Instructions for use (D30003)
Reprocessing of surgical instruments and accessories

Recommended reprocessing, maintenance, and care – please read before use

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These Instructions for Use are for reusable surgical instruments from Silony Spine and the associated accessories (tray basket including storage elements) referred to as "instruments" in the following.

Other sets of manufacturer's instructions 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 links:

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

When using the reusable instrumentation, the indications and contraindications within the applicable Instructions for Use of the implant systems must be observed.

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

Prior to using a product distributed by Silony Spine, the surgeon and those personnel assigned with the processing are expected to closely study the following recommendations, warnings, and advice as well as the product-specific information. Silony Spine also recommends attending the corresponding user training courses.

We kindly request timely notification if complications should occur in connection with the implants and instruments used.

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

1 Product description

The instruments from Silony Spine are always part of a system and intended for use only in conjunction with the associated implant systems from Silony Spine. Our instruments must not be combined with products, components and instruments of other manufacturers, unless:

- these are instruments generally used in the operating theatre or
- are instruments or third-party medical devices described in the Instrumentation Guide, which are certified for autonomous combination with universal third-party products while meeting the specific requirements for use

Combinations with products from other manufacturers may adversely affect the outcome of the procedure, because the components used are not coordinated with one another. Please note the system compatibility indicated 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 Spine!

The accessories from Silony Spine comprise trays (mesh trays) including storage elements and are used to hold and store surgical instruments from Silony Spine during transport and sterilization.

2 General Information and Warnings

These instructions for use contain all information as defined in EN ISO 17664 that is necessary for reprocessing reusable medical devices.

Warning:
All instruments and corresponding accessories provided by Silony Spine may be used only for the intended purpose. The use of instruments and accessories for purposes other than those intended may lead to premature wear or failure, which can in turn lead to serious patient injuries or even death.
Please note the directions regarding Creutzfeldt-Jakob disease / variant Creutzfeldt-Jakob disease in Section 5.

Silony Spine has instrumentation that is intended for single use only and must not be reused (see also "3.6 Reusability")!

General handling of the instrumentation in conjunction with trays:
For storing instruments during automated cleaning and thermal disinfection, standard hospital trays can be used.

For steam sterilization, the trays provided by Silony must be used. These are equipped with holders that are adapted to the instruments.

The trays loaded with instruments are placed in sterilization containers provided by Silony, which then undergo steam sterilization while closed.

The trays and containers and their handling comply with the usual hospital standards.

The accessories from Silony Spine are intended for use in combination with the instruments from Silony Spine and must not be used for products from other systems.

Using imaging devices to determine location:
Prior to using instruments together with imaging devices, the compatibility should be verified in each individual case.

Handling:
The instruments must not be overly stressed by twisting or using them as a lever as this can result in damage or breakage of instrument parts. All instruments and accessories must be removed from the transport packaging before using for the first time and manually or automatically cleaned before the first sterilization. Before each further use, the instruments and accessories must again be cleaned,

disinfected, and sterilized. During transport and storage as well as cleaning, care, and sterilization, the instruments must always be handled with the utmost care to prevent inadvertently injuring persons or damaging the instruments. This applies in particular to blades, fine tips, and other delicate parts.

Surgical instruments are subject to corrosion and become functionally impaired following contact with aggressive substances (see Section 2).

If instruments are not used as intended or if functional checks are not carried out, or in the event of improper cleaning and incorrect handling, the following hazards can occur:
- Damage to nerves, tendons, ligaments, vessels, tissue, or bones
- Bleeding
- Infections

Instruments are subject to a certain degree of wear and tear and are therefore considered to be consumables. Prior to use they must be inspected to ensure functionality and, if necessary, sent to Silony Spine customer service for repair (see Section 3).

Like the instruments, the accessories are also subject to a certain wear and tear and must be visually inspected before each use for loose, bent, broken, cracked, worn, and/or missing parts.

