral hematoma) Persisting skin irritation: 1/60 patients (1,7 %) (attributed to an insufficient suture of the fascia and had to be revised. Implant failure: 1/60 patients (1,7%) (due to breakage of a cranial pedicle screw of a bisegmental fixator).
Ramo et al. 2012, [99]	Most devices used were TSRH Medtronic, only very few CD Horizon devices of Medtronic (N=2 of 452) were used. The percentages indicated, however, refer to the whole number of patients treated. 34 patients (7.5%) cases of reoperation; 8 (1.8%) cases of infection, 11 (2.4%) of symptomatic implant, 2 (0.4%) cases of pseudoarthrosis, 3 (0.7%) cases of dislodged/disassembled Implant, 9 (2%) curve progression, 4 (0.9%) cases of incision related problems.
Smals et al. 2021, [100]	Revision surgery: 6/91 (6,6%) patients Rod fracture: 1/91 (1,1%) patients Painful protruding hook: 1/91 (1,1%) patients Mental health (invalidating pain): 1/91 (1,1%) patients Pain: 1/91 (1,1%) patients Ventral screw protrusion: 1/91 (1,1%) patients Skin irritation: 1/91 (1,1%) patients Deep wound infection: 1/91 (1,1%) patients Superficial infection: 1/91 (1,1%) patients
Gazzeri 2020, [101]	Asymptomatic cement leakage: 20% (4 of 20 patients) Osteolysis: 5% (1 of 20 patients), (no pain, no screw loosening, no revision surgery necessary) Screw loosening with local discomfort and revision surgery: 5% (1 of 20 patients, patient suffered from severe osteoporosis)
Schlösser et al. 2024,	Risk of axial rod slip (ARS) with (non-similar to VENUS) Mesa2/Stryker device: 27% (56/205 patients). Reoperation due to axial rod slip (ARS) (with Mesa2/Stryker: 21% of all reoperations.

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Publication	Complications in % occurrence
	<p>Risk of axial rod slip (ARS) with (similar) Reline/NuVasive device: 2% (1/56 patients)</p> <p>Mesa2/Stryker-group (not similar to VENUS): Reoperation due to axial rod slip (ARS): 21%; loosening or broken screws: 8 patients (4%) Return to operating room (UPROR) for any reason other than slip (e.g., infection) was 23 (11%).</p> <p>For the Reline/NuVasive (similar to VENUS) cohort: 2 broken screws in 56 patients: 2/56 (3,6%) UPROR (unplanned return to operating room): 1/56 (1,8%)</p> <p>Conclusion: The similar device shows better performance (drastically reduced axial rod slipping, 27% vs. 2%, and revision surgeries, 21% due to rod slipping and 11% for any reason other than slip versus 1,8% revisions in total for the Reline/NuVasive device.</p>

In ClinicalTrials.com were 11 studies regarding similar devices identified. From these 2 studies published results of the study on the website.

No	ClinicalTrials.gov ID and Official title	Relevant similar device	Indication	Follow-up	Patients	Data provided	Status
10	ClinicalTrials.gov ID: NCT03797144 , Fenestrated Screw Study. <u>Official Title:</u> A Prospective, Multicenter, (Interventional) Evaluation of the CD HORIZON® Fenestrated Screw Spinal System With Fenestrated Screw Cement When Used in the Treatment of Spinal Conditions in Subjects With Compromised Bone Quality. <u>Brief Summary:</u> The primary objective of this post-market study is to demonstrate that Oswestry disability index (ODI) score improved significantly at 12 months post-operatively as compared to baseline for each indication (degenerative spinal disease and deformity) in subjects with compromised bone quality, who will receive a surgical procedure requiring posterior stabilization and/or immobilization of one or more spinal segments using CD HORIZON® Fenestrated Screw Spinal System with Fenestrated Screw Cement.	CD HORIZON® Spinal System / Medtronic	Degenerative spinal disease (Deg. disc disease DDD, spondylolisthesis, deg.stenosis acc. to IFU) and deformity	3 and 12 months	21 (but only 1 patient could be analyzed at 12-months FU)	Results available, see below	Terminated, 2019-04 to 2020-07
11	Clinical trial.gov ID: NCT03647501 Title: Lumbar Fusion With Nexxt Spine 3D-Printed Titanium Interbody Cages. Prospective randomized controlled trial. Single Masking	Expedium / DePuy in both study arms	Lumbar Degenerative Disc Disease, Lumbar Spinal Stenosis, Lumbar Spondylolisthesis Lumbar Spinal Deformity, Lumbar Spondylosis	Up to 24 months	Arm 1: 25 patients with 3D printed Titanium cage; Arm 2: 28pat with PEEK cage enrolled	Results available, see below	Completed in 2023

No. 10) NCT03797144: Performance/Efficacy Results of the Fenestrated Screw Study:

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Outcome Measures:

- Change in ODI at 3 months, 12 months (in scores):

ODI change compared to baseline (score on scale)	Study arm "DDD"	Study arm "Deformity"
Change in ODI at 3 months FU	31.5 ± 28.9 (baseline: 11 patients, 3 months: 9 patients)	16.6 ± 19.3 (baseline and 3 months: 10 patients)
Change in ODI at 12 months FU	46,0 (1 patient)	17,8 (1 patient)

- Change in VAS for back pain and leg pain at 3 months and 12 months.

VAS change compared to baseline (score on scale)	Study arm "DDD"	Study arm "Deformity"
Change in back pain at 3 months FU	3,3 ± 2,6 (baseline: 11 patients, 3 months: 9 patients)	5,1 ± 3,2 (10 patients)
Change in back pain at 12 months FU	3,0 (1 patient)	0,0 (1 patient)
Change in leg pain at 3 months FU	6,2 ± 2,7 (baseline: 11 patients, 3 months: 9 patients)	5,8 ± 2,5 (10 patients)
Change in leg pain at 12 months FU	6,0 (1 patient)	1,0 (10 patients)

- Change in quality of life (EQ-5D 5L, European Quality of Life – 5 Dimensions)*

Change of index score	Study arm "DDD"	Study arm "Deformity"
Change in index score at 3 months FU	0.43 ± 0.36 (baseline: 11 patients, 3 months: 9 patients)	0,28 ± 0,33 (10 patients)
Change in index score at 12 months FU	0,423 (1 patient)	0,423 (1 patient)
Change in Health State score at 3 months FU	11,9 ± 35,8 (baseline: 11 patients, 3 months: 9 patients)	24,7 ± 20,3 (10 patients)
Change in Health State score at 12 months FU	6,0 (1 patient)	1,0 (10 patients)

- Rate of intraoperative cement extravasation/leakage (patients)

	Study arm "DDD"	Study arm "Deformity"
Overall Number of Participants Analyzed	11	10
Patients with cement extravasation	3	5
Patients with symptomatic extravasation	0	0

- Rate of intraoperative cement extravasation/leakage (screws)

	Study arm DDD	Study arm Deformity
Overall Number of Participants Analyzed	11	10
Number of Cemented Fenestrated Screws	39	97
Fenestrated Screws with cement extravasation	3	8
Fenestrated screws with symptomatic cement extravasation	0	0

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- Device and/or procedure-related adverse events through 12 months
 - Study arm “DDD”: AE: 2/11 patients, SAE: 1/11 patients, SADE: 1/11 patients, no USADE, no SAE related to procedure, access system, anterior plate, bone grafts and substitutes, rods, fenestrated screw cement, fenestrated screw. SAE related to an underlying disease (according to a sponsor assessment): 1/11 patients. SAE related to other components of the fixation (stabilization) system: 1/11 patients.
 - Study arm “Deformity”: AE: 8/10 patients, SAE: 6/10 patients, SADE: 5/10 patients, SAE related to procedure: 5/10 patients, 1 SAE related to bone grafts and substitutes, 1 SAE related to rods, no SAE related to fenestrated screw cement, to fenestrated screws, to other components of the fixation (stabilization) system, 1 or 2 SAE related to underlying condition or disease (acc. to sponsor or investigator assessment respectively,
- Rate of secondary spinal surgeries at index and/or adjacent levels, rate of secondary spinal surgeries resulting from an AE up to 12 months after surgery.
 - Study arm “DDD”: 0/11 patients (0%)
 - Study arm “Deformity”: 1/10 patients (10%)
- Radiographic confirmation of stabilization of the pedicle screw instrumentation at 12 months: Stable construct achieved 1/1 patients (100%), unstable construct: 0/1 patients (0%)
- Radiographic fusion at 12 months (“unable to determine”)

No 11) Performance Results of NCT03647501:

Outcomes

50 of 53 enrolled patients completed the study and could be analyzed.

Radiographic fusion rate: Interbody fusion will be graded using the Brantigan, Steffee, Fraser (BSF) Scale which classifies fusion between the interbody cage and adjacent bone on a scale of 1-3 where a higher score indicates a better outcome. The grades are defined as follows: Brantigan, Steffee, Fraser-Grade 1 (BSF-1) indicates radiographical pseudarthrosis, Brantigan, Steffee, Fraser-Grade 2 (BSF-2) is defined by radiographical locked pseudarthrosis, and Brantigan, Steffee, Fraser-Grade 3 (BSF-3) is radiographical fusion , indicating the best outcome. The subject will be considered a success if fusion is a Grade BSF-3 at 6 months.	3D-printed Titanium Cage supported by Expedium	(PEEK) Cage supported by Expedium
Overall Number of Participants Analyzed	24	26
all Number of Units Analyzed	34	40
Level with BSF Grade 3* (fusion successful)	27	10
Level with BSF Grade 2*	6	24
Level with BSF Grade 1*	0	6
Level with Cage Removed- Grade Not Applicable*	1	0

*Measure Type: Number | Unit of Measure: Cages/Spinal Levels

Post-operative timing of fusion: Fusion at one year was defined as a difference in Cobb angle of the operated levels between flexion and extension views. More than 2 degrees of change between views indicated non-union at one year.	3D-printed Titanium Cage supported by Expedium	(PEEK) Cage supported by Expedium
Overall Number of Participants Analyzed	16	18
Overall Number of Units Analyzed	24	29
Surgical levels over 2 degrees of change	5	12
Surgical levels under 2 degrees of change (fusion)*	19	17

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*Measure Type: Number | Unit of Measure: Surgical Levels

6. Safety Database Review (MAUDE, BfArM, SwissMedic)

A review of safety databases (US-FDA MAUDE, BfArM, SwissMedic) was conducted.

The following devices were investigated:

VENUS, HumanTech Spine
 Xia, Stryker
 Zodiac, Alphatec
 Firebird, Orthofix
 Expedium, DePuy
 Viper, DePuy
 Polaris, Zimmer
 uCentum, Ulrich
 Momentum, Ulrich
 Reline, NuVasive
 CREO, Globus
 CD Horizon, Medtronic
 REVERE, Globus

A **product recall** was identified in the SwissMedic and BfArM databases. The MAUDE database showed a range of device problems and patient outcomes. However, no unknown risk was identified.

5.4. An overall summary of the clinical performance and safety

The VENUS® and VENUS®nano devices are produced within the certified quality management system ISO 13485:2021 of the legal manufacturer. The evaluation of its performance (and safety) considers

- The state of the art
- Technical testing
- Biocompatibility Evaluation
- Usability Evaluation
- Post-market surveillance data
- Clinical data generated by the manufacturer (surgery reports, observational application, a PMCF study is planned)
- Data from literature and vigilance database review delivering additional safety information about similar devices.

Performance

The VENUS® and VENUS®nano devices are produced within the certified quality management system DIN EN ISO 13485:2021 of the legal manufacturer.

Implants and instruments are designed, manufactured, packaged, sterilized and processed according to applicable standards in such a way that the clinical condition or the safety of patients, users or other persons is not compromised. Only materials which have proven themselves to be safe in clinical practice on the market are used, see biocompatibility evaluation and state of the art. In recent years, toxicity and neurotoxicity of metal implants is more and more discussed, however, titanium alloy and commercially pure titanium are still the mostly used and best investigated material for implantation and evidence of clinical relevance of elevated metal concentrations is still lacking. A correlation between elevated metal concentrations in the serum or accumulation in different organs and e.g. neurotoxic or other diseases has not been proven.

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According to MDCG 2020-6, clinical data of similar devices can be used as clinical evidence for VENUS and VENUSnano, the devices under evaluation, because they are legacy devices which are based on well-established technologies.

The IFU underwent a revision since the last clinical evaluation: the intended purpose, indications, warnings and precautions and side effects/adverse have been precised and supplemented by additional information which is well-known by the state of the art but which was lacking in the IFU, contraindications have been divided in absolute and relative contraindications and the intended patient group has been adapted to clinical reality, because a group of surgeons used VENUS in 52 young patients under 18 years. Compared with the previous IFU, this was considered an off-label use, however the surgeons preferred VENUS to VENUSnano in children and adolescents e.g. due to higher activity levels, obesity or other conditions putting more strain on the screw-rod construct. The use of VENUS in patients under 18 years had already been known from surgery reports.

Mainly high-quality user surveys (HQUS), 4 HQUS with VENUS and 2 HQUS with VENUSnano, delivering long-term data and surgery reports delivering valuable intraoperative procedural information, have been used to demonstrate safety, performance and efficacy of VENUS and VENUSnano devices. In 4 HQUS, 160 patients treated with VENUS were included and analyzed retrospectively and additionally, more than 300 surgery reports have been evaluated. A separate statistical analysis of 460 surgery reports has been performed and revealed at least 95% functionality of the VENUS devices. Combinations are considered with at least 197 surgery reports with VENUS/ADONIS and 20 treatments with VENUS/SAMSON. All the kits of VENUS have successfully been applied in the HQUS. The HQUS/VENUS showed 96,1%-100% partial or complete achievement of predefined surgical/clinical objectives. The complete achievement of the single goals was between 76,3% and 88,4% at 12 months and 70,9%-100% at >24 months follow-up for pain reduction, functional, motoric, sensory and deformity improvements. Only the complete achievement of cosmetic improvement was lower with 61,9%-67,4% between 12 and >24 months follow-up.

The overall complication rate of the 4 HQUS is with 32,5% lower as comparable studies with similar devices identified in the ClinicalTrials.gov-database (47,2% and 47,6%).

For VENUSnano, 2 HQUS with 39 patients and 29 surgery reports and are available. The complete achievement of the single treatment goals in the HQUS was between 23,8%-100% at 12 months and 23,1%-87,5% at 24 months follow-up. However, The HQUS/VENUSnano showed 92,3%-100% partial or complete achievement of predefined surgical/clinical objectives.

Although the level of evidence of the surgery reports is relatively low, they are a valuable source of very direct user feedback, include a relatively large number of cases, are well documented with a high level of detail, cover the intended indications and reflect real life in clinical practice. Surgery reports were used to recognize potential risks, to take appropriate risk mitigation measures to reduce the risks as far as possible. This method was especially useful to optimize the surgical instruments at an early time point after product launch.

All indications mentioned in the IFU are either covered by the HQUS and also surgery reports or by the state of the art. Multiple levels were used (up to at least 12 levels for VENUS and VENUSnano). The publications and ClinicalTrials.gov-studies describing treatments with similar devices confirm the favourable performance of screw-rod systems in the relevant indications defined in the IFU and supported by the State of the Art.

A further (in the meantime stopped) observational application performed in Mexico with 23 patients included showed that most surgical aims could be achieved in all 23 surgeries, that three-dimensional deformities could be treated successfully and the devices could be applied independently of the bone quality. Nevertheless, in rare cases (one known case from a surgery report), under conditions of very severe osteoporosis, a surgeon may decide not to conduct the planned surgical procedure.

Regarding the observational application, no implant defects, no dislocation or loosening of device components are reported. Several user errors were identified in surgery reports and complaint analysis.

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In many cases, e.g. breakage or loosening of screws reported in complaints could have been avoided if the surgeons had adhered to the recommended Surgical Technique. Furthermore, training on product application and handling is essential. The IFU clarifies that the adherence to the surgical technique is mandatory for the implantation. The IFU mentions, that the product should only be used by surgeons with the necessary knowledge, experience and training on the product usage. Trainings for the clinical staff are performed by sales representatives and are documented. It can be concluded that the wording of these sections in the IFU is right.

The literature and safety database review provided no additional performance data because no publications and no entries in vigilance databases exist for the devices under evaluation. The very low complaint rates for the implants in the last 5 years suggest the safe usage of the devices within their intended use. Long-term data of similar devices were identified with follow-up periods of up to 52 months and cover the indications of VENUS and VENUSnano. The following indications were covered: Degenerative disease (DDD, degenerative stenosis, degenerative spondylolisthesis), Trauma, Tumor, Infection, Osteochondrosis of thoracal and lumbar spine (Instabilities), Spondylolisthesis, Instabilities, Fractures, Scoliosis, Spinal stenosis, discogenic axial low back pain (LBP) (degenerative disc disease DDD) and Spondylodiscitis.

The clinical data generated by the manufacturer, particularly the HQUS with 160 patients providing long-term data until more than 24 months, show that implants and instruments of the VENUS and VENUSnano system are state-of-the-art products. The complication rates for the single adverse events were at least in the range of those identified in the literature or even lower. The favourable results of the HQUS measured in complete achievement and partial or complete achievement of several predefined aims for surgical and clinical outcomes as well as the extremely low complaint rates for VENUS and VENUS within the considered 5-years period suggest that the products are safe and effective in their intended use. VENUS, VENUSnano and the similar devices in the literature show clear improvements of relevant clinical parameters compared to preoperative baseline conditions of the patients and the frequencies of occurrence are comparable to those of the broader generic product group considered in the SOTA. The performance of the devices is confirmed by similar devices in the literature.

Safety

The nature of adverse events identified in literature and vigilance databases are very similar to those listed in the IFU of VENUS® and VENUS®nano. The complaint rates of VENUS® and VENUS®nano implants and instruments are very low and the clinical data sets available (HQUS, surgery reports, literature review of similar devices) only show a small fraction of the adverse events reported in the MAUDE vigilance database.

No adverse events are known from the patients included in the observational application. The surgery reports describe e.g. failures such as breakage, loosening or dismantling of components, another problem was the lack of experience with the VENUS® devices and their handling in one surgery team (training was recommended by the sales representative).

Other non-implant-related adverse events reported in complaints since product launch were: failure of set screw insertion, rod breakage (possibly due to fatigue or due to not mapping the natural lordosis), rod breakage due to bending in two directions (not permitted according to IFU), rod slipping (because the rod was not sufficiently blocked), screw jamming due to unfavourable positioning limiting polyaxiality, failure to attach the hexagon of the screw to the instrument, loosening of the set screw caused by not using the counterholder. One metallosis was reported in a complaint which was however no material problem but the consequence of a user error causing abrasion.

Such user errors were no issue any more during the 5-years period of this clinical evaluation.

The instrument surveys were used to recognize deficiencies of the devices and appropriate measures were taken to optimize the instruments. The very low complaint rates for instruments show that these measures in the past were successful.

Vulnerable patients who are in need of special protection and care as the over 70s and children or adolescents are considered in the high-quality user surveys, the safety and performance literature

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review about similar devices as well as in indication-specific medical guidelines (because the indications are typical for specific age groups as e.g degenerative diseases which occur predominantly in elderly patients and scoliosis treatments which are more frequent in children and adolescents).

Based on the very low complaint rates and the favourable clinical results of the HQUS suggest that the devices are safe, their use is well-known and the trainings effective. The fact that no unknown or unassessed risk could be identified in literature and vigilance databases suggest that the risk profile of the similar devices (and also the broader generic device group considered in the state of the art SOTA VENUS/ADONIS) is very well known and that the risks are appropriately described in the IFU. The overall complication rate of the 4 VENUS-HQUS is with 32,5% lower than that of 2 studies with similar devices, including 21 and 53 patients, identified in the ClinicalTrial.gov database (47,6% and 47,2%). The complication rate here is the number of adverse events per number of patients included in the 4 HQUS or studies, respectively.

The high-quality user surveys with VENUS and VENUSnano only show adverse events which are manageable by the trained user and in line with the state of the art, including literature and safety database review of the defined similar devices.

The clinical benefit of VENUS and VENUSnano for the patient is improving the patient's quality of life through pain reduction, clinically relevant improvement in function, and/or stabilization to support the natural curvature.

The clinical benefit is measured in the HQUS by the parameters "complete achievement" and "partial or complete achievement" of:

- Pain reduction is addressed by the parameter "Reduction of pain" compared to baseline,
- Improvement in function is addressed by: "Functional improvement", "Motoric improvement", "Sensory improvement".
- Stabilization to support the natural curvature is addressed by "Stopping progression of deformities", "Spinal stabilization" and „Improvement of the lordosis/kyphosis“and „Correction of deformities“.

In literature studies, clinical parameters as ODI, VAS and others are used to assess the efficacy of the similar devices.

The devices under evaluation used in HQUS as well as the similar devices show clear improvement of the clinical parameters and that the side effects / adverse events were manageable to the trained user.

This allows the conclusion that in the light of the favourable results of the HQUS and literature studies, the side effects of VENUS and VENUSnano are acceptable.

5.5. Ongoing or planned post market clinical follow up

Every regular update of the clinical evaluation will include a review of literature and vigilance databases to obtain performance and safety data about VENUS and VENUSnano and the product group of similar pedicle screw systems on the market. HQUSs as well as surgery reports will continuously be performed or collected and evaluated. Furthermore, complaint data will periodically be analyzed and summarized (with each update of the clinical evaluation). All these sets of clinical data will also be utilized to identify off-label use of the device

If any new risks arise during a (periodically updated) clinical evaluation, they will be assessed in the Risk Management File and appropriate measures will be taken to reduce the risks as far as possible.

6. Possible diagnostic or therapeutic alternatives

Posterior instrumentation can be indicated in different diseases. The following summarizes different indication in which posterior instrumentation is indicated and possible alternative treatment options.

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2.2.1. Traumatic Injuries of the Spine

The S1-AWMF Guideline from the German Society of Trauma Surgery provides recommendations for treating spinal injuries in adults, excluding osteoporotic fractures without adequate trauma. Spinal injuries can result from indirect or direct force application, most commonly excessive axial compression and flexion forces, or from hyperextension and rotational stresses. Common causes include traffic accidents, sports accidents, work-related falls, minor trauma in cases of reduced bone quality (e.g., osteoporosis), or pathological fractures due to tumor diseases. Rare causes include direct violence such as gunshot wounds.

Treatment decisions depend on assessing and classifying the injury and spinal stability, which can be challenging. A fracture is considered stable if no neurological deterioration or positional change is expected with functional therapy. **Highly unstable fractures, where mobilization threatens neurological deterioration, typically require immediate treatment.** For fractures between these two extremes, treatment decisions are more complex and depend heavily on the surgeon's experience.

The guideline outlines four morphological modifications to standardize decision-making, based on differences in sagittal and scoliotic angles, vertebral body distraction, spinal canal stenosis, and disc injury. These are combined with the AO Spine classification to **determine the necessity of surgical intervention.** Stable A- (compression) and B- (distraction) injuries can generally be treated non-surgically, especially if the posterior column is intact and specific angular deviations are within limits.

Non-operative therapy principles (an alternative to instrumentation) include: general or local contraindications to surgery, no risk of significant deformity, early mobilization with pain management, close cooperation among healthcare providers, and regular clinical and radiological checks until healing. X-ray checks in a standing position are crucial for detecting malpositions. **Deterioration during follow-up can lead to an indication for surgery.**

2.2.2. Lumbar Disc Herniation with Radiculopathy

The endoscopic nucleotomy/sequestrectomy is a surgical technique gaining acceptance, comparable to arthroscopy but using a uniportal endoscope with an intraendoscopic working channel (typically 6mm diameter, 4mm working channel, 25° viewing angle). Transforaminal and interlaminar approaches are used for full-endoscopic operations on herniated lumbar discs, making it technically possible to reach all such discs. The general complication rate ranges from 2.9% to 13.75%, with dural injuries at 0-5% and nerve injuries at 0-2.5%. A meta-analysis indicates a lower overall complication rate compared to microsurgical procedures, with infections or operation-related instabilities rarely reported. Other complications like wrong level, general medical complications, hematoma, or wound problems are also less frequent (1.1%) than with microsurgery. The recurrence rate for herniated discs ranges from 0.5% to 8%.

Thoracic disc herniation surgery is less common and often challenging, aiming for sufficient decompression without myelom manipulation. Minimally invasive techniques (microsurgery, full endoscopy, foraminotomy) can reduce access-related problems for lateral or intraforaminal herniations with radiculopathy. Additive stabilization may be needed when resecting dorsal stabilizing structures or more than half of a vertebral body. Percutaneous intradiscal procedures aim to reduce intervertebral disc volume, especially in the nucleus, to relieve pressure on surrounding structures.

2.2.3. Inflammatory Diseases of the Spine

In addition to radical debridement, **ventral procedures for postoperative spondylodiscitis involve excising affected discs and vertebral bodies.** Reconstruction with bone interposition or cages is recommended as fusion rates are higher than with pure debridement (97% vs. 90% after ten years). Studies show good clinical and radiological results with approaches like ALIF (Anterior Lumbar Interbody Fusion) and XLIF (eXtreme Lateral Interbody Fusion).

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Axial spondyloarthritis (AxSpA) is a group of chronic inflammatory rheumatic musculoskeletal diseases primarily affecting the axial skeleton (spine and sacroiliac joints), also manifesting in peripheral joints, entheses, and digits. AxSpA includes Ankylosing Spondylitis (AS), which shows visible structural damage on X-ray, and non-radiographic axial Spondyloarthritis (nr-axSpA), where inflammatory signs are present without definitive radiographic changes. Prevalence ranges from 0.4% to 2%, influenced by regional factors like HLA-B27 gene frequency. The global prevalence of AS is estimated between 0.1% and 1.4%, with Germany likely at 0.3-0.5%. SpA generally has a male-to-female ratio of at least 2:1, but nr-axSpA has a 1:1 gender ratio.

Deformity correction via single- or two-level pedicle PSO (pedicle subtraction osteotomy) can improve disability, pain from muscle fatigue, respiratory function, and quality of life. Classic open two-level osteotomies are major procedures with complication risks, although recent literature has not reported hemorrhage, vascular injuries, or postoperative infection. A combined open and percutaneous approach is feasible for major deformity correction in ankylosing spondylitis to reduce access-related morbidity. AS patients are susceptible to spontaneous vertebral fractures due to reduced bone density and ossified intervertebral discs/joints, even without trauma.

2.2.4. Degenerative Spondylolisthesis

Spondylolisthesis involves the subluxation of one vertebral body over another in the sagittal plane. Degenerative lumbar spondylolisthesis (DLS), a common orthopedic condition, affects about 10% of adults over 40 and is a frequent cause of back pain. While spondylolysis itself is often asymptomatic, spondylolisthesis can cause deep back pain, exacerbated by exertion, due to strain on spinal ligaments. Severe cases may also lead to radicular pain from nerve stretching.

Conservative Therapy: Initial treatment for symptomatic spondylolysis or spondylolisthesis is conservative. This includes pain management, infiltrations, reducing mechanical stress on the affected segment (e.g., sport breaks, corsets), adjusting daily activities, physiotherapy, occupational therapy, core-stabilizing exercises, and physical therapy. Chronic cases may involve complex pain therapy, behavioral therapy, and psychotherapy.

Indications for Surgery and Surgical Approaches: Surgical fusion is an effective method for stabilizing the spine and reducing pain and disability in patients with spondylolisthesis. A meta-analysis comparing decompression alone versus decompression with additional fusion for DLS showed significantly better improvement in VAS for back pain in the decompression and fusion group. Postoperative back pain was also reduced in this group. Other outcomes like leg pain, ODI, and complication rates were comparable.

Fusion is often considered for patients with lumbar spinal stenosis (LSS) and spondylolisthesis. The SLIP study indicated that instrumented posterolateral fusion led to significantly greater improvement in the SF-36 Physical Component Summary compared to decompression alone after 2-4 years, and a lower reoperation rate (14% vs. 34%). However, there was no difference in reducing disability-related back pain. The overall impact of fusion remains controversial, with some literature suggesting it does not always provide additional clinical benefits over decompression alone but can lead to longer surgery times, increased blood loss, and higher complication rates.

Alternatives to Fusion: Alternatives to decompression with or without fusion include **percutaneously implanted interspinous spacers (ISS)**. These have shown improved clinical performance and better pain/function scores over 2-5 years in treating LSS with stable, mild to moderate DLS (Grade I). ISS can be implanted percutaneously in patients with flexion-based relief of neurogenic claudication symptoms. Another alternative is **percutaneous image-guided lumbar decompression (PILD)**, a decompressive strategy that focuses on removing or reducing hypertrophied Ligamentum flavum (contributing to LSS in up to 85% of cases). This approach is indicated when hypertrophy is 2.5 mm or more in the presence

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of neurogenic claudication, and evidence suggests it improves pain and function for LSS patients after 2 years.

2.2.5. Lumbar Spinal Stenosis

Lumbar Spinal Stenosis (LSS) is a condition characterized by the narrowing of the spinal canal, nerve root canals, or intervertebral foramina in the lumbar spine, leading to compression of the neural elements. This narrowing can be caused by various factors, including degenerative changes of the intervertebral discs, facet joint hypertrophy, ligamentum flavum thickening, or spondylolisthesis. The most common symptom is neurogenic claudication, which presents as leg pain, numbness, or weakness that is exacerbated by walking or standing and relieved by sitting or bending forward.

Conservative Treatment: Initial management of LSS is typically conservative. This includes physical therapy, exercise programs, pain medication (NSAIDs, muscle relaxants, neuropathic agents), epidural steroid injections, and lifestyle modifications. The goal of conservative treatment is to alleviate symptoms, improve function, and avoid surgery where possible. However, conservative therapy may not always provide long-term relief, especially in severe cases.

Indications for Surgery: Surgical intervention is generally considered for LSS when conservative treatments fail to provide adequate relief, when there is progressive neurological deficit (e.g., worsening weakness or numbness), or in cases of severe pain significantly impacting quality of life. The primary surgical goal is to decompress the neural structures, thereby alleviating symptoms.

Surgical Approaches and Alternatives: Traditional surgical approaches for LSS include laminectomy, which involves removing part of the vertebral bone and ligaments to create more space for the nerves. However, this can sometimes lead to spinal instability, necessitating additional fusion.

