Instructions for Use (D30008)

for Implants for Posterior Spinal Fixation VERTICALE®

Important Information — Please Read Before Use!

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These instructions for use apply to all spinal implants of the available VERTICALE systems. Other manufacturer's instructions are available that contain information that is required for application of the system. The additional information, such as instrumentation guides, inserts containing useful information, and other product-specific information, may be viewed under the following two links:

- elabeling.silony-medical.com/contact
- www.silony-medical.com

Instructions for use D30003 may be used as reference for reprocessing instruments. Instructions for use D30011 are for sterile instruments.

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

Prior to using a product distributed by Silony Medical, the surgeon is expected to closely study the following recommendations, warnings, and advice as well as the product-specific information. Silony Medical also recommends attending the corresponding user training courses.

We kindly request timely notification if complications should occur in connection with the implants and instruments used.

These instructions for use do not apply to the USA or its territories.

1 Product description

VERTICALE is a posterior double rod fixation system for stabilizing the thoracic, lumbar and iliosacral spine.

VERTICALE implants are manufactured from titanium alloy in accordance with ASTM F136/ISO 5832-3, cobalt chromium molybdenum as per ISO 5832-12 and ultra-high-molecular-weight-polyethylene Type 1 in accordance with ISO 5834-2, ISO 5834-1 and ASTM F 648-13. The materials are mutually compatible.

The product designation, article number, and lot number are indicated on the product label. When removing the implant from the packaging, the implant must be verified against the description on the packaging (article number / lot number / size). The article number is preceded by an "S" on the label of implants delivered sterile.

Implants of the VERTICALE System are supplied sterile and non-steril.

1.1 Sterile Implants

Sterile products are packaged in accordance with EN ISO 11607 Parts 1+2 and sterilized using gamma radiation at a minimum dose of 25 kGy.

Implants delivered by the manufacturer in a sterile condition may not be resterilized!

The implants must not be resterilized after opening the package—even if they were not used. Resterilization has not been validated for the implants.

The patient labels in the primary packaging must be attached to the patient file or the surgical report.

1.2 Non-sterile Implants

Implants that are supplied non-sterile must not be implanted without prior cleaning/disinfection and sterilization; see section 6 of these instructions for use.

2 General Information and Warnings

The VERTICALE System may only be used in the field of human medicine for the indications listed in section 3.

The VERTICALE System may only be used by surgeons who are familiar with spinal surgery and experienced in the product-specific surgical techniques. The surgical technique for implants from Silony Medical can be learned as part of guest visits during surgical procedures for demonstration purposes, workshops, and courses at a hospital familiar with these implants.

Implants are always part of a system. They may only be implanted with original parts belonging to the same system and used with the original instruments belonging to the same system unless they are instruments generally used in an operating room or instruments described in the instrumentation guide. Please note the system compatibility indicated in the instrumentation guide. Any liability for third-party instruments used by the purchaser or user is excluded. Exceptions to these rules require the express permission of Silony Medical.

The use of implants for other purposes is prohibited.

Complications or other consequences that may be due to an incorrect indication or surgical technique, unsuitable choice of material or treatment, improper use or treatment of the instruments, asepsis, etc., are the responsibility of the surgeon and cannot be attributed to the manufacturer, the importers, or suppliers of products of Silony Medical.

Preoperative planning:

The implantation of the VERTICALE must be precisely planned using a suitable imaging method. The potential success of surgery depends directly on the correct choice of implant. Radiographic images provide important information about the type of implant that is suitable, its size, and possible combinations. Neglecting to carry out appropriate preoperative planning can have a negative impact on the surgical outcome. Prior to the surgery, it must also be clarified whether the patient has an allergy to the implant material.

For the surgical procedure, all implants that may be required in the combination recommended by the manufacturer as well as the instruments needed for implantation must be available in the event that a different size or a different implant becomes necessary.