3 Cleaning, Disinfection, and Sterilization

The instruments and accessories must not be used without previous cleaning/disinfection and sterilization. Effective cleaning and disinfection is a prerequisite for effective and adequate sterilization of the instruments and accessories. The original packaging must be completely removed before cleaning the product for the first time.

Within the scope of your responsibility for the sterility of the products before use, please note that only process- and product-specific validated procedures for cleaning/disinfection and sterilization may be used and that the correspondingly validated processes must be complied with for each cycle.

Please also comply with the applicable legal provisions and the relevant hygiene regulations of the health authorities in your country.

Staff members are required to wear protective gloves that meet the requirements of Directive 89/686/EEC, especially when handling any used and unclean instruments and accessories. Used and contaminated instruments and accessories must be transferred to cleaning and disinfection as soon as possible to ensure the maximum safety of staff members.

Notes:
The instruments and the associated accessories must be cleaned, disinfected, and sterilized as soon as possible (at least within 4 hours of use).

Sharp objects must not be used to remove residues. Metal brushes or steel wool must not be used. Instruments and their accessories that are not entirely clean must be cleaned and disinfected again.

Cleaning agents and disinfectants
Excessively high concentrations of cleaning agents and disinfectants as well as highly acidic and alkaline cleaning agents can damage the protective oxide film and cause pitting. When these agents are used, the concentrations and exposure times recommended by the manufacturers must be observed. When automated cleaning is used, the instructions provided by the manufacturer of the cleaning agent and device must be followed.

Steel wool, steel brushes
The use of steel wool, steel brushes, or files to clean surgical instruments and accessories is **not** permitted. The mechanical, abrasive treatment of the instruments damages the passivation layer, which leads to corrosion.

Contact between instruments

Stainless steel instruments that come into contact for longer periods of time with other materials, such as non-stainless steels with damaged surfaces, can develop rust near the contact points if these are moistened with an electrolyte, such as water, steam, or ultrasonic cleaning solutions, at the same time. It is essential to remove and replace instruments on which rust has formed. Instruments must always be cleaned while open and after disassembly in order to prevent crevice and frictional corrosion.

3.1 Preparing the instruments

In general, the following steps apply to cleaning preparation:

- Instruments with ratchet locks, speed locks, and hinges must be opened.
- To avoid injuries, handle all pointed and sharp instruments with extreme care.
- Instruments with removable parts must be disassembled. All small parts, such as screws, springs, sleeves, nuts, bolts, etc. must be collected in a suitable container to prevent them from getting lost during cleaning. Please follow the advice in the product-specific insert in this regard.

3.2 Automated cleaning process

The following general rule applies: automated processing must be used for cleaning / disinfection. Due to the often markedly lower efficacy of manual processing, manual processing must not be used if automated processing is available.

3.2.1 Manual pre-wash

1. Cleaning bath:	Place the instruments and accessories in cold water or in a suitable cleaning bath (e.g., Neodisher MediClean forte (Dr. Weigert)) for at least 10–30 minutes. In doing so, ensure that all lumens are filled with water. The instructions from the manufacturer must be followed.
2. Brushes:	The entire surface of the instruments and accessories must be brushed with cleaning brushes while immersed in the water bath. To prevent contamination of the surroundings, ensure that the cleaning solution is not flicked around. It must be ensured that all surfaces, lumens, cannulations, and openings have been cleaned without leaving residues. Movable parts, joints, and hinges must be cleaned and brushed at least 5 times while open and closed until all residues have been removed. The entire length of the insides of cavities must be brushed. Clean long, narrow cannulations and blind holes with particular care. Cannulated instruments must be cleaned with particular care. To remove blood and tissue residues, appropriately sized and suitable brushes must be guided through the cannulated opening repeatedly and then the opening must be rinsed thoroughly until all residues have been removed completely. Cleaning is only completed when no more residues (including inside the cavities) are visible. Cleaning brushes must be decontaminated or disposed of after use.
3. Rinsing	All instruments, instrument parts, and accessories must then be thoroughly rinsed under running tap water to prevent any remaining media residues from drying and agglutinating and so that no adverse effects can be expected during subsequent automated processing. In doing so, it must be ensured that cannulations are flushed and blind holes are repeatedly rinsed with water and emptied. Instruments with hinges must be rinsed under running tap water both when fully open and when fully closed. Joints and cavities are rinsed for at least 15 seconds with a water gun at 3–4 bar flushing pressure using demineralized water. In doing so, instruments with hinges must be rinsed both when fully open and when fully closed. Only water or aldehyde-free disinfectants or combination products may be used as the rinsing fluid (undesirable fixing of blood stains may occur with

