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This package leaflet applies to

Surgical instruments

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CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

0. Preamble

These instructions are provided in accordance with ISO 17664 and are intended to supplement a hospital's existing instrument cleaning and disinfecting protocols. Use of these guidelines does not remove or limit the end-users ultimate responsibility for the cleanliness and sterility of any surgical device used in their facility. This guide applies only to Silony surgical instruments with its current spinal implant systems.

It does not apply to any implant which is delivered sterile. For information about handling of the sterile implants please refer to the instructions for use of the corresponding implant system. For information to the surgical technique please refer to the corresponding instrumentation guide related to the spinal implant systems of Silony.

1. Indications for use

The following instructions must be used prior to sterilizing the surgical instruments. For the indications for use of the implant systems please refer to the Instructions for Use of the related implant system.

2. Warnings & Precautions

Always follow the instructions provided by the manufacturer(s) of cleaning solutions and / or equipment used in cleaning Silony surgical instruments.

Instruments should always be thoroughly inspected before each use and after a cleaning cycle for broken, worn or damaged instruments. Damaged or non-functional instruments should be returned to your Silony representative for replacement. Damaged instruments should be cleaned and sterilized per these guidelines prior to being returned to Silony.

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 in section 5 of this guideline.

When selecting the cleaning agents and disinfectants, please ensure that they do not contain the following chemicals: Organic solvents (ketones, ester, ether, phenols, halo alkanes, ethyl alcohol, cyclohexanone), highly alkaline solutions, strong acids, hypochlorite, organic, mineral and oxidizing acids, stronger lyes, halogenated hydrocarbons, chlorine, iodine, organic solvents (like alcohols, acetone), ammonia.

No defined limits for the pH value of the cleaning agent can be given. Cleaning agents with a pH value in the cleaning step of < 10.5 are recommended. We recommend using MediClean forte. It is crucial that the concentrations indicated by the manufacturer of the cleaning agents and, where applicable, disinfectants are taken into consideration.

Any instruments that may have been exposed to transmissible pathogenic agents, such as but not limited to Creutzfeldt-Jakob Disease (CJD) should be processed according to the health care facility's

prion decontamination protocol. Contact the Centers for Disease Control and/ or the World Health Organization for the most recent information on the transmission and deactivation of CJD or any other known transmissible pathogenic agents.

Always wear personal protective equipment (PPE) when cleaning and processing Silony Surgical Instruments as defined by the health care facility's policies and procedures.

The health care facility is to comply with all laws and ordinances in countries where the reprocessing requirements are more stringent than defined in these guidelines.

3. Limitations on reprocessing

Repeated reprocessing as defined in this document and the cleaning and sterilization instructions as defined in the "Instructions For Use" (IFU) supplied with each Silony device system, should have only minor effects on the reuse and the life of devices listed on this document. End of instrument life is to be determined through the inspection of each instrument after the reprocessing cycle. Damaged or non-functional instruments should be returned to your Silony representative for replacement.

4. Method of Manual and Automated Cleaning

All instruments must first be thoroughly cleaned using the following validated methods described before sterilization and introduction into a sterile surgical field.

4.1 Point of use

Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. Remove excess soil and debris with disposable cloth or paper wipes.
Silony recommends a combination of manual and automated surgical instrument cleaning prior to sterilization. Complex instruments (instruments consisting of more than one piece, having small holes, cannulae, moving parts or threaded holes) require a more thorough cleaning regimen, which are outlined in this cleaning guideline. Pre-soaking is recommended prior manual cleaning.

4.2 Preparation for decontamination

Instruments should be cleaned as soon as practical to ensure ease of cleaning according to the health care facility's infection control and hazardous waste management procedures.

Prior to soaking the instruments in an enzymatic cleaning solution, rinse the instruments under cool running tap water and wipe off any residual soil or debris with a disposable towel. Ensure to flush out any lumens, cracks or crevices while rinsing under running cool tap water. Disassemble-able instruments should be disassembled for cleaning. Please contact your Silony representative for additional disassembly information.

4.3 Cleaning manual

Place and move around the instruments in cold water or in a suitable cleaning bath as per the chemical manufacturer's instructions.

Brush until all visible residues have been removed - Brush the entire surface of the instruments with cleaning brushes while immersed in the water bath. After that, brush again under running water. Do not use steel brushes. Movable parts, joints and hinges must be cleaned and brushed repeatedly while open and closed until all residues have been removed. Brush along the entire length on the insides of cavities. Clean long, narrow cannulations and blind holes with particular care.

Cleaning of cannulated instruments must be done particularly thoroughly. To remove blood and tissue residues, insert a fitting and suitable brush through the cannulated opening repeatedly and then rinse the opening thoroughly several times until all residues have been removed completely. Cleaning is only completed when no more residues (including inside the cavities) are visible! Decontaminate and, if necessary, sterilise or dispose of cleaning brushes after use.

