Instruction for use
Implants - EN

Instruction for use (D30182)

VERTICALE® Cervical Screw Rod System

Important Information – please read before use!

Table of contents

1 Product description 2
2 Clinical application 3
3 Risks and possible negative side effects 4
4 Packaging, sterility and storage 4
5 Notes for application 5
6 Labeling and Symbols 8

This Instruction for use covers the implants of the VERTICALE Cervical Screw Rod System.

This and other product specific information (e.g. instrumentation guides) as well as product accompanying information in other relevant official languages are available under the following links:

- https://elabeling.silony-medical.com
- www.silonyspine.com

Instruction for use D30223 must be used as reference for reprocessing instruments.

The summaries of safety and clinical performance (SSCP) of Silony implants are available in the European Database for Medical Products (EUDAMED) and are provided by Silony Spine upon request.

Any manufacturer liability is excluded in the event of non-compliance with the manufacturer's product information.

Prior to using a product distributed by Silony Spine, the surgeon is expected to carefully study the following indications/contraindications, recommendations, warnings, and advice as well as the product specific information. Silony Spine also recommends participation in appropriate user training.

Users and/or patients are required to report any (serious) adverse events related to the device to the manufacturer and to the state competent authority.

This instruction for use does not apply to the USA or its territories.

1 Product description

1.1 General Information

VERTICALE Cervical is a posterior double rod fixation system for correction, immobilization/fusion and stabilization of the occipito-cervico-thoracic regions of the spine.

The VERTICALE Cervical system consists of screws, rods, plates, connectors and the corresponding instruments. The VERTICALE Cervical system comprises polyaxial and far angle screws solid or cannulated, available in different lengths and diameters, with or without smooth shank. With a diameter of 3.5 mm and 4.0 mm straight rods in titanium alloy are available in different lengths. Additionally, the VERTICALE Cervical system provides prebent rods as well as transition rods to attach the VERTICALE system components. For cranial connection the VERTICALE Cervical system consists of occipital plates with or without lateral wings and with 3, 4 or 5 holes as well as the corresponding occiput screws. Furthermore, cross connectors for additional stabilization and rod connectors for extension are available. The associated instruments as well as instruments for navigated applications are also available.

If required, the stability of the system can be increased by additional ventral support or reconstruction if deemed appropriate by the surgeon.

1.2 Performance characteristics

Screws and rods are used to create a fixed-angle, posterior frame construct for correction, immobilization and stabilization of the spine.

The load-bearing anchorage of pedicle screws is achieved through insertion of the screws into the pedicle and cervical vertebrae. The pedicle screw forms an anchor in the vertebral arch and vertebral body to support in vivo loads and hold the vertebra in its position. In combination with the rod inserted into the screw head and the set screws, a fixed-angle, load-bearing frame construct is created.

Rods are used to connect the individual screws. In combination with the set screws, a fixed-angle frame construct is created. The rods take up the loads of the screws and transfer them to the caudal and cranial load-transmitting structures of the musculoskeletal system, thereby providing temporary load reduction of the spine during the phase of fusion and healing.

Cross connectors are connecting two rods and thereby increase the angular stability of the entire frame construct. Rod connectors are used to extend the construct by providing a connection of 2 rod segments and / or to increase the stiffness of the frame structure (e.g. 3- or 4-rods system) in case of e.g. anatomically indicated circumstances or in case of revision surgery.

1.3 Combination with other products

The VERTICALE Cervical system can be combined with the VERTICALE Posterior Spinal Fixation System using transition rods.
The VERTICALE Cervical fixation system can be used in combination with navigable systems.
Please refer to the corresponding product information.

1.4 Material

Implants of the VERTICALE Cervical system are manufactured from titanium alloy Ti6Al4V ELI (ELI = extra low interstitials) in accordance with ASTM F136 and ISO 5832-3.

Chemical composition (elements) according to ASTM F136	Percentage of chemical elements in the total product [% (mass/mass)]
[Al] Aluminum	5.5 - 6.5 (5.5 - 6.75)*
[V] Vanadium	3.5 - 4.5
[Fe] Iron	0.25 maximum (0.3 maximum)*
[O] Oxygen	0.13 maximum (0.2 maximum)*
[C] Carbon	0.08 maximum
[N] Nitrogen	0.05 maximum
[H] Hydrogen	0.012 maximum (0.015 maximum**)*
[Ti] Titanium	88.478 – 91 (88.105 – 91)*

** Specification according to ISO 5832-3*
***(from ISO 5832-3) for using blocks as raw material, the maximum hydrogen content must not exceed 0.01%.*

1.5 Information about special substances

Implants of the VERTICALE Cervical system do not contain medicinal substances, or components of tissue or cell components of human animal origin or substances derived from human blood.