	aldehyde-based disinfectants). Be advised that disinfectants that are used for pre-treatment are for the protection of staff members only and are not a substitute for subsequent disinfection.
4. Cleaning in an ultrasonic bath	- To prevent the formation of air bubbles, the ultrasonic bath must be filled with cold water and degassed prior to use. - Place the instruments in the ultrasonic bath, ensuring that instruments with hinges are placed in the bath in the open position. - Ensure that lumened instruments are filled with liquid without any air bubbles. - Exposure time: 10 min. in demineralized water with, e.g., 0.5% Neodisher MediClean forte (Dr. Weigert) - A temperature of 40°C must not be exceeded. - Follow the instructions provided by the manufacturer of the cleaning agent used.
5. Final pre-wash	Finally, rinse joints and cavities for at least 15 seconds with a water gun at 3–4 bar flushing pressure using demineralized water. In doing so, instruments with hinges must be rinsed both when fully open and when fully closed. To finish, rinse off thoroughly under running water for at least 5 seconds.

3.2.2 Automated cleaning and disinfection

Requirements for the cleaning and disinfection procedure:

- The cleaning and disinfection equipment (CDE) used must comply with the standard EN ISO 15883 and be CE marked.
- Validated reprocessing procedures
- Regular servicing and testing of the CDE
- The program used must meet the minimum requirements in Table 1.

Selecting cleaning agents and disinfectants:

When selecting the cleaning agent to be used, you must make sure that

- it is generally suitable for cleaning instruments,
- if thermal disinfection is not possible, a disinfectant with proven efficacy (e.g., VAH (German Association for Applied Hygiene) or CE mark) that is both listed and suitable for automated disinfection of instruments is also used and that the product is compatible with the cleaning agent used, and
- the chemicals used are compatible with the instruments and accessories, particularly in regards to material compatibility.

Cleaning agents and disinfectants must not contain the following chemicals:

- Organic solvents (among others ketones, esters, haloalkanes, alcohols, acetone, cyclohexanone)
- Highly alkaline solutions (> pH 11), pH should be between pH 10 and pH 11:
  - > pH 10 to ensure prion inactivation
  - < pH 11 to ensure material compatibility
- Strong acids
- Hypochlorite
- Organic, mineral, and oxidizing acids
- Halogenated hydrocarbons, chlorine, iodine
- Ammonia

For cleaning, a cleaning agent with a pH value of > 10 is recommended. The pH value of the Neodisher MediClean forte (Dr. Weigert) product used for the validation is between 10.4 and 10.8 at the dosage indicated in Table 1. When using a highly alkaline cleaner (pH > 11), an appropriate neutralizer must be added to the neutralization step (as defined in Table 1). It is essential that the concentrations stated by the manufacturer of the cleaning agents and disinfectants are observed.

Workflow:

1. Carefully place the instruments and accessories into a tray basket onto the loading rack of the cleaning and disinfecting equipment (CDE) or place the accessories (tray baskets with holding elements) directly in the CDE so that all surfaces are exposed during cleaning. Place

instruments with ratchet locks, speed locks, and hinges into the tray basket in an open position. For instruments with cavities, make sure that they are flushed and emptied during the cleaning process inside the CDE. Flushing connections or MIC racks may be necessary for this. Openings must be flushed and cavities with blind holes must be accessible for rinsing with no hindrances. (Attention: do not stack multiple trays on top of one another. Place the instruments in the tray so that the rinsing fluid can drain easily. Arrange cavities, blind holes, etc. as much as possible so that the rinsing fluid can flow out by gravity and no cavities have liquid left in them at the end of the thermal disinfection.