Notes on Use:

Implantation should generally only ever be considered if all other conservative treatment options have been carefully assessed and established as not being the better option. The attending physician is responsible for considering the possibility of implant surgery. VERTICALE is a system in which the physician can select the implant on a patient-specific basis.

Even a successfully implanted device is inferior to the healthy movement element(s) of the spinal column. Conversely, an implant can represent a beneficial replacement of one or more pathological and/or symptomatic movement element(s) for the patient because it can eliminate pain and therefore achieve improved mobility and stability.

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. This can lead to, e.g., implant fracture, wear, aging, and loosening, which can result in revision surgery. An infection in the vicinity of an implant is generally associated with negative consequences for the patient, as it usually becomes necessary to remove the implant.

Removal of the implant is possible, provided it is performed in accordance with the instrumentation guide. The decision must be made by the attending physician. If fusion has already occurred, the implant can be removed without additional measures. However, this is not necessary and is usually not done due to the high levels of stress associated with the surgery. However, if additional stabilization of the spinal column is necessary, this must be done by replacing the implants. For revisions, the VERTICALE System also provides a means of replacing individual elements and extending the fusion length.

Warnings:

Implants must not be mechanically processed or modified in any other way unless this is expressly stipulated in the instrumentation guide. In case of doubt, a written recommendation must be obtained from the manufacturer. Implants that are contaminated, non-sterile, damaged, or scratched or implants that have been improperly treated or processed without authorization must not be implanted under any circumstances. They must be returned to the supplier for checking and proper disposal.

Prior to implantation, the implant must be visually inspected for damage. Damaged implants must not be used.

Implants are for single use only and must not be reprocessed after use in a patient and contamination with blood or tissue. Reusing an implant or implant component that was previously implanted in the body of the patient or reusing an implant that has come into contact with body fluids or tissues of a third person is prohibited.

Violations may result in the following health risks:

- Risk of transfer of pathogens due to inadequate cleaning
- Limited functionality due to cleaning, disinfection and sterilization
- Risk of cross-infection

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.

When removing the implants from the trays, particular attention must be paid to ensure that those implants remaining in the tray are not contaminated with blood, tissue, or other contaminants. Implants must always be removed with the utmost care and never while wearing contaminated gloves.

In the event of overloading, damage or improper implantation or handling, implants may fracture, become loose, wear out or become functionally impaired. In isolated cases, there may be corrosion of the implant.

Any additional warnings (e.g. warning label on the packaging) must be observed.

Magnetic resonance compatibility:
The VERTICALE implants have not been tested for migration or warming in the MR environment. In computed tomography (CT) or magnetic resonance imaging (MRI) examinations, the implant may become displaced or surrounding bone tissue may become warm. The formation of artifacts due to the in-situ implant can make it more difficult to evaluate the examination result.

Patient information:
The physician is responsible for informing the patient about the risks of implantation and about the outcome of the surgery and any negative effects. In addition, the patient must be informed about the measures he/she can take to minimize the possible effects of these factors. The patient must also be issued with an implant pass.

The patient must be informed that implants can have an impact on the outcome of CT scan or MRI examination as well as about possible negative consequences. The patient must also be instructed to inform the examining physician about the implant and to show his/her implant pass prior to a scheduled CT scan or MRI examination.

All information given to the patient should be documented by the surgeon in writing.