Artificial Disc Replacements (TDR): Total disc replacement (TDR) has emerged as an alternative to lumbar fusion for treating symptomatic single-level degenerative disc disease (DDD) in the lumbar spine, particularly for younger patients (typically aged 10-50 years). The rationale behind TDR is to preserve motion at the affected segment, potentially reducing the risk of adjacent segment disease, which can occur after fusion.

- **Indications:** Lumbar artificial disc arthroplasty is indicated for single-level symptomatic DDD from L3-S1 where pain persists despite at least six months of conservative treatment.
- **Outcomes vs. Fusion:** A systematic review and meta-analysis comparing TDR to lumbar fusion found that TDR significantly improved ODI (Oswestry Disability Index), VAS (Visual Analog Scale), SF-36 (Short Form 36 health survey), patient satisfaction, overall success, and reduced reoperation rates. TDR also led to shorter operation times, reduced hospital stay, and fewer postsurgical complications compared to lumbar fusion. However, there were no significant differences in blood loss, analgesic consumption, neurologic success, or device success. While charges were lower for single-level TDR, they were similar for two-level cases.
- **Drawbacks:** Major drawbacks of TDR include potential for subsidence, malpositioning of the implant, excessive facet joint loading, and increased axial rotational instability. These issues can lead to revision surgery in 6-14% of patients.

The choice between decompression alone, decompression with fusion, or TDR depends on various factors, including the patient's age, the extent of degenerative changes, presence of instability, and surgeon's preference. The aim is always to achieve adequate decompression while maintaining or restoring spinal stability and function.

2.2.6. Low Back Pain

Low back pain (LBP) is a highly prevalent condition, affecting a large percentage of the population at some point in their lives, and is a leading cause of disability worldwide. It is a complex issue with various

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potential underlying causes, ranging from mechanical problems (e.g., muscle strain, ligamentous sprain, degenerative disc disease, facet joint arthritis, spondylolisthesis) to inflammatory conditions, infections, tumors, or systemic diseases. LBP can be acute (lasting less than 6 weeks), subacute (6 weeks to 3 months), or chronic (more than 3 months).

Diagnosis and Classification: A thorough clinical evaluation is crucial to identify the specific type of low back pain and rule out serious underlying conditions ("red flags" such as neurological deficits, fever, unexplained weight loss, history of cancer, or trauma). LBP is often categorized into:

- **Non-specific low back pain:** The most common type, where no specific identifiable cause (like a fracture or tumor) can be found. It is often attributed to muscle or ligamentous strain, or minor degenerative changes.
- **Radicular pain (sciatica):** Pain radiating into the leg due to compression or irritation of a spinal nerve root, commonly caused by disc herniation or spinal stenosis.
- **Specific low back pain:** LBP caused by an identifiable pathology, such as a vertebral fracture, infection (e.g., spondylodiscitis), tumor (e.g., spinal metastases), or inflammatory arthritis (e.g., axial spondyloarthritis).

Conservative Treatment: For most cases of non-specific LBP, conservative management is the first line of treatment. This typically includes:

- **Education and reassurance:** Informing the patient about the benign nature of most LBP and encouraging active coping strategies.
- **Activity modification:** Advising against prolonged bed rest and encouraging continuation of daily activities within pain limits.
- **Pharmacological interventions:** Over-the-counter pain relievers (NSAIDs, acetaminophen), muscle relaxants, or in some cases, neuropathic pain medications or weak opioids for short-term severe pain.
- **Physical therapy:** Exercise programs focusing on core strengthening, stretching, aerobic conditioning, and postural correction. Manual therapy, massage, and other physical modalities may also be used.
- **Injections:** Epidural steroid injections or facet joint injections may be considered for radicular pain or facetogenic pain, respectively, to provide temporary pain relief.
- **Psychological interventions:** For chronic LBP, cognitive behavioral therapy (CBT) or other psychological approaches can be beneficial to address pain-related distress and improve coping mechanisms.

Indications for Surgery: Surgical intervention for low back pain is reserved for specific cases where:

- **Conservative treatment has failed** after an adequate trial (typically 6 weeks to 3 months or more, depending on the cause).
- There is **progressive neurological deficit**, such as worsening weakness or cauda equina syndrome (a medical emergency).
- There is an **identifiable structural pathology** (e.g., severe spinal stenosis, significant disc herniation causing persistent radiculopathy, unstable spondylolisthesis, vertebral fracture with instability, tumor, or infection) that is amenable to surgical correction and is clearly correlated with the patient's symptoms.
- Persistent, severe, and disabling pain despite maximal conservative efforts.

Surgical Approaches: Surgical options vary widely depending on the underlying cause of LBP and may include:

- **Decompression:** Such as laminectomy or microdiscectomy, to relieve pressure on nerves.
- **Spinal fusion:** To stabilize unstable segments of the spine (e.g., in spondylolisthesis or severe degenerative instability).

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- **Total Disc Replacement (TDR):** As discussed in 2.2.5, for specific cases of symptomatic single-level DDD.
- **Minimally Invasive Spine Surgery (MISS):** Techniques aiming to reduce tissue damage, blood loss, and recovery time.

The decision for surgery is complex and involves careful consideration of the patient's symptoms, imaging findings, functional impairment, and response to conservative treatments, as well as the potential risks and benefits of the procedure.

2.2.7. Spinal Metastases

Spinal metastases are the most common tumors affecting the spine, representing a significant cause of pain, neurological dysfunction, and reduced quality of life in cancer patients. They result from the spread of cancer cells from primary tumors (e.g., breast, prostate, lung, kidney, thyroid, multiple myeloma) to the vertebral column. The spine is a frequent site for metastases due to its rich vascular supply. Metastatic disease can lead to vertebral body destruction, spinal instability, and compression of the spinal cord or nerve roots, resulting in severe pain, weakness, sensory deficits, or even paralysis.

Diagnosis: Diagnosis typically involves a combination of clinical evaluation (pain, neurological symptoms), imaging studies (MRI is the gold standard for assessing spinal cord compression and soft tissue involvement; CT provides better bony detail and is useful for assessing stability; bone scans can detect widespread metastatic activity), and sometimes biopsy to confirm the diagnosis and identify the primary tumor type.

Treatment Goals and Considerations: Treatment for spinal metastases is often palliative, aiming to:

- Alleviate pain.
- Preserve or improve neurological function.
- Restore spinal stability.
- Improve quality of life.
- Local tumor control.

Treatment decisions are multidisciplinary and individualized, considering factors such as:

- **Spinal segment stability:** Assessed using scores like SINS (Spinal Instability Neoplastic Score), which helps quantify instability and guide surgical planning.
- **Tumor biology:** The type of primary cancer, its aggressiveness, and its sensitivity to radiation or chemotherapy.
- **Patient's overall prognosis and life expectancy:** This heavily influences the invasiveness and extent of treatment.
- **Extent of neurological deficit:** Presence and severity of spinal cord or nerve root compression.
- **Prior treatments:** History of radiation or surgery to the affected area.

Treatment Modalities and Indications for Surgery:

1. Radiotherapy:

- **Indication: Radiotherapy is the primary treatment for stable lesions with irrelevant neurocompression.** It is highly effective for pain control and local tumor control for many radiosensitive tumors. It can be conventional external beam radiation therapy (EBRT) or more targeted approaches like stereotactic body radiation therapy (SBRT), especially for radioresistant tumors or re-irradiation.
- **Role:** Often used alone for stable lesions, or as an adjuvant to surgery.

2. Systemic Therapy:

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- **Role:** Chemotherapy, targeted therapy, immunotherapy, and hormonal therapy are crucial for systemic disease control and can shrink tumors, including spinal metastases. They are often used in conjunction with local treatments.

3. Surgical Intervention:

- **Indications:** Surgery is generally indicated in cases of:
 - **Acute neurological deficits:** Such as rapidly progressing spinal cord compression leading to weakness or paralysis.
 - **Unstable lesions:** Where there is a significant risk of collapse, deformity, or further neurological compromise, as assessed by scores like SINS.
 - **Pain refractory to conservative management (including radiotherapy).**
 - **Biopsy for diagnosis** when the primary tumor is unknown or to confirm metastatic nature.
 - **Radioresistant tumors** where radiation alone is unlikely to achieve adequate control.
- **Surgical Approaches:** Surgical approaches vary by spinal section and the specific location of the tumor and compression:
 - **Dorsal/Posterior Approaches:** Common for laminectomy and posterior stabilization (e.g., with pedicle screws).
 - **Ventral/Anterior Approaches:** Used for direct decompression of the spinal cord from the front, often involving corpectomy (removal of vertebral body) and reconstruction with cages or bone grafts.
 - **Dorsolateral Approaches:** Preferred for Th2-Th5 metastases, allowing access to both anterior and posterior elements.
 - **Minimally Invasive Techniques:** Increasingly used to reduce surgical morbidity, especially in patients with limited life expectancy.
- **Goal of Surgery:** To achieve rapid decompression of neural structures, restore spinal stability, and provide pain relief. Surgery is usually followed by adjuvant radiotherapy.

Due to anatomical and biomechanical conditions, the risk of instability and early neurological deficits is lower in thoracolumbar regions compared to cervical localizations, potentially reducing the absolute indication for thoracolumbar surgical interventions in some scenarios. The overall treatment concept for spinal metastases is highly individualized, aiming to optimize patient outcomes given their specific condition and prognosis.

2.2.8. Pediatric Spine Surgery

Pediatric spine surgery addresses a unique set of conditions and challenges due to the distinct anatomical and biomechanical characteristics of the developing spine. Unlike the adult spine, the pediatric spine undergoes continuous growth and ossification, impacting injury patterns, stability, and surgical considerations.

Distinctive Features of the Pediatric Spine:

- **Vertebrae Count:** Children are born with 33 vertebrae (adults have 26 due to sacral/coccygeal fusion).
- **Spinal Cord Maturation:** The spinal cord resembles an adult's by 8-10 years of age.
- **Center of Rotation (COR):** The COR shifts from C2-3 in younger children to C5-6 around 8-10 years, influencing injury distribution. Younger children are more prone to upper cervical spine

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injuries due to a disproportionately large head, weaker neck muscles, and ligamentous laxity, creating a "fulcrum effect" at C2/C3.

- **CSF Volume:** Children have larger total and spinal cerebrospinal fluid (CSF) volumes (50% vs. 33% in adults).
- **Ligamentous Laxity and Incomplete Ossification:** Less densely packed spinal ligaments, underdeveloped spinous processes, shallow/angled facet joints, and incomplete odontoid ossification increase spinal instability risk.
- **Vulnerability to Injury:** The spinal cord in children is more vulnerable to injury due to greater blood supply and immature CNS response, potentially leading to worse functional outcomes.
- **SCIWORA:** Delayed skeletal maturation makes children susceptible to Spinal Cord Injury Without Radiographic Abnormality (SCIWORA), where neurological deficits are present without visible bony injury on initial X-rays.

Pediatric Spinal Cord Injury (SCI): Pediatric SCI is rare (less than 4% of all SCI cases). Injury levels are age-dependent: C2 in younger children, C4 in teenagers, and C4-C5 in adults. Traumatic causes include motor vehicle accidents, sports injuries, falls, and child abuse. Non-traumatic etiologies are more frequent in children, including congenital anomalies, tumors, infections, and vascular malformations.

Common Complications in Pediatric SCI:

- **Pain management:** Often challenging, requiring experienced teams and neuropathic pain medication.
- **Spasticity:** Appears after spinal shock (up to 2 months post-injury) and requires individualized management.
- **Bowel and Bladder Dysfunction:** Common, with patterns varying based on injury level.
- **Spinal Deformity and Hip Dislocation:** Spinal deformity is common in children injured before growth spurts (up to 97%), often treated with bracing or surgery. Hip dislocation occurs in over 90% of children under 10.
- **Hypercalcemia:** Affects ~23% of children, especially adolescent males, leading to symptoms like abdominal pain and polyuria, and increasing risks of nephrocalcinosis and renal failure.

Indications for Surgery in Pediatric Spine Conditions: Surgical intervention in pediatric spine conditions is guided by the specific diagnosis, severity, and potential for progression. General indications include:

- **Unstable fractures:** Where there is a risk of further displacement or neurological compromise.
- **Progressive neurological deficits:** Such as worsening weakness, sensory loss, or bladder/bowel dysfunction.
- **Significant post-traumatic deformities:** Beyond the child's spontaneous corrective potential or progressing rapidly.
- **Scoliosis or Kyphosis:** When conservative treatments (e.g., bracing) fail, or the curve magnitude is severe and progressive (e.g., Cobb angle >40° for scoliosis).
- **Spinal tumors:** For biopsy, decompression, or resection.
- **Spinal infections:** For debridement and stabilization if conservative management is insufficient.

Surgical Principles: Treatment goals are to restore stability, protect neurogenic structures, and restore anatomical relationships. Minimally invasive surgery is often recommended to minimize tissue damage and preserve growth potential. Transpedicular instrumentation can be used even in small children, adapting techniques to the smaller vertebral dimensions. Surgical planning must carefully consider the child's ongoing growth and skeletal maturation to minimize long-term complications and optimize outcomes.

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2.2.9. Further Medical Conditions

This section serves as a broad category encompassing various other medical conditions affecting the spine that may necessitate surgical consideration, beyond those specifically detailed in the preceding subsections. While the provided document snippets do not offer an exhaustive list or detailed descriptions of these "further medical conditions," they implicitly refer to a range of pathologies that spinal surgeons might encounter.

These conditions could include, but are not limited to:

- **Spinal Infections (other than Spondylodiscitis post-op):** This might cover primary bacterial or fungal spondylodiscitis, epidural abscesses, or osteomyelitis of the vertebrae not directly related to a postoperative complication. Indications for surgery typically involve failure of antibiotic therapy, neurological deficit, spinal instability, or persistent pain.
- **Primary Spinal Tumors:** While spinal metastases (2.2.7) are common, the spine can also be affected by primary tumors originating from bone (e.g., osteosarcoma, chondrosarcoma, osteoid osteoma) or neural elements (e.g., schwannoma, meningioma, ependymoma). Surgical indications vary widely based on tumor type, location, size, and presence of neurological compromise or instability.
- **Congenital Spinal Deformities:** Conditions such as congenital scoliosis or kyphosis, vertebral anomalies (e.g., hemivertebrae, block vertebrae), or myelomeningocele can cause significant spinal deformities and neurological deficits. Surgical correction and stabilization are often indicated for progressive curves or neurological impairment.
- **Spinal Vascular Malformations:** Arteriovenous malformations (AVMs) or fistulas within or around the spinal cord can lead to myelopathy, hemorrhage, or neurological deficits. Surgical or endovascular embolization may be indicated to prevent further neurological deterioration or bleeding.
- **Post-Laminectomy Syndrome / Failed Back Surgery Syndrome (FBSS):** While not a distinct "condition" in itself, FBSS refers to persistent or new pain after spinal surgery. Management can be complex and may involve revision surgery if there's an identifiable correctable cause (e.g., recurrent disc herniation, pseudarthrosis, adjacent segment disease, hardware failure) or multimodal conservative pain management.
- **Vertebral Fractures (other than traumatic or metastatic):** This might include pathological fractures due to underlying bone diseases (e.g., osteoporosis, although the document excludes these from 2.2.1 if without adequate trauma) or stress fractures. Surgical indications for osteoporotic fractures, for example, might include persistent pain, progressive kyphosis, or neurological compromise despite conservative management, potentially involving kyphoplasty or vertebroplasty.
- **Rheumatoid Arthritis and other Systemic Inflammatory Conditions:** These can affect the cervical spine (e.g., atlantoaxial instability) or other spinal segments, potentially leading to instability, pain, or neurological deficits requiring surgical stabilization or decompression.

For all these "further medical conditions," the decision for surgical intervention, if any, is based on a comprehensive assessment of the patient's symptoms, neurological status, imaging findings, the specific underlying pathology, the failure of conservative management, and the potential risks versus benefits of surgery. The goal remains to alleviate pain, preserve or restore neurological function, and maintain spinal stability.

General Conclusion

This overview of the medical state of the art concern various spinal conditions requiring interventions, covering traumatic injuries, disc herniation, inflammatory diseases, degenerative conditions, spinal

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metastases, and pediatric spine surgery. It details current knowledge, diagnostic approaches, and treatment strategies, including conservative and surgical methods, and discusses the evolution and effectiveness of different implants and surgical techniques, as well as associated complications and outcomes.

In summary, while spinal fusion using pedicle screws and cages is a well-established and highly effective treatment, it is part of a broader spectrum of therapies. The choice between conservative management, alternative surgical techniques, dynamic stabilization, and fusion must be individualized, guided by evidence-based recommendations and clinical judgment.

7. Suggested profile and training for users

Primary users - surgeon

The devices of the VENUS® and VENUS®nano system may only be implanted by surgeons who have completed the necessary training in spinal surgery.

The

- professional judgement and/or clinical skills and experience of the surgeon with regard to careful patient selection
 - preoperative planning and implant selection
 - knowledge of the anatomy and biomechanics of the spine
 - understanding of the material and the mechanical properties of the used implants
 - training and skills in spinal surgery and the use of the instruments required for inserting the implants
 - surgeon's ability to gain the patient's consent to adhere to a clearly defined post-operative treatment regimen and to conduct scheduled follow-up examinations
- is/are necessary for the use of the devices of the system.

Secondary users – surgical assistant

The surgeons are supported in the operating theater environment by surgical assistants. General knowledge in surgical procedures, the surgical technique and special training and skills regarding the correct use of the devices of the system and the use of the instruments required for inserting the implants is/are necessary for the use of the devices.

Secondary users – persons responsible for processing procedures

Unsterile delivered products must be cleaned, disinfected and sterilized before use on the patient by persons responsible for processing procedures. For a correct execution of the processing procedure, general hygienic principles regarding the processing of medical devices and the knowledge of the defined steps of the processing instruction are necessary.

Indirect or tertiary users

Not applicable. Devices of the VENUS® / VENUS®nano and are not intended to be handled by indirect or tertiary users.

8. Reference to any harmonised standards and CS applied

Standards	Title	Version
DIN EN ISO 10993-10	Biologische Beurteilung von Medizinprodukten - Teil 10: Prüfungen auf Hautsensibilisierung	2023-04
DIN EN ISO 10993-12	Biologische Beurteilung von Medizinprodukten - Teil 12: Probenvorbereitung und Referenzmaterialien	2021-08

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Standards	Title	Version
DIN EN ISO 10993-17	Biologische Beurteilung von Medizinprodukten - Teil 17: Toxikologische Risikobewertung von Medizinproduktbestandteilen	2024-02
DIN EN ISO 10993-18	Biologische Beurteilung von Medizinprodukten - Teil 18: Chemische Charakterisierung von Werkstoffen für Medizinprodukte im Rahmen eines Risikomanagementsystems	2023-11
DIN EN ISO 10993-23	Biologische Beurteilung von Medizinprodukten - Teil 23: Prüfungen auf Irritation	2021-10
DIN EN ISO 11137-1	Sterilisation von Produkten für die Gesundheitsfürsorge – Strahlen – Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte	2020-04
DIN EN ISO 11137-2	Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 2: Festlegung der Sterilisationsdosis	2023-08
DIN EN ISO 11607-1	Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 1: Anforderungen an Materialien, Sterilbarriersysteme und Verpackungssysteme (ISO 11607-1:2014);	2024-02
DIN EN ISO 11607-2	Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte – Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens	2024-02
DIN EN ISO 11737-1	Sterilisation von Produkten für die Gesundheitsfürsorge – Mikrobiologische Verfahren – Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten	2021-10
DIN EN ISO 11737-2	Sterilisation von Medizinprodukten – Mikrobiologische Verfahren – Teil 2: Prüfungen der Sterilität bei der Definition, Validierung und Aufrechterhaltung eines Sterilisationsverfahrens	2020-07
DIN EN ISO 13485	Medizinprodukte - Qualitätsmanagementsystem- Anforderungen für regulatorische Zwecke	2021-12
DIN EN ISO 14971	Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte	2022-04
DIN EN ISO 15223-1	Medizinprodukte - Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen - Teil 1: Allgemeine Anforderungen	2022-02
DIN EN ISO 17664-1	Aufbereitung von Produkten für die Gesundheitsfürsorge - Vom Medizinprodukt-Hersteller bereitzustellende Informationen für die Aufbereitung von Medizinprodukten - Teil 1: Kritische und semi-kritische Medizinprodukte	2021-11

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9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body	
01	23.05.2025	New	<input type="checkbox"/>	Yes Validation language: English
			<input checked="" type="checkbox"/>	No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2 nd paragraph) for which the SSCP is not yet validated by the NB)
02	15.07.2025	Update of the SSCP to proceed non-conformities identified by the notified body during MDR certification and to be in line with the technical documentation and with the update of the PSUR and CER (VENUS_CER-03)	<input type="checkbox"/>	Yes Validation language: English
			<input checked="" type="checkbox"/>	No
03	29.07.2025	Addition of warnings regarding the treatment of pregnant women	<input type="checkbox"/>	Yes Validation language: English
			<input type="checkbox"/>	No

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10. Summary of Safety and Clinical Performance intended for patients

A summary of the safety and clinical performance of the device, intended for patients, is given below.

10.1 Summary of safety and clinical performance

Document revision: 01

Date issued: 2023-05-25

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

10.2 Device identification and general information

- Device trade name: VENUS, VENUSnano
- Manufacturer: HumanTech Spine, Gewerbestraße 5, D-71144 Steinenbronn
- Basic UDI-DI: see Article List, Appendix
- Year when the device was first CE-marked: 2010 (VENUS), 2013 (VENUSnano)

10.3 Intended use of the device

Intended purpose

VENUS

The implants of the VENUS® Spinal Fixation System are intended for posterior mono- or multisegmental fixation, after prior correction if necessary, and immobilization during bony fusion to achieve stabilization of the thoracic, lumbar and iliosacral spine. The VENUS® Spinal Fixation System can be used in an open or a minimally invasive surgical approach. The implants are intended for long-term stand-alone use.

VENUS nano

The implants of the VENUS®nano Spinal Fixation System are intended for mono- or multisegmental fixation, after prior correction if necessary, and immobilization during bony fusion to achieve stabilization of the thoracic, lumbar and iliosacral spine. VENUS®nano is used in a posterior and VENUS®nano VDS in an anterior open surgical approach. Ventral derotation spondylodesis (VDS) with VENUS®nanoVDS can be performed with a minimized incision size. The implants are intended for long-term stand-alone use.

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Indications

VENUS and VENUSnano

A treatment of the following diseases and injuries with VENUS® and VENUS®nano Spinal Fixation Systems is only intended if surgical spondylodesis is indicated.

- instabilities
- degenerative disc disease
- (degenerative) spondylolisthesis
- (degenerative) stenosis (spinal canal stenosis, neuroforaminal stenosis)
- deformities as (idiopathic) scoliosis, kyphosis or lordosis
- pseudarthrosis
- spinal trauma
- tumours
- inflammation (spondylitis, spondylodiscitis)
- conditions requiring revision surgery

Intended patient groups

VENUS:

There are no general limitations of the patient population in addition to the defined indications and contraindications. The patient's age may lead to restrictions, e.g. due to immature skeleton in pediatric patients or limited availability of implant sizes. This requires the consideration by an experienced surgeon to assess the suitability of the implant with respect to incomplete growth phase in pediatric patients or infants and other conditions as e.g. the expected activity of the individual patient. Age-related or other comorbidities may limit the surgical success, which requires careful risk-benefit weighting by the responsible surgeon.

VENUSnano:

There are no general limitations of the patient population in addition to the defined indications and contraindications. The patient's age may lead to restrictions, e.g. due to immature skeleton in pediatric patients or limited availability of implant sizes. This requires the consideration by an experienced surgeon to assess the suitability of the implant with respect to incomplete growth phase in pediatric patients or infants and other conditions as e.g. the expected activity of the individual patient. In elderly patients, e.g. comorbidities may limit the surgical success, which requires careful risk-benefit weighting by the responsible surgeon.

The implant sizes of VENUSnano are suitable for patients of small stature. As a Guideline: for patients weighing less than 45 kg at the time of surgery.

Contraindications

Contraindications may be either relative or absolute.

Absolute contraindications

- Suspected or documented allergy or intolerance to the materials used.
- Medical or surgical condition which would preclude a potential benefit of spinal implant surgery, such as the presence of congenital abnormalities.
- Inadequate tissue coverage over the operative site.
- Inadequate bone stock or bone quality making implant anchoring impossible

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- Anatomical structures expected to interfere with the usage of the implant (e.g. extreme anatomic abnormalities) or to impair the instrumentation
- If the implant is expected not being able to perform adequately after implantation.
- If the implant components selected for use would be too large or too small to achieve a successful result.

For minimally invasive/percutaneous procedures only:

- Severe neural deficits, which require canal decompression

Relative contraindications

Relative contraindications are conditions that may decrease the surgical success and its outcomes. The responsible physician has to weigh the risks and benefits of an implantation in each individual case. If the implantation is performed despite the presence of a relative contraindication, special care or procedures may be required.

- Fever or leucocytosis
- Acute or chronic infection
- Significant risk of infection (e.g. in case of immune deficiencies)
- Signs of local inflammation
- Open wounds
- Wound healing disorders
- Pregnancy: Operations on pregnant women must be avoided if possible. If they are nevertheless performed, they require special care or procedures.
- If the use of components other than the metals or alloys used in this system is required.
- Local bone tumors
- Concomitant diseases or conditions that could negatively affect the function and success of the implant, e.g.
 - advanced age
 - smoking
 - diabetes
 - osteoporosis, osteopenia, osteomalacia, joint disease, bone absorption
 - obesity
 - chronic kidney disease
 - depression or conditions of reduced mental health
 - neuromuscular diseases that would place excess strain on the implant during the healing period.
- If the patient is unwilling or not able to follow postoperative instructions.

For minimally invasive/percutaneous procedures only:

- All the situations causing difficulty in imaging such as rotational deformities, obesity and osteopenia
- Multilevel vertebral fractures
- Pedicle fractures
- Adjacent body fracture
- Patient with significant kyphosis or sagittal malalignment

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10.4 Device description

10.4.1 Device description and mode of action and material/substances in contact with patient tissues

Device Description

The VENUS® Spinal Fixation System is a medical implant system used to stabilize parts of the spine during surgery. This helps the spine to heal naturally through bone fusion. The system consists of screws that are anchored into the vertebrae on both sides of the spine. These screws are connected by rods, creating a stable framework that takes pressure off the affected spinal segments. This stabilization supports the natural fusion of the bones. Once the bones have fused, the implants no longer have an active function but can safely remain in the body.

The system comes with different types of screws and rods to adapt to the patient's needs, including options for minimally invasive surgery, complex spinal deformities like scoliosis, or poor bone quality. For example, special screws can be used that allow for cement reinforcement in patients with weak bones.

Additionally, the VENUS®nano Spinal Fixation System is a smaller version designed for patients with a smaller body size, typically those under 45 kg. Like the larger system, VENUS®nano helps stabilize the spine and promotes bone fusion, with specific implant sizes and configurations for smaller anatomies. Both systems can also be combined with other spinal implants, like cages or vertebral body replacements, for more comprehensive treatments. The materials used—titanium and cobalt-chrome—are well-established, safe, and compatible with the human body.

For each specific use, tailored instruments and detailed surgical techniques are provided to ensure proper and safe implantation.

Materials in contact with patient tissues

All components of the VENUS® Spinal Fixation System and VENUS®nano Spinal Fixation System including all components of preassembled assemblies, but except CoCr rods, are made of titanium alloy Ti6Al4V according to DIN EN ISO 5832-3.

CoCr rods are manufactured of cobalt-chromium-alloy CoCr28Mo6 according to ISO 5832-12.

The materials are proven materials in implant technology and have been used in clinical practice for decades.

Description of accessories, if any

Different accessories like trays, handles and torque drives available which are intended to be use with the VENUS Implants.

10.4.2 Information about medicinal substances in the device

Devices of the VENUS® and VENUS®nano Spinal Fixation System do not incorporate, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8) of EU-Regulation 2017/745 (MDR). No further evaluation is therefore required in this regard.

Devices of the VENUS® and VENUS®nano Spinal Fixation System are not manufactured utilising tissues or cells of human or animal origin, or their derivatives, that are covered by the EU-Regulation 2017/745 (MDR) in accordance with points (f) and (g) of Article 1(6). Furthermore devices of the VENUS® and VENUS®nano Spinal Fixation System do not incorporate, as an integral part, tissues or

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cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by the EU-Regulation 2017/745 (MDR) in accordance with the first subparagraph of Article 1(10). No further evaluation is therefore required in this regard.

Devices of the VENUS® and VENUS®nano Spinal Fixation System are partially composed of substances or combinations of substances that are intended to be introduced into the human body but are not intended to be absorbed by or locally dispersed in the human body. No further evaluation is therefore required in this regard.

10.4.3 Description of how the device is achieving its intended mode of action

The VENUS® Spinal Fixation System and VENUS®nano Spinal Fixation System achieve their intended mode of action by providing mechanical stabilization of spinal segments that are weakened due to disease, trauma, deformity, or surgical intervention. The system consists of pedicle screws that are anchored into the vertebral pedicles on both sides of the spine. These screws are connected by rigid rods, forming a screw-rod construct that stabilizes the affected spinal segment.

This construct functions as an internal scaffold, immobilizing the treated spinal segment and thereby reducing mechanical stress and motion at the affected vertebral levels. By minimizing movement between the vertebrae, the system creates optimal conditions for the natural bone fusion process (spondylodesis) to occur. This fusion gradually stabilizes the spine biologically, while the implant maintains mechanical stability during the healing period.

Once bone fusion is complete, the implant no longer has an active mechanical role but can remain in the body as it is made of biocompatible materials (titanium alloy and cobalt-chrome). In cases where bone quality is poor, the VENUS® Spinal Fixation System offers augmented fixation options, such as fenestrated screws with cement injection, to further enhance stability.

Through this mechanism, the VENUS® Spinal Fixation System and VENUS®nano Spinal Fixation System aim to achieve pain reduction, improve spinal alignment, restore or preserve function, and support the natural curvature of the spine, contributing to an improved quality of life for the patient.

10.5 Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

How potential risks have been controlled or managed

A risk analysis according to the standard DIN EN ISO 14971:2022 has been performed for the medical device. This standard specifies the methods to be used for the analysis and assessment of risks with the aim to determine the residual risks and side effects. All known hazards of the medical device have been collected and assessed by the legal manufacturer and the acceptability of the single risks and the total risk has been determined. Appropriate risk control measures were taken to reduce the risks as far as possible and the effectivity of the measures was verified.

