**Instruction for use (D30307)**

# VERTICALE® SI Fixation System
# VERTICALE® Triangular Fixation System

**Important Information – please read before use!**

## Table of contents



This Instruction for use covers implants of the VERTICALE SI Fixation System / VERTICALE Triangular Fixation system.

This and other product specific information (e.g. instrumentation guides) as well as product accompanying information in other relevant official languages are available under the following links:

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

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

The short summaries of safety and performance (SSCP) of Silony implants are available in the European Database for Medical Products (EUDAMED) and are provided by Silony Spine upon request.

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

Prior to using a product distributed by Silony Spine, the surgeon is expected to carefully study the following indications/contraindications, recommendations, warnings, and advice as well as the product specific information. Silony Spine also recommends participation in appropriate user training.

Users and/or patients are required to report any (serious) adverse events related to the device to the manufacturer and to the state competent authority.

This Instruction for use does not apply to the USA or its territories.

# 1 Product description

## 1.1 General Information

VERTICALE SI Fixation system (SI System)

The VERTICALE SI Fixation system is intended for the stabilization of the posterior pelvic ring and the sacroiliac region in skeletally mature patients.

The VERTICALE SI system provides stabilization of the fracture site in order to enable bone healing. By screwing a fully threaded or partially threaded SI screw through the fracture plane, both ends of the fracture site are held together. The SI lag screw allows for compression in the non-threaded section. With the fully threaded screw a compression is not possible.

The SI fixation screw is intended to provide additional stabilisation. The SI screws can be augmented. Both the washer and the plate are used to prevent subsidence of the screws into the bony surface, due to its increased surface.

VERTICALE Triangular Fixation system (TriFix System)

The VERTICALE Triangular Fixation System consists of iliac screws, SI screws, SI plate fixation screws, a polyaxial head and cap as well as related instruments. It combines the iliac screws with UHMWPE-inlay and SI screws from the VERTICALE SI Fixation System to perform a triangular stabilization procedure.

The iliac screw has a dual core shank, while the proximal shank is enlarged to support fixation in the os ilium. This proximal shank region includes a window for accepting an UHMWPE insert. This feature allows the user to select the orientation intraoperatively and to enable a screw in screw placement of a SI screw through a lateral access. Placement of the SI screw through the UHMWPE-inlay of the iliac screw shall enhance primary fixation.

The iliac screw offers the possibility of in-situ assembly of a polyaxial head for a lumbosacral connection to the VERTICALE system. If desired by the surgeon, a cap can be used to cover the proximal region of the iliac screw if the polyaxial head is not used. This means the iliac screw shank can be left in the os ilium during revision surgery.

The construct of the lumbo-pelvic fixation is called a triangular osteosynthesis.

## 1.2 Performance characteristics

The SI screw is inserted laterally through the ilium and the ala into the sacrum. If a partially threaded screw (SI lag screw) is used, compression of a fracture can also be performed. An additional option for augmentation with bone cement can improve the anchoring of the SI screw. The SI screw is available in two versions. With the VERTICALE SI screw with washer, the load is distributed, and the SI screw is prevented from sinking into the lateral cortex of the ilium. The VERTICALE SI screw with plate enables fixation using a locking screw and prevents the SI screw from sinking into the lateral cortex of the ilium.

Iliac screws are inserted into the ilium (iliac crest). They are used to introduce and distribute spinal loads into the pelvic ring. They can be used alone or in combination with the VERTICALE rod-screw system to achieve correction, immobilization and stabilization of the pelvic ring, thoraco-lumbar and ilio-sacral spine. Due to the proximal fenestration of the screw shaft, a VERTICALE SI (ilio-sacral) screw can be placed laterally through this fenestration.

## 1.3 Combination with other products

The iliac screw of the VERTICALE Triangular Fixation System is designed to be combined with the VERTICALE SI Fixation System.
For additional stabilization of the VERTICALE system, the SI screw can be used with a bone cement that is suitable and specifically designed for the spine.
The VERTICALE Triangular Fixation System can be combined with the VERTICALE posterior spinal fixation system.

Please refer to the corresponding product information.

