LSMMed

Reusable surgical instruments

Non sterile implants

Instructions for disinfection

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Instructions for disinfection, washing and sterilization

Reusable surgical instruments

1 REUSABLE SURGICAL INSTRUMENTS

1.1 Warnings, precautions and restrictions

a) **LSM-Med Srl** has designed a set of specific instruments for each type of implantable medical device: other instruments are not to be used if not specified by the surgical technique for that implant.

b) Some instruments, such as drill bits and other cutting devices are intended for SINGLE USE ONLY and must not be reused. Check the label of the instrument to see if it is a single use instrument.

c) Personal Protective Equipment (i.e. gown, mask, goggles or face shield, gloves and shoe covers) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment.

d) Do not place heavy instruments on top of delicate devices.

e) Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.

f) Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices.

g) Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.

NOTE. The user has to validate the equipment and the processes for cleaning/ disinfection and sterilization.

NOTE. These instructions are not applicable to trays of other manufacturers or containing devices that are not manufactured and/ or distributed by **LSM-Med Srl**.

1.2 ASSEMBLY AND USE OF INSTRUMENTS

Before performing any surgical operation, the surgeon should be familiar with the surgical technique, the use of the instruments and devices to be implanted. It is recommended neither modify nor alter any instrument; furthermore instruments should not be used for surgical operations other than those indicated.

1.2.1 Shipping conditions

LSM-Med Srl instruments are shipped clean but not sterile.

LSM-Med Srl advises against the sterilization of instruments with ethylene oxide (Eto), gas plasma and dry-heat.

Steam sterilization (autoclave) is suitable for the sterilization of **LSM-Med Srl** instruments.

A list of codes are included inside the instrument trays. Instruments shipped singularly are packaged in a closed pouch. All instruments must be checked, in order to be sure they are suitable for the surgical operation, and then washed and sterilized.

1.3 CLEANING AFTER USE

Before starting the cleaning and sterilization procedures check the label of the instrument to see if it is a single use instrument.

1.3.1 Indications

Instruments must be washed and disinfected as soon as possible after use, in order to minimize hazards of infections (for medical staff) and corrosion (for instruments). Immediately after surgery remove excess body fluids and tissue with a suitable disposable, non shedding wipe.

Instruments should be cleaned within 30 minutes after their use to reduce the probability of drying.
After cleaning instruments are to be dried with a suitable non-shedding wipe.

Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk. Enzymatic and cleaning agents with a neutral pH or between 4.5 and 8.5 are recommended for cleaning **LSM-Med Srl** reusable devices.
Do not use strong acids nor oxidizing agents or corrosive chemicals which can alter the instrument surface (i.e. chlorine, iodine, fluorine, organic solvents, ammonia, mercury), especially if they are plastic or other polymeric components. Do not soak instruments in Ringer solution or similar saline solutions.

Alkaline agents with pH < 12 may be used to clean stainless steel and some polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob Disease (CJD) are a concern. It is critical that alkaline cleaning agents be completely and thoroughly neutralized and rinsed from devices.
Strong basis must be avoided for the cleaning of trays made of aluminium and aluminium alloy. Softened tap water may be used to prepare cleaning agents.

Use of recommended temperatures is important for optimal performance of cleaning agents.

NOTE. Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/ or turbid).

NOTE. After their use, boxes and instruments are to be washed separately; place the instruments in the boxes only after the cleaning and disinfection phase.

1.3.2 Manual Cleaning/Disinfection Procedure

Phase 1	Disassembly all instruments and check all threads are drawn back. It's recommended to keep together the parts of the disassembled instruments to facilitate the assembly.
Phase 2	Completely submerge instruments for 20 minutes in a water solution with the proper cleaning agent (i.e. : enzymatic detergent for surgical instruments) following the specifications of the manufacturer of the solution. While the instruments are submerged, scrub them with a soft brush, paying special attention to remove all organic residuals and clean also the difficult to reach areas (threads, pivots, hinges). Do not use metal or abrasive brushes! Note. Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.
Phase 3	Rinse instrument in tap water for at least 3 minutes flushing thoroughly lumens, holes and other difficult to reach areas.
Phase 4	Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate (≥ 24 kHz) for 10 minutes. Temperatures higher than 50°C can cause encrustations when blood is still present.
Phase 5	Soak the instruments in a disinfecting solution specific for surgical instruments, following the instructions of the manufacturer for concentration, temperature of solution and length of soak.
Phase 6	Rinse instrument in distilled or demineralised water for at least 5 minutes paying attention to flush thoroughly and aggressively lumens, holes and other difficult to reach areas.
Phase 7	Immediately dry the instruments in a hot air oven (70°C min-90°C max) for at least 10 minutes or with a suitable disposable, non-shedding wipe or with medical compressed air paying special attention to slots, lumens, mated surfaces, connectors and difficult to dry areas (i.e. laser-markings). Long and thin brushes can be used to dry lumens. Completing this significantly reduces the risk of corrosion caused by drops of water on the parts surface.