This monitoring of the potential risks of the device on the market is a continuous process and various clinical data such as high-quality user survey concerning the safety and performance of the devices, evaluation of complaint data, surgery reports, of data from scientific literature databases and safety databases of the German and international competent authorities are considered and compared in a

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Clinical Evaluation Report. The process of clinical evaluation is performed in regular intervals. If any new risks become known during the clinical evaluation, this will trigger – as described above – risk assessment, implementation of appropriate risk mitigation measures (if deemed necessary) and the verification of their effectivity and the adaption of the Instructions for Use (if deemed necessary). HumanTech Spine maintains these processes during the whole life cycle of the medical devices to ensure the continuous safe usage of the device in clinical practice.

Remaining risks and undesirable effects

The side effects and complications for VENUS® and VENUS®nano Spinal Fixation System listed are not only due to the implants, but often also to the surgical procedure and include, but are not limited to:

Possibly related to implant:

- Delayed bone growth or no visible fusion and pseudarthrosis, delayed bone healing or lack of bone healing
- Modification of spinal curvature and stiffness of the vertebral column
- Partial loss of the degree of correction achieved during surgery.
- Reduction of bone density due to stress shielding
- Proximal Junctional Kyphosis (adjacent segment degeneration)
- Altered growth of the fused spine
- Fracture of a vertebra, the pedicle, and/or the sacrum, micro fracture, damage to or penetration of a vertebral body above or below the treated segment/s
- Vertebral joint degeneration due to altered biomechanics in the spine
- Allergic reaction to the implant material
- Persistent skin irritations
- Risk of infection or inflammation
- Autoimmune reaction
- Metallosis due to intra- or postoperative abrasion or corrosion with possible secondary chronic-inflammatory foreign body reactions as scar formation, local tissue necrosis, formation of neoplasia/tumours and/or osteolysis
- Breakage, deformation, loosening or migration of the implant
- Local pain, discomfort or abnormal sensitivity
- Pressure sores on the skin caused by components located in positions with insufficient tissue coverage over the implant, with potential penetration of the skin
- Revision surgery
- Stopped growth of the chest wall and lungs, with associated consequences.

Possible risks of augmentation:

- Allergic reaction to the bone cement used
- Cement leakage (possibly leading to neurological impairment, cement embolism, local pain and/or inflammation, revision surgery depending on the anatomical location of the cement flow)

Possibly related to surgical procedure

- Malposition of the implant
- Superficial infection (wound), deep site infection and inflammatory phenomena
- Neurological complications, e.g.

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- due to injury or irritation of the spinal cord, the root nerves (radiculopathy) or peripheral nerves, e.g. transient or permanent motor weakness, loss of motory or sensory functions or paralysis
- Injury or lesion of the dura mater with risk of loss of cerebrospinal fluid (CSF) or CSF fistula
- Urinary retention or loss of bladder control, or other types of impairment of the urological system, dysfunction of the rectum, genitourinary disorders, gastrointestinal disorders
- Temporary or permanent retrograde ejaculation in men, damage to the reproductive system, sterility and sexual dysfunctions
- Injury or lesion of surrounding soft tissue, blood vessels (e.g. aorta abdominalis, vena cava inferior or other vessels) or lymphatic vessels (including potential lymph leakage)

Possible general surgical risks:

- Delayed wound healing
- Superficial wound dehiscence
- Bleeding and/or haematomas
- Vascular disorders including thrombus, myocardial infarction or death
- Development of respiratory problems, including pulmonary embolism, atelectasis, bronchitis, pneumonia, pneumothorax, transient pleural effusion or death
- Inability to perform daily tasks

Warnings and precautions

General

- When using X-ray equipment for diagnosis or control, the national limit values for the radiation dose must be observed
- VENUS® and VENUS®nano Systems consist of implants and instruments. VENUS® and VENUS®nano implants must only be used with the intended system-specific instruments and accessories described in the surgical techniques in the respective brochures

MR safety information

VENUS® implants have been examined in non-clinical-testings in accordance with ASTM norms and determined as “MR conditional”. Patients with VENUS® implants can be safely examined via MRI on following conditions:

- Static magnetic field of 1.5 T to 3 T
- Spatial gradient magnetic field up to max. 1100 Gauss/cm or 11 T/m
- Whole body specific absorption rate (SAR) up to max. 2 W/kg in normal operating mode and at max. 15 min continuous scan duration

VENUS® implants can heat up to 4,7 °C with continuous scanning time of 15 min. and under the scanning conditions defined above. Under these conditions, a patient can be examined at low risk. To keep the risks of warming low, the scan duration should be kept as short as possible and the SAR as low as possible.

The product has not been examined for artifacts in MR environment. MR image quality may be reduced if the examined area is in relative proximity to VENUS® implants.

A thorough risk-benefit assessment by the attending doctor must be carried out.

Preoperative

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- The use of implants for implantation must be decided upon in accordance with the surgical and medical indications, the potential risks and restrictions associated with this type of surgical procedure, as well as in knowledge of the contraindications, side effects and defined precautions, and in awareness of both the nature and the physical, chemical and biological characteristics of the implant.
- A decision for an implantation must be made in agreement between the doctor and the patient taking into account the general health condition including comorbidities of the patient. The physician has to inform the patient about the consequences of the implantation, especially that the treatment results in segmental stiffness and that the use of the implant in the area of the thoracic spine in children or adolescents can stop the growth of the chest wall and lungs, with associated consequences. As a result, multiple operations must be performed during the growth period in order to adapt the structure to the spine as it grows.
- Moreover, the patient has to be informed, that adapting the structure to a spine that is fully grown can lead to a drastic reduction in the expected service life of the implant. It is therefore advisable to replace the rod and set screw.
- The patient has to be informed in detail about any possible side effects of the implants and the risks of the procedure, including any revisions that may be necessary.
- To exclude a suspected allergy against the implant materials, appropriate tests shall be carried out.
- For elderly patients, the responsible physician must carefully weigh the potentially benefits against the risks, taking into account the patient's general health condition, increased comorbidities such as e.g. osteoporosis, slower healing and an age-related higher risk of general surgical complications such as infections or cardiovascular problems.
- Polypharmacy, especially hyperpolypharmacy, can have a negative impact on the surgical outcome and the patient's health in elderly patients. The number and interactions of prescribed medications in this patient group should be considered prior to surgery.
- The activities / movement behaviour of the patient has a significant influence on the service life of the implant. The patient must be informed that any activity increases the risk of loss, bending or fracture of the implant components. It is crucial to inform the patient about restrictions in activities in the post-operative phase and to monitor the patient post-operatively in order to assess the development of the fusion and the condition of the implant. Even when bone fusion is completed, implant components may still bend, break or loosen. Therefore, the patient must be informed that implant components can also bend, break or loosen if the restrictions in activities are properly followed.
- Surgical therapy should only be considered after conservative treatment options have failed. The treating physician is responsible for the accurate diagnosis and decision-making for or against surgery as well as the appropriate planning and conductance of the surgery. This implies the patient-specific choice of size and design of the implants, taking into account the individual pathology and anatomy.
- The correct selection and placement of implants is crucial for the surgical success and has to be ensured or to be checked based on suitable pre-, intra- and postoperative diagnostic procedures.
- Errors in implant selection can lead to premature clinical implant failure. The number of segments to be treated is to be determined carefully. The surgeon has to ensure the availability of sufficient different implant sizes and required instruments for the surgical procedure.
- Improper preoperative planning can have a negative impact on the surgical result and the patient's health.

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- HumanTech Spine accepts no liability for negative consequences resulting from incorrect diagnosis or indication, an inappropriate choice of implant, incorrect use of implant components and/or an improper surgical technique or asepsis.

Intraoperative

- The instructions in the surgical technique must be adhered to. You can download these online at www.humantech-spine.de or obtain them directly from your HumanTech representative. It is mandatory to use the instruments described in the surgical technique, which are intended to be used with the implant system. No liability can be assumed for the use of third-party instruments.
- Implants showing any signs of damage or contamination must not be implanted.
- Components of the VENUS® and VENUS®-nano System must not be replaced by components / products from other systems from another source or from a different manufacturer. Furthermore, no direct connection of components / products of the system to components of other systems shall be established. If this is not observed or if the products are used improperly or otherwise than according to IFU and the mandatory surgical technique, HumanTech Spine GmbH assumes no responsibility.
- Bending of the rods / revision connector affect the biomechanical properties of the implant. Bending in the area of the fixation of the rod in the Poly- or Monoaxial Screw can have negative influences on the fixation of the rod – bending in this area has to be avoided.
- Breakage, slippage or incorrect use of the instruments or implants can result in an injury of the patient or the surgical personnel or result in an extension of the duration of the surgery.
- Care should be taken to maintain the integrity of the pedicle and vertebral body structures. Damage to the pedicle can lead to a loosening of the implants and to a loss of the stability of the fixation.
- The diameter of the screws should be selected in a sufficiently wide size in order to make use of the maximum compression in the pedicle area. This will ensure the greatest possible stability and counteract implant loosening. However, in order to avoid injury to the pedicle structures, the screw width should not fit too tight into the pedicle.
- The rod must be tightened correctly to pedicle screw with the corresponding setscrew.
- Careful inspection of the implants is recommended before and during surgery to ensure that the implants remain undamaged during insertion.
- Implantation of the implant must be performed under continuous x-ray control in order to avoid misplacement.
- Proceed with extreme caution in the area of the spinal cord and the nerve roots, as any damage to nerves can result in the negative impairment or loss of neurological functions.
- Extreme caution is required to avoid injuries of the aorta abdominalis or the vena cava inferior because this can be life-threatening.
- If an implant component or part of an instrument loosens or breaks in situ, all resulting residues – whether made of implant material or other materials – must be completely removed.
- Implants that have come into contact with a patient's body fluids or tissues or have been soiled must not be reused.
- The rods of the VENUS® Mini-System have marks. It is not allowed to use the area between the ends of the rod and the marks for the fixation of the pedicle screw. In this area the rods must also not be bent. The system stability can be increased with a ventral support. In the lumbar area, especially when the use of pedicle screws with a diameter of 5,5mm or smaller can't be avoided, a ventral support is strongly recommended
- Augmentation: The IFU provided by the manufacturer of the bone cement used as well as the

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IFU “Bone Filler” and the surgical technique of HumanTech Spine must be adhered to. The volumes of cement used for fenestrated / cannulated screws should ultimately be determined by the surgeon based on the individual patient anatomy. Especially in patients with severe heart or lung impairment, the quantity of applied cement must be chosen as low as possible. Bone cement application has to be monitored by suitable imaging to avoid cement leakage as far as possible.

- For the usage of guide wires in minimally invasive procedures, the instructions in the surgical techniques must be adhered to and all the cautions have to be observed strictly. The correct positioning of the guide wire must be monitored by suitable imaging during the whole surgical procedure to allow accurate screw insertion and to avoid vessel perforation or other tissue damage.

Postoperative

- The patient should be instructed to inform his treating physician immediately regarding any unusual changes in the surgical area.
- The patient should be monitored if a change in the area where the implant(s) is/are located is noticed. The treating physician should assess the possibility of clinical implant failure and discuss with the patient the actions required to achieve further healing.
- A prolonged healing phase, lack of bone fusion or subsequent bone resorption can lead to overloading of the implant, which may result in implant failure
- The implants are used for internal fixation and immediate immobilization of the treated segments during the bone healing process lasting a maximum of two years. Once the fusion is complete, the implants have no longer any active function. Removal of the implant is possible, but can cause damage to surrounding tissue and loss of stability and should only be performed after a careful risk-benefit consideration by a qualified surgeon and the patient.
- In case of complications, the surgeon has to decide whether a revision of the implant should be carried out, taking into account the patient’s health condition and the possible risks involved
- Risk of further injuries due to postoperative trauma
- Never reuse the implants. Even if the implant appears to be intact after the revision, alterations within the implant or minute defects resulting from the loading and stressing to which the implant has been exposed can cause the implant to break.
- Handle removed implants in such a way that their reuse is not possible.

Warnings during Pregnancy

The use of the VENUS Spinal Fixation System during pregnancy is associated with increased risk of serious complications. Potential risks include implant displacement, nerve damage, infection, blood clots, and other pregnancy-related complications. Additionally, there is a risk that the implant may pose harm to the developing fetus.

Responsibilities of the Physician:

- **Information and Education:** The physician must thoroughly inform the pregnant patient about the risks and possible complications associated with the use of orthopedic implants.
- **Alternative Treatment Options:** The physician should discuss possible alternatives to implant treatment in order to find the best possible option for the patient.
- **Minimizing Blood Loss:** The physician should take measures to reduce blood loss during the operation. These measures include:
 - **Tourniquet:** The use of a tourniquet can block blood flow to the surgical area and thereby reduce blood loss.

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- **Hemostatic Agents:** Special agents, such as fibrin glue or oxidized cellulose, can be applied to bleeding areas as needed to stop the bleeding.
- **Electrocautery:** Electrocautery can be used to coagulate bleeding vessels and reduce bleeding.
- **Careful Surgical Technique:** The surgeon should work with great precision and carefully ligate blood vessels to avoid unnecessary blood loss.

Anesthesia and Pain Management in Pregnant Women:

Before surgery, a thorough examination and assessment of the patient are necessary:

- **Medical History:** The physician reviews the patient's medical history, including allergies, medications, and previous experiences with anesthesia.
- **Gestational Age:** The exact gestational age must be determined in order to choose the appropriate anesthesia technique.
- **Fetal Monitoring:** The physician must monitor the condition of the fetus, e.g., by using ultrasound.

Anesthesia Techniques:

- **Regional Anesthesia:** In most cases, regional anesthesia (such as epidural or spinal anesthesia) is preferred, as it reduces the risk of respiratory complications.
- **General Anesthesia:** In emergencies or if regional anesthesia is not possible, general anesthesia may be required.

After Anesthesia:

- **Recovery:** The mother and fetus must be closely monitored after the surgery until both are stable.
- **Pain Management:** Pain medications must be chosen carefully, as some drugs could affect the fetus.

Special Considerations:

- **Pregnancy-induced Hypertension:** Special caution is required when selecting anesthetic agents in pregnant women with hypertension, as they may be more susceptible to complications.
- **Gestational Diabetes:** Blood sugar levels must be closely monitored in patients with gestational diabetes, as anesthetic agents can affect metabolism.
- **Multiple Pregnancies:** In cases of twins or multiple pregnancies, higher risks such as premature labor or fetal distress must be expected.

Radiation Protection During Surgery:

If the surgery is performed in an environment with radiation exposure, special attention must be paid to minimizing radiation exposure for both the pregnant patient and the fetus:

- **Risk Assessment:** The physician must assess radiation exposure for both mother and fetus before the operation.
- **Alternative Procedures:** If possible, alternative procedures without radiation exposure should be considered.
- **Patient Education:** The pregnant patient must be informed about the potential risks and benefits of radiation exposure prior to treatment.

Strategies to Reduce Radiation Exposure:

- **Lead Aprons:** A lead apron can be used to protect the abdominal area of the pregnant patient and minimize radiation.
- **Beam Collimation:** Limiting the radiation field to the necessary area only reduces exposure.

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- **Low-Dose Protocols:** Low-dose protocols should be used for imaging procedures such as CT scans or fluoroscopy.
- **Pulsed Fluoroscopy:** Pulsed fluoroscopy can be used to reduce radiation exposure compared to continuous fluoroscopy.

After Surgery:

1. **Radiation Exposure Monitoring:** After surgery, the radiation exposure of the pregnant patient and fetus should be evaluated.
2. **Follow-up and Counseling:** It is important to inform the patient about possible effects of radiation exposure after surgery and to monitor her regularly.

Special Caution Regarding Radiation Exposure:

1. **Fetal Age:** The age of the fetus should be considered when assessing the radiation risk, as the risk varies depending on the stage of pregnancy.
2. **Radiation-Sensitive Tissues:** The physician must be especially careful to consider the sensitivity of tissues such as the fetal central nervous system.

Risks for Mother and Child:

The orthopedic surgeon must consider the physical changes during pregnancy and the potential risks for the fetus. Possible risks include preterm birth, premature placental abruption, abnormal fetal positioning, and even the risk to the mother's life.

Summary of any field safety corrective action, (FSCA including FSN) if applicable

One serious incident was reported to the BfArM. Based on the analysis, the serious incident was caused by an “expected or random component failure without any design or manufacturing issue” and therefore a recall or a Field Safety Notice (FSN) were not necessary. Since one failure could have led to a serious adverse event (in 2014), it was reported to the BfArM followed by the recall of the possibly concerned products and a Field Safety Notice (FSN). One FSN including recall was necessary due to material mix-up of titanium grade 4 and grade 5, but no other FSCA became necessary in the considered period (to date, Juni 2025, no adverse event has been reported):

BfArM Case -No. 8312_14 (2014-12-12):

Number of Field Safety Notice: 20140148, Article-No.: VL-PS2-5-6550, Description: Polyaxial Screw 6T 6,5x50mm, LOT: H1217HJ, Basic UDI-DI: 2505399046N7).

Description: As a result of an error in the further processing process, the above-mentioned pedicle screws have errors in the marking. The products were provided with an incorrect length specification. The marking of the product by means of laser marking and the associated product label indicates a length of 50mm, the actual length of the screw shaft is 55mm. Only the above-mentioned pedicle screws of lot no. H1217HJ are affected.

Material Mix-up BfArM Case -No. 20710/24

In June 2024, HumanTech Spine received the information of deviations in a raw material. A complaint has been sent to the supplier. Therefore, an FSN (Field Safety Notice) was prepared and a (preventive) recall of several VENUS batches was conducted. No adverse event has been reported so far subsequent to this non-conformity. The root cause analysis of the supplier has been completed and appropriate risk mitigation measures have been introduced. To ensure the long-term safety of the (wrong) implants of commercially pure titanium (cpTi) grade 4, biomechanical tests were performed and a finite element model was applied. Both analysis showed no significant difference between the influence of the two different rod materials, Titan Grad 5 (Ti6Al4V) and Titan Grade 4 on the range of motion of the lumbar spinal segments and dynamic stability.

Additionally, several rods for implantation made of cpTi (grade 4) are available on the market and used for more than a decade in clinical practice.

Based on the performed analyses, it could be concluded that there is no increased risk for patients with implanted Ti grade 4 rods.

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10.6 Summary of clinical evaluation and post-market clinical follow-up

- **Clinical background of the device**

Since the **screw rod fixation systems** are frequently used together with other implants as vertebral body replacement systems or interbody fusion cages, the same indications apply for these implants. Therefore, the screw rod fixation systems are used in indications such as such as fractures, Metastatic Spine Disease, deformities in traumatic injuries, thoracic and lumbar trauma, deformities in thoracic and lumbar trauma, inflammatory disease such as spondylitis or spondylodiscitis, degenerative disc disease, but also to treat spondylolisthesis, three-dimensional deformities as scoliosis and kyphosis. The following clinical conditions and corresponding treatment strategies are discussed in detail:

For **traumatic injuries of the spine**, stabilization is achieved through dorsal or anterior instrumentation, depending on the level of instability, the presence of neurological deficits, and fracture morphology. Scoring systems such as MESCC and SINS assist in therapy planning. In cases of instability or neurological compromise, surgical intervention with pedicle screws and cages is considered the standard of care.

In **disc herniation with radiculopathy**, conservative therapy is initially preferred. However, surgical intervention, typically through microdiscectomy, is indicated when conservative treatment fails. In some cases, spinal fusion may be added if there is underlying instability or recurrent herniation.

Inflammatory diseases of the spine, such as spondylodiscitis, are primarily managed with antibiotics. Nevertheless, in cases of instability, progressive neurological deficits, or failure of conservative treatment, surgical intervention involving debridement, decompression, and stabilization with instrumentation and cages becomes necessary.

For **degenerative spondylolisthesis**, guidelines recommend decompression combined with fusion in symptomatic cases, especially when instability contributes to back pain. Posterior approaches using pedicle screws and interbody cages are widely accepted as the gold standard to restore stability and reduce the risk of reoperation.

Lumbar spinal stenosis is often treated conservatively; however, when surgical intervention is necessary, decompression with or without fusion is considered, depending on the presence of coexisting spondylolisthesis or instability.

In the case of **chronic low back pain**, surgery is only indicated when a clear structural cause is identified, such as instability or deformity. Evidence supporting the routine use of spinal fusion in non-specific back pain remains limited.

Spinal metastases require individualized treatment strategies based on tumor biology, spinal stability, neurological status, and life expectancy. Dorsal stabilization, often with cement-augmented pedicle screws, is common, and cages or vertebral body replacement systems may be used for larger defects.

Pediatric spinal surgery addresses deformities such as scoliosis, kyphosis, and spondylolisthesis. Techniques must be adapted to account for growth potential, with particular attention to risks like proximal junctional kyphosis and growth disturbances.

Additionally, spinal fusion may be applied in other conditions, such as ankylosing spondylitis or degenerative disc disease, and for the treatment of failed back surgery syndromes.

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Guidelines provide specific treatment recommendations. For example, the AWMF publishes guidance on spondylodiscitis and specific low back pain, while the NASS addresses degenerative lumbar spondylolisthesis and disc herniation with radiculopathy. The PSPS offers comprehensive reviews on surgical treatment options for degenerative lumbar spine diseases.

Complications remain a concern across all interventions. Common risks include implant loosening, pseudoarthrosis (non-union), infections, cage subsidence, and reoperation. Reported complication rates vary, with pseudoarthrosis occurring in up to 10% of cases, cage subsidence between 3% and 32%, and revision surgery rates ranging from 10% to as high as 48% in complex cases.

Effective risk management involves perioperative prophylaxis, careful patient selection, precise surgical techniques, and the use of advanced imaging and navigation technologies.

After spinal fusion has occurred, the function of the Venus Spinal Fixation System is considered complete, and the implants may theoretically be removed. However, implant removal carries general surgical risks, potentially damage the surrounding tissue and can lead to a loss of spinal stability. Therefore, such a procedure should only be undertaken following a thorough risk-benefit assessment by a qualified surgeon in consultation with the patient.

In summary, the combination of **pedicle screws and interbody cages made of titanium or PEEK** is well established as the standard of care in spinal fusion surgeries. The choice of surgical approach—whether anterior, posterior, or lateral—as well as the selection of implant materials, is guided by the specific pathology, surgical goals, and patient-specific factors. National and international guidelines support these practices, confirming that these technologies represent the **current state of the art** in spine surgery.

• The clinical evidence for the CE-marking

No clinical investigation was conducted before CE marking. VENUS® and VENUS®nano are legacy devices. The devices were CE-certified under MDD on the basis of equivalence to equivalent devices. However, based on the new definition for equivalence of the MDR these devices are not equivalent anymore.

The intended purpose within the intended indications of the devices could be substantiated by clinical data generated by the manufacturer:

- **Proactively collected High-Quality User Surveys** 6 HQUS were performed, 4 for VENUS and 2 for VENUSnano, to retrospectively collect long-term clinical data from the clinical routine. In sum 160 patients were included with follow-ups of 3 to more than 24 months.
- **Proactively collected surgery reports** (from surgeries in Germany / Europe): Although the level of evidence of the surgery reports is relatively low, they are a valuable source of very direct user feedback, include a relatively large number of cases, are well documented with a high level of detail, cover the intended indications and reflect real life in clinical practice. The evaluation of 370 (German) surgery reports for VENUS® and 29 for VENUS®nano with detailed description of surgical procedures, The 399 “German” surgery reports (370 for VENUS® and 29 for VENUS®nano) cover almost all indications, except for the treatment of pseudarthrosis with VENUS®, all the spinal areas indicated in the intended purpose and all the VENUS®/VENUS®nano systems which are marketed. All 399 surgeries described in “German”

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surgery reports could be performed successfully. Multiple levels were used (up to 12 levels for VENUS® and VENUS®nano).

- **Proactively collected surgery reports (from Mexico):** A statistical evaluation of 387 VENUS® surgery reports / Mexico confirms the functionality and benefits of VENUS® and VENUS®nano. The comparability of Mexican and European patient populations has been analyzed in detail by literature evaluation.
- 23 surgical treatments with VENUS® in an **observational application (Mexico):** In all the 23 surgeries, the main objective of the surgery was achieved. No dislocation, device defects or loosening of components occurred. The evaluation will be completed as soon as possible.
- **Literature data and studies regarding similar devices:** Several studies and clinical trails were identified which confirmed the safety and performance of well-established product group of pedicle screw-rod constructs.
- **Evaluation of safety**

The nature of adverse events identified in literature and vigilance databases are very similar to those listed in the IFU of VENUS® and VENUS®nano. The complaint rates of VENUS® and VENUS®nano implants and instruments are very low and the clinical data sets available (HQUS, surgery reports, literature review of similar devices) only show a small fraction of the adverse events reported in the MAUDE vigilance database.

No adverse events are known from the patients included in the observational application. The surgery reports describe e.g. failures such as breakage, loosening or dismantling of components, another problem was the lack of experience with the VENUS® devices and their handling in one surgery team (training was recommended by the sales representative).

Other non-implant-related adverse events reported in complaints since product launch were: failure of set screw insertion, rod breakage (possibly due to fatigue or due to not mapping the natural lordosis), rod breakage due to bending in two directions (not permitted according to IFU), rod slipping (because the rod was not sufficiently blocked), screw jamming due to unfavourable positioning limiting polyaxiality, failure to attach the hexagon of the screw to the instrument, loosening of the set screw caused by not using the counterholder. One metallosis was reported in a complaint which was however no material problem but the consequence of a user error causing abrasion.

Such user errors were no issue any more during the 5-years period of this clinical evaluation.

Vulnerable patients who are in need of special protection and care as the over 70s and children or adolescents are considered in the high-quality user surveys, the safety and performance literature review about similar devices as well as in indication-specific medical guidelines (because the indications are typical for specific age groups as e.g. degenerative diseases which occur predominantly in elderly patients and scoliosis treatments which are more frequent in children and adolescents).

Based on the very low complaint rates and the favourable clinical results of the HQUS suggest that the devices are safe, their use is well-known and the trainings effective. The fact that no unknown or unassessed risk could be identified in literature and vigilance databases suggest that the risk profile of the similar devices (and also the broader generic device group considered in the state of the art SOTA VENUS/ADONIS) is very well known and and that the risks are appropriately described in the IFU. The

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overall complication rate of the 4 VENUS-HQUS is with 32,5% lower than that of 2 studies with similar devices, including 21 and 53 patients, identified in the ClinicalTrial.gov database (47,6% and 47,2%). The complication rate here is the number of adverse events per number of patients included in the 4 HQUS or studies, respectively.

The high-quality user surveys with VENUS and VENUSnano only show adverse events which are manageable by the trained user and in line with the state of the art, including literature and safety database review of the defined similar devices.

The clinical benefit of VENUS and VENUSnano for the patient is improving the patient's quality of life through pain reduction, clinically relevant improvement in function, and/or stabilization to support the natural curvature.

The clinical benefit is measured in the HQUS by the parameters "complete achievement" and "partial or complete achievement" of:

- Pain reduction is addressed by the parameter "Reduction of pain" compared to baseline,
- Improvement in function is addressed by: "Functional improvement", "Motoric improvement", "Sensory improvement".
- Stabilization to support the natural curvature is addressed by "Stopping progression of deformities", "Spinal stabilization" and „Improvement of the lordosis/kyphosis“and „Correction of deformities“.

In literature studies, clinical parameters as ODI, VAS and others are used to assess the efficacy of the similar devices.

The devices under evaluation used in HQUS as well as the similar devices show clear improvement of the clinical parameters and that the side effects / adverse events were manageable to the trained user.

This allows the conclusion that in the light of the favourable results of the HQUS and literature studies, the side effects of VENUS and VENUSnano are acceptable.

Every regular update of the clinical evaluation will include a review of literature and vigilance databases to obtain performance and safety data about VENUS and VENUSnano and the product group of similar pedicle screw systems on the market. HQUSs as well as surgery reports will continuously be performed or collected and evaluated. Furthermore, complaint data will periodically be analyzed and summarized (with each update of the clinical evaluation). All these sets of clinical data will also be utilized to identify off-label use of the device

If any new risks arise during a (periodically updated) clinical evaluation, they will be assessed in the Risk Management File and appropriate measures will be taken to reduce the risks as far as possible.

10.7 Possible diagnostic and therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

Spinal fusion, using pedicle screws and interbody cages made of titanium or PEEK, is widely recognized as the **gold standard** for restoring spinal stability in conditions such as degenerative diseases, deformities, trauma, infections, and neoplastic lesions. However, the document emphasizes that surgery is not always the first-line treatment and that **conservative and non-surgical therapies** play a crucial role, especially in the early stages or less severe cases.

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For **traumatic injuries of the spine**, conservative management is often preferred for **stable fractures** without neurological deficits. This includes functional bracing, physiotherapy, analgesic medication, and structured rehabilitation programs aimed at restoring mobility and preventing further injury. Surgery is reserved for cases with instability, deformity progression, or neurological deterioration, where stabilization through dorsal or anterior instrumentation is necessary.

In cases of **lumbar disc herniation with radiculopathy**, the preferred initial approach is **non-surgical**, involving physical therapy, non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, and in selected cases, **epidural steroid injections** or **nerve root blocks** to manage pain and inflammation. Surgery, typically microdiscectomy or decompression, is considered only when these measures fail or when significant neurological deficits emerge.

Inflammatory diseases of the spine, such as spondylodiscitis, are primarily treated with **targeted antibiotic therapy**, often guided by microbiological diagnostics. Conservative treatment remains the mainstay unless the infection leads to structural instability, abscess formation, or persistent neurological symptoms, in which case surgical debridement and stabilization are indicated.

For **degenerative spondylolisthesis** and **lumbar spinal stenosis**, **physiotherapy**, **postural training**, **pain management**, and sometimes **manual therapy** can improve symptoms and functional capacity. **Multimodal pain therapy programs**, combining physical, psychological, and pharmacological components, are particularly effective in addressing chronic symptoms without immediate recourse to surgery. Fusion surgery becomes relevant when conservative measures fail, especially in patients with spinal instability or severe pain impacting quality of life.