### 1.4 Material

Implants of the VERTICALE SI Fixation System and the VERTICALE Triangular Fixation System are manufactured from titanium alloy Ti6Al4V ELI (ELI = extra low interstitials) in accordance with ASTM F136 and ISO 5832-3. The inlay of the Ilium screw is made of ultra high molecular weight polyethylene (UHMWPE) in accordance with ISO 5834-2, ISO 5834-1 and ASTM F648.

Table 1: Material data implants

| Chemical composition (elements) according to ASTM F136 | Percentage of chemical elements in the total product [% (mass/mass)] |
|---|---|
| [Al] Aluminum | 5.5 - 6.5 (5.5 - 6.75)* |
| [V] Vanadium | 3.5 - 4.5 |
| [Fe] Iron | 0.25 maximum (0.3 maximum)* |
| [O] Oxygen | 0.13 maximum (0.2 maximum)* |
| [C] Carbon | 0.08 maximum |
| [N] Nitrogen | 0.05 maximum |
| [H] Hydrogen | 0.012 maximum (0.015 maximum**)* |
| [Ti] Titanium | 88.478 – 91 (88.105 – 91)* |

Table 1: Material data iliac screw

| Material | Material-specific weight [% (mass/mass)] of the total product | Percentage of chemical elements according to standard [% (mass/mass)] | | Percentage of chemical elements in the total product [% (mass/mass)] |
|---|---|---|---|---|
| Ultra high molecular weight polyethylene | 2.31 – 3.98 | UHMWPE | 100 | 2.31 – 3.98 |
| Ti6Al4V ELI | 96.02- 97.69 | [Al] Aluminum | 5.5 - 6.5 (5.5 - 6.75)* | 5.28 – 6.37 (5.28 – 6.61)* |
| | | [V] Vanadium | 3.5 - 4.5 | 3.36 – 4.41 |
| | | [Fe] Iron | 0.25 maximum (0.3 maximum)* | 0.240 – 0.245 (0.288 – 0.294)* |
| | | [O] Oxygen | 0.13 maximum (0.2 maximum)* | 0.12 – 0.13 (0.192 – 0.196)* |
| | | [C] Carbon | 0.08 maximum | 0.077 – 0.078 |
| | | [N] Nitrogen | 0.05 maximum | 0.048 – 0.049 |
| | | [H] Hydrogen | 0.012 maximum (0.015 maximum**)* | 0.0115 – 0.118 (0.0144-0.0147)* |
| | | [Ti] Titanium | 88.478 – 91 (88.105 – 91)* | 84.69 – 88.63 (84.60 – 88.51)* |

** Specification according to ISO 5832-3*
***(from ISO 5832-3) for using blocks as raw material, the maximum hydrogen content must not exceed 0.01%.*

### 1.5 Information about special substances

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

## 2 Clinical application

### 2.1 Intended use

VERTICALE SI Fixation System

The VERTICALE SI Fixation system is intended for the stabilization of the posterior pelvic ring and the sacroiliac region in skeletally mature patients. The implants can be placed via a posterior or postero-lateral (percutaneous) approach.

VERTICALE Triangular Fixation System

The VERTICALE Triangular Fixation System is intended for the correction, immobilization, and stabilization of the lumbo-sacral spine, the posterior pelvic ring and the sacroiliac region in skeletally mature patients. If required, it can be combined with the VERTICALE pedicle screw system.

### 2.2 Indications

The VERTICALE Triangular Fixation and VERTICALE SI Fixation systems can be used to treat the following indications:

- Pelvic ring instabilities
- Iliosacral instabilities
- Lumbosacral instabilities (applicable for Triangular Fixation system only)

Due to e.g., trauma, degenerative diseases, tumors, osteoporosis.

### 2.3 Contraindications

There may be absolute or relative factors for not using the product. The decision to use a particular implant must be carefully considered, taking into account the patient's anamnesis. The following circumstances can affect the success of the treatment.

