Instruction for use (D30008)

VERTICALE® Posterior Spinal Fixation System

Important Information – please read before use!

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This Instruction for use covers the implants of the VERTICALE posterior spinal fixation 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
- https://www.silonyspine.com/

Instruction for use D30003 must be used as reference for reprocessing instruments. For sterile instruments D30011 must be used as reference.

The short summaries of safety and 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 is a posterior double rod fixation system for stabilizing the thoracic, lumbar and iliosacral spine via both the open and minimally invasive approaches. The system is used for stabilization of the degenerative spine and the correction of deformities.

The VERTICALE System comprises polyaxial, monoaxial, uniplanar, and iliac screws available as short head and long head screws (reduction screws). These screw types are either solid, cannulated, or cannulated and fenestrated available in different lengths and diameters.

With a diameter of 5.5mm curved and straight rods in titanium alloy or cobalt chromium are available in different lengths. Additionally, a variety of hooks and connectors in different sizes, as well as assorted instruments for open surgical and minimally invasive approaches as well as for navigation and augmentation are 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 VERTICALE components

1.2.1 Screws and rods

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

Pedicle screws: The load-bearing anchorage of pedicle screws is achieved through insertion of the screws into the pedicle and vertebral body. If necessary, the anchorage of fenestrated pedicle screws can be improved by additional augmentation with bone cement. The pedicle screw forms an anchor in the vertebral arch and vertebral body to support in vivo loads and holds the vertebra in its position (correction, immobilization and stabilization). In combination with the rod inserted in the screw head and the set screws, a fixed-angle, load-bearing frame construct is created.

Ilium screws: Ilium screws are implanted into the ilium (iliac crest). They are used to transfer spinal loads to the pelvic ring. The final construct for correction, immobilization and stabilization of the spinal segment to be treated is thereby created by combining the ilium screws with additional pedicle screws and rods.

Rods: Rods are used to connect the individual screws and hooks. In combination with the set screws, a fixed-angle frame construct is created for the correction, immobilization and stabilization of the spine. The rods take up the loads of the screws and the hooks 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.

1.2.2 Connectors

The VERTICALE connectors are a part of the VERTICALE system to provide additional stiffening of the fixed-angle frame construct (cross connector) as well as to extend or supplement the frame construct (consisting of screws, hooks and rods) in case of e.g., anatomically indicated circumstances or in case of revision surgery.

Cross connectors connect 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). The construct extension is achieved through a mechanically stable connection of two rods or one rod with a screw (ilium connector).

1.3 Performance characteristics and intended use for VERTICALE Hooks

VERTICALE hooks (as part of the VERTICALE posterior spinal fixation system) are used for the non-pedicular fixation of the vertebrae to provide correction, immobilization and stabilization of spinal

segments of the thoracic and lumbar spine. They supplement pedicular fixation in cases where pedicular fixation is difficult or impossible to achieve (e.g. anatomical conditions, clinical indications). Hooks are placed and anchored in the area of the posterior vertebral arch, such as the lamina, the transverse process, the facet or the outer pedicle.

1.4 Combination with other products

For additional stabilization of the VERTICALE system, a bone cement suitable and designed for spine can be used with fenestrated screws.
The VERTICALE posterior spinal fixation system can be used in combination with navigable systems.
VERTICALE can be combined with the VERTICALE Triangular Fixation System and the VERTICALE Cervical system.

Please refer to the corresponding product information.

1.5 Material

Implants of the VERTICALE system are manufactured from titanium alloy Ti6Al4V ELI (ELI = extra low interstitials) in accordance with ASTM F136 and ISO 5832-3 and cobalt chromium molybdenum in accordance to ISO 5832-12 (rods only). The materials are mutually compatible.

Table 1: Material data Ti6Al4V ELI

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%.*

Table 2: Material data CoCr28Mo6

Chemical composition (elements) according to ISO 5832-12 (equal to ASTM F1537)	Percentage of chemical elements in the total product [% (mass/mass)]
[Fe] Iron	0.75 maximum
[C] Carbon	0.14 maximum
[N] Nitrogen	0.25 maximum
[Cr] Chromium	26 - 30
[Mo] Molybdenum	5 - 7
[Ni] Nickel	1 maximum
[Si] Silicon	1 maximum
[Mn] Manganese	1 maximum
[Co] Cobalt	58.86 - 69

1.6 Information about special substances

Implants of the VERTICALE system do not contain substances of biological or animal origin, medicinal substances, or substances derived from human blood.