In the treatment of **chronic low back pain**, particularly when non-specific, **non-surgical approaches** are prioritized. These include **cognitive behavioral therapy (CBT)**, **structured physical exercise programs**, **pain psychology**, **mindfulness-based stress reduction**, and **interventional pain procedures** such as facet joint injections, radiofrequency ablation, or sacroiliac joint blocks. Surgical fusion is considered a last resort when all other therapies have failed and when imaging correlates with identifiable structural causes.

For patients with **spinal metastases**, treatment strategies are inherently multidisciplinary, incorporating **oncological treatments** like radiotherapy, chemotherapy, and bisphosphonates alongside surgical stabilization if necessary to maintain spinal integrity and neurological function.

In the **pediatric population**, especially in the treatment of spinal deformities like scoliosis, non-surgical methods such as **bracing**, **physical therapy**, and in some cases **growth modulation techniques** are employed to delay or prevent the need for surgery. Surgical fusion is considered when conservative treatments are insufficient to halt deformity progression.

Beyond fusion, there are **motion-preserving surgical alternatives**, such as **artificial disc replacement (ADR)**, designed to maintain segmental motion and reduce the risk of adjacent segment disease, which is a concern following spinal fusion. Additionally, **dynamic stabilization systems** like Dynesys offer a less rigid form of spinal support, aiming to preserve some physiological motion while providing stability.

Minimally invasive surgical (MIS) techniques, including **percutaneous pedicle screw fixation**, provide an important surgical alternative that reduces soft tissue trauma, blood loss, and hospital stay compared to open surgery. However, they require specialized skills and equipment and are not suitable for all patients.

Complementary and alternative treatments, such as **osteopathy**, **acupuncture**, and **homeopathy**, are occasionally integrated into patient care, though evidence for their effectiveness remains limited. These methods may offer symptomatic relief, particularly for patients with chronic pain, but are rarely curative for structural spinal disorders.

In conclusion, while **spinal fusion using pedicle screws and interbody cages** represents the current standard of care for many spinal conditions requiring stabilization, a wide array of **alternative**

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therapies—both conservative and surgical—are available and should be considered based on the patient’s individual condition, preferences, and overall health status. Effective treatment planning relies on a comprehensive, multidisciplinary approach that integrates evidence-based conservative therapies, alternative options, and advanced surgical techniques to optimize patient outcomes.

10.7 Suggested training for users

Surgeon

The devices of the VENUS® and VENUS®nano system may only be implanted by surgeons who have completed the necessary training in spinal surgery.

The

- professional judgement and/or clinical skills and experience of the surgeon with regard to careful patient selection
- preoperative planning and implant selection
- knowledge of the anatomy and biomechanics of the spine
- understanding of the material and the mechanical properties of the used implants
- training and skills in spinal surgery and the use of the instruments required for inserting the implants
- surgeon’s ability to gain the patient’s consent to adhere to a clearly defined post-operative treatment regimen and to conduct scheduled follow-up examinations is/are necessary for the use of the devices of the system.

Surgical assistant

The surgeons are supported in the operating theater environment by surgical assistants. General knowledge in surgical procedures, the surgical technique and special training and skills regarding the correct use of the devices of the system and the use of the instruments required for inserting the implants is/are necessary for the use of the devices.

Persons responsible for processing procedures

Unsterile delivered products must be cleaned, disinfected and sterilized before use on the patient by persons responsible for processing procedures. For a correct execution of the processing procedure, general hygienic principles regarding the processing of medical devices and the knowledge of the defined steps of the processing instruction are necessary.

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Appendix 1: Article List with Basic UDI-DI

Article list VENUS®:

Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
4000115525	2T Can. Monoaxial Screw Ø5.5x25mm	IIb	8.9	4250539940 5ND	0425053991 9755	4665 1	P09070 302	Non Sterile	N/A
4000115525-S	2T Can. Monoaxial Screw Ø5.5x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 8627	4665 1	P09070 302	Sterile	Gamma
4000115530	2T Can. Monoaxial Screw Ø5.5x30mm	IIb	8.9	4250539940 5ND	0425053991 9762	4665 1	P09070 302	Non Sterile	N/A
4000115530-S	2T Can. Monoaxial Screw Ø5.5x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 8634	4665 1	P09070 302	Sterile	Gamma
4000115535	2T Can. Monoaxial Screw Ø5.5x35mm	IIb	8.9	4250539940 5ND	0425053991 9779	4665 1	P09070 302	Non Sterile	N/A
4000115535-S	2T Can. Monoaxial Screw Ø5.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 8641	4665 1	P09070 302	Sterile	Gamma
4000116525	2T Can. Monoaxial Screw Ø6.5x25mm	IIb	8.9	4250539940 5ND	0425053991 9786	4665 1	P09070 302	Non Sterile	N/A
4000116525-S	2T Can. Monoaxial Screw Ø6.5x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 8658	4665 1	P09070 302	Sterile	Gamma
4000116530	2T Can. Monoaxial Screw Ø6.5x30mm	IIb	8.9	4250539940 5ND	0425053991 9793	4665 1	P09070 302	Non Sterile	N/A
4000116530-S	2T Can. Monoaxial Screw Ø6.5x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 8665	4665 1	P09070 302	Sterile	Gamma
4000116535	2T Can. Monoaxial Screw Ø6.5x35mm	IIb	8.9	4250539940 5ND	0425053991 9809	4665 1	P09070 302	Non Sterile	N/A
4000116535-S	2T Can. Monoaxial Screw Ø6.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 8672	4665 1	P09070 302	Sterile	Gamma
4000134825	2T Can. Reduction Screw Ø 4.8mm x 25mm	IIb	8.9	4250539940 5ND	0425053994 2296	4665 1	P09070 302	Non Sterile	N/A
4000134825-S	2T Can. Reduction Screw Ø 4.8mm x 25mm sterile	IIb	8.9	4250539940 6NF	0425053994 2302	4665 1	P09070 302	Sterile	Gamma
4000134830	2T Can. Reduction Screw Ø 4.8mm x 30mm	IIb	8.9	4250539940 5ND	0425053994 2319	4665 1	P09070 302	Non Sterile	N/A
4000134830-S	2T Can. Reduction Screw Ø 4.8mm x 30mm sterile	IIb	8.9	4250539940 6NF	0425053994 2326	4665 1	P09070 302	Sterile	Gamma
4000134835	2T Can. Reduction Screw Ø 4.8mm x 35mm	IIb	8.9	4250539940 5ND	0425053994 2333	4665 1	P09070 302	Non Sterile	N/A
4000134835-S	2T Can. Reduction Screw Ø 4.8mm x 35mm sterile	IIb	8.9	4250539940 6NF	0425053994 2340	4665 1	P09070 302	Sterile	Gamma
4000134840	2T Can. Reduction Screw Ø 4.8mm x 40mm	IIb	8.9	4250539940 5ND	0425053994 2357	4665 1	P09070 302	Non Sterile	N/A
4000134840-S	2T Can. Reduction Screw Ø 4.8mm x 40mm sterile	IIb	8.9	4250539940 6NF	0425053994 2364	4665 1	P09070 302	Sterile	Gamma
4000134845	2T Can. Reduction Screw Ø 4.8mm x 45mm	IIb	8.9	4250539940 5ND	0425053994 2371	4665 1	P09070 302	Non Sterile	N/A
4000134845-S	2T Can. Reduction Screw Ø 4.8mm x 45mm sterile	IIb	8.9	4250539940 6NF	0425053994 2388	4665 1	P09070 302	Sterile	Gamma
4000135525	2T Can. Reduction Screw Ø 5.5mm x 25mm	IIb	8.9	4250539940 5ND	0425053994 2395	4665 1	P09070 302	Non Sterile	N/A
4000135525-S	2T Can. Reduction Screw Ø 5.5mm x 25mm sterile	IIb	8.9	4250539940 6NF	0425053994 2401	4665 1	P09070 302	Sterile	Gamma
4000135530	2T Can. Reduction Screw Ø 5.5mm x 30mm	IIb	8.9	4250539940 5ND	0425053994 2418	4665 1	P09070 302	Non Sterile	N/A
4000135530-S	2T Can. Reduction Screw Ø 5.5mm x 30mm sterile	IIb	8.9	4250539940 6NF	0425053994 2425	4665 1	P09070 302	Sterile	Gamma
4000135535	2T Can. Reduction Screw Ø 5.5mm x 35mm	IIb	8.9	4250539940 5ND	0425053994 2432	4665 1	P09070 302	Non Sterile	N/A
4000135535-S	2T Can. Reduction Screw Ø 5.5mm x 35mm sterile	IIb	8.9	4250539940 6NF	0425053994 2449	4665 1	P09070 302	Sterile	Gamma

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
4000136525	2T Can. Reduction Screw Ø 6.5mm x 25mm	IIb	8.9	4250539940 5ND	0425053994 2456	4665 1	P09070 302	Non Sterile	N/A
4000136525-S	2T Can. Reduction Screw Ø 6.5mm x 25mm sterile	IIb	8.9	4250539940 6NF	0425053994 2463	4665 1	P09070 302	Sterile	Gamma
4000136530	2T Can. Reduction Screw Ø 6.5mm x 30mm	IIb	8.9	4250539940 5ND	0425053994 2470	4665 1	P09070 302	Non Sterile	N/A
4000136530-S	2T Can. Reduction Screw Ø 6.5mm x 30mm sterile	IIb	8.9	4250539940 6NF	0425053994 2487	4665 1	P09070 302	Sterile	Gamma
4000136535	2T Can. Reduction Screw Ø 6.5mm x 35mm	IIb	8.9	4250539940 5ND	0425053994 2494	4665 1	P09070 302	Non Sterile	N/A
4000136535-S	2T Can. Reduction Screw Ø 6.5mm x 35mm sterile	IIb	8.9	4250539940 6NF	0425053994 2500	4665 1	P09070 302	Sterile	Gamma
4000137235	2T Can. Reduction Screw Ø 7.2mm x 35mm	IIb	8.9	4250539940 5ND	0425053994 2517	4665 1	P09070 302	Non Sterile	N/A
4000137235-S	2T Can. Reduction Screw Ø 7.2mm x 35mm sterile	IIb	8.9	4250539940 6NF	0425053994 2524	4665 1	P09070 302	Sterile	Gamma
4000014825	2T Cannulated Screw Ø 4.8 x 25mm	IIb	8.9	4250539940 5ND	0425053991 6372	4665 1	P09070 302	Non Sterile	N/A
4000014825-S	2T Cannulated Screw Ø 4.8 x 25mm sterile	IIb	8.9	4250539940 6NF	0425053992 6135	4665 1	P09070 302	Sterile	Gamma
4000014830	2T Cannulated Screw Ø 4.8 x 30mm	IIb	8.9	4250539940 5ND	0425053991 6389	4665 1	P09070 302	Non Sterile	N/A
4000014830-S	2T Cannulated Screw Ø 4.8 x 30mm sterile	IIb	8.9	4250539940 6NF	0425053992 6142	4665 1	P09070 302	Sterile	Gamma
4000014835	2T Cannulated Screw Ø 4.8 x 35mm	IIb	8.9	4250539940 5ND	0425053991 6396	4665 1	P09070 302	Non Sterile	N/A
4000014835-S	2T Cannulated Screw Ø 4.8 x 35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6159	4665 1	P09070 302	Sterile	Gamma
4000014840	2T Cannulated Screw Ø 4.8 x 40mm	IIb	8.9	4250539940 5ND	0425053991 6402	4665 1	P09070 302	Non Sterile	N/A
4000014840-S	2T Cannulated Screw Ø 4.8 x 40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6166	4665 1	P09070 302	Sterile	Gamma
4000014845	2T Cannulated Screw Ø 4.8 x 45mm	IIb	8.9	4250539940 5ND	0425053991 6419	4665 1	P09070 302	Non Sterile	N/A
4000014845-S	2T Cannulated Screw Ø 4.8 x 45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6173	4665 1	P09070 302	Sterile	Gamma
4000015525	2T Cannulated Screw Ø 5.5 x 25mm	IIb	8.9	4250539940 5ND	0425053991 6426	4665 1	P09070 302	Non Sterile	N/A
4000015525-S	2T Cannulated Screw Ø 5.5 x 25mm sterile	IIb	8.9	4250539940 6NF	0425053992 6180	4665 1	P09070 302	Sterile	Gamma
4000015530	2T Cannulated Screw Ø 5.5 x 30mm	IIb	8.9	4250539940 5ND	0425053991 6433	4665 1	P09070 302	Non Sterile	N/A
4000015530-S	2T Cannulated Screw Ø 5.5 x 30mm sterile	IIb	8.9	4250539940 6NF	0425053992 6197	4665 1	P09070 302	Sterile	Gamma
4000015535	2T Cannulated Screw Ø 5.5 x 35mm	IIb	8.9	4250539940 5ND	0425053991 6440	4665 1	P09070 302	Non Sterile	N/A
4000015535-S	2T Cannulated Screw Ø 5.5 x 35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6203	4665 1	P09070 302	Sterile	Gamma
4000016525	2T Cannulated Screw Ø 6.5 x 25mm	IIb	8.9	4250539940 5ND	0425053991 6495	4665 1	P09070 302	Non Sterile	N/A
4000016525-S	2T Cannulated Screw Ø 6.5 x 25mm sterile	IIb	8.9	4250539940 6NF	0425053992 6258	4665 1	P09070 302	Sterile	Gamma
4000016530	2T Cannulated Screw Ø 6.5 x 30mm	IIb	8.9	4250539940 5ND	0425053991 6501	4665 1	P09070 302	Non Sterile	N/A
4000016530-S	2T Cannulated Screw Ø 6.5 x 30mm sterile	IIb	8.9	4250539940 6NF	0425053992 6265	4665 1	P09070 302	Sterile	Gamma
4000016535	2T Cannulated Screw Ø 6.5 x 35mm	IIb	8.9	4250539940 5ND	0425053991 6518	4665 1	P09070 302	Non Sterile	N/A
4000016535-S	2T Cannulated Screw Ø 6.5 x 35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6272	4665 1	P09070 302	Sterile	Gamma

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4000017235	2T Cannulated Screw Ø 7.2 x 35mm	IIb	8.9	4250539940 5ND	0425053991 6563	4665 1	P09070 302	Non Sterile	N/A
4000017235-S	2T Cannulated Screw Ø 7.2 x 35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6326	4665 1	P09070 302	Sterile	Gamma
4000145540	2T Fen. Monoaxial Screw Ø5.5x40mm	IIb	8.9	4250539940 5ND	0425053991 9816	4665 1	P09070 302	Non Sterile	N/A
4000145540-S	2T Fen. Monoaxial Screw Ø5.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 8689	4665 1	P09070 302	Sterile	Gamma
4000145545	2T Fen. Monoaxial Screw Ø5.5x45mm	IIb	8.9	4250539940 5ND	0425053991 9823	4665 1	P09070 302	Non Sterile	N/A
4000145545-S	2T Fen. Monoaxial Screw Ø5.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 8696	4665 1	P09070 302	Sterile	Gamma
4000145550	2T Fen. Monoaxial Screw Ø5.5x50mm	IIb	8.9	4250539940 5ND	0425053991 9830	4665 1	P09070 302	Non Sterile	N/A
4000145550-S	2T Fen. Monoaxial Screw Ø5.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 8702	4665 1	P09070 302	Sterile	Gamma
4000145555	2T Fen. Monoaxial Screw Ø5.5x55mm	IIb	8.9	4250539940 5ND	0425053991 9847	4665 1	P09070 302	Non Sterile	N/A
4000145555-S	2T Fen. Monoaxial Screw Ø5.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 8719	4665 1	P09070 302	Sterile	Gamma
4000146540	2T Fen. Monoaxial Screw Ø6.5x40mm	IIb	8.9	4250539940 5ND	0425053991 9854	4665 1	P09070 302	Non Sterile	N/A
4000146540-S	2T Fen. Monoaxial Screw Ø6.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 8726	4665 1	P09070 302	Sterile	Gamma
4000146545	2T Fen. Monoaxial Screw Ø6.5x45mm	IIb	8.9	4250539940 5ND	0425053991 9861	4665 1	P09070 302	Non Sterile	N/A
4000146545-S	2T Fen. Monoaxial Screw Ø6.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 8733	4665 1	P09070 302	Sterile	Gamma
4000146550	2T Fen. Monoaxial Screw Ø6.5x50mm	IIb	8.9	4250539940 5ND	0425053991 9878	4665 1	P09070 302	Non Sterile	N/A
4000146550-S	2T Fen. Monoaxial Screw Ø6.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 8740	4665 1	P09070 302	Sterile	Gamma
4000146555	2T Fen. Monoaxial Screw Ø6.5x55mm	IIb	8.9	4250539940 5ND	0425053991 9885	4665 1	P09070 302	Non Sterile	N/A
4000146555-S	2T Fen. Monoaxial Screw Ø6.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 8757	4665 1	P09070 302	Sterile	Gamma
4000147240	2T Fen. Monoaxial Screw Ø7.2x40mm	IIb	8.9	4250539940 5ND	0425053991 9892	4665 1	P09070 302	Non Sterile	N/A
4000147240-S	2T Fen. Monoaxial Screw Ø7.2x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 8764	4665 1	P09070 302	Sterile	Gamma
4000147245	2T Fen. Monoaxial Screw Ø7.2x45mm	IIb	8.9	4250539940 5ND	0425053991 9908	4665 1	P09070 302	Non Sterile	N/A
4000147245-S	2T Fen. Monoaxial Screw Ø7.2x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 8771	4665 1	P09070 302	Sterile	Gamma
4000147250	2T Fen. Monoaxial Screw Ø7.2x50mm	IIb	8.9	4250539940 5ND	0425053991 9915	4665 1	P09070 302	Non Sterile	N/A
4000147250-S	2T Fen. Monoaxial Screw Ø7.2x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 8788	4665 1	P09070 302	Sterile	Gamma
4000147255	2T Fen. Monoaxial Screw Ø7.2x55mm	IIb	8.9	4250539940 5ND	0425053991 9922	4665 1	P09070 302	Non Sterile	N/A
4000147255-S	2T Fen. Monoaxial Screw Ø7.2x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 8795	4665 1	P09070 302	Sterile	Gamma
4000147260	2T Fen. Monoaxial Screw Ø7.2x60mm	IIb	8.9	4250539940 5ND	0425053991 9939	4665 1	P09070 302	Non Sterile	N/A
4000147260-S	2T Fen. Monoaxial Screw Ø7.2x60mm sterile	IIb	8.9	4250539940 6NF	0425053992 8801	4665 1	P09070 302	Sterile	Gamma
4000235535	2T Fen. Reduction Screw Ø 5.5mm x 35mm	IIb	8.9	4250539940 5ND	0425053994 2531	4665 1	P09070 302	Non Sterile	N/A
4000235535-S	2T Fen. Reduction Screw Ø 5.5mm x 35mm sterile	IIb	8.9	4250539940 6NF	0425053994 2548	4665 1	P09070 302	Sterile	Gamma

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
4000235540	2T Fen. Reduction Screw Ø 5.5mm x 40mm	IIb	8.9	4250539940 5ND	0425053994 2555	4665 1	P09070 302	Non Sterile	N/A
4000235540-S	2T Fen. Reduction Screw Ø 5.5mm x 40mm sterile	IIb	8.9	4250539940 6NF	0425053994 2562	4665 1	P09070 302	Sterile	Gamma
4000235545	2T Fen. Reduction Screw Ø 5.5mm x 45mm	IIb	8.9	4250539940 5ND	0425053994 2579	4665 1	P09070 302	Non Sterile	N/A
4000235545-S	2T Fen. Reduction Screw Ø 5.5mm x 45mm sterile	IIb	8.9	4250539940 6NF	0425053994 2586	4665 1	P09070 302	Sterile	Gamma
4000235550	2T Fen. Reduction Screw Ø 5.5mm x 50mm	IIb	8.9	4250539940 5ND	0425053994 2593	4665 1	P09070 302	Non Sterile	N/A
4000235550-S	2T Fen. Reduction Screw Ø 5.5mm x 50mm sterile	IIb	8.9	4250539940 6NF	0425053994 2609	4665 1	P09070 302	Sterile	Gamma
4000235555	2T Fen. Reduction Screw Ø 5.5mm x 55mm	IIb	8.9	4250539940 5ND	0425053994 2616	4665 1	P09070 302	Non Sterile	N/A
4000235555-S	2T Fen. Reduction Screw Ø 5.5mm x 55mm sterile	IIb	8.9	4250539940 6NF	0425053994 2623	4665 1	P09070 302	Sterile	Gamma
4000236535	2T Fen. Reduction Screw Ø 6.5mm x 35mm	IIb	8.9	4250539940 5ND	0425053994 2630	4665 1	P09070 302	Non Sterile	N/A
4000236535-S	2T Fen. Reduction Screw Ø 6.5mm x 35mm sterile	IIb	8.9	4250539940 6NF	0425053994 2647	4665 1	P09070 302	Sterile	Gamma
4000236540	2T Fen. Reduction Screw Ø 6.5mm x 40mm	IIb	8.9	4250539940 5ND	0425053994 2654	4665 1	P09070 302	Non Sterile	N/A
4000236540-S	2T Fen. Reduction Screw Ø 6.5mm x 40mm sterile	IIb	8.9	4250539940 6NF	0425053994 2661	4665 1	P09070 302	Sterile	Gamma
4000236545	2T Fen. Reduction Screw Ø 6.5mm x 45mm	IIb	8.9	4250539940 5ND	0425053994 2678	4665 1	P09070 302	Non Sterile	N/A
4000236545-S	2T Fen. Reduction Screw Ø 6.5mm x 45mm sterile	IIb	8.9	4250539940 6NF	0425053994 2685	4665 1	P09070 302	Sterile	Gamma
4000236550	2T Fen. Reduction Screw Ø 6.5mm x 50mm	IIb	8.9	4250539940 5ND	0425053994 2692	4665 1	P09070 302	Non Sterile	N/A
4000236550-S	2T Fen. Reduction Screw Ø 6.5mm x 50mm sterile	IIb	8.9	4250539940 6NF	0425053994 2708	4665 1	P09070 302	Sterile	Gamma
4000236555	2T Fen. Reduction Screw Ø 6.5mm x 55mm	IIb	8.9	4250539940 5ND	0425053994 2715	4665 1	P09070 302	Non Sterile	N/A
4000236555-S	2T Fen. Reduction Screw Ø 6.5mm x 55mm sterile	IIb	8.9	4250539940 6NF	0425053994 2722	4665 1	P09070 302	Sterile	Gamma
4000237240	2T Fen. Reduction Screw Ø 7.2mm x 40mm	IIb	8.9	4250539940 5ND	0425053994 2739	4665 1	P09070 302	Non Sterile	N/A
4000237240-S	2T Fen. Reduction Screw Ø 7.2mm x 40mm sterile	IIb	8.9	4250539940 6NF	0425053994 2746	4665 1	P09070 302	Sterile	Gamma
4000237245	2T Fen. Reduction Screw Ø 7.2mm x 45mm	IIb	8.9	4250539940 5ND	0425053994 2753	4665 1	P09070 302	Non Sterile	N/A
4000237245-S	2T Fen. Reduction Screw Ø 7.2mm x 45mm sterile	IIb	8.9	4250539940 6NF	0425053994 2760	4665 1	P09070 302	Sterile	Gamma
4000237250	2T Fen. Reduction Screw Ø 7.2mm x 50mm	IIb	8.9	4250539940 5ND	0425053994 2777	4665 1	P09070 302	Non Sterile	N/A
4000237250-S	2T Fen. Reduction Screw Ø 7.2mm x 50mm sterile	IIb	8.9	4250539940 6NF	0425053994 2784	4665 1	P09070 302	Sterile	Gamma
4000237255	2T Fen. Reduction Screw Ø 7.2mm x 55mm	IIb	8.9	4250539940 5ND	0425053994 2791	4665 1	P09070 302	Non Sterile	N/A
4000237255-S	2T Fen. Reduction Screw Ø 7.2mm x 55mm sterile	IIb	8.9	4250539940 6NF	0425053994 2807	4665 1	P09070 302	Sterile	Gamma
4000237260	2T Fen. Reduction Screw Ø 7.2mm x 60mm	IIb	8.9	4250539940 5ND	0425053994 2814	4665 1	P09070 302	Non Sterile	N/A
4000237260-S	2T Fen. Reduction Screw Ø 7.2mm x 60mm sterile	IIb	8.9	4250539940 6NF	0425053994 2821	4665 1	P09070 302	Sterile	Gamma
4000061040	2T Fen. Rev. Screw 10,5x40mm	IIb	8.9	4250539940 5ND	0425053991 9595	4665 1	P09070 302	Non Sterile	N/A
4000061040-S	2T Fen. Rev. Screw 10,5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 8931	4665 1	P09070 302	Sterile	Gamma

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
4000061045	2T Fen. Rev. Screw 10,5x45mm	IIb	8.9	4250539940 5ND	0425053991 9601	4665 1	P09070 302	Non Sterile	N/A
4000061045-S	2T Fen. Rev. Screw 10,5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 8948	4665 1	P09070 302	Sterile	Gamma
4000061050	2T Fen. Rev. Screw 10,5x50mm	IIb	8.9	4250539940 5ND	0425053991 9618	4665 1	P09070 302	Non Sterile	N/A
4000061050-S	2T Fen. Rev. Screw 10,5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 8955	4665 1	P09070 302	Sterile	Gamma
4000061055	2T Fen. Rev. Screw 10,5x55mm	IIb	8.9	4250539940 5ND	0425053991 9625	4665 1	P09070 302	Non Sterile	N/A
4000061055-S	2T Fen. Rev. Screw 10,5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 8962	4665 1	P09070 302	Sterile	Gamma
4000061060	2T Fen. Rev. Screw 10,5x60mm	IIb	8.9	4250539940 5ND	0425053991 9632	4665 1	P09070 302	Non Sterile	N/A
4000061060-S	2T Fen. Rev. Screw 10,5x60mm sterile	IIb	8.9	4250539940 6NF	0425053992 8979	4665 1	P09070 302	Sterile	Gamma
4000061065	2T Fen. Rev. Screw 10,5x65mm	IIb	8.9	4250539940 5ND	0425053991 9649	4665 1	P09070 302	Non Sterile	N/A
4000061065-S	2T Fen. Rev. Screw 10,5x65mm sterile	IIb	8.9	4250539940 6NF	0425053992 8986	4665 1	P09070 302	Sterile	Gamma
4000068540	2T Fen. Rev. Screw 8,5x40mm	IIb	8.9	4250539940 5ND	0425053991 9656	4665 1	P09070 302	Non Sterile	N/A
4000068540-S	2T Fen. Rev. Screw 8,5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 8818	4665 1	P09070 302	Sterile	Gamma
4000068545	2T Fen. Rev. Screw 8,5x45mm	IIb	8.9	4250539940 5ND	0425053991 9663	4665 1	P09070 302	Non Sterile	N/A
4000068545-S	2T Fen. Rev. Screw 8,5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 8825	4665 1	P09070 302	Sterile	Gamma
4000068550	2T Fen. Rev. Screw 8,5x50mm	IIb	8.9	4250539940 5ND	0425053991 9670	4665 1	P09070 302	Non Sterile	N/A
4000068550-S	2T Fen. Rev. Screw 8,5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 8832	4665 1	P09070 302	Sterile	Gamma
4000068555	2T Fen. Rev. Screw 8,5x55mm	IIb	8.9	4250539940 5ND	0425053991 9687	4665 1	P09070 302	Non Sterile	N/A
4000068555-S	2T Fen. Rev. Screw 8,5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 8849	4665 1	P09070 302	Sterile	Gamma
4000068560	2T Fen. Rev. Screw 8,5x60mm	IIb	8.9	4250539940 5ND	0425053991 9694	4665 1	P09070 302	Non Sterile	N/A
4000068560-S	2T Fen. Rev. Screw 8,5x60mm sterile	IIb	8.9	4250539940 6NF	0425053992 8856	4665 1	P09070 302	Sterile	Gamma
4000068565	2T Fen. Rev. Screw 8,5x65mm	IIb	8.9	4250539940 5ND	0425053991 9700	4665 1	P09070 302	Non Sterile	N/A
4000068565-S	2T Fen. Rev. Screw 8,5x65mm sterile	IIb	8.9	4250539940 6NF	0425053992 8863	4665 1	P09070 302	Sterile	Gamma
4000069540	2T Fen. Rev. Screw 9,5x40mm	IIb	8.9	4250539940 5ND	0425053991 9533	4665 1	P09070 302	Non Sterile	N/A
4000069540-S	2T Fen. Rev. Screw 9,5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 8870	4665 1	P09070 302	Sterile	Gamma
4000069545	2T Fen. Rev. Screw 9,5x45mm	IIb	8.9	4250539940 5ND	0425053991 9540	4665 1	P09070 302	Non Sterile	N/A
4000069545-S	2T Fen. Rev. Screw 9,5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 8887	4665 1	P09070 302	Sterile	Gamma
4000069550	2T Fen. Rev. Screw 9,5x50mm	IIb	8.9	4250539940 5ND	0425053991 9557	4665 1	P09070 302	Non Sterile	N/A
4000069550-S	2T Fen. Rev. Screw 9,5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 8894	4665 1	P09070 302	Sterile	Gamma
4000069555	2T Fen. Rev. Screw 9,5x55mm	IIb	8.9	4250539940 5ND	0425053991 9564	4665 1	P09070 302	Non Sterile	N/A
4000069555-S	2T Fen. Rev. Screw 9,5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 8900	4665 1	P09070 302	Sterile	Gamma