#### 2.3.1 Absolute contraindications

- Expected or documented allergy or intolerance to the materials used
- Missing bone structures, which would render stable fixation of the implants impossible
- Any conditions not described in the indications

#### 2.3.2 Relative contraindications

- Untreated ventral instability of the pelvic ring
- Expected implant overload
- Acute or chronic infections
- Systemic diseases and metabolic disorders
- Unbalanced diet, medicinal drug abuse; nicotine, alcohol or drug abuse
- Patient who is mentally or physically unable or unwilling to understand and follow the physician's instructions
- Any patient for whom the use of the implant would be in conflict with the anatomical structures
- Any condition that could exclude the potential benefit of the implants must be clarified by the treating physician
- Surgeries on pregnant women should be avoided if possible or require special care. This is at the discretion of the surgeon.

### 2.4 Expected clinical benefit

The clinical benefit for the patient should be an anatomical reconstruction as close to normal as possible until bone healing is achieved, along with a clinically relevant reduction in pain and restoration of function.

### 2.5 Target patient group

The implants are intended for use in human medicine in patients with a mature skeleton.
There is no restriction regarding the intended patient population additional to the indications/contraindications.

### 2.6 Target user group

The products are intended to be used by trauma, neuro- and orthopaedic surgeons who are familiar with the surgical technique.

### 2.7 Use environment

The implants are to be used in a standard surgical environment.

## 3 Risks and possible negative side effects

As with any major surgical procedures there is a risk for adverse events. Prevalence of the possible negative side effects may vary depending on patient-specific pathology and anatomy, as well as implantation levels. Possible negative consequences include among others:

- Injuries, impairments and/or functional disorders of the urogenital area
- Migration, dislocation or loosening of the implants or implant components (e.g. screw backout)
- Mechanical failure of the implant and/or components

- Persistent pain
- Infections
- Leaking bone cement
- Impairment of potency/sexual sensation
- Lack of bone healing/pseudoarthrosis
- Misalignment/asymmetry of the pelvic ring affecting the gait pattern
- Permanent instability of the pelvis
- Injury of tissue, vessels and nerves
- Inability to give birth naturally
- Foreign body (allergic) reaction
- Irritation caused by the implant

# 4 Packaging, sterility and storage

## 4.1 Storage

⚠ **Implants must be stored in the sealed packaging according to the storage conditions indicated on the product label until use.**

## 4.2 Packaging

- The sterile packaging is set up as a double sterile barrier as follows (from the outside to the inside):
  - transport carton
  - first sterile barrier
  - second sterile barrier
  - protective packaging (not applicable for all packaging)- no additional sterile barrier
- The rules of asepsis must be observed during removal from the sterile and protective packaging.

## 4.3 Labeling

- The instructions and symbols given on the packaging must be followed (see section 6).
- The main label is attached to the transport carton. This contains all the necessary information for clear identification of the sterile packaged product (e.g., product description, article and lot number) and further information on the use of the product.
- The first and second sterile barriers are also each marked with a label with reduced content but contain clear identification of the sterile packaged product. The individual packaging layer is labeled as a double or single sterile barrier using appropriate symbols.
- The individual inner protective packaging is not marked separately with a label.
- When withdrawing the implant from the packaging, the direct marking on the implant must be verified against the information on the labels.
- The patient labels in the primary packaging must be attached to the patient file or the surgical report.

## 4.4 Sterilization

- Implants are packaged and sterilized with gamma irradiation at a minimum dose of 25 kGy and delivered sterile. They can be used without further preparation.

⚠ **Implants delivered by the manufacturer in a sterile condition must not be resterilized!**

- Prior to use, labeling and each packaging layer should always be checked for integrity.
- Before using the implant, the expiration date (YYYY/MM/DD) and the sterility marker on the packaging must be checked.

⚠ **The implant must not be used if the packaging is damaged, if the expiry date has expired or if the sterility marking is not present or does not indicate that the product has been correctly irradiated (marker must be colored red).**

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

# 5 Notes for application

## 5.1 General

- The surgical technique for Silony Spine implants can be learned by observing surgical procedures for demonstration purposes, workshops, and courses in a hospital familiar with these implants.