2 Clinical application

2.1 Intended use

The VERTICALE spine system is a posterior fixation system for open and minimally invasive (MIS) surgical procedures for correction and stabilization by immobilization / fusion of spinal segments in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and iliosacral spine (T1-S2/Ilium).

2.2 Indications

The VERTICALE spine system is intended for pedicle fixation and non-pedicle-based fixation (using hooks and ilium screws) of the thoracic, lumbar and iliosacral spine for the following indications:

- Degenerative disc disease (defined as back pain of discogenic origin due to degeneration of the disc, confirmed by history and X-ray examinations)
- Spondylolisthesis
- Trauma (i.e. fracture / dislocation)
- Stenosis of the spinal canal / foramen with simultaneous instability
- Deformities (i.e. scoliosis, pathological kyphosis and/or lordosis)
- Tumors
- Pseudoarthrosis
- Revision
- Spondylitis

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

- Anticipated or documented allergy or intolerance to the materials (e.g., titanium or cobalt-chromium)
- Any case in which the chosen implants would be too large or too small to achieve a successful result
- Any patient for whom the use of the implant would conflict with anatomical structures
- Missing bony structures, which would render solid anchoring of the implant impossible (e.g., in the case of fractures, tumors)

2.3.2 Relative contraindications

- Patient overweight
- Deformities
- Fever or leukocytosis
- Local bone tumors
- Acute or chronic infections, local or systemic
- Systemic diseases and metabolic disorders
- Unbalanced diet, medicinal drug abuse; nicotine, alcohol or drug consumption
- Physical activities involving violent vibrations during which the implant is exposed to impacts and/or excessive loads (e.g., heavy physical work, competitive sports, marathons, alpine skiing, jumping and team sports)
- Patient who is mentally unable to understand and follow the physician’s instructions
- Severe Osteoporosis (T-Score < -2,5) or osteomalacia
- Any patients with insufficient tissue coverage
- Severe muscle, nerve, or vascular disorders that endanger the affected extremities
- Operations on pregnant women must be avoided if possible. If they are nevertheless performed, they require special care or procedures.
- All concomitant diseases that could affect the function and success of the implant

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

There is no restriction regarding the intended patient population additional to the indications/contraindications.

The patient’s age may lead to restrictions which are included in the contraindications. For example, use in infants or young children may be contraindicated due to the limited selection of implant sizes or immature skeleton. In general, this warrants the consideration by the experienced surgeon who must

make a rigorous assessment of the suitability and size of the implant, particularly for children with respect to the still incomplete growth phase.

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:

- Implants or implant components can break, become loose, pull out or migrate as a result of overstress, non-physiological use, damages, improper handling or implantation.
- Incorrect placement, loss of correction and stability, loss of mechanical function, connection instability
- Loosening of the implant due to changed conditions of load transmission, e.g., destruction of the bone bed and/or reaction of the tissue to the implant
- Implant failure owing to wear
- Loss of correction owing to inadequate fusion
- Early and late infections
- Dislocation, subluxation, inadequate range of motion due to suboptimal positioning/fixation of the implant
- Bone fractures due to unilateral overloading or weakened bone substance
- Temporary or permanent nerve damage due to pressure or hematoma
- Neurological damage, deficits, or impairment culminating in paralysis
- Dural lesion, cerebrospinal fluid (CFS) leakage
- Wound hematoma and delayed wound healing
- Pain and restricted freedom of movement
- Injury to the spinal cord or to vessels
- Injury to soft tissue and other tissues
- Perforation of the vertebral body and subsequent perforation of major vessels
- Intolerance, irritation, skin sensitization—local effects following implantation, irritation and delayed-onset allergic reactions, cancer/death
- Delays in the course of surgery
- Revisions
- Pseudarthrosis
- Loss of global sagittal balance of the spinal column
- Kyphosis/proximal junctional kyphosis (PJK)
- Degeneration of the connecting segments
- Fat embolism and systemic reactions due to cement leakage; danger to life/death; The injected cement displaces the bone marrow into the blood circulation
- Visceral and vascular complications
- Disc prolapse, spinal stenosis, radicular irritation
- Bowel and bladder problems
- Corrosion
- Impotence
- Pulmonary embolism
- Colitis
- Toxic hazards due to insufficient cleaning and sterilization

General surgical risks include anesthesia, postoperative risks, severe blood loss, cardiovascular instability, thrombosis, allergic reactions, rejection reactions, inflammation culminating in life-threatening effects/death.