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
4000069560	2T Fen. Rev. Screw 9,5x60mm	IIb	8.9	4250539940 5ND	0425053991 9571	4665 1	P09070 302	Non Sterile	N/A
4000069560-S	2T Fen. Rev. Screw 9,5x60mm sterile	IIb	8.9	4250539940 6NF	0425053992 8917	4665 1	P09070 302	Sterile	Gamma
4000069565	2T Fen. Rev. Screw 9,5x65mm	IIb	8.9	4250539940 5ND	0425053991 9588	4665 1	P09070 302	Non Sterile	N/A
4000069565-S	2T Fen. Rev. Screw 9,5x65mm sterile	IIb	8.9	4250539940 6NF	0425053992 8924	4665 1	P09070 302	Sterile	Gamma
4000045535	2T Fenestrated Screw Ø5.5x35mm	IIb	8.9	4250539940 5ND	0425053992 3226	4665 1	P09070 302	Non Sterile	N/A
4000045535-S	2T Fenestrated Screw Ø5.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6906	4665 1	P09070 302	Sterile	Gamma
4000045540	2T Fenestrated Screw Ø5.5x40mm	IIb	8.9	4250539940 5ND	0425053991 7423	4665 1	P09070 302	Non Sterile	N/A
4000045540-S	2T Fenestrated Screw Ø5.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6913	4665 1	P09070 302	Sterile	Gamma
4000045545	2T Fenestrated Screw Ø5.5x45mm	IIb	8.9	4250539940 5ND	0425053991 7430	4665 1	P09070 302	Non Sterile	N/A
4000045545-S	2T Fenestrated Screw Ø5.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6920	4665 1	P09070 302	Sterile	Gamma
4000045550	2T Fenestrated Screw Ø5.5x50mm	IIb	8.9	4250539940 5ND	0425053991 7447	4665 1	P09070 302	Non Sterile	N/A
4000045550-S	2T Fenestrated Screw Ø5.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6937	4665 1	P09070 302	Sterile	Gamma
4000045555	2T Fenestrated Screw Ø5.5x55mm	IIb	8.9	4250539940 5ND	0425053991 7454	4665 1	P09070 302	Non Sterile	N/A
4000045555-S	2T Fenestrated Screw Ø5.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6944	4665 1	P09070 302	Sterile	Gamma
4000046535	2T Fenestrated Screw Ø6.5x35mm	IIb	8.9	4250539940 5ND	0425053992 3240	4665 1	P09070 302	Non Sterile	N/A
4000046535-S	2T Fenestrated Screw Ø6.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6968	4665 1	P09070 302	Sterile	Gamma
4000046540	2T Fenestrated Screw Ø6.5x40mm	IIb	8.9	4250539940 5ND	0425053991 7461	4665 1	P09070 302	Non Sterile	N/A
4000046540-S	2T Fenestrated Screw Ø6.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6975	4665 1	P09070 302	Sterile	Gamma
4000046545	2T Fenestrated Screw Ø6.5x45mm	IIb	8.9	4250539940 5ND	0425053991 7478	4665 1	P09070 302	Non Sterile	N/A
4000046545-S	2T Fenestrated Screw Ø6.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6982	4665 1	P09070 302	Sterile	Gamma
4000046550	2T Fenestrated Screw Ø6.5x50mm	IIb	8.9	4250539940 5ND	0425053991 7485	4665 1	P09070 302	Non Sterile	N/A
4000046550-S	2T Fenestrated Screw Ø6.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6999	4665 1	P09070 302	Sterile	Gamma
4000046555	2T Fenestrated Screw Ø6.5x55mm	IIb	8.9	4250539940 5ND	0425053991 7492	4665 1	P09070 302	Non Sterile	N/A
4000046555-S	2T Fenestrated Screw Ø6.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 7002	4665 1	P09070 302	Sterile	Gamma
4000047240	2T Fenestrated Screw Ø7.2x40mm	IIb	8.9	4250539940 5ND	0425053991 7508	4665 1	P09070 302	Non Sterile	N/A
4000047240-S	2T Fenestrated Screw Ø7.2x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 7019	4665 1	P09070 302	Sterile	Gamma
4000047245	2T Fenestrated Screw Ø7.2x45mm	IIb	8.9	4250539940 5ND	0425053991 7515	4665 1	P09070 302	Non Sterile	N/A
4000047245-S	2T Fenestrated Screw Ø7.2x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 7026	4665 1	P09070 302	Sterile	Gamma
4000047250	2T Fenestrated Screw Ø7.2x50mm	IIb	8.9	4250539940 5ND	0425053991 7522	4665 1	P09070 302	Non Sterile	N/A
4000047250-S	2T Fenestrated Screw Ø7.2x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 7033	4665 1	P09070 302	Sterile	Gamma

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4000047255	2T Fenestrated Screw Ø7.2x55mm	IIb	8.9	4250539940 5ND	0425053991 7539	4665 1	P09070 302	Non Sterile	N/A
4000047255-S	2T Fenestrated Screw Ø7.2x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 7040	4665 1	P09070 302	Sterile	Gamma
4000047260	2T Fenestrated Screw Ø7.2x60mm	IIb	8.9	4250539940 5ND	0425053991 7546	4665 1	P09070 302	Non Sterile	N/A
4000047260-S	2T Fenestrated Screw Ø7.2x60mm sterile	IIb	8.9	4250539940 6NF	0425053992 7057	4665 1	P09070 302	Sterile	Gamma
4000124830	2T Monoaxial Screw Ø4.8x30mm	IIb	8.9	4250539940 5ND	0425053993 8305	4665 1	P09070 302	Non Sterile	N/A
4000124830-S	2T Monoaxial Screw Ø4.8x30mm sterile	IIb	8.9	4250539940 6NF	0425053993 8312	4665 1	P09070 302	Sterile	Gamma
4000124835	2T Monoaxial Screw Ø4.8x35mm	IIb	8.9	4250539940 5ND	0425053993 8329	4665 1	P09070 302	Non Sterile	N/A
4000124835-S	2T Monoaxial Screw Ø4.8x35mm sterile	IIb	8.9	4250539940 6NF	0425053993 8336	4665 1	P09070 302	Sterile	Gamma
4000124840	2T Monoaxial Screw Ø4.8x40mm	IIb	8.9	4250539940 5ND	0425053993 8343	4665 1	P09070 302	Non Sterile	N/A
4000124840-S	2T Monoaxial Screw Ø4.8x40mm sterile	IIb	8.9	4250539940 6NF	0425053993 8350	4665 1	P09070 302	Sterile	Gamma
4000124845	2T Monoaxial Screw Ø4.8x45mm	IIb	8.9	4250539940 5ND	0425053993 8367	4665 1	P09070 302	Non Sterile	N/A
4000124845-S	2T Monoaxial Screw Ø4.8x45mm sterile	IIb	8.9	4250539940 6NF	0425053993 8374	4665 1	P09070 302	Sterile	Gamma
4000125525	2T Monoaxial Screw Ø5.5x25mm	IIb	8.9	4250539940 5ND	0425053993 8381	4665 1	P09070 302	Non Sterile	N/A
4000125525-S	2T Monoaxial Screw Ø5.5x25mm sterile	IIb	8.9	4250539940 6NF	0425053993 8398	4665 1	P09070 302	Sterile	Gamma
4000125530	2T Monoaxial Screw Ø5.5x30mm	IIb	8.9	4250539940 5ND	0425053993 8404	4665 1	P09070 302	Non Sterile	N/A
4000125530-S	2T Monoaxial Screw Ø5.5x30mm sterile	IIb	8.9	4250539940 6NF	0425053993 8411	4665 1	P09070 302	Sterile	Gamma
4000125535	2T Monoaxial Screw Ø5.5x35mm	IIb	8.9	4250539940 5ND	0425053993 8428	4665 1	P09070 302	Non Sterile	N/A
4000125535-S	2T Monoaxial Screw Ø5.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053993 8435	4665 1	P09070 302	Sterile	Gamma
4000125540	2T Monoaxial Screw Ø5.5x40mm	IIb	8.9	4250539940 5ND	0425053993 8442	4665 1	P09070 302	Non Sterile	N/A
4000125540-S	2T Monoaxial Screw Ø5.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053993 8459	4665 1	P09070 302	Sterile	Gamma
4000125545	2T Monoaxial Screw Ø5.5x45mm	IIb	8.9	4250539940 5ND	0425053993 8466	4665 1	P09070 302	Non Sterile	N/A
4000125545-S	2T Monoaxial Screw Ø5.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053993 8473	4665 1	P09070 302	Sterile	Gamma
4000125550	2T Monoaxial Screw Ø5.5x50mm	IIb	8.9	4250539940 5ND	0425053993 8480	4665 1	P09070 302	Non Sterile	N/A
4000125550-S	2T Monoaxial Screw Ø5.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053993 8497	4665 1	P09070 302	Sterile	Gamma
4000125555	2T Monoaxial Screw Ø5.5x55mm	IIb	8.9	4250539940 5ND	0425053993 8503	4665 1	P09070 302	Non Sterile	N/A
4000125555-S	2T Monoaxial Screw Ø5.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053993 8510	4665 1	P09070 302	Sterile	Gamma
4000126535	2T Monoaxial Screw Ø6.5x35mm	IIb	8.9	4250539940 5ND	0425053993 8527	4665 1	P09070 302	Non Sterile	N/A
4000126535-S	2T Monoaxial Screw Ø6.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053993 8534	4665 1	P09070 302	Sterile	Gamma
4000126540	2T Monoaxial Screw Ø6.5x40mm	IIb	8.9	4250539940 5ND	0425053993 8541	4665 1	P09070 302	Non Sterile	N/A
4000126540-S	2T Monoaxial Screw Ø6.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053993 8558	4665 1	P09070 302	Sterile	Gamma

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
4000126545	2T Monoaxial Screw Ø6.5x45mm	IIb	8.9	4250539940 5ND	0425053993 8565	4665 1	P09070 302	Non Sterile	N/A
4000126545-S	2T Monoaxial Screw Ø6.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053993 8572	4665 1	P09070 302	Sterile	Gamma
4000126550	2T Monoaxial Screw Ø6.5x50mm	IIb	8.9	4250539940 5ND	0425053993 8589	4665 1	P09070 302	Non Sterile	N/A
4000126550-S	2T Monoaxial Screw Ø6.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053993 8596	4665 1	P09070 302	Sterile	Gamma
4000126555	2T Monoaxial Screw Ø6.5x55mm	IIb	8.9	4250539940 5ND	0425053993 8602	4665 1	P09070 302	Non Sterile	N/A
4000126555-S	2T Monoaxial Screw Ø6.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053993 8619	4665 1	P09070 302	Sterile	Gamma
4000127240	2T Monoaxial Screw Ø7.2x40mm	IIb	8.9	4250539940 5ND	0425053993 8626	4665 1	P09070 302	Non Sterile	N/A
4000127240-S	2T Monoaxial Screw Ø7.2x40mm sterile	IIb	8.9	4250539940 6NF	0425053993 8633	4665 1	P09070 302	Sterile	Gamma
4000127245	2T Monoaxial Screw Ø7.2x45mm	IIb	8.9	4250539940 5ND	0425053993 8640	4665 1	P09070 302	Non Sterile	N/A
4000127245-S	2T Monoaxial Screw Ø7.2x45mm sterile	IIb	8.9	4250539940 6NF	0425053993 8657	4665 1	P09070 302	Sterile	Gamma
4000127250	2T Monoaxial Screw Ø7.2x50mm	IIb	8.9	4250539940 5ND	0425053993 8664	4665 1	P09070 302	Non Sterile	N/A
4000127250-S	2T Monoaxial Screw Ø7.2x50mm sterile	IIb	8.9	4250539940 6NF	0425053993 8671	4665 1	P09070 302	Sterile	Gamma
4000127255	2T Monoaxial Screw Ø7.2x55mm	IIb	8.9	4250539940 5ND	0425053993 8688	4665 1	P09070 302	Non Sterile	N/A
4000127255-S	2T Monoaxial Screw Ø7.2x55mm sterile	IIb	8.9	4250539940 6NF	0425053993 8695	4665 1	P09070 302	Sterile	Gamma
4000127260	2T Monoaxial Screw Ø7.2x60mm	IIb	8.9	4250539940 5ND	0425053993 8701	4665 1	P09070 302	Non Sterile	N/A
4000127260-S	2T Monoaxial Screw Ø7.2x60mm sterile	IIb	8.9	4250539940 6NF	0425053993 8718	4665 1	P09070 302	Sterile	Gamma
4000024825	2T Polyaxial Screw Ø4.8x25mm	IIb	8.9	4250539940 5ND	0425053991 6907	4665 1	P09070 302	Non Sterile	N/A
4000024825-S	2T Polyaxial Screw Ø4.8x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 6388	4665 1	P09070 302	Sterile	Gamma
4000024830	2T Polyaxial Screw Ø4.8x30mm	IIb	8.9	4250539940 5ND	0425053991 6914	4665 1	P09070 302	Non Sterile	N/A
4000024830-S	2T Polyaxial Screw Ø4.8x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 6395	4665 1	P09070 302	Sterile	Gamma
4000024835	2T Polyaxial Screw Ø4.8x35mm	IIb	8.9	4250539940 5ND	0425053991 6921	4665 1	P09070 302	Non Sterile	N/A
4000024835-S	2T Polyaxial Screw Ø4.8x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6401	4665 1	P09070 302	Sterile	Gamma
4000024840	2T Polyaxial Screw Ø4.8x40mm	IIb	8.9	4250539940 5ND	0425053991 6938	4665 1	P09070 302	Non Sterile	N/A
4000024840-S	2T Polyaxial Screw Ø4.8x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6418	4665 1	P09070 302	Sterile	Gamma
4000024845	2T Polyaxial Screw Ø4.8x45mm	IIb	8.9	4250539940 5ND	0425053991 6945	4665 1	P09070 302	Non Sterile	N/A
4000024845-S	2T Polyaxial Screw Ø4.8x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6425	4665 1	P09070 302	Sterile	Gamma
4000025525	2T Polyaxial Screw Ø5.5x25mm	IIb	8.9	4250539940 5ND	0425053991 6952	4665 1	P09070 302	Non Sterile	N/A
4000025525-S	2T Polyaxial Screw Ø5.5x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 6432	4665 1	P09070 302	Sterile	Gamma
4000025530	2T Polyaxial Screw Ø5.5x30mm	IIb	8.9	4250539940 5ND	0425053991 6969	4665 1	P09070 302	Non Sterile	N/A
4000025530-S	2T Polyaxial Screw Ø5.5x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 6449	4665 1	P09070 302	Sterile	Gamma

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4000025535	2T Polyaxial Screw Ø5.5x35mm	IIb	8.9	4250539940 5ND	0425053991 6976	4665 1	P09070 302	Non Sterile	N/A
4000025535-S	2T Polyaxial Screw Ø5.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6456	4665 1	P09070 302	Sterile	Gamma
4000025540	2T Polyaxial Screw Ø5.5x40mm	IIb	8.9	4250539940 5ND	0425053991 6983	4665 1	P09070 302	Non Sterile	N/A
4000025540-S	2T Polyaxial Screw Ø5.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6463	4665 1	P09070 302	Sterile	Gamma
4000025545	2T Polyaxial Screw Ø5.5x45mm	IIb	8.9	4250539940 5ND	0425053991 6990	4665 1	P09070 302	Non Sterile	N/A
4000025545-S	2T Polyaxial Screw Ø5.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6470	4665 1	P09070 302	Sterile	Gamma
4000025550	2T Polyaxial Screw Ø5.5x50mm	IIb	8.9	4250539940 5ND	0425053991 7003	4665 1	P09070 302	Non Sterile	N/A
4000025550-S	2T Polyaxial Screw Ø5.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6487	4665 1	P09070 302	Sterile	Gamma
4000025555	2T Polyaxial Screw Ø5.5x55mm	IIb	8.9	4250539940 5ND	0425053991 7010	4665 1	P09070 302	Non Sterile	N/A
4000025555-S	2T Polyaxial Screw Ø5.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6494	4665 1	P09070 302	Sterile	Gamma
4000026525	2T Polyaxial Screw Ø6.5x25mm	IIb	8.9	4250539940 5ND	0425053991 7027	4665 1	P09070 302	Non Sterile	N/A
4000026525-S	2T Polyaxial Screw Ø6.5x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 6500	4665 1	P09070 302	Sterile	Gamma
4000026530	2T Polyaxial Screw Ø6.5x30mm	IIb	8.9	4250539940 5ND	0425053991 7034	4665 1	P09070 302	Non Sterile	N/A
4000026530-S	2T Polyaxial Screw Ø6.5x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 6517	4665 1	P09070 302	Sterile	Gamma
4000026535	2T Polyaxial Screw Ø6.5x35mm	IIb	8.9	4250539940 5ND	0425053991 7041	4665 1	P09070 302	Non Sterile	N/A
4000026535-S	2T Polyaxial Screw Ø6.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6524	4665 1	P09070 302	Sterile	Gamma
4000026540	2T Polyaxial Screw Ø6.5x40mm	IIb	8.9	4250539940 5ND	0425053991 7058	4665 1	P09070 302	Non Sterile	N/A
4000026540-S	2T Polyaxial Screw Ø6.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6531	4665 1	P09070 302	Sterile	Gamma
4000026545	2T Polyaxial Screw Ø6.5x45mm	IIb	8.9	4250539940 5ND	0425053991 7065	4665 1	P09070 302	Non Sterile	N/A
4000026545-S	2T Polyaxial Screw Ø6.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6548	4665 1	P09070 302	Sterile	Gamma
4000026550	2T Polyaxial Screw Ø6.5x50mm	IIb	8.9	4250539940 5ND	0425053991 7072	4665 1	P09070 302	Non Sterile	N/A
4000026550-S	2T Polyaxial Screw Ø6.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6555	4665 1	P09070 302	Sterile	Gamma
4000026555	2T Polyaxial Screw Ø6.5x55mm	IIb	8.9	4250539940 5ND	0425053991 7089	4665 1	P09070 302	Non Sterile	N/A
4000026555-S	2T Polyaxial Screw Ø6.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6562	4665 1	P09070 302	Sterile	Gamma
4000027235	2T Polyaxial Screw Ø7.2x35mm	IIb	8.9	4250539940 5ND	0425053991 7096	4665 1	P09070 302	Non Sterile	N/A
4000027235-S	2T Polyaxial Screw Ø7.2x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6579	4665 1	P09070 302	Sterile	Gamma
4000027240	2T Polyaxial Screw Ø7.2x40mm	IIb	8.9	4250539940 5ND	0425053991 7102	4665 1	P09070 302	Non Sterile	N/A
4000027240-S	2T Polyaxial Screw Ø7.2x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6586	4665 1	P09070 302	Sterile	Gamma
4000027245	2T Polyaxial Screw Ø7.2x45mm	IIb	8.9	4250539940 5ND	0425053991 7119	4665 1	P09070 302	Non Sterile	N/A
4000027245-S	2T Polyaxial Screw Ø7.2x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6593	4665 1	P09070 302	Sterile	Gamma

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4000027250	2T Polyaxial Screw Ø7.2x50mm	IIb	8.9	4250539940 5ND	0425053991 7126	4665 1	P09070 302	Non Sterile	N/A
4000027250-S	2T Polyaxial Screw Ø7.2x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6609	4665 1	P09070 302	Sterile	Gamma
4000027255	2T Polyaxial Screw Ø7.2x55mm	IIb	8.9	4250539940 5ND	0425053991 7133	4665 1	P09070 302	Non Sterile	N/A
4000027255-S	2T Polyaxial Screw Ø7.2x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6616	4665 1	P09070 302	Sterile	Gamma
4000027260	2T Polyaxial Screw Ø7.2x60mm	IIb	8.9	4250539940 5ND	0425053991 7140	4665 1	P09070 302	Non Sterile	N/A
4000027260-S	2T Polyaxial Screw Ø7.2x60mm sterile	IIb	8.9	4250539940 6NF	0425053992 6623	4665 1	P09070 302	Sterile	Gamma
4000034825	2T Reduction Screw Ø4.8x25mm	IIb	8.9	4250539940 5ND	0425053991 7157	4665 1	P09070 302	Non Sterile	N/A
4000034825-S	2T Reduction Screw Ø4.8x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 6630	4665 1	P09070 302	Sterile	Gamma
4000034830	2T Reduction Screw Ø4.8x30mm	IIb	8.9	4250539940 5ND	0425053991 7164	4665 1	P09070 302	Non Sterile	N/A
4000034830-S	2T Reduction Screw Ø4.8x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 6647	4665 1	P09070 302	Sterile	Gamma
4000034835	2T Reduction Screw Ø4.8x35mm	IIb	8.9	4250539940 5ND	0425053991 7171	4665 1	P09070 302	Non Sterile	N/A
4000034835-S	2T Reduction Screw Ø4.8x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6654	4665 1	P09070 302	Sterile	Gamma
4000034840	2T Reduction Screw Ø4.8x40mm	IIb	8.9	4250539940 5ND	0425053991 7188	4665 1	P09070 302	Non Sterile	N/A
4000034840-S	2T Reduction Screw Ø4.8x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6661	4665 1	P09070 302	Sterile	Gamma
4000034845	2T Reduction Screw Ø4.8x45mm	IIb	8.9	4250539940 5ND	0425053991 7195	4665 1	P09070 302	Non Sterile	N/A
4000034845-S	2T Reduction Screw Ø4.8x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6678	4665 1	P09070 302	Sterile	Gamma
4000035525	2T Reduction Screw Ø5.5x25mm	IIb	8.9	4250539940 5ND	0425053991 7201	4665 1	P09070 302	Non Sterile	N/A
4000035525-S	2T Reduction Screw Ø5.5x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 6685	4665 1	P09070 302	Sterile	Gamma
4000035530	2T Reduction Screw Ø5.5x30mm	IIb	8.9	4250539940 5ND	0425053991 7218	4665 1	P09070 302	Non Sterile	N/A
4000035530-S	2T Reduction Screw Ø5.5x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 6692	4665 1	P09070 302	Sterile	Gamma
4000035535	2T Reduction Screw Ø5.5x35mm	IIb	8.9	4250539940 5ND	0425053991 7225	4665 1	P09070 302	Non Sterile	N/A
4000035535-S	2T Reduction Screw Ø5.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6708	4665 1	P09070 302	Sterile	Gamma
4000035540	2T Reduction Screw Ø5.5x40mm	IIb	8.9	4250539940 5ND	0425053991 7232	4665 1	P09070 302	Non Sterile	N/A
4000035540-S	2T Reduction Screw Ø5.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6715	4665 1	P09070 302	Sterile	Gamma
4000035545	2T Reduction Screw Ø5.5x45mm	IIb	8.9	4250539940 5ND	0425053991 7249	4665 1	P09070 302	Non Sterile	N/A
4000035545-S	2T Reduction Screw Ø5.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6722	4665 1	P09070 302	Sterile	Gamma
4000035550	2T Reduction Screw Ø5.5x50mm	IIb	8.9	4250539940 5ND	0425053991 7256	4665 1	P09070 302	Non Sterile	N/A
4000035550-S	2T Reduction Screw Ø5.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6739	4665 1	P09070 302	Sterile	Gamma
4000035555	2T Reduction Screw Ø5.5x55mm	IIb	8.9	4250539940 5ND	0425053991 7263	4665 1	P09070 302	Non Sterile	N/A
4000035555-S	2T Reduction Screw Ø5.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6746	4665 1	P09070 302	Sterile	Gamma

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
4000036525	2T Reduction Screw Ø6.5x25mm	IIb	8.9	4250539940 5ND	0425053991 7270	4665 1	P09070 302	Non Sterile	N/A
4000036525-S	2T Reduction Screw Ø6.5x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 6753	4665 1	P09070 302	Sterile	Gamma
4000036530	2T Reduction Screw Ø6.5x30mm	IIb	8.9	4250539940 5ND	0425053991 7287	4665 1	P09070 302	Non Sterile	N/A
4000036530-S	2T Reduction Screw Ø6.5x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 6760	4665 1	P09070 302	Sterile	Gamma
4000036535	2T Reduction Screw Ø6.5x35mm	IIb	8.9	4250539940 5ND	0425053991 7294	4665 1	P09070 302	Non Sterile	N/A
4000036535-S	2T Reduction Screw Ø6.5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6777	4665 1	P09070 302	Sterile	Gamma
4000036540	2T Reduction Screw Ø6.5x40mm	IIb	8.9	4250539940 5ND	0425053991 7300	4665 1	P09070 302	Non Sterile	N/A
4000036540-S	2T Reduction Screw Ø6.5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6784	4665 1	P09070 302	Sterile	Gamma
4000036545	2T Reduction Screw Ø6.5x45mm	IIb	8.9	4250539940 5ND	0425053991 7317	4665 1	P09070 302	Non Sterile	N/A
4000036545-S	2T Reduction Screw Ø6.5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6791	4665 1	P09070 302	Sterile	Gamma
4000036550	2T Reduction Screw Ø6.5x50mm	IIb	8.9	4250539940 5ND	0425053991 7324	4665 1	P09070 302	Non Sterile	N/A
4000036550-S	2T Reduction Screw Ø6.5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6807	4665 1	P09070 302	Sterile	Gamma
4000036555	2T Reduction Screw Ø6.5x55mm	IIb	8.9	4250539940 5ND	0425053991 7331	4665 1	P09070 302	Non Sterile	N/A
4000036555-S	2T Reduction Screw Ø6.5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6814	4665 1	P09070 302	Sterile	Gamma
4000037235	2T Reduction Screw Ø7.2x35mm	IIb	8.9	4250539940 5ND	0425053991 7348	4665 1	P09070 302	Non Sterile	N/A
4000037235-S	2T Reduction Screw Ø7.2x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 6821	4665 1	P09070 302	Sterile	Gamma
4000037240	2T Reduction Screw Ø7.2x40mm	IIb	8.9	4250539940 5ND	0425053991 7355	4665 1	P09070 302	Non Sterile	N/A
4000037240-S	2T Reduction Screw Ø7.2x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6838	4665 1	P09070 302	Sterile	Gamma
4000037245	2T Reduction Screw Ø7.2x45mm	IIb	8.9	4250539940 5ND	0425053991 7362	4665 1	P09070 302	Non Sterile	N/A
4000037245-S	2T Reduction Screw Ø7.2x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6845	4665 1	P09070 302	Sterile	Gamma
4000037250	2T Reduction Screw Ø7.2x50mm	IIb	8.9	4250539940 5ND	0425053991 7379	4665 1	P09070 302	Non Sterile	N/A
4000037250-S	2T Reduction Screw Ø7.2x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6852	4665 1	P09070 302	Sterile	Gamma
4000037255	2T Reduction Screw Ø7.2x55mm	IIb	8.9	4250539940 5ND	0425053991 7386	4665 1	P09070 302	Non Sterile	N/A
4000037255-S	2T Reduction Screw Ø7.2x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6869	4665 1	P09070 302	Sterile	Gamma
4000037260	2T Reduction Screw Ø7.2x60mm	IIb	8.9	4250539940 5ND	0425053991 7393	4665 1	P09070 302	Non Sterile	N/A
4000037260-S	2T Reduction Screw Ø7.2x60mm sterile	IIb	8.9	4250539940 6NF	0425053992 6876	4665 1	P09070 302	Sterile	Gamma
1005125540	6T Fen. Reduction Screw Ø 5.5mm x 40mm	IIb	8.9	4250539940 5ND	0425053994 2838	4665 1	P09070 302	Non Sterile	N/A
1005125540-S	6T Fen. Reduction Screw Ø 5.5mm x 40mm sterile	IIb	8.9	4250539940 6NF	0425053994 2845	4665 1	P09070 302	Sterile	Gamma
1005125545	6T Fen. Reduction Screw Ø 5.5mm x 45mm	IIb	8.9	4250539940 5ND	0425053994 2852	4665 1	P09070 302	Non Sterile	N/A
1005125545-S	6T Fen. Reduction Screw Ø 5.5mm x 45mm sterile	IIb	8.9	4250539940 6NF	0425053994 2869	4665 1	P09070 302	Sterile	Gamma

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
1005125550	6T Fen. Reduction Screw Ø 5.5mm x 50mm	IIb	8.9	4250539940 5ND	0425053994 2876	4665 1	P09070 302	Non Sterile	N/A
1005125550-S	6T Fen. Reduction Screw Ø 5.5mm x 50mm sterile	IIb	8.9	4250539940 6NF	0425053994 2883	4665 1	P09070 302	Sterile	Gamma
1005125555	6T Fen. Reduction Screw Ø 5.5mm x 55mm	IIb	8.9	4250539940 5ND	0425053994 2890	4665 1	P09070 302	Non Sterile	N/A
1005125555-S	6T Fen. Reduction Screw Ø 5.5mm x 55mm sterile	IIb	8.9	4250539940 6NF	0425053994 2906	4665 1	P09070 302	Sterile	Gamma
1005126540	6T Fen. Reduction Screw Ø 6.5mm x 40mm	IIb	8.9	4250539940 5ND	0425053994 2913	4665 1	P09070 302	Non Sterile	N/A
1005126540-S	6T Fen. Reduction Screw Ø 6.5mm x 40mm sterile	IIb	8.9	4250539940 6NF	0425053994 2920	4665 1	P09070 302	Sterile	Gamma
1005126545	6T Fen. Reduction Screw Ø 6.5mm x 45mm	IIb	8.9	4250539940 5ND	0425053994 2937	4665 1	P09070 302	Non Sterile	N/A
1005126545-S	6T Fen. Reduction Screw Ø 6.5mm x 45mm sterile	IIb	8.9	4250539940 6NF	0425053994 2944	4665 1	P09070 302	Sterile	Gamma
1005126550	6T Fen. Reduction Screw Ø 6.5mm x 50mm	IIb	8.9	4250539940 5ND	0425053994 2951	4665 1	P09070 302	Non Sterile	N/A
1005126550-S	6T Fen. Reduction Screw Ø 6.5mm x 50mm sterile	IIb	8.9	4250539940 6NF	0425053994 2968	4665 1	P09070 302	Sterile	Gamma
1005126555	6T Fen. Reduction Screw Ø 6.5mm x 55mm	IIb	8.9	4250539940 5ND	0425053994 2975	4665 1	P09070 302	Non Sterile	N/A
1005126555-S	6T Fen. Reduction Screw Ø 6.5mm x 55mm sterile	IIb	8.9	4250539940 6NF	0425053994 2982	4665 1	P09070 302	Sterile	Gamma
1005127240	6T Fen. Reduction Screw Ø 7.2mm x 40mm	IIb	8.9	4250539940 5ND	0425053994 2999	4665 1	P09070 302	Non Sterile	N/A
1005127240-S	6T Fen. Reduction Screw Ø 7.2mm x 40mm sterile	IIb	8.9	4250539940 6NF	0425053994 3002	4665 1	P09070 302	Sterile	Gamma
1005127245	6T Fen. Reduction Screw Ø 7.2mm x 45mm	IIb	8.9	4250539940 5ND	0425053994 3019	4665 1	P09070 302	Non Sterile	N/A
1005127245-S	6T Fen. Reduction Screw Ø 7.2mm x 45mm sterile	IIb	8.9	4250539940 6NF	0425053994 3026	4665 1	P09070 302	Sterile	Gamma
1005127250	6T Fen. Reduction Screw Ø 7.2mm x 50mm	IIb	8.9	4250539940 5ND	0425053994 3033	4665 1	P09070 302	Non Sterile	N/A
1005127250-S	6T Fen. Reduction Screw Ø 7.2mm x 50mm sterile	IIb	8.9	4250539940 6NF	0425053994 3040	4665 1	P09070 302	Sterile	Gamma
1005127255	6T Fen. Reduction Screw Ø 7.2mm x 55mm	IIb	8.9	4250539940 5ND	0425053994 3057	4665 1	P09070 302	Non Sterile	N/A
1005127255-S	6T Fen. Reduction Screw Ø 7.2mm x 55mm sterile	IIb	8.9	4250539940 6NF	0425053994 3064	4665 1	P09070 302	Sterile	Gamma
1005127260	6T Fen. Reduction Screw Ø 7.2mm x 60mm	IIb	8.9	4250539940 5ND	0425053994 3071	4665 1	P09070 302	Non Sterile	N/A
1005127260-S	6T Fen. Reduction Screw Ø 7.2mm x 60mm sterile	IIb	8.9	4250539940 6NF	0425053994 3088	4665 1	P09070 302	Sterile	Gamma
10060985100	Cannulated Revision 6T Ø8,5x100 mm	IIb	8.9	4250539940 5ND	0425053991 0158	4665 1	P09070 302	Non Sterile	N/A
10060985100-S	Cannulated Revision 6T Ø8,5x100 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4698	4665 1	P09070 302	Sterile	Gamma
1006098535	Cannulated Revision 6T Ø8,5x35 mm	IIb	8.9	4250539940 5ND	0425053990 4034	4665 1	P09070 302	Non Sterile	N/A
1006098535-S	Cannulated Revision 6T Ø8,5x35 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4605	4665 1	P09070 302	Sterile	Gamma
1006098540	Cannulated Revision 6T Ø8,5x40 mm	IIb	8.9	4250539940 5ND	0425053990 4041	4665 1	P09070 302	Non Sterile	N/A
1006098540-S	Cannulated Revision 6T Ø8,5x40 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4612	4665 1	P09070 302	Sterile	Gamma
1006098545	Cannulated Revision 6T Ø8,5x45 mm	IIb	8.9	4250539940 5ND	0425053990 4089	4665 1	P09070 302	Non Sterile	N/A
1006098545-S	Cannulated Revision 6T Ø8,5x45 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4629	4665 1	P09070 302	Sterile	Gamma