Warnings:
- In case of fractures and tumors with poor anterior support, additional anterior support or reconstruction of the spine is required.
- Severe comorbidities require interdisciplinary consultation.
- Any condition that could exclude the potential benefit of a spinal implantation must be clarified by the physician using the implant. This may include tumors, local fractures in the surgical area, unexplained elevation of the blood sedimentation rate, elevated leukocyte count, or a significant leftward shift in the differential blood count or other parameters.
- Implants may lead to artifacts during imaging procedures.
- 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.
- Asymmetrical insertion results in insufficient space for inserting the screws with the instruments, screw shaft not inserted analogous to the end plates, angles were not varied—collision of the screw heads, locking of the pressure piece disengages with increased application of force. When inserting the guide wires, always try to position them as symmetrically as possible along the path of the pedicle.
- The cannulated screws can be implanted under guidance with a guide wire.
- You must check under the image intensifier 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. You must make sure that the guide wires do not slip out before the screws are inserted.
- Only guide wires with a diameter less than 1.6 mm may be used. Silony Medical recommends a guide wire with a diameter of 1.5 mm. One type of screw (ilium screw) requires a 3.2 mm guide wire. 3.2 mm guide wires are supplied with the general instruments for this specific procedure.
- If the implant is used in patients with osteoporosis, additional anchoring stability, for example, by using bone cement, should be considered.
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- For augmentation, one VERTICALE Cement Delivery Needle 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.
- Follow the instructions for use of the bone cement manufacturer to ensure correct application.
- 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.
- It is recommended to continuously monitor the cement flow radiographically (AP and lateral). In case of an uncontrolled escape of cement or 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.
- If the screws are too short, the bone cement is easily injected too close to the pedicle. If the screws are too long or placed bicortically, the anterior wall of the cortex may be perforated and cement leakage may occur. The perforation of the screw must be located in the vertebral body, close to the anterior wall of the cortex.
- In patients with reduced bone density or poor screw anchorage, screws can become loose despite the augmentation procedure. Therefore, all active corrections should be made with additional monitoring.
- Implants and implant components that consist of or are assembled using various components have to be cleaned from impurities that have developed during the surgery prior to the reduction or assembly, as impurities such as foreign particles, bone chips or residual bone cement may lead to wear, functional impairment, insufficient stability of the connection or breakage of the implants or implant components.

3 Indications

The VERTICALE system is indicated for use in the thoracic and lumbar spine and for iliosacral fixation procedures (T1–S2/ilium). This includes all kinds of thoracic, lumbar and iliosacral instabilities or deformities that require comprehensive posterior screw and rod fixation:

- Degenerative disc diseases
- Spondylolisthesis of all etiologies
- Stenosis
- Deformities such as scoliosis and kyphosis
- Fractures
- Spondylitis

- Tumors
- Revisions
- Pseudarthrosis

There are no restrictions with regard to the sex of the patient. 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. 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. There is no upper age limit.

4 Contraindications

4.1 Absolute Contraindications

Under certain circumstances, implantation is prohibited or associated with substantial risks, even though it may be indicated. These include in particular:

- 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, or osteoporosis).

4.2 Relative contraindications

- Overweight patient
- Deformities
- Fever or leukocytosis
- Local bone tumors
- 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
- Osteoporosis or osteomalacia
- 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.
- Any patients with insufficient tissue coverage
- Severe muscle, nerve, or vascular disorders that endanger the affected extremities
- Acute or chronic infections, local or systemic

5 Possible Negative Consequences

Possible risks that were identified in connection with use of this system, and which may require further treatments, include the following:

- 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
- 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.

6 Cleaning/Disinfection and Sterilization

This section applies only to implants that are supplied non-sterile. Implants delivered by the manufacturer in a sterile condition may not be resterilized.

Implants that are delivered non-sterile must not be implanted without prior cleaning/disinfection and sterilization. Effective cleaning and disinfection is a prerequisite for effective and adequate sterilization of the implants. The original packaging must be completely removed before cleaning the product for the first time.

The Silony Medical accessories comprise trays (mesh trays) including storage elements and are used to hold and store implants during automated cleaning, thermal disinfection, steam sterilization and transport.

To this purpose the trays are equipped with holders that are adapted to the implants.

After cleaning and disinfection in the WD, the trays loaded with implants are placed in the sterilization container, which is then subjected to steam sterilization while closed.

The trays and containers and thus their handling comply with the usual hospital standards. For the reprocessing of accessories (trays and containers) the Reprocessing Instructions for Instruments (D30003) must be observed.

The Silony Medical accessories are intended for use in combination with the implants from Silony Medical and must not be used for products from other systems.

