Processing instructions

Manufacturer:

Medentis Medical GmbH, Walporzheimer Str. 48-52, 53474 Bad Neuenahr-Ahrweiler

The following reprocessing instructions have been validated for the listed medical devices of medentis medical GmbH using the listed materials and methods.

The abutments, instruments as well as the drills are supplied non-sterile if they are not explicitly labelled as "sterile" (observe product labelling and instructions for use). They must be cleaned, disinfected and sterilised before first use on the patient. Products labelled for reuse must be cleaned, disinfected and sterilised before each further use on the patient.

Method: Manual or automatic cleaning and disinfection with subsequent sterilisation by moist heat. The machine 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.

Products: 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.

Warnings	The use of non-sterile components can lead to tissue infections or infectious diseases. Medical devices labelled as sterile must not be cleaned and resterilised and are intended for single use only. Without carrying out the pre-cleaning of the products described below (see section "Preparation before manual and mechanical cleaning/disinfection"), the necessary cleaning result cannot be guaranteed.
Restrictions on reprocessing	The service life of products marked as reusable is determined by their use. Dispose of damaged, worn or corroded products.

Instructions	
Procedure after use	After use on the patient, place the instruments directly in a container of water. The water should not be warmer than max. 40°C. Coarse impurities 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 leads to pitting corrosion and stress corrosion cracking.*

Transport	After use, move the products to the place where cleaning is to take place. Avoid allowing contamination 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/).
	***Caution**: Tissue remnants or blood must never be allowed to dry on*
	Use a soft brush for this purpose only and tap water to pre-clean the products. Rinse the products under running cold water (approx. 1 minute). Clean all exterior and interior surfaces with the plastic brush for approx. 2 minutes. Rinse all cavities min. five times (5x) with deionised water using a disposable syringe (minimum volume 20 ml).
	***Caution**: Never use metal brushes or steel wool to manually remove contamination*
Manual cleaning and disinfection	Equipment: Ultrasonic bath, plastic brush, syringe, almost pH-neutral, enzymatic cleaning agent (e.g. Cidezyme (Johnson & Johnson Medical, Norderstedt), disinfectant with the active ingredient ortho-phthalaldehyde (e.g. Cidex OPA, Johnson & Johnson Medical, Norderstedt), lint-free cloth. *The instructions for use of the detergent manufacturer and the disinfectant manufacturer as well as the ultrasonic bath manufacturer must be observed!* **Cleaning:** Place the products for min. 5 minutes at a frequency of 25-50 kHz in an ultrasonic bath that has been mixed with (almost) pH-neutral, enzymatic cleaning agent. Deionised water (deionised 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 3x with 20ml disinfectant (syringe) at the beginning and end of 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 detergent 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 or at least 5 min. at 90°C for older devices). The washer-disinfector should be regularly maintained and checked. Deionised water (DI water) should always be used. We recommend the following parameters for automatic cleaning and disinfection: • Pre-rinse with cold water for 5 minutes • 10 minutes with 40-45°C warm water and pH-neutral Wash detergent • Rinse with cold water for 5 minutes. • 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. Ensure 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.
Examination, inspection and tests	Visually inspect all products for damage and wear. Ensure the legibility of the markings. 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 the assembly with matching components. Dispose of damaged or corroded instruments.

Packing	1. reassemble the disassembled instruments according to the corresponding instructions. Pack the products in a sterilisation container or in a sterilisation bag that meets the requirements of EN ISO 11607.
Sterilisation	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 maintained 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 period: at least 5 minutes • Drying time: min. 20 minutes After sterilisation, the sterile packaging must be checked for damage, sterilisation indicators must be checked.
	***Warning: A** temperature of 137°C should not be exceeded during sterilisation.*
Storage	The products should be stored in a dry place at room temperature. We recommend using the product immediately after sterilisation. For information on storage conditions and expiry dates, refer to the instructions provided by the manufacturer of the sterilisation container or the sterilisation packaging.
	***Warning:** The products must no longer be used if the packaging is damaged or has been opened.*
Additional information	Instructions for disassembly/assembly, maintenance and inspection/testing are documented separately (https://ifu.medentis.de/).
Contact the manufacturer	Medentis medical GmbH Walporzheimer Str. 48-52 53474 Bad Neuenahr-Ahrweiler Tel.: +49 (0)2641 9110-0 Fax: +49 (0)2641 9110-120 E-mail: info@medentis.de https://medentis.de

The above instructions have been validated as SUITABLE by the medical device manufacturer for the preparation of a medical device for its reuse. The reprocessor has the responsibility

under EN ISO 17664 to ensure that the actual reprocessing performed with equipment, materials and personnel used in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process.

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