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1006098550	Cannulated Revision 6T Ø8,5x50 mm	IIb	8.9	4250539940 5ND	0425053990 5529	4665 1	P09070 302	Non Sterile	N/A
1006098550-S	Cannulated Revision 6T Ø8,5x50 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4636	4665 1	P09070 302	Sterile	Gamma
1006098555	Cannulated Revision 6T Ø8,5x55 mm	IIb	8.9	4250539940 5ND	0425053990 5536	4665 1	P09070 302	Non Sterile	N/A
1006098555-S	Cannulated Revision 6T Ø8,5x55 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4643	4665 1	P09070 302	Sterile	Gamma
1006098560	Cannulated Revision 6T Ø8,5x60 mm	IIb	8.9	4250539940 5ND	0425053990 5543	4665 1	P09070 302	Non Sterile	N/A
1006098560-S	Cannulated Revision 6T Ø8,5x60 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4650	4665 1	P09070 302	Sterile	Gamma
1006098570	Cannulated Revision 6T Ø8,5x70 mm	IIb	8.9	4250539940 5ND	0425053990 5550	4665 1	P09070 302	Non Sterile	N/A
1006098570-S	Cannulated Revision 6T Ø8,5x70 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4667	4665 1	P09070 302	Sterile	Gamma
1006098580	Cannulated Revision 6T Ø8,5x80 mm	IIb	8.9	4250539940 5ND	0425053990 5567	4665 1	P09070 302	Non Sterile	N/A
1006098580-S	Cannulated Revision 6T Ø8,5x80 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4674	4665 1	P09070 302	Sterile	Gamma
1006098590	Cannulated Revision 6T Ø8,5x90 mm	IIb	8.9	4250539940 5ND	0425053990 5574	4665 1	P09070 302	Non Sterile	N/A
1006098590-S	Cannulated Revision 6T Ø8,5x90 mm sterile	IIb	8.9	4250539940 6NF	0425053992 4681	4665 1	P09070 302	Sterile	Gamma
1008044825	Cannulated Screw Ø4.8 x 25mm	IIb	8.9	4250539940 5ND	0425053990 5703	4665 1	P09070 302	Non Sterile	N/A
1008044830	Cannulated Screw Ø4.8 x 30mm	IIb	8.9	4250539940 5ND	0425053990 5710	4665 1	P09070 302	Non Sterile	N/A
1008044835	Cannulated Screw Ø4.8 x 35mm	IIb	8.9	4250539940 5ND	0425053990 5727	4665 1	P09070 302	Non Sterile	N/A
1008044840	Cannulated Screw Ø4.8 x 40mm	IIb	8.9	4250539940 5ND	0425053990 5734	4665 1	P09070 302	Non Sterile	N/A
1008044845	Cannulated Screw Ø4.8 x 45mm	IIb	8.9	4250539940 5ND	0425053990 5741	4665 1	P09070 302	Non Sterile	N/A
1008045525	Cannulated Screw Ø5.5 x 25mm	IIb	8.9	4250539940 5ND	0425053990 5758	4665 1	P09070 302	Non Sterile	N/A
1008045530	Cannulated Screw Ø5.5 x 30mm	IIb	8.9	4250539940 5ND	0425053990 5765	4665 1	P09070 302	Non Sterile	N/A
1008045535	Cannulated Screw Ø5.5 x 35mm	IIb	8.9	4250539940 5ND	0425053990 5772	4665 1	P09070 302	Non Sterile	N/A
1008045540	Cannulated Screw Ø5.5 x 40mm	IIb	8.9	4250539940 5ND	0425053990 5789	4665 1	P09070 302	Non Sterile	N/A
1008045545	Cannulated Screw Ø5.5 x 45mm	IIb	8.9	4250539940 5ND	0425053990 5796	4665 1	P09070 302	Non Sterile	N/A
1008045550	Cannulated Screw Ø5.5 x 50mm	IIb	8.9	4250539940 5ND	0425053990 5802	4665 1	P09070 302	Non Sterile	N/A
1008045555	Cannulated Screw Ø5.5 x 55mm	IIb	8.9	4250539940 5ND	0425053990 5819	4665 1	P09070 302	Non Sterile	N/A
1008046525	Cannulated Screw Ø6.5 x 25mm	IIb	8.9	4250539940 5ND	0425053990 5826	4665 1	P09070 302	Non Sterile	N/A
1008046530	Cannulated Screw Ø6.5 x 30mm	IIb	8.9	4250539940 5ND	0425053990 5833	4665 1	P09070 302	Non Sterile	N/A
1008046535	Cannulated Screw Ø6.5 x 35mm	IIb	8.9	4250539940 5ND	0425053990 5840	4665 1	P09070 302	Non Sterile	N/A
1008046540	Cannulated Screw Ø6.5 x 40mm	IIb	8.9	4250539940 5ND	0425053990 5857	4665 1	P09070 302	Non Sterile	N/A
1008046545	Cannulated Screw Ø6.5 x 45mm	IIb	8.9	4250539940 5ND	0425053990 5864	4665 1	P09070 302	Non Sterile	N/A
1008046550	Cannulated Screw Ø6.5 x 50mm	IIb	8.9	4250539940 5ND	0425053990 5871	4665 1	P09070 302	Non Sterile	N/A

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
1008046555	Cannulated Screw Ø6.5 x 55mm	IIb	8.9	4250539940 5ND	0425053990 5888	4665 1	P09070 302	Non Sterile	N/A
1008047235	Cannulated Screw Ø7.2 x 35mm	IIb	8.9	4250539940 5ND	0425053990 5895	4665 1	P09070 302	Non Sterile	N/A
1008047240	Cannulated Screw Ø7.2 x 40mm	IIb	8.9	4250539940 5ND	0425053990 5901	4665 1	P09070 302	Non Sterile	N/A
1008047245	Cannulated Screw Ø7.2 x 45mm	IIb	8.9	4250539940 5ND	0425053990 5918	4665 1	P09070 302	Non Sterile	N/A
1008047250	Cannulated Screw Ø7.2 x 50mm	IIb	8.9	4250539940 5ND	0425053990 5925	4665 1	P09070 302	Non Sterile	N/A
1008047255	Cannulated Screw Ø7.2 x 55mm	IIb	8.9	4250539940 5ND	0425053990 5932	4665 1	P09070 302	Non Sterile	N/A
1008047260	Cannulated Screw Ø7.2 x 60mm	IIb	8.9	4250539940 5ND	0425053990 5949	4665 1	P09070 302	Non Sterile	N/A
1001090145	CoCr Rod 450 mm	IIb	8.9	4250539906 0MZ	0425053990 2696	6511 6	P09070 304	Non Sterile	N/A
1001090145-S	CoCr Rod 450 mm sterile	IIb	8.9	4250539906 1N3	0425053992 4919	6511 6	P09070 304	Sterile	Gamma
1004080000	Domino Connector	IIb	8.9	4250539905 0MW	0425053990 1057	6511 4	P09070 304	Non Sterile	N/A
1004080000-S	Domino Connector sterile	IIb	8.9	4250539905 1MY	0425053992 5015	6511 4	P09070 304	Sterile	Gamma
1010045540	Fenestrated 6T Screw Ø5,5 x 40mm	IIb	8.9	4250539940 5ND	0425053990 5956	4665 1	P09070 302	Non Sterile	N/A
1010045540-S	Fenestrated 6T Screw Ø5,5 x 40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6005	4665 1	P09070 302	Sterile	Gamma
1010045545	Fenestrated 6T Screw Ø5,5 x 45mm	IIb	8.9	4250539940 5ND	0425053990 5963	4665 1	P09070 302	Non Sterile	N/A
1010045545-S	Fenestrated 6T Screw Ø5,5 x 45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6012	4665 1	P09070 302	Sterile	Gamma
1010045550	Fenestrated 6T Screw Ø5,5 x 50mm	IIb	8.9	4250539940 5ND	0425053990 5970	4665 1	P09070 302	Non Sterile	N/A
1010045550-S	Fenestrated 6T Screw Ø5,5 x 50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6029	4665 1	P09070 302	Sterile	Gamma
1010045555	Fenestrated 6T Screw Ø5,5 x 55mm	IIb	8.9	4250539940 5ND	0425053990 5987	4665 1	P09070 302	Non Sterile	N/A
1010045555-S	Fenestrated 6T Screw Ø5,5 x 55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6036	4665 1	P09070 302	Sterile	Gamma
1010046540	Fenestrated 6T Screw Ø6,5 x 40mm	IIb	8.9	4250539940 5ND	0425053990 5994	4665 1	P09070 302	Non Sterile	N/A
1010046540-S	Fenestrated 6T Screw Ø6,5 x 40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6043	4665 1	P09070 302	Sterile	Gamma
1010046545	Fenestrated 6T Screw Ø6,5 x 45mm	IIb	8.9	4250539940 5ND	0425053990 6007	4665 1	P09070 302	Non Sterile	N/A
1010046545-S	Fenestrated 6T Screw Ø6,5 x 45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6050	4665 1	P09070 302	Sterile	Gamma
1010046550	Fenestrated 6T Screw Ø6,5 x 50mm	IIb	8.9	4250539940 5ND	0425053990 6014	4665 1	P09070 302	Non Sterile	N/A
1010046550-S	Fenestrated 6T Screw Ø6,5 x 50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6067	4665 1	P09070 302	Sterile	Gamma
1010046555	Fenestrated 6T Screw Ø6,5 x 55mm	IIb	8.9	4250539940 5ND	0425053990 6021	4665 1	P09070 302	Non Sterile	N/A
1010046555-S	Fenestrated 6T Screw Ø6,5 x 55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6074	4665 1	P09070 302	Sterile	Gamma
1010047240	Fenestrated 6T Screw Ø7,2 x 40mm	IIb	8.9	4250539940 5ND	0425053990 6038	4665 1	P09070 302	Non Sterile	N/A
1010047240-S	Fenestrated 6T Screw Ø7,2 x 40mm sterile	IIb	8.9	4250539940 6NF	0425053992 6081	4665 1	P09070 302	Sterile	Gamma
1010047245	Fenestrated 6T Screw Ø7,2 x 45mm	IIb	8.9	4250539940 5ND	0425053990 6045	4665 1	P09070 302	Non Sterile	N/A

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1010047245-S	Fenestrated 6T Screw Ø7,2 x 45mm sterile	IIb	8.9	4250539940 6NF	0425053992 6098	4665 1	P09070 302	Sterile	Gamma
1010047250	Fenestrated 6T Screw Ø7,2 x 50mm	IIb	8.9	4250539940 5ND	0425053990 6052	4665 1	P09070 302	Non Sterile	N/A
1010047250-S	Fenestrated 6T Screw Ø7,2 x 50mm sterile	IIb	8.9	4250539940 6NF	0425053992 6104	4665 1	P09070 302	Sterile	Gamma
1010047255	Fenestrated 6T Screw Ø7,2 x 55mm	IIb	8.9	4250539940 5ND	0425053990 6069	4665 1	P09070 302	Non Sterile	N/A
1010047255-S	Fenestrated 6T Screw Ø7,2 x 55mm sterile	IIb	8.9	4250539940 6NF	0425053992 6111	4665 1	P09070 302	Sterile	Gamma
1010047260	Fenestrated 6T Screw Ø7,2 x 60mm	IIb	8.9	4250539940 5ND	0425053990 6076	4665 1	P09070 302	Non Sterile	N/A
1010047260-S	Fenestrated 6T Screw Ø7,2 x 60mm sterile	IIb	8.9	4250539940 6NF	0425053992 6128	4665 1	P09070 302	Sterile	Gamma
10061272100	Fenestrated Iliac Screw Ø 7.2mm x 100mm	IIb	8.9	4250539940 5ND	0425053994 3095	4665 1	P09070 302	Non Sterile	N/A
10061272100-S	Fenestrated Iliac Screw Ø 7.2mm x 100mm sterile	IIb	8.9	4250539940 6NF	0425053994 3101	4665 1	P09070 302	Sterile	Gamma
1006127270	Fenestrated Iliac Screw Ø 7.2mm x 70mm	IIb	8.9	4250539940 5ND	0425053994 3118	4665 1	P09070 302	Non Sterile	N/A
1006127270-S	Fenestrated Iliac Screw Ø 7.2mm x 70mm sterile	IIb	8.9	4250539940 6NF	0425053994 3125	4665 1	P09070 302	Sterile	Gamma
1006127280	Fenestrated Iliac Screw Ø 7.2mm x 80mm	IIb	8.9	4250539940 5ND	0425053994 3132	4665 1	P09070 302	Non Sterile	N/A
1006127280-S	Fenestrated Iliac Screw Ø 7.2mm x 80mm sterile	IIb	8.9	4250539940 6NF	0425053994 3149	4665 1	P09070 302	Sterile	Gamma
1006127290	Fenestrated Iliac Screw Ø 7.2mm x 90mm	IIb	8.9	4250539940 5ND	0425053994 3156	4665 1	P09070 302	Non Sterile	N/A
1006127290-S	Fenestrated Iliac Screw Ø 7.2mm x 90mm sterile	IIb	8.9	4250539940 6NF	0425053994 3163	4665 1	P09070 302	Sterile	Gamma
10061285100	Fenestrated Iliac Screw Ø 8.5mm x 100mm	IIb	8.9	4250539940 5ND	0425053994 3170	4665 1	P09070 302	Non Sterile	N/A
10061285100-S	Fenestrated Iliac Screw Ø 8.5mm x 100mm sterile	IIb	8.9	4250539940 6NF	0425053994 3187	4665 1	P09070 302	Sterile	Gamma
1006128570	Fenestrated Iliac Screw Ø 8.5mm x 70mm	IIb	8.9	4250539940 5ND	0425053994 3194	4665 1	P09070 302	Non Sterile	N/A
1006128570-S	Fenestrated Iliac Screw Ø 8.5mm x 70mm sterile	IIb	8.9	4250539940 6NF	0425053994 3200	4665 1	P09070 302	Sterile	Gamma
1006128580	Fenestrated Iliac Screw Ø 8.5mm x 80mm	IIb	8.9	4250539940 5ND	0425053994 3217	4665 1	P09070 302	Non Sterile	N/A
1006128580-S	Fenestrated Iliac Screw Ø 8.5mm x 80mm sterile	IIb	8.9	4250539940 6NF	0425053994 3224	4665 1	P09070 302	Sterile	Gamma
1006128590	Fenestrated Iliac Screw Ø 8.5mm x 90mm	IIb	8.9	4250539940 5ND	0425053994 3231	4665 1	P09070 302	Non Sterile	N/A
1006128590-S	Fenestrated Iliac Screw Ø 8.5mm x 90mm sterile	IIb	8.9	4250539940 6NF	0425053994 3248	4665 1	P09070 302	Sterile	Gamma
1006105540	Fenestrated Screw Ø5,5x40mm	IIb	8.9	4250539940 5ND	0425053990 5581	4665 1	P09070 302	Non Sterile	N/A
1006105545	Fenestrated Screw Ø5,5x45mm	IIb	8.9	4250539940 5ND	0425053990 5598	4665 1	P09070 302	Non Sterile	N/A
1006105550	Fenestrated Screw Ø5,5x50mm	IIb	8.9	4250539940 5ND	0425053990 5604	4665 1	P09070 302	Non Sterile	N/A
1006105555	Fenestrated Screw Ø5,5x55mm	IIb	8.9	4250539940 5ND	0425053990 5611	4665 1	P09070 302	Non Sterile	N/A
1006106540	Fenestrated Screw Ø6,5x40mm	IIb	8.9	4250539940 5ND	0425053990 5628	4665 1	P09070 302	Non Sterile	N/A
1006106545	Fenestrated Screw Ø6,5x45mm	IIb	8.9	4250539940 5ND	0425053990 5635	4665 1	P09070 302	Non Sterile	N/A
1006106550	Fenestrated Screw Ø6,5x50mm	IIb	8.9	4250539940 5ND	0425053990 5642	4665 1	P09070 302	Non Sterile	N/A

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
1006106555	Fenestrated Screw Ø6,5x55mm	IIb	8.9	4250539940 5ND	0425053990 5659	4665 1	P09070 302	Non Sterile	N/A
1006107240	Fenestrated Screw Ø7,2x40mm	IIb	8.9	4250539940 5ND	0425053990 5666	4665 1	P09070 302	Non Sterile	N/A
1006107245	Fenestrated Screw Ø7,2x45mm	IIb	8.9	4250539940 5ND	0425053990 5673	4665 1	P09070 302	Non Sterile	N/A
1006107250	Fenestrated Screw Ø7,2x50mm	IIb	8.9	4250539940 5ND	0425053990 5680	4665 1	P09070 302	Non Sterile	N/A
1006107255	Fenestrated Screw Ø7,2x55mm	IIb	8.9	4250539940 5ND	0425053990 5697	4665 1	P09070 302	Non Sterile	N/A
1001060505	Inline Rod Connector 5/5 cpl V2	IIb	8.9	4250539905 0MW	0425053990 0517	6511 4	P09070 304	Non Sterile	N/A
1001060505-S	Inline Rod Connector 5/5 cpl V2 sterile	IIb	8.9	4250539905 1MY	0425053992 4773	6511 4	P09070 304	Sterile	Gamma
1004070000	Lateral Connector	IIb	8.9	4250539905 0MW	0425053990 1064	6511 4	P09070 304	Non Sterile	N/A
1004070100	Lateral Connector L	IIb	8.9	4250539905 0MW	0425053991 7737	6511 4	P09070 304	Non Sterile	N/A
1004070100-S	Lateral Connector L sterile	IIb	8.9	4250539905 1MY	0425053992 5008	6511 4	P09070 304	Sterile	Gamma
1004070000-S	Lateral Connector sterile	IIb	8.9	4250539905 1MY	0425053992 4995	6511 4	P09070 304	Sterile	Gamma
VL-PMS-M3	MIS Setscrew	IIb	8.9	4250539906 8NH	0425053991 0400	6555 3	P09070 302	Non Sterile	N/A
VL-PMS-M3-S	MIS Setscrew sterile	IIb	8.9	4250539905 5N8	0425053992 7422	6555 3	P09070 302	Sterile	Gamma
VL-MS-5-4830	Monoaxial Screw Ø4.8 mm x 30 mm	IIb	8.9	4250539940 5ND	0425053991 0349	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-4835	Monoaxial Screw Ø4.8 mm x 35 mm	IIb	8.9	4250539940 5ND	0425053991 0356	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-4840	Monoaxial Screw Ø4.8 mm x 40 mm	IIb	8.9	4250539940 5ND	0425053991 0363	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-4845	Monoaxial Screw Ø4.8 mm x 45 mm	IIb	8.9	4250539940 5ND	0425053991 0370	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-5525	Monoaxial Screw Ø5.5 mm x 25 mm	IIb	8.9	4250539940 5ND	0425053990 0012	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-5530	Monoaxial Screw Ø5.5 mm x 30 mm	IIb	8.9	4250539940 5ND	0425053990 0029	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-5535	Monoaxial Screw Ø5.5 mm x 35 mm	IIb	8.9	4250539940 5ND	0425053990 0036	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-5540	Monoaxial Screw Ø5.5 mm x 40 mm	IIb	8.9	4250539940 5ND	0425053990 0043	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-5545	Monoaxial Screw Ø5.5 mm x 45 mm	IIb	8.9	4250539940 5ND	0425053990 0050	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-5550	Monoaxial Screw Ø5.5 mm x 50 mm	IIb	8.9	4250539940 5ND	0425053990 0067	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-5555	Monoaxial Screw Ø5.5 mm x 55 mm	IIb	8.9	4250539940 5ND	0425053990 0074	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-6535	Monoaxial Screw Ø6.5 mm x 35 mm	IIb	8.9	4250539940 5ND	0425053990 0081	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-6540	Monoaxial Screw Ø6.5 mm x 40 mm	IIb	8.9	4250539940 5ND	0425053990 0098	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-6545	Monoaxial Screw Ø6.5 mm x 45 mm	IIb	8.9	4250539940 5ND	0425053990 0104	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-6550	Monoaxial Screw Ø6.5 mm x 50 mm	IIb	8.9	4250539940 5ND	0425053990 0111	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-6555	Monoaxial Screw Ø6.5 mm x 55 mm	IIb	8.9	4250539940 5ND	0425053990 0128	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-7240	Monoaxial Screw Ø7.2 mm x 40 mm	IIb	8.9	4250539940 5ND	0425053990 0135	4665 1	P09070 302	Non Sterile	N/A

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VL-MS-5-7245	Monoaxial Screw Ø7.2 mm x 45 mm	IIb	8.9	4250539940 5ND	0425053990 0142	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-7250	Monoaxial Screw Ø7.2 mm x 50 mm	IIb	8.9	4250539940 5ND	0425053990 0159	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-7255	Monoaxial Screw Ø7.2 mm x 55 mm	IIb	8.9	4250539940 5ND	0425053990 0166	4665 1	P09070 302	Non Sterile	N/A
VL-MS-5-7260	Monoaxial Screw Ø7.2 mm x 60 mm	IIb	8.9	4250539940 5ND	0425053990 0173	4665 1	P09070 302	Non Sterile	N/A
1006063000	Parallel Connector	IIb	8.9	4250539905 0MW	0425053991 3623	6511 4	P09070 304	Non Sterile	N/A
1006063000-S	Parallel Connector sterile	IIb	8.9	4250539905 1MY	0425053992 5565	6511 4	P09070 304	Sterile	Gamma
10061172100	Polyaxial Iliac Screw Ø 7.2mm x 100mm	IIb	8.9	4250539940 5ND	0425053991 4385	4665 1	P09070 302	Non Sterile	N/A
10061172100-S	Polyaxial Iliac Screw Ø 7.2mm x 100mm sterile	IIb	8.9	4250539940 6NF	0425053992 7095	4665 1	P09070 302	Sterile	Gamma
1006117270	Polyaxial Iliac Screw Ø 7.2mm x 70mm	IIb	8.9	4250539940 5ND	0425053991 4354	4665 1	P09070 302	Non Sterile	N/A
1006117270-S	Polyaxial Iliac Screw Ø 7.2mm x 70mm sterile	IIb	8.9	4250539940 6NF	0425053992 5695	4665 1	P09070 302	Sterile	Gamma
1006117280	Polyaxial Iliac Screw Ø 7.2mm x 80mm	IIb	8.9	4250539940 5ND	0425053991 4361	4665 1	P09070 302	Non Sterile	N/A
1006117280-S	Polyaxial Iliac Screw Ø 7.2mm x 80mm sterile	IIb	8.9	4250539940 6NF	0425053992 5701	4665 1	P09070 302	Sterile	Gamma
1006117290	Polyaxial Iliac Screw Ø 7.2mm x 90mm	IIb	8.9	4250539940 5ND	0425053991 4378	4665 1	P09070 302	Non Sterile	N/A
1006117290-S	Polyaxial Iliac Screw Ø 7.2mm x 90mm sterile	IIb	8.9	4250539940 6NF	0425053992 5718	4665 1	P09070 302	Sterile	Gamma
10061185100	Polyaxial Iliac Screw Ø 8.5mm x 100mm	IIb	8.9	4250539940 5ND	0425053991 4422	4665 1	P09070 302	Non Sterile	N/A
10061185100-S	Polyaxial Iliac Screw Ø 8.5mm x 100mm sterile	IIb	8.9	4250539940 6NF	0425053992 7101	4665 1	P09070 302	Sterile	Gamma
10061185120	Polyaxial Iliac Screw Ø 8.5mm x 120mm	IIb	8.9	4250539940 5ND	0425053991 4439	4665 1	P09070 302	Non Sterile	N/A
10061185120-S	Polyaxial Iliac Screw Ø 8.5mm x 120mm sterile	IIb	8.9	4250539940 6NF	0425053992 7118	4665 1	P09070 302	Sterile	Gamma
1006118570	Polyaxial Iliac Screw Ø 8.5mm x 70mm	IIb	8.9	4250539940 5ND	0425053991 4392	4665 1	P09070 302	Non Sterile	N/A
1006118570-S	Polyaxial Iliac Screw Ø 8.5mm x 70mm sterile	IIb	8.9	4250539940 6NF	0425053992 5725	4665 1	P09070 302	Sterile	Gamma
1006118580	Polyaxial Iliac Screw Ø 8.5mm x 80mm	IIb	8.9	4250539940 5ND	0425053991 4408	4665 1	P09070 302	Non Sterile	N/A
1006118580-S	Polyaxial Iliac Screw Ø 8.5mm x 80mm sterile	IIb	8.9	4250539940 6NF	0425053992 5732	4665 1	P09070 302	Sterile	Gamma
1006118590	Polyaxial Iliac Screw Ø 8.5mm x 90mm	IIb	8.9	4250539940 5ND	0425053991 4415	4665 1	P09070 302	Non Sterile	N/A
1006118590-S	Polyaxial Iliac Screw Ø 8.5mm x 90mm sterile	IIb	8.9	4250539940 6NF	0425053992 5749	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-4825	Polyaxial Screw 6T 4,8x25mm	IIb	8.9	4250539940 5ND	0425053991 0417	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-4825-S	Polyaxial Screw 6T 4,8x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 7439	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-4830	Polyaxial Screw 6T 4,8x30mm	IIb	8.9	4250539940 5ND	0425053991 0424	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-4830-S	Polyaxial Screw 6T 4,8x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 7446	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-4835	Polyaxial Screw 6T 4,8x35mm	IIb	8.9	4250539940 5ND	0425053991 0431	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-4835-S	Polyaxial Screw 6T 4,8x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 7453	4665 1	P09070 302	Sterile	Gamma

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
VL-PS2-5-4840	Polyaxial Screw 6T 4,8x40mm	Iib	8.9	4250539940 5ND	0425053991 0448	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-4840-S	Polyaxial Screw 6T 4,8x40mm sterile	Iib	8.9	4250539940 6NF	0425053992 7460	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-5525	Polyaxial Screw 6T 5,5x25mm	Iib	8.9	4250539940 5ND	0425053991 0455	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-5525-S	Polyaxial Screw 6T 5,5x25mm sterile	Iib	8.9	4250539940 6NF	0425053992 7477	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-5530	Polyaxial Screw 6T 5,5x30mm	Iib	8.9	4250539940 5ND	0425053991 0462	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-5530-S	Polyaxial Screw 6T 5,5x30mm sterile	Iib	8.9	4250539940 6NF	0425053992 7484	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-5535	Polyaxial Screw 6T 5,5x35mm	Iib	8.9	4250539940 5ND	0425053991 0479	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-5535-S	Polyaxial Screw 6T 5,5x35mm sterile	Iib	8.9	4250539940 6NF	0425053992 7491	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-5540	Polyaxial Screw 6T 5,5x40mm	Iib	8.9	4250539940 5ND	0425053991 0486	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-5540-S	Polyaxial Screw 6T 5,5x40mm sterile	Iib	8.9	4250539940 6NF	0425053992 7507	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-5545	Polyaxial Screw 6T 5,5x45mm	Iib	8.9	4250539940 5ND	0425053991 0493	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-5545-S	Polyaxial Screw 6T 5,5x45mm sterile	Iib	8.9	4250539940 6NF	0425053992 7514	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-5550	Polyaxial Screw 6T 5,5x50mm	Iib	8.9	4250539940 5ND	0425053991 0509	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-5550-S	Polyaxial Screw 6T 5,5x50mm sterile	Iib	8.9	4250539940 6NF	0425053992 7521	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-5555	Polyaxial Screw 6T 5,5x55mm	Iib	8.9	4250539940 5ND	0425053991 0516	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-5555-S	Polyaxial Screw 6T 5,5x55mm sterile	Iib	8.9	4250539940 6NF	0425053992 7538	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-6525	Polyaxial Screw 6T 6,5x25mm	Iib	8.9	4250539940 5ND	0425053991 0523	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-6525-S	Polyaxial Screw 6T 6,5x25mm sterile	Iib	8.9	4250539940 6NF	0425053992 7545	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-6530	Polyaxial Screw 6T 6,5x30mm	Iib	8.9	4250539940 5ND	0425053991 0530	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-6530-S	Polyaxial Screw 6T 6,5x30mm sterile	Iib	8.9	4250539940 6NF	0425053992 7552	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-6535	Polyaxial Screw 6T 6,5x35mm	Iib	8.9	4250539940 5ND	0425053991 0547	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-6535-S	Polyaxial Screw 6T 6,5x35mm sterile	Iib	8.9	4250539940 6NF	0425053992 7569	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-6540	Polyaxial Screw 6T 6,5x40mm	Iib	8.9	4250539940 5ND	0425053991 0554	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-6540-S	Polyaxial Screw 6T 6,5x40mm sterile	Iib	8.9	4250539940 6NF	0425053992 7576	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-6545	Polyaxial Screw 6T 6,5x45mm	Iib	8.9	4250539940 5ND	0425053991 0561	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-6545-S	Polyaxial Screw 6T 6,5x45mm sterile	Iib	8.9	4250539940 6NF	0425053992 7583	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-6550	Polyaxial Screw 6T 6,5x50mm	Iib	8.9	4250539940 5ND	0425053991 0578	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-6550-S	Polyaxial Screw 6T 6,5x50mm sterile	Iib	8.9	4250539940 6NF	0425053992 7590	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-6555	Polyaxial Screw 6T 6,5x55mm	Iib	8.9	4250539940 5ND	0425053991 0585	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-6555-S	Polyaxial Screw 6T 6,5x55mm sterile	Iib	8.9	4250539940 6NF	0425053992 7606	4665 1	P09070 302	Sterile	Gamma

