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Instructions for Use for Spinal Implants for the Triangular Fixation System of

VERTICALE®

CE 0483

Important Information—Please Read Before Use!

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These instructions for use apply to VERTICALE Triangular Fixation implants. Other manufacturer's instructions are available containing information required for application of the system:

- Reprocessing Instructions for Instruments (D30003)
- Instrumentatin Guide for VERTICALE Triangular Fixation (D30XXX)
- Instrumentation Guide for VERTICALE Spine Fixation System (D30000)
- IFU for sterile instruments (D30011)
- Product-specific inserts

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 attendance at applicable user training courses. We kindly request timely notification if complications 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

The VERTICALE Triangular Fixation System is intended to be used for lumbo-pelvic, posterior pelvic ring and sacro-iliac stabilization procedures.

The VERTICLE Triangular Fixation implants are manufactured from titanium alloy in accordance with ASTM F136 / ISO 5832-3 and Ultra-high-molecular-weight polyethylene Type 1 in accordance with ISO 5834-2:2011, ISO 5834-1:2005 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).

Implants of the VERTICALE Triangular Fixation System are supplied sterile.
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 re-sterilized!

The implants must not be re-sterilized after opening the package - even if they were not used. Re-sterilization 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 General Information and Warnings

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

The VERTICALE Triangular Fixation System may only be used by surgeons who are familiar with pelvic ring and iliosacral 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 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 Triangular Fixation 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, trajectory 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 Triangular Fixation 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 lumbar spine, the pelvic ring and the iliosacral region.

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 lumbo-pelvic, posterior pelvic or iliosacral region is necessary, this must be done by replacing the implants. For revisions, the VERTICALE Triangular Fixation System also provides a means for revision surgery.

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.

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.

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 artefacts 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 spinal fractures and tumours with poor anterior support, additional anterior support or reconstruction of the spine is required.
- In case of an anterior pelvic ring instability additional anterior support of the pelvic ring may be considered.
- 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 tumours, 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 artefacts 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 has 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).
- During setup for surgery, it is important to confirm the adequacy of C-arm imaging. This is essential to avoid errors during implantation. It is important to identify the sacral foramina, spinal canal and S1 body intraoperatively. If these structures cannot be clearly seen, a safe trajectory of the implant cannot be determined.
- Inadequate placement, selecting the incorrect size for the implants or other errors, such as a faulty alignment of the guide wire, initial pre-drilling or using an awl that is too pointed, may lead to injury of the neurological or vascular structures and to paralysis or to the implant 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 implant. The tip of the guide wire in particular should be monitored under imaging to ensure that it does not perforate the bony structure and potentially damage the neurological or vascular structures.
- 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.
- 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 Screw type (iliac screw) requires a 3.2mm guide wire. 3.2mm guide wires are provided with the general instruments for this specific procedure.
- If the implant is used in patients with osteoporosis, additional anchoring stability such as bone cement should be considered.
- For augmentation, dedicated Cement Delivery systems are required for each screw. Follow the instructions for self-secure anchorage of the cement delivery system 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 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. 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 spinal pedicle screws are too short, the bone cement is easily injected too close to the pedicle. If those 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 spinal pedicle screw must be located in the vertebral body, close to the anterior wall of the cortex.
- If the SI screws are too short, the bone cement is easily injected too close to the SI-joint. The perforation of the SI screw must be located in a secure bony structure.
- 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 Triangular Fixation System is intended to be used for lumbo-pelvic, posterior pelvic ring and sacro-iliac stabilization procedures.
This includes:

- Pelvic ring instabilities
- Iliosacral instabilities
- Lumbo-pelvic instabilities

due to fractures, tumours, osteoporoses, trauma, injuries, etc.

There are no restrictions with regard to the sex of the patient. The VERTICALE Triangular Fixation System is intended to be used by (experienced) trauma, neuro- and orthopaedic surgeons.
The VERTICALE Triangular Fixation System is intended to be used in skeletally mature patients.

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 polymer).
- 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 fractures, tumours, or osteoporosis).

4.2 Relative Contraindications

- Untreated anterior instability of the pelvic ring
- Bony deformities in the region of treatment
- Overweight patient
- Deformities
- Fever or leukocytosis
- Local bone tumours
- 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
- Deformities
- 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 neurological or to vascular structures

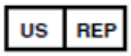
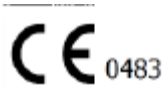
- Injury to soft tissue and other tissues
- Perforation of the vertebral body and subsequent perforation of major vessels
- Intolerance, irritation, skin sensitization, local effects following implantation, irritation, and delayed-onset allergic reactions, cancer/death
- Delays in the course of surgery
- 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
- Periprosthetic osteolysis.

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

6 Handling and Storage

Implants are sensitive to damage. Even minor scratches or impact sites on the surfaces lead to excessive wear and tear and can give rise to complications. Careful handling is essential. Only the respective Silony Medical instruments must be used when selecting and adjusting the implants.
Implants must be stored in the unopened original packaging and must not be damaged. Implants 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 is damaged, they must not be used. 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.

7 Glossary of Symbols

	Manufacturer
	US representative
	Catalogue number
	Batch code
	Quantity
	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 *Including the year and month in the following format: YYYY-MM-DD*

	Sterilized using irradiation
	Non-sterile
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Contact
	Torx connection
	Hex connection
S	S Size indicator Iliac screw
M	M Size indicator Iliac screw
L	L Size indicator Iliac screw
Ø	Durchmesser
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.