Within the scope of your responsibility for the sterility of the implants before use, please ensure that only process- and product-specific validated procedures for cleaning/disinfection and sterilization may be used and that the correspondingly validated processes must be complied with for each cycle.

Please also comply with the applicable legal provisions and the relevant hygiene regulations of the health authorities in your country.

6.1 Cleaning/Disinfection

The following general rule applies: automated processing must be used for cleaning and disinfection. Manual reprocessing—even if this includes use of an ultrasonic cleaning bath—must not be used because of its markedly lower effectiveness.

Requirements for the cleaning and disinfection procedure:

- The cleaning and disinfection equipment (WD) used must comply with the standard EN ISO 15883 and must have the CE mark.
- Validated reprocessing procedures
- Regular servicing and testing of the CDE
- The program used must meet the minimum requirements in Table 1.

Selecting cleaning agents and disinfectants:

When selecting the cleaning agent system to be used, please ensure that the chemicals used are compatible with the implants. The implants must not come into contact with agents containing chlorine, phosphorus, formaldehyde or fluorine, bleaching agents, detergents containing fats, or strong acids and alkalis (bases).

It is crucial that the concentrations and exposure times indicated by the manufacturer of the cleaning agents and, where applicable, disinfectants are observed.

For cleaning, a cleaning agent with a pH value of > 10 is recommended. The pH value of the Neodisher MediClean forte (Dr. Weigert) product used for the validation is between 10.4 and 10.8 at the dosage indicated in Table 1.

Workflow:

1. Remove the implants from the protective packaging and place them into the fixture in the tray insert.
2. Position the tray according to the validated procedures into the washer-disinfector, ensuring that no areas are left unwashed (attention: do not stack multiple trays on top of one another. Automated cleaning in the WD must always be carried out without a cover.)
3. Starting the program
   The cleaning process was specified by us for the validation as follows:

Level	**Water**	**Cleaning agent**	**Temperature**	**Holding time**
Pre-wash	Tap water	-	unheated	2 min
Emptying	-	-	-	-
Main cleaning	Tap water	DOS 0.5%*	55°C	5 min
Emptying	-	-	-	-
Rinsing	Demineralized water**	-	unheated	3 min
Emptying	-	-	-	-
Rinsing	Demineralized water**	-	unheated	2 min
Emptying	-	-	-	-
Thermal	CDE program on thermal disinfection:			

disinfection	The country-specific national requirements for the applicable A_0 value must be taken into account. If no other value is specified, an A_0 value of at least 3000 must be used.
Drying	Drying with hot air using the program and parameters validated by the WD manufacturer. Program with adequate drying of the products with at least 10 minutes holding time. Please also note the instructions of the WD device manufacturer.

*Neodisher MediClean forte (Dr. Weigert) **Demineralized water: *Table 1*

4. After the program has ended, remove the tray from the WD and release the cleaning lot.
5. Pack the tray as soon as possible after removal and, if applicable, cool.

Proof of basic suitability of the implants for effective automated processing was provided by an independent, certified test laboratory using the WD: Cleaning and Disinfection Equipment: Getinge 88/Miele G7836CD. The procedure outlined above was taken into consideration.

6.2 Sterilization

Only sufficiently cleaned, disinfected implants packaged in a suitable and approved SBS (Sterile Barrier System) may be sterilized. The implants may be sterilized only with a validated steam sterilization method in accordance with EN ISO 17665. A fractioned vacuum procedure must be used.
The following requirements for the parameters apply:

- Steam sterilizer in accordance with EN 13060 and EN 285
- Valid commissioning and performance evaluation
- Minimum sterilization temperature 134°C
- Maximum sterilization temperature 137°C (value corresponds to minimum temperature plus tolerance of + 3°C in accordance with EN 285)
- Minimum sterilization time (holding time): 3 minutes
- Sufficient drying of the products at the end of the process of at least 10 min

Proof of basic suitability of the implants for effective steam sterilization was provided by an independent, accredited test laboratory using the fractionated vacuum procedure (Selectomat HP 666-1 HRED of the company MMM Münchener Medizin Mechanik GmbH, Planegg). The procedure outlined above was taken into consideration.