2. Automated cleaning in the WD must always be carried out without the cover.)
3. Starting the program

The cleaning process was specified for the validation by Silony Spine as follows:

Level	**Water**	**Cleaning agent**	**Temperature**	**Holding time**
Pre-wash	Drinking water	-	unheated	2 min.
Emptying	-	-	-	-
Main cleaning	Drinking water	DOS 0.5*	55°C	5 min
Emptying	-	-	-	-
Neutralization	Demineralized water**	-	cold	3 min
Emptying	-		-	-
Rinsing	Demineralized water**	-	cold	2 min
Emptying	-	-	-	-
Thermal disinfection***	CDE program on thermal disinfection: The country-specific national requirements for the applicable A_0 value must be taken into account. If no other value is specified, an A_0 value of at least 3000 must be used.			
Drying	Drying with hot air using the program and parameters validated by the WD manufacturer. Program with adequate drying of the products with at least 20 minutes holding time. Please also note the instructions of the CDE manufacturer.			

Table 1

**Neodisher MediClean forte (Dr. Weigert)*
***Demineralized water*
****A laboratory examination was not performed due to the specification of the A_0 value.*

4. When the program has ended, remove the instruments from the WD with clean single-use gloves or clean, disinfected hands.
5. After automated cleaning, check whether residues are visible. If residues are visible, the cleaning/disinfection must be repeated.
6. After drying, the instruments must be inspected visually for moisture / residual liquid. If the drying is incomplete, remove the residual liquid with a suitable lint-free cloth or medical compressed air.
7. Check the function of the instruments (see Section 3.3.1).
8. Package the instruments as soon as possible (see Section 3.4), if necessary after additional drying in a clean location (see "Hygiene Requirements for the Reprocessing of Medical Devices" on the website of the Robert Koch Institute)

Proof of basic suitability of the instruments for effective automated cleaning and disinfection was provided by an independent, accredited test laboratory using the cleaning and disinfection equipment Miele G7735 CD / Miele G7836 CD (thermal disinfection), the cleaning agent Neodisher MediClean forte (Dr. Weigert), and demineralized water for neutralization. The procedure outlined above was taken into consideration.

When using other procedures, their basic suitability and efficacy must be confirmed as part of a validation.

3.3 Inspection and care

3.3.1 Visual inspection and functional check

A visual inspection and subsequent function test must be performed for each instrument after cleaning.

- Instruments must be inspected for visible residues immediately after cleaning. The instruments and any cannulations must be free of any visually detectable residues.
- Check critical areas, such as hinges, joint connections, cavities, lumens, handles, and connectors, with particular care.
- Inspect the instruments immediately after cleaning for signs of parts that have become loose, e.g., loose screws.
- Check instruments for intact surfaces as well as for correct alignment and function. It is essential that poorly functioning, damaged, corroded, or blunt instruments are repaired or replaced.
- Check instruments before every use for fractures, cracks, completeness, and functionality, particularly areas such as blades, Torx, hinges, catches, and ratchets as well as all moving parts.
- Do not use damaged instruments.
- Do not carry out repairs yourself. Servicing and repairs may be carried out only by Silony Spine members of staff. Silony Spine employees will be happy to answer your questions.

3.3.2 Care

In order to retain the functionality of the instruments, we recommend the application of maintenance oils to prevent friction corrosion. Only biocompatible oils authorized for this purpose may be used. The oil must be suitable for steam sterilization and vapor permeable. Please note the requirements of the valid European and other applicable guidelines.

The oil is applied to the critical areas of the instruments prior to sterilization. Critical areas include joints, friction surfaces, threads, and hinges of forceps with a scissor function. Finally, move the joints and connections to ensure that the oil is distributed evenly. Excessive or superfluous oil must be carefully removed with a lint-free cloth. Please note the advice in the product-specific insert.

