Instruction for Use (D30011)

VERTICALE
Sterile Instruments

Important Information – please read before use!

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This Instructions for Use covers the sterile Instruments of the VERTICALE spinal 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

Instructions for Use D30003 must be used as reference for reprocessing instruments.

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

The sterile instruments of the VERTICALE posterior spinal fixation system are intended for cementing cannulated and fenestrated pedicle screws of the VERTICALE system, for revision procedures (screw loosening / screw pullout), and in osteoporosis patients using an appropriate cement application system.

1.2 Material

The sterile instruments are made of stainless steels in accordance with ASTM F899 and/or DIN EN ISO 16061, which are suitable for the manufacture of surgical instruments.

1.3 Clinical application

When using sterile spinal instruments, the indications and contraindications of the implant in question shall apply. Please follow the applicable instructions for use.

2 Packaging, sterility and storage

2.1 Storage

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

2.2 Packaging

- The product description, article number and LOT number are indicated on the product label. When withdrawing the instrument from the packaging, the instrument must be verified against the information on the packaging (article number / lot number / size).
- The instructions and symbols given on the packaging must be followed.

2.3 Sterilization

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

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

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

⚠ **The instrument 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 coloured red).**

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

3 Notes for application

3.1 General

- Silony Spine products may only be used by surgeons who are familiar with spinal surgery and experienced in the product-specific surgical techniques.
- 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 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.**

3.2 Handling of the instruments

- Instruments are sensitive to damage. Even minor scratches or impact sites on the surfaces lead to premature failure can give rise to complications. Careful handling is required.

⚠ **Instruments must not be mechanically processed or modified. Unless this is expressly foreseen in the design and instrumentation guide.**

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

- In the event of overloading, damage, improper implantation, or improper handling, instruments may fracture, become loose, wear out, or become functionally impaired.

3.3 Reuse

⚠ **Sterile instruments 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.**

⚠ **Silony Spine bears and accepts no responsibility for complications resulting from an incorrect choice or use of material, improper use or handling of the instruments and/or an improper surgical technique or asepsis.**

3.4 Intra-operative use instructions

- Prior to use, the instrument must be visually inspected for damage.

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

- The rules of asepsis must be observed during removal from the protective packaging.

3.5 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.

3.6 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.

4 Labelling and Symbols

Symbol	Description according to ISO 15223-1 and Silony specifications
	Manufacturer
	Date of manufacture *Including the date in the following format: YYYY-MM-DD*
CH REP	Swiss authorised Representative agent
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

Symbol	Description according to ISO 15223-1 and Silony specifications
MD	Medical device
UDI	Unique device identification
	Use by *Including the date in the following format: YYYY-MM-DD*
www.silony-medical.com/ifu	Consult Instruction for Use
	Caution
	Single sterile barrier system
	Double sterile barrier system
STERILE R	Sterilized using irradiation
	Do not re-use
	Do not resterilize
	Do not use if the package is damaged
	Keep dry
	Keep away from sunlight
	Contact
	Silony Logo (for identification of the legal manufacturer in the course of direct marking of products)

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

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