As a general rule, sterilization with hot air must not be used (implants can be destroyed). The use of other sterilization procedures (e.g., ethylene oxide, formaldehyde, radiation, and low-temperature plasma sterilization) is beyond the manufacturer's responsibility.

6.3 Directions for Recleaning and Resterilization:

Implants that are supplied non-sterile can be added to the cleaning and sterilization process multiple times provided that they have not been contaminated with body fluids, blood, bone, and the like, including via gloves. Prior to resterilization, the parts must be inspected for damage and then cleaned and disinfected in a validated procedure separately from soiled and contaminated material.

In the event of contamination of the holders or other points of the storage system supplied by Silony Medical, this must be brushed off thoroughly and rinsed until no more soiling is visible.

Important advice:
If a product from Silony Medical is sterilized or resterilized by the user, this must be documented and the relevant verification documents must be archived.

The cleaning and sterilization or resterilization process used in the hospital must be revalidated at regular intervals and the correct settings of the relevant equipment in particular must be checked at regular intervals.

The rules of asepsis must be observed for the implantation.

7 Handling and Storage

Implants are extremely sensitive to damage. Even minor scratches or impact sites on the surfaces lead to excessive wear and tear and can give rise to complications. Extremely careful handling is therefore required.

Only the respective Silony Medical instruments and manipulation implants (trial implants) must be used when selecting and adjusting the implants.

Implants must be stored in the unopened original packaging and must not be damaged.

Implants that are supplied sterile must be stored until use in the sealed sterile packaging in accordance with the storage conditions indicated on the product label. Sterile packed products for which the expiration date of the sterile packaging has expired must not be used. The integrity of the packaging must always be checked in order to ensure that sterility has not been impaired. If the protective packaging of sterile packed products has been opened but the product was not used for the surgical procedure, the product is considered used and must not be used. The rules of asepsis must be observed during removal from the sterile packaging.

Implants that can no longer be used can be disposed of in accordance with the 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 Medical if the products are still in the undamaged original package or have been cleaned, disinfected, and sterilized. Proof of such treatment is to be attached to the outermost packaging.

When transferring Silony Medical products (for payment or free of charge), every entity transferring a product must ensure that the product can be traced at all times (lot tracking).

8 Summary of Safety and Clinical Performance (SSCP)

According to Article 32 of the MDR, manufacturers of implantable medical devices and of risk class III medical devices must compile an SSCP, which will be verified by the Notified Body and then published by the Notified Body in the European database (EUDAMED).

9 Labeling and Symbols

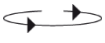
Each implant is labeled using laser inscription and contains the following information: the manufacturer's logo, the article number, the article name, the lot number, and the CE mark.
The CE mark with the code number of the Notified Body (CE_{0483}) applies for class IIb and class III implants.
In addition, the information and symbols on the packaging must be observed.

Manufacturer

US representative

Article number

Batch code

QTY	Number of items
	Store in a dry place
	Keep away from sunlight
	Do not use if the packaging is damaged
	Consult instructions for use
	Caution—consult instructions for use
CE 0483	The product meets the requirements of EU Directive 93/42/EEC.
	Do not reuse
	Do not resterilize
	Use by *Including the year and month in the following format: YYYY-MM-DD*
STERILE R	Sterilized using irradiation
	Non-sterile
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Contact
Color on the label	The color on the label helps to make the correct choice of cage size: please consult the instrumentation guide for more information.
	Cannulated screw
	Cannulated fenestrated screw
	Solid screw
	Torx connection
	Hex connection
	MultiLocking screw
	Polyaxial screw
	Uniplanar screw
R	Offset hook, right
L	Offset hook, left

S	Size S (short/small)
M	Size M (medium)
L	Size L (long/large)
Ø	Diameter

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