Instructions for use (D60080) for sterile instruments* of the system

VERTICALE®

Important information - Please read before use!

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These instructions for use apply to sterile spinal instruments from Silony.

Further manufacturer information is available, containing information required for application of the system.

This information such as instrumentation guide, product specific inserts and other product- specific information's, can be viewed at the following two links:

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

In case of non-compliance with the manufacturer's information, any liability of the manufacturer is rejected.

Before using a product marketed by Silony Medical, the operator is advised to carefully study the following recommendations, warnings and notes as well as the product-specific information. Silony Medical also recommends that the relevant user training courses be attended.

1. Product description

The sterile instruments of the VERTICALE system are intended for cementing cannulated and fenestrated pedicle screws. They are mainly used in revision procedures (screw loosening/ screw pullout) and in osteoporotic patients and are applied by means of a corresponding cement system.

1.1 Intended Use

Sterile semi-rigid or rigid tube that is attached to the distal end of a bone cement dispenser and through which the cement is delivered from the dispenser into the vertebral body via the pedicle screw.

These are sterile surgically invasive medical devices intended for transient and single use.

1.2 Indication/ Contraindication

When using sterile spinal instruments, the Indications and contraindications of the implant system (VERTICALE) used apply.
Please also observe the respective instructions for use.

2. General notes

Silony Medical products may only be used by surgeons who are familiar with spinal surgery and have mastered the product-specific surgical techniques.
The different surgical techniques can be learned by observing demo surgeries, workshops and/or courses at a clinic familiar with these systems. The staff of Silony Medical is at your disposal for mediation.

The sterile instruments of Silony Medical are designed, manufactured and made of materials that comply with the state of the art for medical devices. The evaluation of the materials used for the biological aspects takes place within the Biological Assessment. They are made of stainless steels suitable for the manufacture of surgical instruments according to ASTM F899 and/or DIN EN ISO 16061.

The product designation as well as article number, date of manufacture, LOT No., UDI marking and expiry date can be found on the product label.
When removing sterile instruments from the packaging, check that the instrument corresponds to the designation on the packaging (article number / LOT no./...) and the shelf life.

The sterile instruments must be stored in the unopened original packaging and must not be damaged. The integrity of the packaging and the seal label should be checked before use. Please observe the further instructions in Chapter 4. Storage and handling of sterile instruments.

When passing on (against payment or free of charge) a Silony Medical product, each person passing on the product must ensure that the corresponding traceability (LOT tracking) of the medical product is always possible.

Complications or other effects that may result from reasons such as incorrect indication and/or surgical technique, inappropriate choice or treatment of materials or instruments, asepsis, etc., are the responsibility of the surgeon and cannot be blamed on the manufacturer, importer or supplier of Silony Medical products.

2.1 Important notes:

- Instruments are always part of a system. They may only be combined with original parts belonging to the same system.
- Silony Medical instruments must never be combined or used with products, components or instruments from other manufacturers, unless they are general instruments used in the operating room and/or described in the instrumentation guide. Any liability for third party instruments used by the purchaser or user is excluded.
- Exceptions to these regulations require the express approval of Silony Medical.
- Instruments must not be mechanically processed or otherwise modified unless the design and instrumentation guide expressly provide for this. In case of doubt, obtain a written recommendation from the manufacturer.
- The use of the instruments for other purposes is prohibited.
- Any additional instructions (e.g. information stickers on the packaging) must be observed.

2.2 Warnings:

- Sterile instruments must not be reused. Reuse may impair the properties of the instrument and thus patient safety.
- Do not use the instrument after the expiration date.
- Neither reprocessing nor resterilization of the instrument is permitted. Reprocessing or resterilization can lead to changes in the material properties and design. The function and properties of the instrument may be changed or impaired as a result and pose a significant risk to patient safety.
- Reuse of a sterile instrument can lead to mutual contamination and infection of patients.
- When removing from protective packaging, the rules of asepsis must be observed.
- It is essential to ensure that the sterile instruments are presented aspetically. When removing the instruments from the packaging, there must be no contami- nation with blood, tissue or other contamination. The instruments must always be removed with extreme care and must not be removed with contaminated gloves.
- Instruments can break, become loose, wear excessively or their function can be impaired in the event of overloading, damage or improper handling.
- Occurring additional warnings (e.g. warning stickers on the packaging) must be observed.
- Before the operation, it must also be clarified whether the patient is allergic to the materials / implant materials used.

3. Preoperative planning

The operation must be planned precisely using appropriate imaging techniques. The X-rays provide important information about the appropriate implant, its size and possible combinations. All possible implants and implant parts in the combination recommended by the manufacturer, as well as the instruments required for their implantation, must be available for the operation. In case, for example, another size or another implant is required.

Warning:

Failure to perform adequate preoperative planning can lead to malocclusions (e.g., in terms of malpositions, choice of implant and its size).

4. Storage and handling of sterile instruments

- Sterile instruments are sensitive to damage. Even small scratches or impact points on the surfaces can lead to changes in the material properties and can thus give rise to material failure or complications. Extremely careful handling is therefore indicated.
- The sterile instruments must be stored in the unopened original packaging and must not be damaged. If the packaging is damaged or opened, the instrument is no longer sterile and must not be used. The integrity of the packaging and the seal label must always be checked before use. The shelf life of the sterile instrument must be checked using the product label. The instrument must not be used after the expiration date.
- Instruments that are no longer usable can be returned to the manufacturer free of charge for proper disposal.
- The instructions and symbols on the packaging must be observed.

5. Marking and symbol glossary

Each sterile instrument is marked by laser inscription and contains at least the manufacturer's logo, article number, article designation and Lot.

Symbol	Designation according to ISO 15223-1 and Silony specifications
	Manufacturer
	Date of manufacture
	Catalogue Number

Symbol	Designation according to ISO 15223-1 and Silony specifications
LOT	Batch Code
SN	Serial number
QTY	Quantity
MD	Medical device
UDI	Unique Device identifier
STERILE R	Double sterile barrier system sterilized by irradiation with additional protective packaging
	Single sterile barrier system
	Double sterile barrier system
STERILE R	Sterilized using irradiation
	Do not re-use
	Do not resterilize
	Use by date
Rx ONLY	Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physicians.
	Keep Dry
	Keep away from sunlight
	Do not use if packaging is damaged and Consult Instructions for Use
www.silony-medical.com/ifu	Consult Instructions for Use

Symbol	Designation according to ISO 15223-1 and Silony specifications
	Caution

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