⚠ **Implants and instruments are always part of a system. Only instruments, trials and accessories described in the accompanying manufacturer's instructions (e.g. instrumentation guides or note inserts) must be used in order not to impair the performance of the device or surgical outcome.**

⚠ **Compatibility is only guaranteed with these instruments and accessories.**

## 5.2 Handling of the implants

- Implants are sensitive to damage. Even minor scratches or impact sites on the surfaces can lead to premature failure and result in complications. Careful handling is required.

⚠ **Implants must not be mechanically processed or modified.**

⚠ **Implants that are contaminated, non-sterile, damaged, or scratched or that have been improperly treated or processed in an unauthorized way must not be implanted under any circumstances.**

- In the event of overloading, damage, improper implantation, or improper handling, implants may fracture, become loose, wear out, or become functionally impaired. In rare cases, there may be corrosion of the implant.
- Any implant is subject to inevitable wear and tear. An implant that was initially stable upon implantation may become loose or functionally impaired over time, which can result in revision surgery.

## 5.3 Reuse

⚠ **Implants are for single use only and strictly must not be reprocessed after use in a patient and contamination with blood, tissue or other body fluids. Reuse, reprocessing or resterilization can lead to limited functionality, transfer of pathogens or cross-infection may lead to patient injuries, diseases or death.**

- Even if the implant appears to be intact, it may have minor defects and invisible damages due to excessive stress that can lead to premature wear and tear.

## 5.4 Preoperative use instructions

- Implant surgery should generally only be considered if all other conservative treatment options have been carefully assessed and have not proven to be the better option. The treating physician is responsible for considering the possibility of implant surgery.
- In case of ventral instability of the pelvic ring, additional anterior support of the pelvic ring is required.
- The surgeon is responsible for the proper performance of the surgery, including:
  - Patient-specific selection of size, shape and design of the implant
  - Planning of the surgery based on X-ray images
  - Checking possible allergies of the patient to the implant material
  - Ensure availability of different implant sizes and required instruments for the surgical procedure
- Neglecting to carry out preoperative planning can have a negative impact on the surgical outcome and lead to health damage. The potential success of surgery depends directly on the correct choice of the implant.
- When planning implantation, the patient-specific pathology and anatomy as well as the implantation levels must also be taken into account.

⚠ **Silony Spine bears and accepts no responsibility for complications resulting from an incorrect diagnosis or indication, an unsuitable choice of implant, incorrectly combined implant components and/or an improper surgical technique or asepsis.**

## 5.5 Intra-operative use instructions

- Prior to implantation, the implant must be visually inspected for damage.

⚠ **Damaged implants must not be used.**

## 5.6 Notes on Guiding

- The cannulated screws can be implanted under guidance with a guide wire (Ø 3,2mm).

- The position of each guide wire must be checked under the image intensifier to ensure that each guide wire is positioned suitably for the insertion of the screw. The tip of the guide wire in particular should be monitored under imaging to ensure that it does not perforate the bony structure and possibly damage the neurological or vascular structures.
- The guide wires must remain in the correct position throughout the entire surgical procedure. It has to be ensured that guide wires stay in position before the screws are inserted.

## 5.7 Augmentation (SI-Screw)

- Wenn eine zusätzliche Verankerungsstabilität erforderlich ist, sollte die Verwendung der SI-Schraube in Kombination mit Knochenzement erwogen werden.
- Die Iliumschraube mit UHMWPE-Einlage darf nicht augmentiert werden!

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

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

⚠ **The risks of cement leakage can have a negative impact on the patient's state of health.**

## 5.8 Post-operative use instructions

- Post-operative evaluation of the fusion and the implant status are mandatory.
- Post-operative mobilization and rehabilitation are at the discretion of the surgeon dependent on clinical and radiological progress.

## 5.9 Information to the patient

- Even a successfully implanted product is inferior to the healthy motion segment(s) of the spine. Similarly, an implant can represent a beneficial replacement of one or more pathological and/or symptomatic motion segment(s) for the patient, as it can help eliminate pain and therefore achieve improved mobility and stability.
- Pre- and post-operative instructions and warnings of the surgeon to the patient and their compliance are essential. The surgeon is responsible for informing the patient about the risks of implantation and about the outcome of the surgery as well as any potential negative consequences. The patient should be made aware of the limitations and the measures to minimize the possible complications. The patient should be instructed to limit the post-operative activity as this will reduce the risk of bending, breaking and/or loosening the implants.
- The patient must be issued with an implant pass.
- The patient must be informed that implants can have an impact on the diagnostic imaging of CT scans or MRI examinations. The patient must also be instructed to inform the examining physician about the implant and to show the implant pass prior to a scheduled CT scan or MRI examination.
- All information given to the patient should be documented in writing by the surgeon.