The oil must always be applied manually because an automated process does not offer sufficient protection. Immersion baths must not be used. The maintenance oil may be used only on metal instruments. Plastic surfaces must not be treated with maintenance oil.

3.4 Packaging

Surgical instruments and accessories are supplied to the user non-sterile either as a set in sterilization containers or individually packed in polyethylene pouches (protective packaging). Any instruments or accessories from a set that are subsequently delivered are also individually packaged in polyethylene pouches. In these cases, the protective packaging must be removed before the reprocessing. Sterilization in this packaging is not permitted. The individually packaged instruments should be arranged for sterilization in the intended position in the accompanying instrument tray.

The instruments along with the tray levels must be packaged before sterilization in the supplied sterilization container. Any packaging materials located in the sterilization containers must be removed before reprocessing.

Silony Spine has validated the sterilization of individually packaged instruments in autoclavable double sterilization pouches. The use of other sterile goods barrier systems (SBS) for steam sterilization of the individually packaged instruments is the responsibility of the user.

The sterile goods barrier system must be suitable in accordance with the valid standards and requirements for packaging systems as well as the sterilization procedure used and must be taken into account in the validation of the procedure.

3.5 Sterilization

Only sufficiently cleaned, disinfected instruments packaged in a suitable and approved SBS may be sterilized. The instruments may be sterilized only using a validated steam sterilization method in accordance with EN ISO 17665. A fractioned vacuum procedure must be used.

Parameters for the sterilization in sterilization containers:
- Minimum sterilization temperature: 134°C
- Maximum sterilization temperature: 137°C
  (value corresponds to minimum temperature plus tolerance of 3°C in accordance with EN 285)
- Minimum sterilization time (holding time): 3 minutes
- Sufficient drying of the products of at least 20 min at the end of the process
- Steam sterilizer in accordance with EN 13060 and EN 285
- Valid commissioning and performance evaluation

Parameters for sterilization in autoclavable double sterilization pouches:
- Three pre-vacuum phases
- Sterilization temperature: 134°C
- Minimum sterilization time (holding time): 5 minutes
- Sufficient drying of the products of at least 10 min at the end of the process

Safeguarding the sterile barriers of the double sterilization pouches is the responsibility of the hospitals, which must have specified adequate, compatible, and validated procedures and parameters for this purpose. The sterilization pouches must be sufficiently large for the instrument so that the seal is not placed under tension. The sterilization pouches must be fitted with steam indicators and comply with the relevant requirements (e.g., DIN 58953-4, EN 868, ISO 11140-1, ISO 11607-1,-2). Selecting the products and ensuring that they function correctly is the responsibility of the hospitals.

When using other types of packaging suitable for steam sterilization, the sterilization parameters must be validated and defined by the user.

Proof of basic suitability of the instruments and accessories for effective steam sterilization was provided by an independent, accredited test laboratory using the fractionated vacuum procedure (Selectomat HP 666-1 HRED from MMM Münchener Medizin Mechanik GmbH, Planegg). The procedure outlined above was taken into consideration.

As a general rule, sterilization with hot air must not be used (instruments can be destroyed). The use of other sterilization procedures (e.g., ethylene oxide or low-temperature plasma sterilization) is beyond the manufacturer's responsibility. The responsibility for the validation of the sterilization processes lies with the user.

3.6 Reusability

Provided that there is no visible functional or surface damage, the instruments and accessories may be reprocessed and reused.

Exception: The cementing instruments (VERTICALE cement applicator and VERTICALE MIS(MIS) cement cannula) are intended for single use only and must not be reused!

The products must be inspected after each cleaning, disinfection, and drying for dryness, cleanliness, function, and damage, e.g., corroded, loose, bent, broken, cracked, worn or missing parts. The longevity of the instruments depends on how often they are used, the type of care they receive, and on whether the reprocessing procedures are observed and maintained. The user is obliged to check the instruments and accessories before each use. The operator bears the responsibility as well as the risk if dirty or damaged instruments are used (no compensation for damages).

