Instructions for Use (D30011) for sterile instruments* of the system

VERTICALE®

Important information for the surgeon

Please read before use!

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These Instructions for Use apply to Silony sterile spinal instruments.

Other sets of manufacturer's information are available containing information 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

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 the attendance of corresponding user training courses.

***These Instructions for Use do not apply to the USA and its territories.**

1. Product description

The sterile instruments of the VERTICALE system are intended for cementing cannulat-ed and fenestrated pedicle screws of the VERTICALE system, for revision procedures (screw loosening / screw pullout), and in osteoporosis patients using an appropriate cement applica-tion system.

2. General Information

Silony Medical products may only be used by surgeons who are familiar with spinal surgery and experienced in the product-specific surgical techniques. The surgical tech-nique for Si-lony Medical products can be learnt by observing surgical procedures per-formed for demonstration purposes, by participating in workshops, and by attending courses at a hospi-tal familiar with these systems. Silony Medical employees will be glad to help you organize a training opportunity.

The sterile instruments are made of stainless steels as defined by DIN EN ISO 7153-1 or ti-tanium alloys as defined by ASTM F136 and EN ISO 5832-3 that are suitable for the manu-facture of surgical instruments.
The product designation, article number, LOT number, and expiration date are indicat-ed on the product label. When removing sterile instruments from the packaging, it must be con-firmed that the instrument corresponds with the description on the packag-ing (article num-ber / lot number) and the shelf life. The instrument must not be used after the expiration date has passed.
The sterile instruments must be stored unopened in the original packaging and must not be damaged. The integrity of the packaging and the security seal must be verified before use. Please follow the additional directions under “Storage”.
Prior to use, the instrument must be visually inspected for damage. Damaged instru-ments must not be used. When passing on Silony Medical products (in return for pay-ment or free of charge), any party passing on a product must ensure that appropriate traceability (lot tracking) is possible at all times.

Complications or other consequences that may be due to an incorrect indication or surgical technique, unsuitable choice of material or treatment, improper use or treat-ment of the in-struments, asepsis, etc., are the responsibility of the surgeon and cannot be attributed to the manufacturer, the importers, or suppliers of Silony Medical prod-ucts.

Important advice

- Instruments are always part of a system. They may only be combined with original parts belonging to the same system and used with original instruments belonging to the same system.
- Silony Medical instruments must never be combined or used with products, compo-nents, or instruments from other manufacturers unless they are instruments that are generally used in an operating room and/or instruments described in the instrumenta-tion 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.
- Instruments must not be mechanically processed or modified in any other way, un-less this is expressly intended by the construction and instrumentation guide. In case of doubt, a written recommendation must be obtained from the manufacturer.

- The use of the instruments for other purposes is prohibited.
- Any additional advice (e.g., advice label on the packaging) must be observed.

Warnings:

- Sterile instruments must not be reused. Reuse can impair the characteristics of the instrument and thus compromise patient safety.
- Neither reprocessing nor resterilization of the instruments is permitted. Repro-cessing or resterilization can result in modification of material properties and the design. The function and characteristics of the instrument can be changed or im-paired as a result and can pose a substantial risk to patient safety.
- Reusing a sterile instrument can result in cross-contamination and infection of patients.
- The rules of asepsis must be observed during removal from the sterile packaging.
- When removing the sterile instrument from the packaging, particular attention must be paid to ensuring that the instrument is not contaminated with blood, tissue, or other impurities. Implants must always be removed with the utmost care and never while wearing contaminated gloves.
- Instruments can break, become loose, wear excessively, or be functionally impaired in the event of excessive force, damage or improper handling.
- Any additional warnings (e.g., advice label on the packaging) must be observed.

3. Preoperative planning

The operation must be precisely planned using a suitable imaging method. The X-ray images provide important information about implant suitability, sizing, and possible combinations. For the surgical procedure, all implants and implant parts in the combi-nation recommended by the manufacturer that may be required as well as the instru-ments needed for implantation must be available. This may be necessary if, for exam-ple, a different size or different implant is required.
Prior to surgery, it must also be clarified whether the patient is allergic to the materials / implant materials used.

Warning:

Failure to perform adequate preoperative planning can lead to errors (e.g., with regard to misalignment, the choice of implant, and its size).

3.1 Indications/ contraindications

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

4. Storage and handling of sterile instruments

- Sterile instruments are sensitive to damage. Even minor scratches or points of impact on the surface can lead to changes in the material properties and thus result in material failure or complications. Extremely careful handling is therefore indicated.
- The sterile instruments must be stored unopened in the original packaging and must not be damaged. If the packaging has been damaged or opened, the instrument is no longer sterile and must not be used. The integrity of the packaging and the security seal must

always be verified before use. The shelf life of the sterile instrument must be verified using the product label. The instrument must no longer be used after the expiration date has passed.

- Instruments that can no longer be used can be returned to the manufacturer free of charge for proper disposal.
- The information and symbols on the packaging must be observed.

5. Reporting of incidents

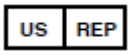
Users and/or patients are obliged to report all serious incidents involving the device to the manufacturer and the competent authority of the Member State.

6. Labelling and glossary of symbols

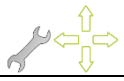
Each instrument and each tray level is labelled using laser inscription with the manufacturer's logo, article number, article name, lot number, and a CE mark.

The CE mark with the code number of the Notified Body applies for class IIa instruments in the VERTICALE system.

For class I devices, a CE mark without a code number for the Notified Body is sufficient.

Symbol	Description according to ISO 15223-1 and Silony specifications
	Manufacturer
	US representative
	Article number
	Lot number
	Serial number
	Number of items
	Medical device
	Store in a dry place
	Keep away from sunlight
	Do not use if the packaging is damaged

Symbol	Description according to ISO 15223-1 and Silony specifications
	Consult Instructions for Use
	Important – consult the Instructions for Use
	The product meets the requirements of EU Directive 93/42/EEC and Regulation (EU) 2017/745.
	The product meets the requirements of EU Directive 93/42/EEC and Regulation (EU) 2017/745.
	Non-sterile
	Do not reuse
	Federal law in the USA restricts this device to sale by or on the order of a physician
	Flushing of cannulations
	Follow the sequence
	Contact
	Limited shelf life *Including the year and month in accordance with the following format: "YYYY-MM-DD"*
	Number of calendar years from the date of manufacture
	Reprocessing as shown *Including the possible addition of the number of potential reprocessing cycles*
	Direction indicator for opening; disengaging the connection between the implant and the instrument

Symbol	Description according to ISO 15223-1 and Silony specifications
	Direction indicator for closing; firm connection between the implant and the instrument
	Assembly
	Disassembly
	Oiling
	Double sterile barrier system sterilized by irradiation with additional protective packaging
STERILE EO	Sterilized by ethylene dioxide
STERILE R	Sterilized by irradiation

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Distribution countries / Official language			
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