Instructions for Use (D30174) SI Fixation System

VERTICALE®

Important Information—Please Read Before Use!

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These Instructions for Use apply to VERTICALE SI Fixation implants.
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:

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

In addition, the:

- Instructions for Use D30003 must be used as reference for reprocessing instruments.
- Instructions for Use D30011 must be used 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 attendance at applicable 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

The VERTICALE SI Fixation System is intended for surgical use in pelvic ring and iliosacral stabilization procedures.

VERTICLE SI Fixation implants are manufactured from titanium alloy in accordance with ASTM F136 / ISO 5832-3. 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 SI 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 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 General information and warnings

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

The VERTICALE SI 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 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 SI 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 SI 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 pelvic ring and 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 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 pelvic ring or iliosacral region is necessary, this must be done by replacing the implants. For revisions, the VERTICALE SI Fixation 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 inspection 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 damage 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 SI Fixation 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:

- 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.
- 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 vertebral body intraoperatively. If these structures cannot be clearly seen, safe insertion of the implant cannot be ensured.
- Inadequate placement, selecting the incorrect size for the implants or other errors, such as incorrect 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.
- 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.
- In patients with reduced bone density or poor screw anchorage, screws can become loose. Therefore, all active corrections should be made with additional monitoring.

3 Indications / Intended purpose

The VERTICALE SI Fixation System
is intended for surgical use in pelvic ring and iliosacral stabilization procedures. The VERTICALE SI Fixation System is intended to be used for the following indications:

- Pelvic ring instabilities
- Iliosacral instabilities

There are no restrictions with regard to the sex of the patient. The VERTICALE SI Fixation System is intended to be used by (experienced) trauma, neuro- and orthopedic surgeons.
The VERTICALE SI Fixation System is intended to be used in skeletally mature patients.
Dependent on the complexity of the fracture and choice of the surgeon, the VERTICALE SI Fixation System is placed via a posterior or postero-lateral (percutaneous) approach.

Product-specific intended purpose of the SI screw (iliosacral screw)
The SI screw is inserted from lateral through the iliac bone and the ala into the sacrum. Through the use of the partially threated SI screw (lag screw) option, an additional compression of the fracture can be achieved. The screws can be augmented with bone cement with the objective to increase fixation of the SI screw.

The SI screw is offered in two options:
VERTICALE SI Screw with washer:
The washer distributes the load and avoids subsidence of the SI screw into the lateral iliac cortex.

VERTICALE SI Screw w. plate:

The plate enables fixation as a stable angle locking screw (VERTICALE SI Plate fixation screw) and avoids subsidence of the SI screw into the lateral iliac cortex.

4 Contraindications

4.1 Absolute contraindications

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

- Anticipated or documented allergy or intolerance to the materials (e.g., titanium)
- 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 bone structures that render good anchoring of the implant impossible.

4.2 Relative contraindications

- Untreated ventral instability of the pelvic ring
- Bony deformities in the region of treatment
- Overweight patient
- 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
- 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
- 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
- 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
- Intolerance, irritation, skin sensitization—local effects following implantation, irritation, and delayed-onset allergic reactions, cancer/death
- Delays in the course of surgery
- Revisions
- Visceral and vascular complications

- Corrosion
- Toxic hazards due to insufficient cleaning and sterilization
- Pseudarthrosis
- Perforation of the cortex

General surgical risks include anesthesia and postoperative risks include 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 and 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.

Only the respective Silony Medical instruments must be used when selecting and adjusting the implants. The 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. 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.

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.

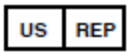
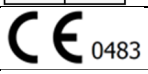
The information and symbols on the packaging must be observed.

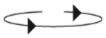
7 Reporting of incidents

Users and/or patients are obliged to report all serious incidents involving the device to the manufacturer and the competent authority of the Member State.

8 Glossary of symbols

The CE mark with the code number of the Notified Body applies to all class IIb implants in the VERTICALE SI Fixation System.

Symbol	Description according to ISO 15223-1 and Silony specifications
	Manufacturer
	US representative
	Swiss agent
	The device meets the requirements of EU Regulation MDR 2017/745
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Article number
	Batch code
	Number of items
	Medical device
	Unique Device Identification
	Use by *Including the year and month in the following format: YYYY-MM-DD*
	Consult Instructions for Use
	Caution – consult Instructions for Use
	Double sterile barrier system sterilized by irradiation with additional protective packaging
	Sterilized using irradiation
	Non-sterile
	Do not reuse
	Do not resterilize
	Do not use if the packaging is damaged
	Store in a dry place
	Keep away from sunlight
	MR* safe

Symbol	Description according to ISO 15223-1 and Silony specifications
	Caution MR* conditional safe
	Attention MR* unsafe
	Metal detectors can trigger alarm due to the implant
	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
	Far-angle 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

*the term MR is synonymous with MRI and means magnetic resonance imaging

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