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VL-PS2-5-7240	Polyaxial Screw 6T 7,2x40mm	IIb	8.9	4250539940 5ND	0425053991 0592	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-7240-S	Polyaxial Screw 6T 7,2x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 7613	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-7245	Polyaxial Screw 6T 7,2x45mm	IIb	8.9	4250539940 5ND	0425053991 0608	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-7245-S	Polyaxial Screw 6T 7,2x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 7620	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-7250	Polyaxial Screw 6T 7,2x50mm	IIb	8.9	4250539940 5ND	0425053991 0615	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-7250-S	Polyaxial Screw 6T 7,2x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 7637	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-7255	Polyaxial Screw 6T 7,2x55mm	IIb	8.9	4250539940 5ND	0425053991 0622	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-7255-S	Polyaxial Screw 6T 7,2x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 7644	4665 1	P09070 302	Sterile	Gamma
VL-PS2-5-7260	Polyaxial Screw 6T 7,2x60mm	IIb	8.9	4250539940 5ND	0425053991 0639	4665 1	P09070 302	Non Sterile	N/A
VL-PS2-5-7260-S	Polyaxial Screw 6T 7,2x60mm sterile	IIb	8.9	4250539940 6NF	0425053992 7651	4665 1	P09070 302	Sterile	Gamma
VL-PS-5-4825	Polyaxial Screw Ø4.8 mm x 25 mm	IIb	8.9	4250539940 5ND	0425053990 0180	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-4830	Polyaxial Screw Ø4.8 mm x 30 mm	IIb	8.9	4250539940 5ND	0425053990 0197	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-4835	Polyaxial Screw Ø4.8 mm x 35 mm	IIb	8.9	4250539940 5ND	0425053990 0203	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-4840	Polyaxial Screw Ø4.8 mm x 40 mm	IIb	8.9	4250539940 5ND	0425053990 0210	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-4845	Polyaxial Screw Ø4.8 mm x 45 mm	IIb	8.9	4250539940 5ND	0425053991 0646	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-5525	Polyaxial Screw Ø5.5 mm x 25 mm	IIb	8.9	4250539940 5ND	0425053990 0227	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-5530	Polyaxial Screw Ø5.5 mm x 30 mm	IIb	8.9	4250539940 5ND	0425053990 0234	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-5535	Polyaxial Screw Ø5.5 mm x 35 mm	IIb	8.9	4250539940 5ND	0425053990 0241	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-5540	Polyaxial Screw Ø5.5 mm x 40 mm	IIb	8.9	4250539940 5ND	0425053990 0258	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-5545	Polyaxial Screw Ø5.5 mm x 45 mm	IIb	8.9	4250539940 5ND	0425053990 0265	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-5550	Polyaxial Screw Ø5.5 mm x 50 mm	IIb	8.9	4250539940 5ND	0425053990 0272	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-5555	Polyaxial Screw Ø5.5 mm x 55 mm	IIb	8.9	4250539940 5ND	0425053990 0289	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-6525	Polyaxial Screw Ø6.5 mm x 25 mm	IIb	8.9	4250539940 5ND	0425053990 0296	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-6530	Polyaxial Screw Ø6.5 mm x 30 mm	IIb	8.9	4250539940 5ND	0425053990 0302	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-6535	Polyaxial Screw Ø6.5 mm x 35 mm	IIb	8.9	4250539940 5ND	0425053990 0319	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-6540	Polyaxial Screw Ø6.5 mm x 40 mm	IIb	8.9	4250539940 5ND	0425053990 0326	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-6545	Polyaxial Screw Ø6.5 mm x 45 mm	IIb	8.9	4250539940 5ND	0425053990 0333	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-6550	Polyaxial Screw Ø6.5 mm x 50 mm	IIb	8.9	4250539940 5ND	0425053990 0340	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-6555	Polyaxial Screw Ø6.5 mm x 55 mm	IIb	8.9	4250539940 5ND	0425053990 0357	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-7235	Polyaxial Screw Ø7.2 mm x 35 mm	IIb	8.9	4250539940 5ND	0425053991 0653	4665 1	P09070 302	Non Sterile	N/A

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
VL-PS-5-7240	Polyaxial Screw Ø7.2 mm x 40 mm	IIb	8.9	4250539940 5ND	0425053990 0364	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-7245	Polyaxial Screw Ø7.2 mm x 45 mm	IIb	8.9	4250539940 5ND	0425053990 0371	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-7250	Polyaxial Screw Ø7.2 mm x 50 mm	IIb	8.9	4250539940 5ND	0425053990 0388	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-7255	Polyaxial Screw Ø7.2 mm x 55 mm	IIb	8.9	4250539940 5ND	0425053990 0395	4665 1	P09070 302	Non Sterile	N/A
VL-PS-5-7260	Polyaxial Screw Ø7.2mm x 60 mm	IIb	8.9	4250539940 5ND	0425053990 0401	4665 1	P09070 302	Non Sterile	N/A
VL-PMS	Polyaxial/Monoaxial Setscrew	IIb	8.9	4250539906 8NH	0425053990 0005	6555 3	P09070 302	Non Sterile	N/A
1006062001	RC Break-Off Setscrew	IIb	8.9	4250539906 8NH	0425053991 6013	6555 3	P09070 302	Non Sterile	N/A
1006062001-S	RC Break-Off Setscrew sterile	IIb	8.9	4250539905 5N8	0425053992 5558	6555 3	P09070 302	Sterile	Gamma
1006061000	RC Hex-Nut	IIb	8.9	4250539906 8NH	0425053990 4003	6555 3	P09070 304	Non Sterile	N/A
1006061000-S	RC Hex-Nut sterile	IIb	8.9	4250539905 5N8	0425053992 5534	6555 3	P09070 304	Sterile	Gamma
1005104825	Reduction Screw 6T 4,8x25mm	IIb	8.9	4250539940 5ND	0425053991 3838	4665 1	P09070 302	Non Sterile	N/A
1005104825-S	Reduction Screw 6T 4,8x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 5220	4665 1	P09070 302	Sterile	Gamma
1005104830	Reduction Screw 6T 4,8x30mm	IIb	8.9	4250539940 5ND	0425053991 3845	4665 1	P09070 302	Non Sterile	N/A
1005104830-S	Reduction Screw 6T 4,8x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 5237	4665 1	P09070 302	Sterile	Gamma
1005104835	Reduction Screw 6T 4,8x35mm	IIb	8.9	4250539940 5ND	0425053991 3852	4665 1	P09070 302	Non Sterile	N/A
1005104835-S	Reduction Screw 6T 4,8x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 5244	4665 1	P09070 302	Sterile	Gamma
1005104840	Reduction Screw 6T 4,8x40mm	IIb	8.9	4250539940 5ND	0425053991 3869	4665 1	P09070 302	Non Sterile	N/A
1005104840-S	Reduction Screw 6T 4,8x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 5251	4665 1	P09070 302	Sterile	Gamma
1005105525	Reduction Screw 6T 5,5x25mm	IIb	8.9	4250539940 5ND	0425053991 3876	4665 1	P09070 302	Non Sterile	N/A
1005105525-S	Reduction Screw 6T 5,5x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 5268	4665 1	P09070 302	Sterile	Gamma
1005105530	Reduction Screw 6T 5,5x30mm	IIb	8.9	4250539940 5ND	0425053991 3883	4665 1	P09070 302	Non Sterile	N/A
1005105530-S	Reduction Screw 6T 5,5x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 5275	4665 1	P09070 302	Sterile	Gamma
1005105535	Reduction Screw 6T 5,5x35mm	IIb	8.9	4250539940 5ND	0425053991 3890	4665 1	P09070 302	Non Sterile	N/A
1005105535-S	Reduction Screw 6T 5,5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 5282	4665 1	P09070 302	Sterile	Gamma
1005105540	Reduction Screw 6T 5,5x40mm	IIb	8.9	4250539940 5ND	0425053991 3906	4665 1	P09070 302	Non Sterile	N/A
1005105540-S	Reduction Screw 6T 5,5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 5299	4665 1	P09070 302	Sterile	Gamma
1005105545	Reduction Screw 6T 5,5x45mm	IIb	8.9	4250539940 5ND	0425053991 3913	4665 1	P09070 302	Non Sterile	N/A
1005105545-S	Reduction Screw 6T 5,5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 5305	4665 1	P09070 302	Sterile	Gamma
1005105550	Reduction Screw 6T 5,5x50mm	IIb	8.9	4250539940 5ND	0425053991 3920	4665 1	P09070 302	Non Sterile	N/A
1005105550-S	Reduction Screw 6T 5,5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 5312	4665 1	P09070 302	Sterile	Gamma

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Artikel-Nr.	Description	Class	Rule	Basic-UDI-DI	UDI-DI	GM DN	EMDN	Sterility	Sterilization Type
1005105555	Reduction Screw 6T 5,5x55mm	IIb	8.9	4250539940 5ND	0425053991 3937	4665 1	P09070 302	Non Sterile	N/A
1005105555-S	Reduction Screw 6T 5,5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 5329	4665 1	P09070 302	Sterile	Gamma
1005106525	Reduction Screw 6T 6,5x25mm	IIb	8.9	4250539940 5ND	0425053991 3944	4665 1	P09070 302	Non Sterile	N/A
1005106525-S	Reduction Screw 6T 6,5x25mm sterile	IIb	8.9	4250539940 6NF	0425053992 5336	4665 1	P09070 302	Sterile	Gamma
1005106530	Reduction Screw 6T 6,5x30mm	IIb	8.9	4250539940 5ND	0425053991 3951	4665 1	P09070 302	Non Sterile	N/A
1005106530-S	Reduction Screw 6T 6,5x30mm sterile	IIb	8.9	4250539940 6NF	0425053992 5343	4665 1	P09070 302	Sterile	Gamma
1005106535	Reduction Screw 6T 6,5x35mm	IIb	8.9	4250539940 5ND	0425053991 3968	4665 1	P09070 302	Non Sterile	N/A
1005106535-S	Reduction Screw 6T 6,5x35mm sterile	IIb	8.9	4250539940 6NF	0425053992 5350	4665 1	P09070 302	Sterile	Gamma
1005106540	Reduction Screw 6T 6,5x40mm	IIb	8.9	4250539940 5ND	0425053991 3975	4665 1	P09070 302	Non Sterile	N/A
1005106540-S	Reduction Screw 6T 6,5x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 5367	4665 1	P09070 302	Sterile	Gamma
1005106545	Reduction Screw 6T 6,5x45mm	IIb	8.9	4250539940 5ND	0425053991 3982	4665 1	P09070 302	Non Sterile	N/A
1005106545-S	Reduction Screw 6T 6,5x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 5374	4665 1	P09070 302	Sterile	Gamma
1005106550	Reduction Screw 6T 6,5x50mm	IIb	8.9	4250539940 5ND	0425053991 3999	4665 1	P09070 302	Non Sterile	N/A
1005106550-S	Reduction Screw 6T 6,5x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 5381	4665 1	P09070 302	Sterile	Gamma
1005106555	Reduction Screw 6T 6,5x55mm	IIb	8.9	4250539940 5ND	0425053991 4002	4665 1	P09070 302	Non Sterile	N/A
1005106555-S	Reduction Screw 6T 6,5x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 5398	4665 1	P09070 302	Sterile	Gamma
1005107240	Reduction Screw 6T 7,2x40mm	IIb	8.9	4250539940 5ND	0425053991 4019	4665 1	P09070 302	Non Sterile	N/A
1005107240-S	Reduction Screw 6T 7,2x40mm sterile	IIb	8.9	4250539940 6NF	0425053992 5404	4665 1	P09070 302	Sterile	Gamma
1005107245	Reduction Screw 6T 7,2x45mm	IIb	8.9	4250539940 5ND	0425053991 4026	4665 1	P09070 302	Non Sterile	N/A
1005107245-S	Reduction Screw 6T 7,2x45mm sterile	IIb	8.9	4250539940 6NF	0425053992 5411	4665 1	P09070 302	Sterile	Gamma
1005107250	Reduction Screw 6T 7,2x50mm	IIb	8.9	4250539940 5ND	0425053991 4033	4665 1	P09070 302	Non Sterile	N/A
1005107250-S	Reduction Screw 6T 7,2x50mm sterile	IIb	8.9	4250539940 6NF	0425053992 5428	4665 1	P09070 302	Sterile	Gamma
1005107255	Reduction Screw 6T 7,2x55mm	IIb	8.9	4250539940 5ND	0425053991 4040	4665 1	P09070 302	Non Sterile	N/A
1005107255-S	Reduction Screw 6T 7,2x55mm sterile	IIb	8.9	4250539940 6NF	0425053992 5435	4665 1	P09070 302	Sterile	Gamma
1005107260	Reduction Screw 6T 7,2x60mm	IIb	8.9	4250539940 5ND	0425053991 4057	4665 1	P09070 302	Non Sterile	N/A
1005107260-S	Reduction Screw 6T 7,2x60mm sterile	IIb	8.9	4250539940 6NF	0425053992 5442	4665 1	P09070 302	Sterile	Gamma
1006060000	Revisionconnector Cap	IIb	8.9	4250539906 8NH	0425053990 3990	6511 4	P09070 304	Non Sterile	N/A
1006060000-S	Revisionconnector Cap sterile	IIb	8.9	4250539905 5N8	0425053992 5527	6511 4	P09070 304	Sterile	Gamma
VL-RMC2-5-100	Rod Mini Curved2 Ø 5.5 mm x 100 mm	IIb	8.9	4250539907 0N4	0425053991 2800	6511 6	P09070 302	Non Sterile	N/A
VL-RMC2-5-100-S	Rod Mini Curved2 Ø 5.5 mm x 100 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8252	6511 6	P09070 302	Sterile	Gamma

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VL-RMC2-5-110	Rod Mini Curved2 Ø 5.5 mm x 110 mm	IIb	8.9	4250539907 0N4	0425053991 2817	6511 6	P09070 302	Non Sterile	N/A
VL-RMC2-5-110-S	Rod Mini Curved2 Ø 5.5 mm x 110 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8269	6511 6	P09070 302	Sterile	Gamma
VL-RMC2-5-40	Rod Mini Curved2 Ø 5.5 mm x 40 mm	IIb	8.9	4250539907 0N4	0425053991 2749	6511 6	P09070 302	Non Sterile	N/A
VL-RMC2-5-40-S	Rod Mini Curved2 Ø 5.5 mm x 40 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8276	6511 6	P09070 302	Sterile	Gamma
VL-RMC2-5-45	Rod Mini Curved2 Ø 5.5 mm x 45 mm	IIb	8.9	4250539907 0N4	0425053991 6037	6511 6	P09070 302	Non Sterile	N/A
VL-RMC2-5-45-S	Rod Mini Curved2 Ø 5.5 mm x 45 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8283	6511 6	P09070 302	Sterile	Gamma
VL-RMC2-5-50	Rod Mini Curved2 Ø 5.5 mm x 50 mm	IIb	8.9	4250539907 0N4	0425053991 2756	6511 6	P09070 302	Non Sterile	N/A
VL-RMC2-5-50-S	Rod Mini Curved2 Ø 5.5 mm x 50 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8290	6511 6	P09070 302	Sterile	Gamma
VL-RMC2-5-60	Rod Mini Curved2 Ø 5.5 mm x 60 mm	IIb	8.9	4250539907 0N4	0425053991 2763	6511 6	P09070 302	Non Sterile	N/A
VL-RMC2-5-60-S	Rod Mini Curved2 Ø 5.5 mm x 60 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8306	6511 6	P09070 302	Sterile	Gamma
VL-RMC2-5-70	Rod Mini Curved2 Ø 5.5 mm x 70 mm	IIb	8.9	4250539907 0N4	0425053991 2770	6511 6	P09070 302	Non Sterile	N/A
VL-RMC2-5-70-S	Rod Mini Curved2 Ø 5.5 mm x 70 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8313	6511 6	P09070 302	Sterile	Gamma
VL-RMC2-5-80	Rod Mini Curved2 Ø 5.5 mm x 80 mm	IIb	8.9	4250539907 0N4	0425053991 2787	6511 6	P09070 302	Non Sterile	N/A
VL-RMC2-5-80-S	Rod Mini Curved2 Ø 5.5 mm x 80 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8320	6511 6	P09070 302	Sterile	Gamma
VL-RMC2-5-90	Rod Mini Curved2 Ø 5.5 mm x 90 mm	IIb	8.9	4250539907 0N4	0425053991 2794	6511 6	P09070 302	Non Sterile	N/A
VL-RMC2-5-90-S	Rod Mini Curved2 Ø 5.5 mm x 90 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8337	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-100	Rod Mini2 Ø 5,5mmx100 mm	IIb	8.9	4250539907 0N4	0425053991 2695	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-100-S	Rod Mini2 Ø 5,5mmx100 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8078	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-110	Rod Mini2 Ø 5,5mmx110 mm	IIb	8.9	4250539907 0N4	0425053991 2701	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-110-S	Rod Mini2 Ø 5,5mmx110 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8085	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-130	Rod Mini2 Ø 5,5mmx130 mm	IIb	8.9	4250539907 0N4	0425053991 2718	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-130-S	Rod Mini2 Ø 5,5mmx130 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8092	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-150	Rod Mini2 Ø 5,5mmx150 mm	IIb	8.9	4250539907 0N4	0425053991 2725	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-150-S	Rod Mini2 Ø 5,5mmx150 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8108	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-170	Rod Mini2 Ø 5,5mmx170 mm	IIb	8.9	4250539907 0N4	0425053991 2732	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-170-S	Rod Mini2 Ø 5,5mmx170 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8115	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-190	Rod Mini2 Ø 5,5mmx190 mm	IIb	8.9	4250539907 0N4	0425053991 2923	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-190-S	Rod Mini2 Ø 5,5mmx190 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8122	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-40	Rod Mini2 Ø 5,5mmx40 mm	IIb	8.9	4250539907 0N4	0425053990 9688	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-40-S	Rod Mini2 Ø 5,5mmx40 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8184	6511 6	P09070 302	Sterile	Gamma

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VL-RM2-5-45	Rod Mini2 Ø 5,5mmx45 mm	IIb	8.9	4250539907 0N4	0425053991 6020	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-45-S	Rod Mini2 Ø 5,5mmx45 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8191	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-50	Rod Mini2 Ø 5,5mmx50 mm	IIb	8.9	4250539907 0N4	0425053991 2640	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-50-S	Rod Mini2 Ø 5,5mmx50 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8207	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-60	Rod Mini2 Ø 5,5mmx60 mm	IIb	8.9	4250539907 0N4	0425053991 2657	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-60-S	Rod Mini2 Ø 5,5mmx60 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8214	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-70	Rod Mini2 Ø 5,5mmx70 mm	IIb	8.9	4250539907 0N4	0425053991 2664	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-70-S	Rod Mini2 Ø 5,5mmx70 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8221	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-80	Rod Mini2 Ø 5,5mmx80 mm	IIb	8.9	4250539907 0N4	0425053991 2671	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-80-S	Rod Mini2 Ø 5,5mmx80 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8238	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-90	Rod Mini2 Ø 5,5mmx90 mm	IIb	8.9	4250539907 0N4	0425053991 2688	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-90-S	Rod Mini2 Ø 5,5mmx90 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8245	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-210	Rod Mini2 Ø 5.5 mm x 210 mm	IIb	8.9	4250539907 0N4	0425053991 2930	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-210-S	Rod Mini2 Ø 5.5 mm x 210 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8139	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-230	Rod Mini2 Ø 5.5 mm x 230 mm	IIb	8.9	4250539907 0N4	0425053991 2947	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-230-S	Rod Mini2 Ø 5.5 mm x 230 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8146	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-250	Rod Mini2 Ø 5.5 mm x 250 mm	IIb	8.9	4250539907 0N4	0425053991 2954	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-250-S	Rod Mini2 Ø 5.5 mm x 250 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8153	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-270	Rod Mini2 Ø 5.5 mm x 270 mm	IIb	8.9	4250539907 0N4	0425053991 2961	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-270-S	Rod Mini2 Ø 5.5 mm x 270 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8160	6511 6	P09070 302	Sterile	Gamma
VL-RM2-5-300	Rod Mini2 Ø 5.5 mm x 300 mm	IIb	8.9	4250539907 0N4	0425053991 2978	6511 6	P09070 302	Non Sterile	N/A
VL-RM2-5-300-S	Rod Mini2 Ø 5.5 mm x 300 mm sterile	IIb	8.9	4250539907 1N6	0425053992 8177	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-11	Rod Ø 5.5 mm / 110 mm curved	IIb	8.9	4250539907 0N4	0425053991 3630	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-11-S	Rod Ø 5.5 mm / 110 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 7927	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-12	Rod Ø 5.5 mm / 120 mm curved	IIb	8.9	4250539907 0N4	0425053991 3647	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-12-S	Rod Ø 5.5 mm / 120 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 7934	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-13	Rod Ø 5.5 mm / 130 mm curved	IIb	8.9	4250539907 0N4	0425053991 3654	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-13-S	Rod Ø 5.5 mm / 130 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 7941	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-14	Rod Ø 5.5 mm / 140mm curved	IIb	8.9	4250539907 0N4	0425053991 3661	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-14-S	Rod Ø 5.5 mm / 140 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 7958	6511 6	P09070 302	Sterile	Gamma

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VL-RC-5-10	Rod Ø5,5 mm / 100 mm curved	IIb	8.9	4250539907 0N4	0425053990 0715	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-10-S	Rod Ø5,5 mm / 100 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 7910	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-15	Rod Ø5,5 mm / 150 mm curved	IIb	8.9	4250539907 0N4	0425053990 0722	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-15-S	Rod Ø5,5 mm / 150 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 7965	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-20	Rod Ø5,5 mm / 200 mm curved	IIb	8.9	4250539907 0N4	0425053990 0739	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-20-S	Rod Ø5,5 mm / 200 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 7972	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-25	Rod Ø5,5 mm / 250 mm curved	IIb	8.9	4250539907 0N4	0425053990 0746	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-25-S	Rod Ø5,5 mm / 250 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 7989	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-4	Rod Ø5,5 mm / 40 mm curved	IIb	8.9	4250539907 0N4	0425053990 2351	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-4-S	Rod Ø5,5 mm / 40 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 7996	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-4	Rod Ø5,5 mm / 40 mm straight	IIb	8.9	4250539907 0N4	0425053991 3708	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-4-S	Rod Ø5,5 mm / 40 mm straight sterile	IIb	8.9	4250539907 1N6	0425053992 8443	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-4,5	Rod Ø5,5 mm / 45 mm curved	IIb	8.9	4250539907 0N4	0425053991 0660	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-4,5-S	Rod Ø5,5 mm / 45 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 8009	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-5	Rod Ø5,5 mm / 50 mm curved	IIb	8.9	4250539907 0N4	0425053990 0708	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-5-S	Rod Ø5,5 mm / 50 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 8016	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-6	Rod Ø5,5 mm / 60 mm curved	IIb	8.9	4250539907 0N4	0425053990 2368	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-6-S	Rod Ø5,5 mm / 60 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 8023	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-6	Rod Ø5,5 mm / 60 mm straight	IIb	8.9	4250539907 0N4	0425053991 4064	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-6-S	Rod Ø5,5 mm / 60 mm straight sterile	IIb	8.9	4250539907 1N6	0425053992 8504	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-7	Rod Ø5,5 mm / 70 mm curved	IIb	8.9	4250539907 0N4	0425053990 2375	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-7-S	Rod Ø5,5 mm / 70 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 8030	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-8	Rod Ø5,5 mm / 80 mm curved	IIb	8.9	4250539907 0N4	0425053990 2382	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-8-S	Rod Ø5,5 mm / 80 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 8047	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-8	Rod Ø5,5 mm / 80 mm straight	IIb	8.9	4250539907 0N4	0425053991 4071	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-8-S	Rod Ø5,5 mm / 80 mm straight sterile	IIb	8.9	4250539907 1N6	0425053992 8542	6511 6	P09070 302	Sterile	Gamma
VL-RC-5-9	Rod Ø5,5 mm / 90 mm curved	IIb	8.9	4250539907 0N4	0425053990 2399	6511 6	P09070 302	Non Sterile	N/A
VL-RC-5-9-S	Rod Ø5,5 mm / 90 mm curved sterile	IIb	8.9	4250539907 1N6	0425053992 8054	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-10	Rod Ø5.5 mm / 100 mm, straight	IIb	8.9	4250539907 0N4	0425053990 0586	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-10-S	Rod Ø5.5 mm / 100 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8344	6511 6	P09070 302	Sterile	Gamma

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VL-RS-5-11	Rod Ø5.5 mm / 110 mm, straight	IIb	8.9	4250539907 0N4	0425053990 2429	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-11-S	Rod Ø5.5 mm / 110 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8351	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-13	Rod Ø5.5 mm / 130 mm, straight	IIb	8.9	4250539907 0N4	0425053990 2436	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-13-S	Rod Ø5.5 mm / 130 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8368	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-15	Rod Ø5.5 mm / 150 mm, straight	IIb	8.9	4250539907 0N4	0425053990 0593	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-15-S	Rod Ø5.5 mm / 150 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8375	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-20	Rod Ø5.5 mm / 200 mm, straight	IIb	8.9	4250539907 0N4	0425053990 0609	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-20-S	Rod Ø5.5 mm / 200 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8382	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-25	Rod Ø5.5 mm / 250 mm, straight	IIb	8.9	4250539907 0N4	0425053990 0616	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-25-S	Rod Ø5.5 mm / 250 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8399	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-30	Rod Ø5.5 mm / 300 mm, straight	IIb	8.9	4250539907 0N4	0425053990 0623	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-30-HEX	Rod Ø5.5 mm / 300 mm, straight hex	IIb	8.9	4250539907 0N4	0425053990 0661	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-30-HEX-S	Rod Ø5.5 mm / 300 mm, straight hex sterile	IIb	8.9	4250539907 1N6	0425053992 8412	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-30-S	Rod Ø5.5 mm / 300 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8405	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-35	Rod Ø5.5 mm / 350 mm, straight	IIb	8.9	4250539907 0N4	0425053990 0630	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-35-HEX	Rod Ø5.5 mm / 350 mm, straight hex	IIb	8.9	4250539907 0N4	0425053990 0678	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-35-HEX-S	Rod Ø5.5 mm / 350 mm, straight hex sterile	IIb	8.9	4250539907 1N6	0425053992 8436	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-35-S	Rod Ø5.5 mm / 350 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8429	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-40	Rod Ø5.5 mm / 400 mm, straight	IIb	8.9	4250539907 0N4	0425053990 0647	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-40-HEX	Rod Ø5.5 mm / 400 mm, straight hex	IIb	8.9	4250539907 0N4	0425053990 0685	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-40-HEX-S	Rod Ø5.5 mm / 400 mm, straight hex sterile	IIb	8.9	4250539907 1N6	0425053992 8467	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-40-S	Rod Ø5.5 mm / 400 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8450	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-45	Rod Ø5.5 mm / 450 mm, straight	IIb	8.9	4250539907 0N4	0425053990 0654	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-45-HEX	Rod Ø5.5 mm / 450 mm, straight hex	IIb	8.9	4250539907 0N4	0425053990 0692	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-45-HEX-S	Rod Ø5.5 mm / 450 mm, straight hex sterile	IIb	8.9	4250539907 1N6	0425053992 8481	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-45-S	Rod Ø5.5 mm / 450 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8474	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-5	Rod Ø5.5 mm / 50 mm, straight	IIb	8.9	4250539907 0N4	0425053990 0579	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-5-S	Rod Ø5.5 mm / 50 mm, straight sterile	IIb	8.9	4250539907 1N6	0425053992 8498	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-60	Rod Ø5.5 mm / 600 mm, straight	IIb	8.9	4250539907 0N4	0425053991 0790	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-60-HEX	Rod Ø5.5 mm / 600 mm, straight hex	IIb	8.9	4250539907 0N4	0425053991 0806	6511 6	P09070 302	Non Sterile	N/A

