

Reprocessing Instruction

1 Scope

The following reprocessing instructions have been validated for the listed medical devices of medentis medical GmbH using the listed materials and methods and apply to all medentis medical products for which reprocessing before use is recommended according to the instructions for use (URL:ifu.medentis.de/, URL:ifu.davinci-implant.de/). The surgical boxes are suitable for the sterilisation described below.

2 Implementation

2.1 Cleaning / disinfection

Method:

Manual or automatic cleaning and disinfection followed by moist heat sterilization. The automated reprocessing method in the washer-disinfector (WD) is preferable to the manual method. The reprocessing of critical medical devices must always be carried out mechanically in the washer-disinfector.

Warnings:

The use of non-sterile components can lead to tissue infections or infectious diseases.

Medical devices intended for single use and already supplied sterile must not be cleaned and resterilized.

Without performing the pre-cleaning of the products described below (see section "Preparation prior to manual and mechanical cleaning/disinfection"), the necessary cleaning result cannot be guaranteed.

Limitation of reprocessing:

The service life of products marked as reusable is determined by their use. Dispose of damaged, worn or corroded products.

Procedure after use

Place instruments directly into containers of water after use on the patient. The water should not be warmer than max. 40°C. Coarse contaminants must be removed from the instruments immediately after use (within max. 2 hours).

Caution: Instruments made of stainless steel must never be placed in isotonic solution (such as physiological saline solution), as prolonged contact will lead to pitting corrosion and stress corrosion cracking.

Transport: After use, take the products to the place where cleaning is to take place. Avoid allowing contaminants to dry on. Transport should take place in a closed vessel/container to protect the products, the environment as well as the users.

Preparation before manual and automatic cleaning/disinfection**Equipment:** water bath, soft plastic brush

Multi-part instruments must be disassembled according to the respective instructions for use (e.g. ratchet, see <https://ifu.medentis.de/>).

Preparation: Use a soft brush for this purpose only and tap water to pre-clean the products. Rinse the products under running cold water (< 25 °C) (approx. 1 minute). Clean all external and internal surfaces with the plastic brush for approx. 2 minutes. Rinse all cavities at least five times (5x) with deionized water using a disposable syringe (minimum volume 20 ml)(approx. 1 min).

Caution: Tissue residues or blood must never be allowed to dry on. Never use metal brushes or steel wool to remove contamination manually.

Manual cleaning and disinfection**Equipment:** Ultrasonic bath, plastic brush, syringe, almost pH-neutral, enzymatic cleaning agent (e.g. 0.8 % Cidezyme (pH value: 7.8-8.8, Johnson & Johnson Medical, Norderstedt) or 1.5% Medizym, (pH value: 8.2, Chemische Fabrik Dr.Weigert, Hamburg)), disinfectant with the active ingredient ortho-phthalaldehyde (e.g. Cidex OPA, Johnson & Johnson Medical, Norderstedt), lint-free cloth.

The instructions for use of the cleaning agent manufacturer and the disinfectant manufacturer as well as the ultrasonic bath manufacturer must be observed!

Cleaning: Place the products for at least 5 minutes at a frequency of 25-50 kHz and a temperature lower than 45°C in an ultrasonic bath that has been mixed with (almost) pH-neutral, enzymatic cleaning agent. Deionised water (DI water) should be used. If the products have an opening/cavity, make sure that the cleaning solution can drain off after the treatment. All products should be covered by the cleaning solution. The temperature of the cleaning solution must not exceed 45°C. Then rinse 3x with running, deionised water (rinse cavities 3x with 20ml deionised water with a syringe). A fresh, unused cleaning solution should be used for each product. The previous steps should be repeated until there is no visible contamination left. Then rinse each product (and cavity, if applicable) thoroughly with deionised water (approx. 1 min).**Disinfection:** The products are disinfected in a disinfectant with the active ingredient ortho-phthalaldehyde for 12 min (rinse cavities and lumen 3 times with 20 ml disinfectant (syringe) at the beginning and end of the disinfection). Then rinse again five times under running deionised water (deionised water) Rinse cavities five times with 20ml deionised water (deionised water) using a syringe. A fresh, unused disinfectant solution should be used for each product.**Drying:** The products are then dried completely with a soft lint-free cloth.