2 Clinical application

2.1 Intended use

The VERTICALE Cervical system is a posterior double rod fixation system for immobilization and stabilization of the spinal segments of the craniocervical junction (occiput-C2), subaxial cervical spine (C3-C7), and upper thoracic spine (T1-T3) in skeletally mature patients.

2.2 Indications

The VERTICALE Cervical system can be used in the occipito-cervico-thoracic regions to treat the following indications:

- Degenerative disc diseases
- Deformities
- Instabilities
- Trauma

2.3 Contraindications

There may be absolute or relative factors for not using the product. The decision to use a particular implant must be carefully considered, taking into account the patient's anamnesis. The following circumstances can affect the success of the treatment.

2.3.1 Absolute contraindications

- Expected or documented allergy or intolerance to the materials used
- Missing bony structures, which would render solid anchoring of the implant impossible
- Any conditions not described in the indications

2.3.2 Relative contraindications

- Expected implant overload
- Acute or chronic infections, of local or systemic nature
- Systemic diseases and metabolic disorders
- Unbalanced diet, medicinal drug abuse; nicotine, alcohol or drug abuse
- Patient who is mentally or physically unable or unwilling to understand and follow the physician’s instructions
- Any patient for whom the use of the implant would be in conflict with the anatomical structures
- Any condition that could exclude the potential benefit of a spinal implantation must be clarified by the treating physician.
- Surgeries on pregnant women must be avoided if possible or require special care. This is at the discretion of the surgeon.

2.4 Expected clinical benefit

As clinical benefit for the patient quality of life should be increased by pain reduction and a clinically relevant improvement in function as well as support in physiological relordosis.

2.5 Target patient group

The implants are intended for use in human medicine in patients with a mature skeleton.
There is no restriction regarding the intended patient population additional to the indications/contraindications.

2.6 Target user group

The implants are intended for use by orthopedic surgeons and neurosurgeons familiar with spinal surgery and experienced in the product-specific surgical techniques.

2.7 Use environment

The implants are to be used in a standard surgical environment.

3 Risks and possible negative side effects

As with any major surgical procedures there is a risk for adverse events. Prevalence of the possible negative side effects may vary depending on patient-specific pathology and anatomy, as well as implantation levels. Possible negative consequences include among others:

- Migration, dislocation or loosening of the implants or implant components (e.g. screw backout)
- Mechanical failure of the implant and/or components
- Damage/fracture of the vertebral bone
- Pain
- Infection
- Foreign body (allergic) reaction
- Loss of correction
- Pseudoarthrosis/non-union
- Injury of tissue, vessels and nerves
- Spinal cord injury
- Reduction in the bone density (Osteolysis) or bone loss due to resorption or stress shielding
- Adjacent segment degeneration

4 Packaging, sterility and storage

4.1 Storage

⚠ **Implants must be stored in the sealed packaging according to the storage conditions indicated on the product label until use.**

4.2 Packaging

- The sterile packaging is set up as a double sterile barrier as follows (from the outside to the inside):
  - transport carton
  - first sterile barrier
  - second sterile barrier
  - protective packaging (not applicable for all packaging) - no additional sterile barrier
- The rules of asepsis must be observed during removal from the sterile and protective packaging.

4.3 Labeling

- The instructions and symbols given on the packaging must be followed (see section 6).
- The main label is attached to the transport carton. This contains all the necessary information for clear identification of the sterile packaged product (e.g., product description, article and lot number) and further information on the use of the product.
- The first and second sterile barriers are also each marked with a label with reduced content but also contain clear identification of the sterile packaged product. The individual packaging layer is labeled as a double or single sterile barrier using appropriate symbols.
- The individual inner protective packaging is not marked separately with a label.
- When withdrawing the implant from the packaging, the direct marking on the implant must be verified against the information on the labels.
- The patient labels in the primary packaging must be attached to the patient file or the surgical report.

4.4 Sterilization

- Implants are packaged and sterilized with gamma irradiation at a minimum dose of 25 kGy and delivered sterile. They can be used without further preparation.

⚠ **Implants delivered by the manufacturer in a sterile condition must not be resterilized!**

- Prior to use, labeling and each packaging layer should always be checked for integrity.
- Before using the implant, the expiration date (YYYY/MM/DD) and the sterility marker on the packaging must be checked.

⚠ **The implant must not be used if the packaging is damaged, if the expiry date has expired or if the sterility marking is not present or does not indicate that the product has been correctly irradiated (marker must be colored red).**

- Sterile packaged products whose protective packaging is damaged, even if the product was not used for the surgical procedure, are considered used and must be disposed.

5 Notes for application

5.1 General

- The surgical technique for Silony Spine implants can be learned by observing surgical procedures for demonstration purposes, workshops, and courses in a hospital familiar with these implants.