1.3.3 Manual/Automated Cleaning/Disinfection Procedure

Before starting with the automated cleaning/disinfection procedure it's advisable to perform an accurate manual cleaning by carrying out phases 1 to 3 as indicated at point 1.3.2.

Put the instruments inside a cleaning disinfection system compliant to ISO 15883, properly installed and validated.

Washer disinfector cycle: A0 value > 3000 (e.g. al least 5 min at 90 °C).

Recommendations:

- Avoid contact between instruments in order to prevent damages during washing.

- In order to assist drainage place the instruments so that cannulations are not horizontal and blind holes are downwards.

- Follow the cleaning agent manufacturer's instructions for the correct diluition, temperature, water quality and exposure time.

- At the end of the cycle visually inspect each instrument for dryness, if necessary dry the instruments in a hot air oven (70 °C min - 90 °C max) or with a suitable disposable non-shedding wipe, or with medical grade compressed air.

LSM-Med Srl advises against the performance of the sole automated cleaning/disinfection using automated cleaning/disinfection equipment as this procedure can be inefficacious for orthopaedic instruments.

1.4 INSPECTION, MAINTENACE, AND LUBRICATION

Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/ disinfection process.

Where instruments form part of a larger assembly, ensure a check is completed that devices assemble readily with compatible components.

Hinged, rotating, or articulating instruments should be lubricated with a water soluble product (e.g. Lubrimilk or equivalent lubricant) intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial.

Manufacturer's expiration dates should be adhered. Follow the lubricant manufacturer's instructions for both stock and use dilution concentrations.

1.4.1 Packaging

After inspection the instruments are to be placed in the proper slots of the boxes/trays suitable for steam sterilization.

All devices must be arranged to ensure steam penetration to all instrument surfaces. Instruments should not be stacked or placed in close contact.

The user must ensure that the instrument case is not tipped or the contents shifted once the devices are arranged in the case.

Commercially available, medical grade steam sterilization pouches or wrap may be used to package individual instruments.

Trays and cases with lids may also be wrapped in standard medical grade, steam sterilization wrap or placed in an approved sterilization container with gasket lid for sterilization.

Follow the sterilization containers' manufacturer's instructions for inserting and replacing sterilization filters within sterilization containers.

NOTE. Areas designated for specific devices shall contain only devices specifically intended for these areas.

1.5 STERILIZATION

LSM-Med Srl recommends moist heat sterilization (autoclave) with an operating cycle that employs forced air removal. Autoclaves should comply with the requirements of EN 285 or EN 13060. Autoclaves should be installed, validated and maintained in accordance with EN 285 or EN 13060. In case the user chooses another sterilization method the individual and/or hospital location takes on the responsibility for the sterilization efficacy and possible damages of **LSM-Med Srl** instruments.

Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contact with all surfaces. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded. Disinfection is only acceptable as a precursor to full sterilization for reusable surgical instruments.

The following minimum sterilization parameters are recommended to provide a sterility assurance level (SAL 10^{-6}).

Method	**Moist heat sterilization**	**According to ISO 17665**
Cycle	**Pre-Vacuum**	
Temperature	**132 - 134 °C**	
Holding time	**4 minutes minimum**	**Time for which the load and the entire chamber are continuosly within the sterilization temperature band.**
Dry time	**30 minutes minimum**	**In chamber. Dry times depends from several parameters (total mass, sterilizer performance, wraps, instruments material ecc.), the user should perform visual inspections to confirm adequate drying.**

NOTE. The instructions of the sterilization equipment use, configuration and maximum load issued by the manufacturer must be strictly followed.

Once sterilized the instruments must be handled with aseptic procedures.

1.6 STORAGE

Instruments are to be kept and carried in their boxes, this will provide suitable protection from impacts and damages, and at the same time will shield users from risks of cuts. Instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/ humidity extremes.

NOTE. Store instruments in their boxes. Protect components from involuntary contact with other instruments as it may lead to damaging their finishing. Before use check possible visible damages of each instrument.

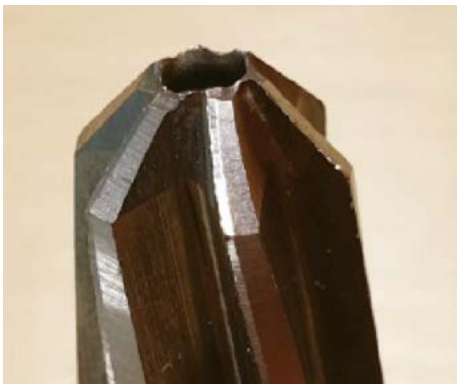
1.7 HOSPITAL RESPONSIBILITIES FOR LSM-Med Srl LOANER INSTUMENTS

Loaner sets, should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to **LSM-Med Srl**. Documentation of decontamination should be provided with instruments being returned to **LSM-Med Srl**. Instruments are to be returned in their boxes and the boxes are to be properly packaged inside a cardboard box suitable for preventing possible damages during transport.