Next step: Examination, inspection and tests

Automatic cleaning and disinfection

Equipment: Cleaning and disinfection device (WD), almost pH-neutral, enzymatic cleaning agent (e.g. Neodisher MediZym, Chemische Fabrik Dr. Weigert, Hamburg).

The instructions for use of the cleaning agent manufacturer and the WD manufacturer must be observed!

Suitable washer-disinfectors (WDs) that meet the requirements of EN ISO 15883 and bear a CE mark should be used for cleaning. The washing programme should be validated (A0 value > 3000, at least 5 min. at 90°C). The washer-disinfector should be regularly maintained and checked. Deionised water (DI water) should always be used.

Parameters:

- Pre-rinse with cold water for 5 min.
- Wash for 10 minutes with 40-45°C water and pH-neutral detergent
- 5 minutes intermediate rinse with cold water
- 5 minutes thermal disinfection with water at min. 93°C

Disinfection should be carried out at a maximum of 95°C for 10 minutes.

Drying: We recommend drying for 10 minutes at 80 - 90°C. Make sure that all instruments are completely dry after automatic drying in the WD. Cavities that are difficult to access can be dried with residue-free compressed air.

After cleaning, check the products, especially cavities and blind holes. Repeat the cleaning process if there is still visible contamination.

2.2 Packaging

Reassemble the disassembled instruments according to the appropriate instructions. Pack the products in a sterilisation container or in a sterilisation bag that meets the requirements of EN ISO 11607.

2.3 Sterilisation

The items supplied non-sterile are suitable for steam sterilisation. However, the original packaging is not suitable for steam sterilisation. Therefore, before sterilisation, the products intended for sterilisation must be packed in sterilisation packaging according to EN 868 or ISO 11607, e.g. in a transparent bag according to standard EN 868-5. The bag must be large enough for the product to be sterilised. The seal must not be under tension. When using clear packaging, ensure that the sealing process is validated (see manufacturer information).

Place the sealed products prepared for use in the steriliser. The steam sterilisers used must bear a CE marking and comply with the requirements of EN 13060 or EN 285. Only device- or product-specific validated procedures in accordance with ISO 17665 may be used. The instructions for use of the steriliser must be followed and the device should be serviced and checked regularly.

We recommend sterilisation by the fractionated vacuum method with the following parameters:

- Temperature: 134°C
- Pressure: 3 pre-vacuum phases with min. 60 millibar pressure, during holding time 3 bar
- Holding time: min. 5 minutes
- Drying time: min. 20 minutes

After sterilisation, the sterile packaging must be checked for damage, sterilisation indicators must be checked.

Caution: During sterilisation, a temperature of 137°C should not be exceeded.

2.4 Storage

Suitable storage should be ensured until the sterilised product is used. The products should be stored in a dry place at room temperature. The maximum storage time is determined by the type of packaging and the storage conditions and is the responsibility of the user. We recommend using the product immediately after sterilisation. Information on storage conditions and expiry dates can be found in the instructions of the manufacturer of the sterilisation container or the sterilisation packaging.

Caution: The products must no longer be used if the packaging is damaged or has been opened.

2.5 Testing and inspection

Visually inspect all instruments for damage and wear. Ensure that the markings are legible.

Locking mechanisms (ratchets, etc.) should be checked for function.

Maintain and lubricate the ratchet as described (<https://ifu.medentis.de/>).

Check long slender instruments (especially rotary instruments) for distortion.

If instruments are part of a larger assembly, check assembly with matching components.

Dispose of damaged or corroded instruments.

2.6 Additional information

Instructions for disassembly/assembly, maintenance and inspection/testing are documented separately (<https://ifu.medentis.de/>).

The above instructions have been validated as SUITABLE by the medical device manufacturer for preparing a medical device for reuse. It is the responsibility of the reprocessor to ensure that the actual reprocessing performed with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process.