## 5.10 Magnetic resonance (MR) compatibility

- The implants are MR conditional.

⚠ **The implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment.**

- Based on a systematic literature search of the State-of-the-Art for similar devices and materials, it can be assumed that safe MR can be performed on patients under the following conditions:
  - Static magnetic field of 3 Tesla or less
  - Maximum spatial gradient of magnetic field of 720-Gauss/cm (a higher value for the spatial gradient of magnetic field may apply if properly calculated)
  - Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (per pulse sequence).
- MRI related Heating: Possible heat generation is acceptable for a whole body averaged specific absorption rate (SAR) of 2W/kg for 15 minutes (per pulse sequence) of scanning using a 3-Tesla MR system.
- Migration: Due to the material used (titanium alloy), no forces or moments are to be expected which cause the implant to migrate during the MR examination.

- Artifacts: MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant.
- In all cases, the treating physician is responsible for MR conditions, MR imaging quality and patient safety.

5.11 Implant removal and revision

- The implants are not intended to be removed in case of a good outcome.
- Removal of a stable implant can lead to loss of stability and damage to surrounding tissue.
- However, adverse events might warrant removal of the implant.
- Removal of the implant is possible. This should be carefully considered by the treating surgeon and the patient, considering the risks and benefits.

5.10 Disposal

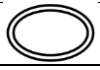
- Implants and instruments that can no longer be used can be disposed of in accordance with the national regulations applicable at the place of use or be returned to the manufacturer free of charge for proper disposal.
- Implants and instruments may only be returned to Silony Spine if they are still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

5.11 Traceability

- When passing on Silony Spine products (in return for payment or free of charge), each party passing on a product must ensure that appropriate traceability (lot tracking) is possible at all times.

## 6 Labeling and Symbols

| Symbol | Description according to ISO 15223-1 and Silony specifications |
|---|---|
|  | Manufacturer |
|  | Date of manufacture<br>*Including the date in the following format: YYYY-MM-DD* |
| CH REP | Swiss Authorized Representative |
| UK REP | United Kingdom Representative |
| CE 0483 | The device meets the requirements of EU Regulation MDR 2017/745. |
| Rx only | Federal law in the USA restricts this device to sale by or on the order of a physician. |
| REF | Article number |
| LOT | Lot number |
| QTY | Number of items |
| MD | Medical device |
| UDI | Unique device identification |
|  | Use by<br>*Including the date in the following format: YYYY-MM-DD* |
|  | Consult Instruction for use |
|  | Caution |

| Symbol | Description according to ISO 15223-1 and Silony specifications |
|---|---|
|  | Single sterile barrier system |
|  | Double sterile barrier system |
|   | Sterilized using irradiation |
|  | Do not re-use |
|  | Do not resterilize |
|  | Do not use if the package is damaged |
|  | Keep dry |
|  | Keep away from sunlight |
|   | MR* conditional (The term MR is synonymous with MRI and means magnetic resonance imaging.) |
|  | Metal detectors can trigger alarm due to the implant |
|  | Patient Identification |
|  | Health care centre or doctor |
|   | Date (of implantation) |
|  | Contact |
|  | Silony Logo (for identification of the legal manufacturer in the course of direct marking of products) |
|  | Torx connection |
|  | Hex connection |
| S | Size S |
| M | Size M |
| L | Size L |
| Ø | Diameter |

Silony Medical GmbH
Leinfelder Straße 60
70771 Leinfelden-Echterdingen
Germany

Telephone: +49 (0)711-782 525 0
Fax: +49 (0)711-782 525 11
E-Mail: info.stuttgart@silony-medical.com

https://www.silonyspine.com/contact

www.silony-medical.com/ifu

CE 0483