Rinse all instruments and instrument parts to prevent residues from becoming dry and agglutinating. In doing so make sure that cannulations are flushed and blind holes are repeatedly rinsed with water and emptied. Joints and cavities are flushed for at least 15 seconds with a water gun at 3-4 bar flushing pressure.

Immerse the instruments into the ultrasonic bath. Insert hinged instruments in an open position. Ensure that lumened instruments are filled without containing air bubbles. Exposure time: 10 min. 40° C (example: 0.5%). Joints and cavities are then flushed for at least 5 seconds with a water gun at 3-4 bar flushing pressure. To finish, thoroughly rinse off instruments under running water.

Manual disinfection should be performed in accordance with the disinfectant manufacturer's instructions. When selecting the disinfectant to be used, careful attention must be paid to ensuring that it is suitable for the intended use, product group and materials and has e.g., been authorised by the VAH (Association for Applied Hygiene) and is listed in the disinfectant list of the VAH for efficacy-tested products.

The indicated concentrations, exposure times, rinsing and secondary rinsing cycles must be observed in order to ensure efficient disinfection. The following general rule applies: automated processing is superior to manual processing and preference should always be given to automated processing.

4.4 Automated cleaning and disinfection

All instruments must be manually cleaned as prescribed above prior to any automated cleaning process to ensure best possible cleanliness and removal of debris, blood and tissue prior to sterilization.

Level	Water	Cleaning agent	Temperature	Hold time
Pre-wash	Tap water	-	unheated	2 min.
Emptying				
Main cleaning	Tap water	DOS 0.5 %*	55°C	5 min
Emptying				
Neutralisation	Demineralized water	-	cold	3 min
Emptying				
Rinsing	Demineralized water	-	cold	2 min
Emptying				
Thermal disinfection	The CDE program on thermal disinfection must have a A_0 value of at least 3,000. In addition the country-specific national requirements must be taken into account.**			
Drying	Program with adequate drying of the products with at least 20 minutes holding time. Please also note the instructions of the CDE device manufacturer!			

* Neodisher MediClean forte (Dr. Weigert) *Table 1*

** A laboratory examination was not performed due to the specification of the A_0 value.

Workflow

- Carefully place the instruments into a tray basket onto the loading rack of the cleaning and disinfecting equipment (CDE) making sure no areas are left unwashed. Place instruments with ratchet locks, speed locks and hinges into the tray basked 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.
- Start the program (based on Table 1).
- Once the program has ended, remove the instruments from the cleaning and disinfecting equipment (CDE) using clean disposable gloves.
- Check cleanliness: after the automated cleaning inspect the instruments to see whether residues are visible. If residues are visible, the cleaning / disinfecting processes have to be repeated.
- Check the function of the instruments (see section 3.5).
- Package the instruments as soon as possible (see section 3.6, if necessary after additional drying in a clean place).

4.5 Inspection and Maintenance

Inspect the instrument for visible residues immediately after cleaning. The instrument must be free from any visible residues. Inspect the instrument for signs of parts that have become loose, e.g. loose screws, immediately after cleaning. Check instruments for intact surfaces and for correct alignment and function. It is essential for poorly functioning, damaged, corroded or blunt instruments to be repaired or replaced. Check the instrument for signs of breakage, tears and functionality before each use. Especially areas such as blades, tips, torx, hinges, locks and catches as well as all movable parts must be checked carefully.

In order to retain the functionality of the instruments, we recommend the targeted 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 vapour-permeable. 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. After that, even distribution of the oil must be ensured by moving the joints and connections. 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, as an automated process does not offer adequate protection. Immersion baths are not recommended. The maintenance oil must only be used on metal instruments. Synthetic surfaces must not be treated with maintenance oil.

4.6 Packaging

Prior to sterilization, the instruments have to be packaged with a suitable sterile goods barrier system (sterilization in the PE protective packaging in which the instruments are supplied is not permissible). Single damaged or non-functional instruments should be returned to your Silony Representative.

4.7 Sterilization

Sterilization parameters are provided in the IFU supplied with the Silony device systems are specially designed to maximize instrument surface contact during the sterilization process. Ensure that all instruments are placed in their proper location and orientation prior to sterilization. Individual instruments can be placed in an appropriate size autoclave bag or wrapping. Use of FDA-cleared sterilization wraps or FDA-cleared accessory is required to allow sterilant penetration and to subsequently maintain sterility.

4.8 Storage

Packaged and sterilized instruments are only to be stored in areas that provide protection from dust, moisture, insects and extremes of temperature and humidity.

5. Method of Sterilization

All instruments are provided non-sterile and must be sterilized prior to use. All components are sterilizable by steam autoclave using standard hospital practices.
The sterile goods barrier system:

- must be suitable for use with the packaging systems and sterilization procedures in accordance with the applicable standards and requirements
- must be taken into consideration accordingly in the process validation

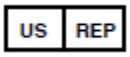
In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the following parameters:

Sterilization Method: Steam

- 3 pre-vacuum phases
- sterilization temperature 132°C
- holding time: 3 min (full cycle)
- sufficient drying (at least 20 minutes)

In addition, periodically inspect the instruments for wear and tear, such as corrosion or discoloration. For instruments that are no longer functional, or exhibit excessive wear and tear, please return instruments to Silony. Before proceeding with surgery, verify that all devices are correctly assembled and that all instruments and implants are undamaged.