⚠ **Implants and instruments are always part of a system. Only instruments, trials and accessories described in the accompanying manufacturer's instructions (e.g. instrumentation guides or note inserts) must be used in order not to impair the performance of the device or surgical outcome.**

⚠ **Compatibility is only guaranteed with these instruments and accessories.**

5.2 Handling of the implants

- Implants are sensitive to damage. Even minor scratches or impact sites on the surfaces can lead to premature failure and result in complications. Careful handling is required.

⚠ **Implants must not be mechanically processed or modified in any other way unless this is expressly stipulated in the instrumentation guide.**

⚠ **Implants that are contaminated, non-sterile, damaged, or scratched or that have been improperly treated or processed in an unauthorized way must not be implanted under any circumstances.**

- In the event of overloading, damage, improper implantation, or improper handling, implants may fracture, become loose, wear out, or become functionally impaired. In rare cases, there may be corrosion of the implant.
- Any implant is subject to inevitable wear and tear. An implant that was initially stable upon implantation may become loose or functionally impaired over time, which can result in revision surgery.

5.3 Reuse

⚠ **Implants are for single use only and strictly must not be reprocessed after use in a patient and contamination with blood, tissue or other body fluids. Reuse, reprocessing or resterilization can lead to limited functionality, transfer of pathogens or cross-infection, which may lead to patient injuries, diseases or death.**

- Even if the implant appears to be intact, it may have minor defects and invisible damages due to excessive stress that can lead to premature wear and tear.

5.4 Preoperative use instructions

- Implant surgery should generally only be considered if all other conservative treatment options have been carefully assessed and have not proven to be the better option. The treating physician is responsible for considering the possibility of implant surgery.
- The surgeon is responsible for the proper performance of the surgery, including:
  - Patient-specific selection of size, shape and design of the implant
  - Planning of the surgery based on X-ray images
  - Checking possible allergies of the patient to the implant material
  - Ensure availability of different implant sizes and required instruments for the surgical procedure
- Neglecting to carry out preoperative planning can have a negative impact on the surgical outcome and lead to health damage. The potential success of surgery depends directly on the correct choice of the implant.
- When planning implantation, the patient-specific pathology and anatomy as well as the implantation levels must also be taken into account.

⚠ **Silony Spine bears and accepts no responsibility for complications resulting from an incorrect diagnosis or indication, an unsuitable choice of implant, incorrectly combined implant components and/or an improper surgical technique or asepsis.**

5.5 Intra-operative use instructions

- Prior to implantation, the implant must be visually inspected for damage.

⚠ **Damaged implants must not be used.**

⚠ **In general, and due to the anatomical conditions of the cervical spine, placing of implants under imaging control is recommended.**

- To prevent anterior perforation of the vertebral body and subsequent perforation of large vessels during probing, pre-drilling, when using the guide wires and when inserting the screws, the required length of the pedicle screw and the diameter of the pedicle have to be determined on the basis of the A-P x-ray image. The length of the screw should be at least 2/3 of the diameter of the vertebral body and should in the best case extend as far as the anterior edge of the vertebral body.
- Inadequate placement, selecting the incorrect size for the implants or other errors, such as a faulty alignment of the initial pre-drilling, drilling too deep, using an awl that is too pointed, or excessively deep probing of the pedicle, may lead to injury of the spinal cord or vessels and to paralysis or to the screw not being anchored sufficiently.
- An incorrectly positioned screw that is too deep reduces the mobility of the screw head.
- The screws must be positioned in a way that sufficient space for insertion is ensured.
- Increased application of force may cause to disengagement of implant components.
- Prior to correction or reduction maneuvers or insertion of implant components in the respective screw heads, it must be ensured that the implant interfaces are cleaned from impurities and residues (e.g. bone cement, foreign particles, bone chips) in order to avoid functional impairment, insufficient stability of the connection to other implant components or breakage of the implants or implant components.

5.6 Notes on guiding

- The cannulated screws can be implanted under guidance with a guide wire.
- When inserting the guide wires, always try to position them as symmetrically as possible along the path of the pedicle.
- The guide wires must remain in the correct position throughout the entire surgical procedure. The tip of the guide wire in particular should be monitored under imaging to ensure that it does not perforate the anterior wall of the vertebral body and potentially damage the vessels that lie in front of it. Under image intensifier control, it must be ensured that each guide wire is suitably positioned for screw insertion and remains correctly positioned before the screw is inserted.
- Only guide wires with a diameter less than 1.4 mm may be used. Silony Spine recommends a guide wire with a diameter of 1.3 mm

5.7 Post-operative use instructions

- Post-operative evaluation of the fusion and the implant status are mandatory.
- Post-operative mobilization and rehabilitation are at the discretion of the surgeon dependent on clinical and radiological progress.