1.8 NO LONGER USABLE INSTRUMENTS

Since most orthopaedic instruments are reusable, it is reasonable to expect some degree of general wear. If defects due to wear (e.g. scratches) do not alter the effectiveness of the instrument, the instrument can be used indicatively for about sixty uses.
If, on the other hand, these defects can deteriorate quality and functionality of the instrument, or can cause release of small particles of material inside the patient, the instrument must no longer be used even if the indicated number of uses has not been reached.
Some cases are reported below to let the user understand when a surgical instrument should no longer be used:

– Loss of cutting edge and wear of perforating parts



– Wear of closing devices, junctions, connecting and sliding parts

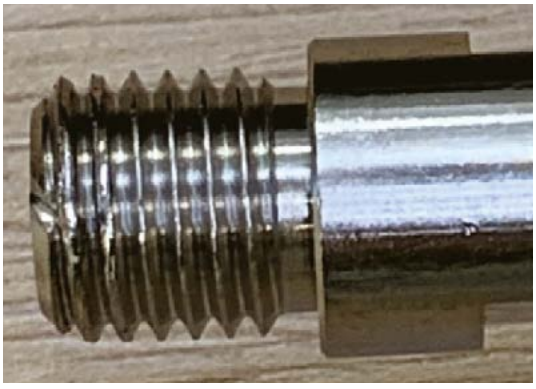
– Deformation of instruments with long and thin parts

– Presence of visible cracks and rifts



– Relevant signs of hits and dents


– Visibly damaged threaded part




– No longer readable graduated optical scales on the instrument

– Signs of oxidation and loss of anodized color

– Visibly deformed supports

2. NON-STERILE IMPLANTS

The informations provided are related to unsoiled implants. Explanted implants or implants that have become in contact with a patient must never be reprocessed and should be handled according to hospital protocol.

Products supplied in a non-sterile condition must be cleaned and steam sterilized before surgical use.

2.1 Cleaning and disinfection
2.1.1 Manual method

Remove all packaging before to clean the implant, clean the implant before first and every sterilization.

Phase 1	Prepare a new detergent solution with the proper cleaning agent (i.e. enzymatic cleaner or detergent solution), follow the cleaning agent manufacturer's instructions for the correct diluition, temperature, water quality and exposure time.
Phase 2	Place prepared cleaning agents in a sonication unit, completely submerge implants in cleaning solution and sonicate for a minimum of 15 minutes.
Phase 3	Rinse the implants in distilled or demineralised water for at least 5 minutes.
Phase 4	Immediately dry the implants in a hot air oven (70 °C minimum) for at least 10 minutes or with a suitable disposable non-shedding wipe, or with medical grade compressed air.

2.1.2 Automated washer disinfector

Equipment: washer disinfector properly installed and validated compliant to ISO 15883. Washer disinfector cycle: A0 value > 3000 (e.g. al least 5 min at 90 °C).

Recommendations.

• Avoid contact between devices in order to prevent damages to the implants during washing.

• In order to assist drainage place the implants so that cannulations are not horizontal and blind holes are downwards.

• Follow the cleaning agent manufacturer's instructions for the correct diluition, temperature, water quality and exposure time.

• At the end of the cycle visually inspect each implant for dryness, if necessary dry the implants in a hot air oven (70 °C minimum) for at least 10 minutes or with a suitable disposable non-shedding wipe, or with medical grade compressed air.

2.1.3 Warnings

• Contact of implants with strong acid or alkaline detergents / disinfectants or cleaning agents containing iodine or metal salts can cause corrosion of the implants.

• Always read the data sheet and other information from the manufacturer of the cleaning agent in order to verify the compatibility with the implant material.

• Careless handling, attacks of a chemical, electrochemical nature can adversely affect the corrosion resistance. After cleaning and disinfection inspect the implants in order to verify the absence of scratches, corrosion, debris, do not use implants with such defects.

• Avoid cross contamination of implants with soiled devices.

2.2 STERILIZATION

LSM-Med Srl recommends moist heat sterilization (autoclave) with an operating cycle that employs forced air removal.

Autoclaves should comply with the requirements of EN 285 or EN 13060.

Autoclaves should be installed, validated and maintained in accordance with EN 285 or EN 13060.

Place clean and dry implant in an approved wrap or container before to steam sterilization.

Method	**Moist heat sterilization**	**According to ISO 17665**
Cycle	**Pre-Vacuum**	
Temperature	**132 - 134 °C**	
Holding time	**4 minutes minimum**	**Time for which the load and the entire chamber are continuosly within the sterilization temperature band.**
Dry time	**30 minutes minimum**	**In chamber. Dry times depends from several parameters (total mass, sterilizer performance, wraps, instruments material ecc.), the user should perform visual inspections to confirm adequate drying.**

The user must validate and control the process implemented in its reprocessing facility.

Bibliography

EN 285
Sterilization, steam sterilizers, large sterilezers.

EN 13060
Small steam sterilzers

EN ISO 17664-1
Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices.

EN 17665
Sterilization of healthcare products - moist heat

European Pharmacopoeia

Info

LSM-Med Srl
reserves the right to make changes.

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