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 contains 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).**

- Damaged sterile packaging of products that haven't been used for the surgical procedure are considered as 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 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.**

- 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. A sacral screw fixation should be barely bicortical (perforation of the anterior cortex with at most one thread).
- 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 position of each guide wire must be checked under the image intensifier to ensure that each guide wire is positioned suitably for the insertion of the screw.
- 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.
- The guide wires must remain in the correct position throughout the entire surgical procedure. It has to be ensured that guide wires stay in position before the screws are inserted.
- Only guide wires with a diameter less than 1.6 mm may be used. Silony Spine recommends a guide wire with a diameter of 1.5 mm.

5.7 Augmentation

- If additional anchoring stability is required, using fenestrated screws in combination with bone cement should be considered.

⚠ **To ensure correct application of the bone cement the corresponding instructions for use of the manufacturer of the bone cement must be considered.**

⚠ **Augmentation of the implants must be carried out with continuous monitoring by imaging.**

- The quantity of cement and the number of vertebrae to be reinforced must be assessed carefully by the treating physician. In patients with a severely impaired capacity of the heart and lungs, particular care must be taken to use the smallest possible quantity of cement.
- The perforation of the screw must be located in the vertebral body, close to the anterior wall of the cortex. If the implanted screws are too short, the bone cement is easily injected too close to the pedicle. If the implanted screws are too long or placed bicortically, the anterior wall of the cortex may be perforated, and cement leakage may occur.
- In case of an uncontrolled cement leakage, the application must be stopped.

⚠ **The risks associated with cement leakage can adversely impact the patient's health. In the event of perforation, particular care must be taken when applying bone cement. The injected cement can push bone marrow into the bloodstream and cause a fat embolism.**

- One VERTICALE Cement cannula is required for each screw. The needle must be left securely anchored in the screw head until the cement has fully cured, as cement can otherwise leak into the screw head. The screw head must be checked for traces of cement. Any cement residue must be removed.
- In patients with reduced bone density or poor screw anchorage, screws can become loose despite the augmentation procedure. Therefore, all active correction maneuvers should be made with additional monitoring.

5.8 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.

5.9 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 or implant components.
- 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.

5.10 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 patients with these implants can be scanned safely immediately after placement 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 2 W/kg for 15 minutes (per pulse sequence) of scanning using a 3-Tesla MR system.
- Migration: Due to the material used (titanium alloy / cobalt chromium molybdenum) 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.

5.11 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 System provides a means of replacing individual elements and extending the fusion length.

5.12 Disposal

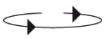
- Implants and instruments that can no longer be used can be disposed of in accordance with the national regulations applicable at the place of use or be returned to the manufacturer free of charge for proper disposal.
- Implants and instruments may only be returned to Silony Spine if they are still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

5.13 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*
CH REP	Swiss Authorized Representative
UK REP	United Kingdom Representative
CE 0483	The device meets the requirements of EU Regulation MDR 2017/745.
Rx only	Federal law in the USA restricts this device to sale by or on the order of a physician.
REF	Article number
LOT	Lot number
QTY	Number of items
MD	Medical device
UDI	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
STERILE R	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

Symbol	Description according to ISO 15223-1 and Silony specifications
	Patient Identification
	Health care center or doctor
	Date (of implantation)
	Contact
	Silony Logo (for identification of the legal manufacturer in the course of direct marking of products)
	Cannulated screw
	Cannulated fenestrated screw
	Solid screw
	MultiLocking screw
	Polyaxial screw
	Uniplanar screw
R	Offset hook right
L	Offset hook left
S	Size S
M	Size M
L	Size L
Ø	Diameter

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