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Sterile instruments of the system

VERTICALE®

CE 0483

Instructions for use

Important information for the surgeon
Please read before use!

These instructions for use apply to sterile spinal instruments. Separate manufacturer's information is additionally applicable for the implants and the non-sterile instruments required for implantation:

- Reprocessing of instruments (D30003)
- Instrumentation Guide VERTICALE (D30000)
- Instrumentation Guide for VERTICALE Augmentation (D30015)
- Instrumentation Guide for VERTICALE MIS (D30049)
- Product-specific guidance insert

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 attending the corresponding user training courses.

These instructions for use do not apply to the USA and its territories

Product description

The sterile instruments of the VERTICALE 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. 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 technique for Silony Medical products can be learnt by observing surgical procedures performed for demonstration purposes, by participating in workshops, and by attending courses at a hospital 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 titanium alloys as defined by ASTM F136 and EN ISO 5832-3 that are suitable for the manufacture of surgical instruments.
The product designation, article number, LOT number, and expiration date are indicated on the product label. When removing sterile instruments from the packaging, it must be confirmed that the instrument corresponds with the description on the packaging (article number / 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 instruments must not be used. 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.

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 Silony Medical products.

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, components, or instruments from other manufacturers unless they are instruments that are generally used in an operating room and/or instruments described 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.
- Instruments must not be mechanically processed or modified in any other way, unless 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. Reprocessing or resterilization can result in modification of material properties and the design. The function and characteristics of the instrument can be changed or impaired 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.

2. 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 combination recommended by the manufacturer that may be required as well as the instruments needed for implantation must be available. This may be necessary if, for example, 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:

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

2.1 Indications/contraindications

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

3. 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.

4. Glossary of symbols

Symbol	Explanation	Symbol	Explanation
	Manufacturer		Contact
 www.silony-medical.com/ifu	Consult instructions for use		Store in a dry place
REF	Order number / article number		Do not reuse
LOT	Lot number		Use by *Including the year and month in the following format: YYYY-MM-DD*
STERILE EO	Sterilized using ethylene dioxide	STERILE R	Sterilized using irradiation
	Do not use if the packaging is damaged		Caution: Additional notes must be observed.
	Do not resterilize		Keep away from sunlight
		QTY	Number of items
CE 0483	The product meets the requirements of EU Directive 93/42/EEC	US REP	US representative

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