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VL-RS-5-7	Rod Ø5.5 mm / 70 mm, straight	Iib	8.9	4250539907 0N4	0425053990 2405	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-7-S	Rod Ø5.5 mm / 70 mm, straight sterile	Iib	8.9	4250539907 1N6	0425053992 8535	6511 6	P09070 302	Sterile	Gamma
VL-RS-5-9	Rod Ø5.5 mm / 90 mm, straight	Iib	8.9	4250539907 0N4	0425053990 2412	6511 6	P09070 302	Non Sterile	N/A
VL-RS-5-9-S	Rod Ø5.5 mm / 90 mm, straight sterile	Iib	8.9	4250539907 1N6	0425053992 8559	6511 6	P09070 302	Sterile	Gamma
1001050500	Transverse Connector Ø5,5 mm V2	Iib	8.9	4250539905 0MW	0425053990 0425	6511 4	P09070 304	Non Sterile	N/A
1001050500-S	Transverse Connector Ø5,5 mm V2 sterile	Iib	8.9	4250539905 1MY	0425053992 4766	6511 4	P09070 304	Sterile	Gamma
VL-TR-100	Transverse Connector Rod 100mm	Iib	8.9	4250539905 0MW	0425053990 2450	6511 6	P09070 304	Non Sterile	N/A
VL-TR-100-S	Transverse Connector Rod 100mm sterile	Iib	8.9	4250539905 1MY	0425053992 8566	6511 6	P09070 304	Sterile	Gamma
VL-TR-50	Transverse Connector Rod 50mm	Iib	8.9	4250539905 0MW	0425053990 0456	6511 6	P09070 304	Non Sterile	N/A
VL-TR-50-S	Transverse Connector Rod 50mm sterile	Iib	8.9	4250539905 1MY	0425053992 8573	6511 6	P09070 304	Sterile	Gamma
VL-TR-60	Transverse Connector Rod 60mm	Iib	8.9	4250539905 0MW	0425053990 0463	6511 6	P09070 304	Non Sterile	N/A
VL-TR-60-S	Transverse Connector Rod 60mm sterile	Iib	8.9	4250539905 1MY	0425053992 8580	6511 6	P09070 304	Sterile	Gamma
VL-TR-70	Transverse Connector Rod 70mm	Iib	8.9	4250539905 0MW	0425053990 0470	6511 6	P09070 304	Non Sterile	N/A
VL-TR-70-S	Transverse Connector Rod 70mm sterile	Iib	8.9	4250539905 1MY	0425053992 8597	6511 6	P09070 304	Sterile	Gamma
VL-TR-80	Transverse Connector Rod 80mm	Iib	8.9	4250539905 0MW	0425053990 0487	6511 6	P09070 304	Non Sterile	N/A
VL-TR-80-S	Transverse Connector Rod 80mm sterile	Iib	8.9	4250539905 1MY	0425053992 8603	6511 6	P09070 304	Sterile	Gamma
VL-TR-90	Transverse Connector Rod 90mm	Iib	8.9	4250539905 0MW	0425053990 2443	6511 6	P09070 304	Non Sterile	N/A
VL-TR-90-S	Transverse Connector Rod 90mm sterile	Iib	8.9	4250539905 1MY	0425053992 8610	6511 6	P09070 304	Sterile	Gamma

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2200124545	LP Domino Connector Ø4.5/4.5	IIb	8.9	42505399080N7	04250539912503	65114	P09070304	Non Sterile	N/A
2200124545-S	LP Domino Connector Ø4.5/4.5 sterile	IIb	8.9	42505399081N9	04250539929907	65114	P09070304	Sterile	Gamma
2200124555	LP Domino Connector Ø4.5/5.5	IIb	8.9	42505399080N7	04250539912510	65114	P09070304	Non Sterile	N/A
2200124555-S	LP Domino Connector Ø4.5/5.5 sterile	IIb	8.9	42505399081N9	04250539929914	65114	P09070304	Sterile	Gamma
2200160020	LP Dual Washer	IIb	8.9	42505399080N7	04250539912633	65114	P09070399	Non Sterile	N/A
2200160010	LP Dual Washer SP	IIb	8.9	42505399080N7	04250539912626	65114	P09070399	Non Sterile	N/A
2200160010-S	LP Dual Washer SP sterile	IIb	8.9	42505399081N9	04250539930033	65114	P09070399	Sterile	Gamma
2200160020-S	LP Dual Washer sterile	IIb	8.9	42505399081N9	04250539930040	65114	P09070399	Sterile	Gamma
2200134545	LP Inline Rod Connector Ø4.5/4.5	IIb	8.9	42505399080N7	04250539912534	65114	P09070304	Non Sterile	N/A
2200134545-S	LP Inline Rod Connector Ø4.5/4.5 sterile	IIb	8.9	42505399081N9	04250539929938	65114	P09070304	Sterile	Gamma
2200134555	LP Inline Rod Connector Ø4.5/5.5	IIb	8.9	42505399080N7	04250539912541	65114	P09070304	Non Sterile	N/A
2200134555-S	LP Inline Rod Connector Ø4.5/5.5 sterile	IIb	8.9	42505399081N9	04250539929945	65114	P09070304	Sterile	Gamma
2200110015	LP Lateral Connector 15mm	IIb	8.9	42505399080N7	04250539912466	65114	P09070304	Non Sterile	N/A
2200110015-S	LP Lateral Connector 15mm sterile	IIb	8.9	42505399081N9	04250539929860	65114	P09070304	Sterile	Gamma
2200110050	LP Lateral Connector 50mm	IIb	8.9	42505399080N7	04250539912480	65114	P09070304	Non Sterile	N/A
2200110050-S	LP Lateral Connector 50mm sterile	IIb	8.9	42505399081N9	04250539929884	65114	P09070304	Sterile	Gamma
LP-PMS	LP Set Screw	IIb	8.9	42505399106MY	04250539912114	65553	P09070302	Non Sterile	N/A
LP-PMS-S	LP Set Screw sterile	IIb	8.9	42505399107N2	04250539930194	65553	P09070302	Sterile	Gamma
2200160000	LP Single Washer	IIb	8.9	42505399080N7	04250539912619	61670	P09070399	Non Sterile	N/A
2200160000-S	LP Single Washer sterile	IIb	8.9	42505399081N9	04250539930026	61670	P09070399	Sterile	Gamma
2200140000	LP Transverse Connector Hook Ø4.5	IIb	8.9	42505399080N7	04250539912558	65114	P09070304	Non Sterile	N/A
2200140000-S	LP Transverse Connector Hook Ø4.5 sterile	IIb	8.9	42505399081N9	04250539929952	65114	P09070304	Sterile	Gamma
2200140040	LP Transverse Connector Rod 40mm	IIb	8.9	42505399080N7	04250539912565	65116	P09070304	Non Sterile	N/A
2200140040-S	LP Transverse Connector Rod 40mm sterile	IIb	8.9	42505399081N9	04250539929969	65116	P09070304	Sterile	Gamma
2200140050	LP Transverse Connector Rod 50mm	IIb	8.9	42505399080N7	04250539912572	65116	P09070304	Non Sterile	N/A
2200140050-S	LP Transverse Connector Rod 50mm sterile	IIb	8.9	42505399081N9	04250539929976	65116	P09070304	Sterile	Gamma
2200140060	LP Transverse Connector Rod 60mm	IIb	8.9	42505399080N7	04250539912589	65116	P09070304	Non Sterile	N/A
2200140060-S	LP Transverse Connector Rod 60mm sterile	IIb	8.9	42505399081N9	04250539929983	65116	P09070304	Sterile	Gamma
2200140070	LP Transverse Connector Rod 70mm	IIb	8.9	42505399080N7	04250539912596	65116	P09070304	Non Sterile	N/A

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220014007 0-S	LP Transverse Connector Rod 70mm sterile	IIb	8.9	425053990 81N9	042505399 29990	6511 6	P09070 304	Sterile	Gamma
220014008 0	LP Transverse Connector Rod 80mm	IIb	8.9	425053990 80N7	042505399 12602	6511 6	P09070 304	Non Sterile	N/A
220014008 0-S	LP Transverse Connector Rod 80mm sterile	IIb	8.9	425053990 81N9	042505399 30002	6511 6	P09070 304	Sterile	Gamma
220006402 5	Monoaxial Screw LP Ø4x25mm	IIb	8.9	425053990 90NA	042505399 12053	4665 1	P09070 302	Non Sterile	N/A
220006402 5-S	Monoaxial Screw LP Ø4x25mm sterile	IIb	8.9	425053990 91NC	042505399 29433	4665 1	P09070 302	Sterile	Gamma
220006403 0	Monoaxial Screw LP Ø4x30mm	IIb	8.9	425053990 90NA	042505399 12060	4665 1	P09070 302	Non Sterile	N/A
220006403 0-S	Monoaxial Screw LP Ø4x30mm sterile	IIb	8.9	425053990 91NC	042505399 29440	4665 1	P09070 302	Sterile	Gamma
220006403 5	Monoaxial Screw LP Ø4x35mm	IIb	8.9	425053990 90NA	042505399 12077	4665 1	P09070 302	Non Sterile	N/A
220006403 5-S	Monoaxial Screw LP Ø4x35mm sterile	IIb	8.9	425053990 91NC	042505399 29457	4665 1	P09070 302	Sterile	Gamma
220006404 0	Monoaxial Screw LP Ø4x40mm	IIb	8.9	425053990 90NA	042505399 12084	4665 1	P09070 302	Non Sterile	N/A
220006404 0-S	Monoaxial Screw LP Ø4x40mm sterile	IIb	8.9	425053990 91NC	042505399 29464	4665 1	P09070 302	Sterile	Gamma
220006404 5	Monoaxial Screw LP Ø4x45mm	IIb	8.9	425053990 90NA	042505399 12091	4665 1	P09070 302	Non Sterile	N/A
220006404 5-S	Monoaxial Screw LP Ø4x45mm sterile	IIb	8.9	425053990 91NC	042505399 29471	4665 1	P09070 302	Sterile	Gamma
220006405 0	Monoaxial Screw LP Ø4x50mm	IIb	8.9	425053990 90NA	042505399 12107	4665 1	P09070 302	Non Sterile	N/A
220006405 0-S	Monoaxial Screw LP Ø4x50mm sterile	IIb	8.9	425053990 91NC	042505399 29488	4665 1	P09070 302	Sterile	Gamma
220006552 5	Monoaxial Screw LP Ø5.5x25mm	IIb	8.9	425053990 90NA	042505399 11933	4665 1	P09070 302	Non Sterile	N/A
220006552 5-S	Monoaxial Screw LP Ø5.5x25mm sterile	IIb	8.9	425053990 91NC	042505399 29556	4665 1	P09070 302	Sterile	Gamma
220006553 0	Monoaxial Screw LP Ø5.5x30mm	IIb	8.9	425053990 90NA	042505399 11940	4665 1	P09070 302	Non Sterile	N/A
220006553 0-S	Monoaxial Screw LP Ø5.5x30mm sterile	IIb	8.9	425053990 91NC	042505399 29563	4665 1	P09070 302	Sterile	Gamma
220006553 5	Monoaxial Screw LP Ø5.5x35mm	IIb	8.9	425053990 90NA	042505399 11957	4665 1	P09070 302	Non Sterile	N/A
220006553 5-S	Monoaxial Screw LP Ø5.5x35mm sterile	IIb	8.9	425053990 91NC	042505399 29570	4665 1	P09070 302	Sterile	Gamma
220006554 0	Monoaxial Screw LP Ø5.5x40mm	IIb	8.9	425053990 90NA	042505399 11964	4665 1	P09070 302	Non Sterile	N/A
220006554 0-S	Monoaxial Screw LP Ø5.5x40mm sterile	IIb	8.9	425053990 91NC	042505399 29587	4665 1	P09070 302	Sterile	Gamma
220006554 5	Monoaxial Screw LP Ø5.5x45mm	IIb	8.9	425053990 90NA	042505399 11971	4665 1	P09070 302	Non Sterile	N/A
220006554 5-S	Monoaxial Screw LP Ø5.5x45mm sterile	IIb	8.9	425053990 91NC	042505399 29594	4665 1	P09070 302	Sterile	Gamma
220006555 0	Monoaxial Screw LP Ø5.5x50mm	IIb	8.9	425053990 90NA	042505399 11988	4665 1	P09070 302	Non Sterile	N/A
220006555 0-S	Monoaxial Screw LP Ø5.5x50mm sterile	IIb	8.9	425053990 91NC	042505399 29600	4665 1	P09070 302	Sterile	Gamma
220006502 5	Monoaxial Screw LP Ø5x25mm	IIb	8.9	425053990 90NA	042505399 11995	4665 1	P09070 302	Non Sterile	N/A
220006502 5-S	Monoaxial Screw LP Ø5x25mm sterile	IIb	8.9	425053990 91NC	042505399 29495	4665 1	P09070 302	Sterile	Gamma
220006503 0	Monoaxial Screw LP Ø5x30mm	IIb	8.9	425053990 90NA	042505399 12008	4665 1	P09070 302	Non Sterile	N/A

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220006503 0-S	Monoaxial Screw LP Ø5x30mm sterile	IIb	8.9	425053990 91NC	042505399 29501	4665 1	P09070 302	Sterile	Gamma
220006503 5	Monoaxial Screw LP Ø5x35mm	IIb	8.9	425053990 90NA	042505399 12015	4665 1	P09070 302	Non Sterile	N/A
220006503 5-S	Monoaxial Screw LP Ø5x35mm sterile	IIb	8.9	425053990 91NC	042505399 29518	4665 1	P09070 302	Sterile	Gamma
220006504 0	Monoaxial Screw LP Ø5x40mm	IIb	8.9	425053990 90NA	042505399 12022	4665 1	P09070 302	Non Sterile	N/A
220006504 0-S	Monoaxial Screw LP Ø5x40mm sterile	IIb	8.9	425053990 91NC	042505399 29525	4665 1	P09070 302	Sterile	Gamma
220006504 5	Monoaxial Screw LP Ø5x45mm	IIb	8.9	425053990 90NA	042505399 12039	4665 1	P09070 302	Non Sterile	N/A
220006504 5-S	Monoaxial Screw LP Ø5x45mm sterile	IIb	8.9	425053990 91NC	042505399 29532	4665 1	P09070 302	Sterile	Gamma
220006505 0	Monoaxial Screw LP Ø5x50mm	IIb	8.9	425053990 90NA	042505399 12046	4665 1	P09070 302	Non Sterile	N/A
220006505 0-S	Monoaxial Screw LP Ø5x50mm sterile	IIb	8.9	425053990 91NC	042505399 29549	4665 1	P09070 302	Sterile	Gamma
220006602 5	Monoaxial Screw LP Ø6x25mm	IIb	8.9	425053990 90NA	042505399 11872	4665 1	P09070 302	Non Sterile	N/A
220006602 5-S	Monoaxial Screw LP Ø6x25mm sterile	IIb	8.9	425053990 91NC	042505399 29617	4665 1	P09070 302	Sterile	Gamma
220006603 0	Monoaxial Screw LP Ø6x30mm	IIb	8.9	425053990 90NA	042505399 11889	4665 1	P09070 302	Non Sterile	N/A
220006603 0-S	Monoaxial Screw LP Ø6x30mm sterile	IIb	8.9	425053990 91NC	042505399 29624	4665 1	P09070 302	Sterile	Gamma
220006603 5	Monoaxial Screw LP Ø6x35mm	IIb	8.9	425053990 90NA	042505399 11896	4665 1	P09070 302	Non Sterile	N/A
220006603 5-S	Monoaxial Screw LP Ø6x35mm sterile	IIb	8.9	425053990 91NC	042505399 29631	4665 1	P09070 302	Sterile	Gamma
220006604 0	Monoaxial Screw LP Ø6x40mm	IIb	8.9	425053990 90NA	042505399 11902	4665 1	P09070 302	Non Sterile	N/A
220006604 0-S	Monoaxial Screw LP Ø6x40mm sterile	IIb	8.9	425053990 91NC	042505399 29648	4665 1	P09070 302	Sterile	Gamma
220006604 5	Monoaxial Screw LP Ø6x45mm	IIb	8.9	425053990 90NA	042505399 11919	4665 1	P09070 302	Non Sterile	N/A
220006604 5-S	Monoaxial Screw LP Ø6x45mm sterile	IIb	8.9	425053990 91NC	042505399 29655	4665 1	P09070 302	Sterile	Gamma
220006605 0	Monoaxial Screw LP Ø6x50mm	IIb	8.9	425053990 90NA	042505399 11926	4665 1	P09070 302	Non Sterile	N/A
220006605 0-S	Monoaxial Screw LP Ø6x50mm sterile	IIb	8.9	425053990 91NC	042505399 29662	4665 1	P09070 302	Sterile	Gamma
220004402 0	Polyaxial Screw LP Ø4x20mm	IIb	8.9	425053990 90NA	042505399 11278	4665 1	P09070 302	Non Sterile	N/A
220004402 0-S	Polyaxial Screw LP Ø4x20mm sterile	IIb	8.9	425053990 91NC	042505399 28993	4665 1	P09070 302	Sterile	Gamma
220004402 5	Polyaxial Screw LP Ø4x25mm	IIb	8.9	425053990 90NA	042505399 11285	4665 1	P09070 302	Non Sterile	N/A
220004402 5-S	Polyaxial Screw LP Ø4x25mm sterile	IIb	8.9	425053990 91NC	042505399 29006	4665 1	P09070 302	Sterile	Gamma
220004403 0	Polyaxial Screw LP Ø4x30mm	IIb	8.9	425053990 90NA	042505399 11292	4665 1	P09070 302	Non Sterile	N/A
220004403 0-S	Polyaxial Screw LP Ø4x30mm sterile	IIb	8.9	425053990 91NC	042505399 29013	4665 1	P09070 302	Sterile	Gamma
220004403 5	Polyaxial Screw LP Ø4x35mm	IIb	8.9	425053990 90NA	042505399 11308	4665 1	P09070 302	Non Sterile	N/A
220004403 5-S	Polyaxial Screw LP Ø4x35mm sterile	IIb	8.9	425053990 91NC	042505399 29020	4665 1	P09070 302	Sterile	Gamma
220004404 0	Polyaxial Screw LP Ø4x40mm	IIb	8.9	425053990 90NA	042505399 11315	4665 1	P09070 302	Non Sterile	N/A

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220004404 0-S	Polyaxial Screw LP Ø4x40mm sterile	IIb	8.9	425053990 91NC	042505399 29037	4665 1	P09070 302	Sterile	Gamma
220004404 5	Polyaxial Screw LP Ø4x45mm	IIb	8.9	425053990 90NA	042505399 11322	4665 1	P09070 302	Non Sterile	N/A
220004404 5-S	Polyaxial Screw LP Ø4x45mm sterile	IIb	8.9	425053990 91NC	042505399 29044	4665 1	P09070 302	Sterile	Gamma
220004552 5	Polyaxial Screw LP Ø5.5x25mm	IIb	8.9	425053990 90NA	042505399 11339	4665 1	P09070 302	Non Sterile	N/A
220004552 5-S	Polyaxial Screw LP Ø5.5x25mm sterile	IIb	8.9	425053990 91NC	042505399 29136	4665 1	P09070 302	Sterile	Gamma
220004553 0	Polyaxial Screw LP Ø5.5x30mm	IIb	8.9	425053990 90NA	042505399 11346	4665 1	P09070 302	Non Sterile	N/A
220004553 0-S	Polyaxial Screw LP Ø5.5x30mm sterile	IIb	8.9	425053990 91NC	042505399 29143	4665 1	P09070 302	Sterile	Gamma
220004553 5	Polyaxial Screw LP Ø5.5x35mm	IIb	8.9	425053990 90NA	042505399 11353	4665 1	P09070 302	Non Sterile	N/A
220004553 5-S	Polyaxial Screw LP Ø5.5x35mm sterile	IIb	8.9	425053990 91NC	042505399 29150	4665 1	P09070 302	Sterile	Gamma
220004554 0	Polyaxial Screw LP Ø5.5x40mm	IIb	8.9	425053990 90NA	042505399 11360	4665 1	P09070 302	Non Sterile	N/A
220004554 0-S	Polyaxial Screw LP Ø5.5x40mm sterile	IIb	8.9	425053990 91NC	042505399 29167	4665 1	P09070 302	Sterile	Gamma
220004554 5	Polyaxial Screw LP Ø5.5x45mm	IIb	8.9	425053990 90NA	042505399 11377	4665 1	P09070 302	Non Sterile	N/A
220004554 5-S	Polyaxial Screw LP Ø5.5x45mm sterile	IIb	8.9	425053990 91NC	042505399 29174	4665 1	P09070 302	Sterile	Gamma
220004555 0	Polyaxial Screw LP Ø5.5x50mm	IIb	8.9	425053990 90NA	042505399 11384	4665 1	P09070 302	Non Sterile	N/A
220004555 0-S	Polyaxial Screw LP Ø5.5x50mm sterile	IIb	8.9	425053990 91NC	042505399 29181	4665 1	P09070 302	Sterile	Gamma
220004502 5	Polyaxial Screw LP Ø5x25mm	IIb	8.9	425053990 90NA	042505399 11414	4665 1	P09070 302	Non Sterile	N/A
220004502 5-S	Polyaxial Screw LP Ø5x25mm sterile	IIb	8.9	425053990 91NC	042505399 29051	4665 1	P09070 302	Sterile	Gamma
220004503 0	Polyaxial Screw LP Ø5x30mm	IIb	8.9	425053990 90NA	042505399 11421	4665 1	P09070 302	Non Sterile	N/A
220004503 0-S	Polyaxial Screw LP Ø5x30mm sterile	IIb	8.9	425053990 91NC	042505399 29068	4665 1	P09070 302	Sterile	Gamma
220004503 5	Polyaxial Screw LP Ø5x35mm	IIb	8.9	425053990 90NA	042505399 11438	4665 1	P09070 302	Non Sterile	N/A
220004503 5-S	Polyaxial Screw LP Ø5x35mm sterile	IIb	8.9	425053990 91NC	042505399 29075	4665 1	P09070 302	Sterile	Gamma
220004504 0	Polyaxial Screw LP Ø5x40mm	IIb	8.9	425053990 90NA	042505399 11445	4665 1	P09070 302	Non Sterile	N/A
220004504 0-S	Polyaxial Screw LP Ø5x40mm sterile	IIb	8.9	425053990 91NC	042505399 29082	4665 1	P09070 302	Sterile	Gamma
220004504 5	Polyaxial Screw LP Ø5x45mm	IIb	8.9	425053990 90NA	042505399 11452	4665 1	P09070 302	Non Sterile	N/A
220004504 5-S	Polyaxial Screw LP Ø5x45mm sterile	IIb	8.9	425053990 91NC	042505399 29099	4665 1	P09070 302	Sterile	Gamma
220004505 0	Polyaxial Screw LP Ø5x50mm	IIb	8.9	425053990 90NA	042505399 11469	4665 1	P09070 302	Non Sterile	N/A
220004505 0-S	Polyaxial Screw LP Ø5x50mm sterile	IIb	8.9	425053990 91NC	042505399 29105	4665 1	P09070 302	Sterile	Gamma
220005402 0	Reduction Screw LP Ø4x20mm	IIb	8.9	425053990 90NA	042505399 10974	4665 1	P09070 302	Non Sterile	N/A
220005402 0-S	Reduction Screw LP Ø4x20mm sterile	IIb	8.9	425053990 91NC	042505399 29211	4665 1	P09070 302	Sterile	Gamma
220005402 5	Reduction Screw LP Ø4x25mm	IIb	8.9	425053990 90NA	042505399 10981	4665 1	P09070 302	Non Sterile	N/A

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2200054025-S	Reduction Screw LP Ø4x25mm sterile	IIb	8.9	42505399091NC	04250539929228	46651	P09070302	Sterile	Gamma
2200054030	Reduction Screw LP Ø4x30mm	IIb	8.9	42505399090NA	04250539910998	46651	P09070302	Non Sterile	N/A
2200054030-S	Reduction Screw LP Ø4x30mm sterile	IIb	8.9	42505399091NC	04250539929235	46651	P09070302	Sterile	Gamma
2200054035	Reduction Screw LP Ø4x35mm	IIb	8.9	42505399090NA	04250539911001	46651	P09070302	Non Sterile	N/A
2200054035-S	Reduction Screw LP Ø4x35mm sterile	IIb	8.9	42505399091NC	04250539929242	46651	P09070302	Sterile	Gamma
2200054040	Reduction Screw LP Ø4x40mm	IIb	8.9	42505399090NA	04250539911018	46651	P09070302	Non Sterile	N/A
2200054040-S	Reduction Screw LP Ø4x40mm sterile	IIb	8.9	42505399091NC	04250539929259	46651	P09070302	Sterile	Gamma
2200054045	Reduction Screw LP Ø4x45mm	IIb	8.9	42505399090NA	04250539911025	46651	P09070302	Non Sterile	N/A
2200054045-S	Reduction Screw LP Ø4x45mm sterile	IIb	8.9	42505399091NC	04250539929266	46651	P09070302	Sterile	Gamma
220005525	Reduction Screw LP Ø5.5x25mm	IIb	8.9	42505399090NA	04250539911032	46651	P09070302	Non Sterile	N/A
220005525-S	Reduction Screw LP Ø5.5x25mm sterile	IIb	8.9	42505399091NC	04250539929358	46651	P09070302	Sterile	Gamma
220005530	Reduction Screw LP Ø5.5x30mm	IIb	8.9	42505399090NA	04250539911049	46651	P09070302	Non Sterile	N/A
220005530-S	Reduction Screw LP Ø5.5x30mm sterile	IIb	8.9	42505399091NC	04250539929365	46651	P09070302	Sterile	Gamma
220005535	Reduction Screw LP Ø5.5x35mm	IIb	8.9	42505399090NA	04250539911056	46651	P09070302	Non Sterile	N/A
220005535-S	Reduction Screw LP Ø5.5x35mm sterile	IIb	8.9	42505399091NC	04250539929372	46651	P09070302	Sterile	Gamma
220005540	Reduction Screw LP Ø5.5x40mm	IIb	8.9	42505399090NA	04250539911063	46651	P09070302	Non Sterile	N/A
220005540-S	Reduction Screw LP Ø5.5x40mm sterile	IIb	8.9	42505399091NC	04250539929389	46651	P09070302	Sterile	Gamma
220005545	Reduction Screw LP Ø5.5x45mm	IIb	8.9	42505399090NA	04250539911070	46651	P09070302	Non Sterile	N/A
220005545-S	Reduction Screw LP Ø5.5x45mm sterile	IIb	8.9	42505399091NC	04250539929396	46651	P09070302	Sterile	Gamma
220005550	Reduction Screw LP Ø5.5x50mm	IIb	8.9	42505399090NA	04250539911087	46651	P09070302	Non Sterile	N/A
220005550-S	Reduction Screw LP Ø5.5x50mm sterile	IIb	8.9	42505399091NC	04250539929402	46651	P09070302	Sterile	Gamma
2200055025	Reduction Screw LP Ø5x25mm	IIb	8.9	42505399090NA	04250539911117	46651	P09070302	Non Sterile	N/A
2200055025-S	Reduction Screw LP Ø5x25mm sterile	IIb	8.9	42505399091NC	04250539929273	46651	P09070302	Sterile	Gamma
2200055030	Reduction Screw LP Ø5x30mm	IIb	8.9	42505399090NA	04250539911124	46651	P09070302	Non Sterile	N/A
2200055030-S	Reduction Screw LP Ø5x30mm sterile	IIb	8.9	42505399091NC	04250539929280	46651	P09070302	Sterile	Gamma
2200055035	Reduction Screw LP Ø5x35mm	IIb	8.9	42505399090NA	04250539911131	46651	P09070302	Non Sterile	N/A
2200055035-S	Reduction Screw LP Ø5x35mm sterile	IIb	8.9	42505399091NC	04250539929297	46651	P09070302	Sterile	Gamma
2200055040	Reduction Screw LP Ø5x40mm	IIb	8.9	42505399090NA	04250539911148	46651	P09070302	Non Sterile	N/A
2200055040-S	Reduction Screw LP Ø5x40mm sterile	IIb	8.9	42505399091NC	04250539929303	46651	P09070302	Sterile	Gamma
2200055045	Reduction Screw LP Ø5x45mm	IIb	8.9	42505399090NA	04250539911155	46651	P09070302	Non Sterile	N/A

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220005504 5-S	Reduction Screw LP Ø5x45mm sterile	IIb	8.9	425053990 91NC	042505399 29310	4665 1	P09070 302	Sterile	Gamma
220005505 0	Reduction Screw LP Ø5x50mm	IIb	8.9	425053990 90NA	042505399 11162	4665 1	P09070 302	Non Sterile	N/A
220005505 0-S	Reduction Screw LP Ø5x50mm sterile	IIb	8.9	425053990 91NC	042505399 29327	4665 1	P09070 302	Sterile	Gamma
220008454 8H	Rod straight LP CoCr Ø4.5x480mm Hex	IIb	8.9	425053990 98NS	042505399 10899	6511 6	P09070 302	Non Sterile	N/A
220008454 8H-S	Rod straight LP CoCr Ø4.5x480mm Hex sterile	IIb	8.9	425053990 99NU	042505399 30088	6511 6	P09070 302	Sterile	Gamma
220009451 0H	Rod straight LP Ø4.5x100mm Hex	IIb	8.9	425053990 96NN	042505399 10936	6511 6	P09070 302	Non Sterile	N/A
220009451 0H-S	Rod straight LP Ø4.5x100mm Hex sterile	IIb	8.9	425053990 97NQ	042505399 30095	6511 6	P09070 302	Sterile	Gamma
220009451 5H	Rod straight LP Ø4.5x150mm Hex	IIb	8.9	425053990 96NN	042505399 10943	6511 6	P09070 302	Non Sterile	N/A
220009451 5H-S	Rod straight LP Ø4.5x150mm Hex sterile	IIb	8.9	425053990 97NQ	042505399 30101	6511 6	P09070 302	Sterile	Gamma
220009452 0H	Rod straight LP Ø4.5x200mm Hex	IIb	8.9	425053990 96NN	042505399 10950	6511 6	P09070 302	Non Sterile	N/A
220009452 0H-S	Rod straight LP Ø4.5x200mm Hex sterile	IIb	8.9	425053990 97NQ	042505399 30118	6511 6	P09070 302	Sterile	Gamma
220009454 8H	Rod straight LP Ø4.5x480mm Hex	IIb	8.9	425053990 96NN	042505399 10967	6511 6	P09070 302	Non Sterile	N/A
220009454 8H-S	Rod straight LP Ø4.5x480mm Hex sterile	IIb	8.9	425053990 97NQ	042505399 30125	6511 6	P09070 302	Sterile	Gamma

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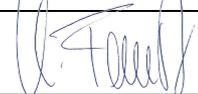
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- complete and correct content
- plausible content
- If applicable, detailed criteria are met

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	Function	Name	Date	Signature
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Reviewer	Research and Development	Ömer Setenci	29.07.2025	
Approver	PRRC	Katrin Faust	29.07.2025	

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