EN

Silony Medical GmbH
Leinfelder Strasse 60
70771 Leinfelden-Echterdingen
Germany

Telephone +49 (0)711-782 525 0
Fax: +49 (0)711-782 525 11

Silony Medical Europe GmbH
An der Weide 27-29
28195 Bremen
Germany

Telephone +49 (0)421-246 956 0
Fax: +49 (0)421-246 956 55
E-mail: info@silony-medical.com

Instructions for Use for Spinal Implants for Posterior Spinal Fixation

VERTICALE® CERVICAL

CE 0483

Important Information—Please Read Before Use!

Table of Contents

These instructions for use apply to VERTICALE cervical sterile spinal implants. Further instructions of Silony are available containing information required for application of the system:

- Reprocessing Instructions for Instruments (D30003)
- Instrumentation Guide for VERTICALE (D30000)
- Instructions for Use for VERTICALE Sterile Instruments (D30011)
- Instrumentation Guide for VERTICALE Augmentation (D30015)
- Instrumentation Guide for VERTICALE Hooks (D30041)
- Instrumentation Guide for VERTICALE MIS (D30049)
- Instrumentation Guide for VERTICALE cervical (D30183)
- Product-specific supplemental information

Any manufacturer´s liability is excluded in the event non-compliance with the manufacturer's instructions for Use during application of the device.

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 supplemental information. Silony Medical also recommends attendance at applicable user training courses. We kindly request of a notification, if complications should occur in connection with Silony Medical implants and instruments used.

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

EN

1 Product Description

VERTICALE cervical is a posterior double rod fixation system immobilization and stabilization of the occipito-cervico-thoracic regions of the spine.

The VERTICALE cervical system is consisting of polyaxial (PA) and far angle (FA) screws, rods, occiput plates, connectors and the related instrumentation. VERTICLE cervical implants are manufactured from titanium alloy in accordance with ASTM F136 / ISO 5832-3.

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 cervical System are supplied sterile and are intended for single use.

1.1 Sterile Implants

Sterile products are packaged in an appropriate sterile barrier consisting from PETG - blister and Tyvek foils and are sterilized using gamma radiation at a minimum dose of 25 kGy.

The packaging conforms with EN ISO 11607 Parts 1+2. 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.

2 Intended Use

The VERTICALE cervical system is intended to to provide immobilization and stabilization of spinal segments of the craniocervical junction (occiput-C2), subaxial cervical spine (C3-C7) and upper thoracic spine (T1-T3).

3 Indications

The VERTICALE cervical system is indicated for use in the occipito-cervico-thoracic regions for the following indications:

- Degenerative disc diseases (DDD)
- Instabilities
- Trauma
- Deformities

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. Particularly for children, this requires weighing up by an experienced surgeon who needs to make a basic assessment about the suitability and size of the implant with respect to the as yet 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.
- Fever or leucocytosis.
- 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 General Information and Warnings

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

The VERTICALE cervical 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 combined with original parts belonging to the same system and implanted 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 occur due to the application of the device for an incorrect indication or due to use of a not suitable 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 cervical 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 and components in the combination recommended by the manufacturer that may be required 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, as it can help 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 stiffening 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 cervical 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 control 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 followed.

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 increase in the blood sedimentation rate, increase in leucocytes or a significant leftward shift in the differential blood count or of 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 insertion of the screws with the instruments, screw shaft not inserted analogous to the end plates, angle not varied—collision of the screw heads, caulking of the pressure piece loosens with increased force. When inserting the guide wires, always try to position them as symmetrically to one another as possible in accordance with the course of the pedicles.
- 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 1.4 mm may be used. Silony Medical recommends a guide wire with a diameter of 1.3 mm.

6 Possible Negative Consequences

Possible risks that were identified in connection with use of this system as with every OCT spinal 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 due to wear
- Loss of correction due 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

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

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.

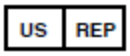
Implants that are supplied sterile must be stored until use in the sealed sterile packaging in accordance with the storage conditions indicated on the product label. Sterile packed products for which the expiration date of the sterile packaging has expired must not be used. The integrity of the packaging 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 has not been used for the surgical procedure, the product is considered used and must be disposed of according to the national laws and regulations. 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 passing on Silony Medical products (in return for payment or free of charge), any party passing on a product must ensure that appropriate traceability (lot tracking) is possible at all times.

The information and symbols on the packaging must be observed.

8 Glossary of Symbols

Symbol	Explanatory Text
	Manufacturer
	US representative
	Catalogue number
	Batch code
	Keep dry / Keep away from rain
	Keep away from sunlight
	Do not use if the packaging is damaged
	Consult instructions for use
	Attention - read instruction for use
	The device complies with European Directive MDD 93/42/EEC
	Do not reuse
	Do not resterilize
	Use- by- date *Including the year and month in the following format: YYYY-MM-DD*
	Sterilized using irradiation
	Non-sterile
	Prescription Use only
	Quantity
	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 and fenestrated screw
	Solid screw

	Polyaxial screw
	Uniplanar screw
	Farangel screw
R	Offset Hook, right
L	Offset Hook, left
S	Connector Size S (short)/ Hook Size S (small)
M	Connector Size M (medium)
L	Connector Size L (long)/ Hook Size L (large)
Ø	Diameter