In the event of contamination of the holders or other points of the storage system supplied by Silony Spine, they must be brushed off thoroughly and rinsed until no more soiling is visible.

Restrictions on repeated reprocessing:

Because repeated processing has only a slight impact on the service life of the instruments and accessories, there are no restrictions regarding repeated processing. As a general rule, the service life is determined by wear and damage resulting from use.

Stability / material resistance:

The instruments must not be exposed to temperatures higher than 137°C. When selecting the cleaning agents and disinfectants, please ensure that they do not contain the chemicals listed in Section 2.2.2. The quality of the water can influence the results of the cleaning and disinfection of instruments. High concentrations of chlorine and other minerals in running water may cause corrosion or other damage. If corrosion occurs and all other causes of corrosion have been ruled out, the quality of the media should be checked.

4 Storage and handling

The sterility of the medical devices is only assured if the instruments were packaged and stored in accordance with the current standards. All of the process and expiration dates relevant for the user must be indicated on the packaging.
The storage periods are determined by the operator on the basis of a risk assessment of the storage conditions and taking into account the sterile barrier and/or packaging systems used. Instruments should be used in the same order in which they were received.
Silony Spine recommends a maximum storage period of 1 year for loaded, sterilized containers.

Instruments and accessories are designed only for the intended purpose and must also be used accordingly. Improper use and reprocessing can lead to overstressing and permanent impairment and can make the instrument or the accessory more susceptible to corrosion.

Defective instruments and damaged accessories must be immediately separated out and sent to Silony Spine customer service for repair. Instruments and accessories may only be returned to Silony Spine if they have been cleaned, disinfected, and sterilized. Proof of such treatment is to be attached to the outermost packaging. A consignment note must always be included with the defective product and must contain the following information:

- Hospital address, contact person, and telephone number
- Article number of the instrument sent in
- Description of the problem
- Decontamination certificate

Customer service assesses the product and ascertains whether it can be repaired. The exchange of instruments that cannot be repaired as well as the replacement of defective or missing parts is carried out by Silony Spine customer service.

Should it no longer be possible to repair or reprocess the instruments, they must be transferred to the usual hospital waste disposal system.

5 Additional information

The national guidelines apply. Furthermore, internal hospital instructions and the recommendations of the manufacturers of cleaning agents and disinfectants and of CDE and sterilization machines must be observed. Silony Spine has validated that the above instructions for the preparation of the instruments are suitable for their reprocessing. The person reprocessing the instruments is responsible for ensuring that the reprocessing actually performed with the equipment and materials used and by the staff members in the reprocessing facility achieves the desired results. This requires that the workflow is validated and routinely monitored. Any deviation from the instructions provided must also be carefully evaluated in terms of its efficacy and possible negative consequences by the person performing the reprocessing. More information about reprocessing medical devices can be found on the RKI and AKI websites.

Warranty:
The products are fabricated in accordance with EN ISO 13485, manufactured using high-quality materials, and are subject to quality control prior to delivery. If, however, faults should nevertheless occur, please contact Silony Spine customer service. Any liability for products that are modified, used for other purposes, or used improperly compared to the original is excluded. Silony does not assume liability if violations of these instructions for use are demonstrated.

Information about Creutzfeldt-Jakob disease (CJD) / variant Creutzfeldt-Jakob disease (vCJD):

As a clinical user, you have reporting obligations to the responsible health office and Silony Spine. As soon as you become aware that a patient with CJD/vCJD has been or will be operated on with Silony Spine instruments, Silony Spine must be informed.

- Report every case immediately to Silony Spine. The report must also be made if the instrument has already been returned to Silony Spine.
- If the instrument has already been returned to Silony Spine, report the case independently and notify which instrument is involved. Provide information about: Silony consignment note number and date, hospital return consignment number, date, and if known, article numbers, and the LOT (batch) of the instruments affected.
- If the instruments are still in your hospital, immediately block all instruments that have come into contact with the patient.