6. Glossary of Symbols

Symbol	Title of Symbol /Explanatory Text	Standard Reference
	Catalogue Number	ISO 15223-1, Clause 5.1.6
	Batch Code	ISO 15223-1, Clause 5.1.5
	Manufacturer	ISO 15223-1, Clause 5.1.1
	U.S. Representative	ISO-15223-1, Clause 5.1.2
	Follow instructions for use	ISO 15223-1, Clause 5.4.3
	Attention – read instruction for use	ISO 15223-1, Clause 5.4.4
	Non-sterile	ISO 15223-1, Clause 5.2.7
	Do not use if package is damaged	ISO 15223-1, Clause 5.2.8
	Keep dry / Keep away from rain	ISO 15223-1, Clause 5.3.4
	Keep away from sunlight	ISO 15223-1, Clause 5.3.2
	The device complies with European Directive MDD 93/42/EEC	MDD 93/42/EEC
	Prescription Use Only	21 CFR 801.109

7. Description of Silony instruments

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

Stainless steels

Silony Medical instruments are manufactured predominantly from corrosion-resistant steels. Because of their high chromium content, stainless steels form a protective layer on the surface of the metal. This passive layer protects the instrument from corrosion. Incorrect handling (e.g. damage of the surface) and attacks of a chemical, physical and thermal nature can impair the resistance to corrosion.

Titanium alloys

Anodized titanium base alloys are used for a small number of applications (e.g. colour coding ring). Pure titanium and titanium alloys are widely used as materials in implant devices. Titanium base alloys are subjected to an electrochemical treatment of the surface (anodization) which forms a

resistant oxide film on the surface of the titanium. Different shades of colours can be set via the thickness of the layer.
The protective oxide film of the titanium alloys can become corroded by treatment with cleaning agents with pH values above 11.

Silicone rubber
All handles are manufactured using Elastosil® silicone.
Silicone rubber is highly resistant to high and low temperatures. There is barely any change in the physical properties between –50°C and +180°C. Resistance to chemicals and environmental factors is also typical of this material.
The handles can be repeatedly treated without problems using the hospital's usual reprocessing procedure. However, as with other instruments, they should also be inspected for damage and material wear after and before each use for safety reasons.

8. Causes of superficial changes and corrosion

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 be cleaned and dried immediately after each use.

Water, saline solutions, iodine tinctures
These solutions contain chloride and iodine ions, which can cause pitting. Contact with these ions should be kept to a minimum. To ensure that all residues are removed, thoroughly rinse instruments 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. Dry instruments immediately and do not leave them lying around wet. Condensation develops during sterilization. This can be prevented by prolonging the drying time.

Cleaning agents and disinfectants
Concentrations of cleaning agents and disinfectants that are too strong as well as highly acidic and alkaline cleaning agents can attack the protective oxide film and cause pitting. When these agents are used, it is essential to observe the concentration and exposure time recommended by the manufacturer. When automated cleaning is used, the instructions of the cleaning agent and device manufacturer must be followed.

Steel wool, steel brushes
The use of steel wool, steel brushes or files to clean surgical instruments is not permitted. The mechanical, abrasive treatment of the instruments attacks the passive layer, which leads to corrosion.

Contact between instruments

Stainless instruments that come into contact over longer periods of time with other materials such as non-stainless steels whose surface has been damaged can develop rust formation near the contact points if these are wetted with an electrolyte at the same time, such as water, steam, ultrasonic cleaning solutions. Instruments with rust formation must always be sorted out and replaced. Instruments should always be cleaned in an open position and after disassembly in order to prevent crevice and frictional corrosion.

Detergent residues in packaging cloths

Cloths that are used for packaging the instruments must be free from detergent residues. The residues can be transferred onto the surface of the instruments by evaporation, which can lead to changes in the surface.

Overstressing of instruments

Instruments were 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 more susceptible to corrosion.

9. Manufacturer Contact and additional information

It remains the responsibility of the processor to ensure that the reprocessing as actually performed using the equipment, materials and trained personnel in the reprocessing facility achieves the desired result. This normally requires validation and routine monitoring of the process at the reprocessing facility.

Defective instruments must be sent to Silony Medical customer service for repair. Customer service assesses the instrument and ascertains whether the instrument can be repaired. A consignment note must always be included with the defective instrument and must contain the following information:

- Hospital address, contact person and telephone number
- Evidence of decontamination
- Article number and LOT of the instrument being sent in
- Description of the problem

The exchange of instruments that cannot be repaired as well as the replacement of defective or missing parts is done by Silony Medical Representative.