5.8 Information to the patient

- Even a successfully implanted device is inferior to the healthy motion segment(s) of the spine. Similarly, an implant can represent a beneficial replacement of one or more pathological and/or symptomatic motion segment(s) for the patient, as it can help eliminate pain and therefore achieve improved mobility and stability.
- Pre- and post-operative instructions and warnings of the surgeon to the patient and their compliance are essential. The surgeon is responsible for informing the patient about the risks of implantation and about the outcome of the surgery as well as any potential negative consequences. The patient should be made aware of the limitations and the measures to minimize the possible complications. The patient should be instructed to limit the post-operative activity as this will reduce the risk of bending, breaking and/or loosening the implants.
- The patient must be issued with an implant pass.
- The patient must be informed that implants can have an impact on the diagnostic imaging of CT scans or MRI examinations. The patient must also be instructed to inform the examining physician about the implant and to show the implant pass prior to a scheduled CT scan or MRI examination.
- All information given to the patient should be documented in writing by the surgeon.

5.9 Magnetic resonance (MR) compatibility

- The implants are MR conditional.

⚠ **The implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment.**

- Based on a systematic literature search of the State-of-the-Art for similar devices and materials, it can be assumed that safe MR can be performed on patients under the following conditions:
  - Static magnetic field of 3 Tesla or less
  - Maximum spatial gradient of magnetic field of 720-Gauss/cm (a higher value for the spatial gradient of magnetic field may apply if properly calculated)
  - Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (per pulse sequence)
- MRI related Heating: Possible heat generation is acceptable for a whole body averaged specific absorption rate (SAR) of 2W/kg for 15 minutes (per pulse sequence) of scanning using a 3-Tesla MR system.
- Migration: Due to the material used (titanium alloy), no forces or moments are to be expected which cause the implant to migrate during the MR examination.
- Artifacts: MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant.
- In all cases, the treating physician is responsible for MR conditions, MR imaging quality and patient safety.

5.10 Implant removal and revision

- The implants are not intended to be removed in case of a good outcome.
- Removal of a stable implant can lead to loss of stability and damage to surrounding tissue.
- However, adverse events might warrant removal of the implant.
- Removal of the implant is possible. This should be carefully considered by the surgeon and the patient, evaluating the risks and benefits.
- For revisions, the VERTICALE Cervical System also provides a means of replacing individual elements and extending the fusion length.

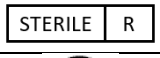
5.11 Disposal

- Implants and instruments that can no longer be used can be disposed of in accordance with the national regulations applicable at the place of use or be returned to the manufacturer free of charge for proper disposal.
- Implants and instruments may only be returned to Silony Spine if they are still in the undamaged original package or have been cleaned, disinfected, and sterilized. Proof of such treatment must be attached to the outer packaging.

5.12 Traceability

- When passing on Silony Spine products (in return for payment or free of charge), each party passing on a product must ensure that appropriate traceability (lot tracking) is possible at all times.

6 Labeling and Symbols

Symbol	Description according to ISO 15223-1 and Silony specifications
	Manufacturer
	Date of manufacture *Including the date in the following format: YYYY-MM-DD*
	Swiss Authorized Representative
	United Kingdom Representative
	The device meets the requirements of EU Regulation MDR 2017/745.
	Federal law in the USA restricts this device to sale by or on the order of a physician.
	Article number
	Lot number
	Number of items
	Medical device
	Unique device identification
	Use by *Including the date in the following format: YYYY-MM-DD*
	Consult Instruction for use
	Caution
	Single sterile barrier system
	Double sterile barrier system
	Sterilized using irradiation
	Do not re-use
	Do not resterilize
	Do not use if the package is damaged
	Keep dry
	Keep away from sunlight
	MR* conditional (The term MR is synonymous with MRI and means magnetic resonance imaging.)
	Metal detectors can trigger alarm due to the implant
	Patient Identification

Symbol	Description according to ISO 15223-1 and Silony specifications
	Health care centre or doctor
	Date (of implantation)
	Contact
	Silony Logo (for identification of the legal manufacturer in the course of direct marking of products)
	Rod angulation
	Cannulated screw
	Solid screw
	Polyaxial screw
	Far-angle-screw
S	Size S
M	Size M
L	Size L
Ø	Diameter

Silony Medical GmbH
Leinfelder Straße 60
70771 Leinfelden-Echterdingen
Germany

Telephone: +49 (0)711-782 525 0
Fax: +49 (0)711-782 525 11
E-Mail: info.stuttgart@silony-medical.com

https://www.silonyspine.com/contact

www.silony-medical.com/ifu

CE 0483