The following safety measures must be complied with:
Patient with signs indicating the presence of CJD/vCJD:

Case A: Clinically probable CJD/vCJD: for all clinical applications—burning of the critical and semi-critical medical devices used (EWC [waste code as defined in the European Waste Catalogue] 18 01 03 for incineration)

Case B: Clinically possible CJD/vCJD: for all clinical applications where possible, use single-use products with subsequent incineration or identification of the used instruments and subsequent secure collection of the instruments in appropriately labelled, closed containers until clarification of the diagnosis as follows:

- Diagnosis confirmed or still unclear: Incineration of the critical and semi-critical medical devices used [EWC 18 01 03 for incineration]
- Confirmed other cause for the clinical presentation or no indication of CJD/vCJD: Reprocess medical devices as usual

Please note the information provided on the websites of the Robert Koch Institute (RKI) and the Working Group for Instrument Reprocessing (AKI).

In the event that the instruments are used in patients with Creutzfeldt-Jakob disease, we do not accept any responsibility for their reuse. It is not possible to take back such instruments without prior agreement and coordination of the measures to be performed.

6 Material science

The instruments of Silony Spine are designed, manufactured and constructed of materials that are compliant 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.

In order for the instruments to be reprocessed and maintained correctly, the user must be familiar with the used materials and their properties.

Metals		
Surgical Steel	NiTi Nitinol alloy	Ti Titanium
Polymers / plastics		
CF/PEEK Carbon fiber reinforced polyether ether ketone	Silicone (Elastosil)	PEEK Polyether ether ketone
POM-C Polyoxymethylencopolymer	PPSU Polyphenylsulfone	PTFE Polytetrafluorethylene

Causes of superficial changes and corrosion

Incorrect handling or contact with physical, thermal, or chemical agents can damage the surface of the instruments. In order to prevent the development of corrosion and material deterioration, the possible causes and remedial measures are listed below.

Secretions, blood, pus

Tissue residues contain chloride ions. If they adhere to or are left to dry on an instrument for longer periods of time, this can lead to corrosion. For this reason, instruments must always be cleaned and dried immediately after use.

Water, saline solutions

Saline solutions contain sodium and chloride ions, which can cause pitting. Contact with these ions must be kept to a minimum. To ensure that all residues are removed, instruments should be thoroughly rinsed with distilled water. Normal tap water often contains concentrations of minerals that are visible on the surfaces of instruments as stains. In most cases, these stains and rings can be removed with non-abrasive stainless steel cleaning agents. Instruments must be dried immediately and never allowed to remain wet for extended periods. Condensation develops during sterilization. This can be prevented by prolonging the drying time.

7 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.

8 Summary of Safety and Clinical Performance (SSCP)

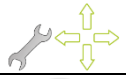
According to Article 32 of the Medical Device Regulation (MDR), manufacturers of implantable medical devices and medical devices of risk class III must provide a summary of safety and clinical performance (SSCP), which is verified and published by the notified body in the European database (EUDAMED). A summary of safety and performance (SSCP) for the reusable instruments is not issued. Information on this can be found in the respective SSCP of the implant system within the EUDAMED database or will be provided on request.

9 Labelling and 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 Ir and class IIa reprocessable instruments. 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
CE	The product meets the requirements of EU Regulation MDR 2017/745.
CE 0483	
CH REP	Swiss agent
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
SN	Serial number
QTY	Number of items
MD	Medical device
UDI	Unique device identification

Symbol	Description according to ISO 15223-1 and Silony specifications
	Consult Instructions for Use
	Important
	Non-sterile
	Do not reuse
	Do not use if the packaging is damaged
	Store in a dry place
	Keep away from sunlight
	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
	Direction indicator for closing; firm connection between the implant and the instrument
	Assembly
	Disassembly
	Oiling

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Distribution countries

Bulgaria
Belgium
Germany
Greece
Italy
Netherlands
Austria
Switzerland
France
Slovakia
Spain
Czech Republic
Hungary
United Kingdom
USA
Cyprus

Official language

Bulgarian
German
English
French
Greek
Italian
Dutch
Slovak
Spanish
Czech
Hungarian

CE 0483