Processing (cleaning, disinfection and sterilization) of GOMINA chisels with accessories (handle, chucks)

General Principles

All handles and chucks, referred to below as instruments, must be cleaned, disinfected and sterilized prior to each application; this is required in particular when using the instruments for the first time after delivery (cleaning and disinfection after removal of the protective transport packaging, sterilization after packaging). Effective cleaning and disinfection is an indispensable requirement for sterilization to be effective.

As part of your responsibility for the sterility of the instruments, please ensure that

- as a matter of principle, only procedures with adequate device- and product-specific validation are used for cleaning, disinfection and sterilization,
- the used devices (WD, sterilizer) are maintained and checked regularly and
- the validated parameters are applied for each cycle.

Please also observe the applicable legal provisions in your country as well as the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different guidelines regarding effective inactivation of prions.

Cleaning and Disinfection

Basics

If possible, an automated procedure (WD (washer-disinfector)) should be used for cleaning and disinfecting the instruments. A manual procedure – even using an ultrasonic bath – should only be used, if an automated procedure is not available, as the efficiency and reproducibility is significantly less[1].

The pre-treatment step must be performed in both cases.

Pre-treatment

Remove coarse impurities from the instruments with a brush immediately after use (within 2 h maximum).

When selecting the cleaning agents to use[2], ensure that

- they are generally suitable for cleaning instruments made of metal,
- the cleaning agent is suitable for ultrasonic cleaning (no foam formation),
- the chemicals used are compatible with the instruments (see section on "Material Resistance").

The cleaning agent manufacturer's instructions regarding concentration, temperature and exposure time as well as rinsing requirements must be strictly observed. Only use freshly prepared solutions.

Manual Cleaning

Procedure:

1. Rinse the instruments for at least 1 minute under running water (temperature < 35°C / 95°F).
2. Place the instruments in an ultrasonic bath with the cleaning solution for the required exposure time. Make sure that the instruments are sufficiently submerged and are not touching each other. Manually remove all visible contamination (in particular from the inner contours of the handle and from the thread in the case of chucks) using a clean, soft brush used solely for this purpose, but never a metal brush or steel wool.
3. Also activate the ultrasonic cleaning for the required exposure time.
4. Rinse again for at least 1 minute under running water.
5. Repeat Steps 2 to 4 until no further contamination is visible.

Automated cleaning/disinfection (WD (washer-disinfector)

When selecting the WD, ensure that

- the WD has the generally approved efficiency (e.g. DGHM or FDA approval/clearance/registration or CE marking according to EN ISO 15883),
- if possible, an approved program for thermal disinfection (A_0 value > 3000 or – in the case of older devices - at least 5 min at 90°C / 194°F) is used (risk of disinfectant residue on the instruments with chemical disinfection),
- the program used is suitable for the instruments and includes sufficient rinse cycles,
- only sterile water or water with low bioburden (max. 10 germs/mL, max. 0.25 endotoxin units/mL) (e.g. purified/highly purified water) is used,
- the air used for drying is filtered air (oil-free, with a low microbial and particle count) and
- the WD is regularly maintained and checked.

When selecting the cleaning agent system used, ensure that

- it is fundamentally suitable for cleaning instruments made of metallic material,
- if thermal disinfection is not used, a suitable disinfectant with approved efficiency (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is used in addition and this is compatible with the cleaning agents used and
- the chemicals used are compatible with the instruments (see section on "Material Resistance").

The instructions provided by the manufacturer of the cleaning agent and, if applicable, the disinfectant regarding concentration, temperature, exposure time and rinsing must be strictly observed.

Procedure:

1. Transfer the disassembled instruments (the extraction bolt from the handle) into the WD in a small parts basket. The handle itself must be placed in the small parts basket opened and disassembled. Ensure that the instruments do not touch each other.
2. Start the program.
3. Remove the instruments from the WD after the end of the program.
4. Check and pack the instruments as soon after removal as possible (see the sections on "Inspection", "Maintenance" and "Packaging" if necessary, after additional drying in a clean place).

The fundamental suitability of the instruments for effective automated cleaning and disinfection was demonstrated by an independent accredited *and recognized* test laboratory *(section 15(5) MPG [Medical Devices Act])* using WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh) (D-V-MEDFORTE program identical to Miele DES-VAR-TD) and the cleaning agent Neodisher mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account in the process.

Inspection

After cleaning or cleaning/disinfection, inspect all the instruments for corrosion, damaged or chipped surfaces, impurities including bone and tissue remnants in particular) or discoloration and discard damaged instruments (for restriction on the number of re-use cycles, see the section

[1] Use of a manual cleaning and disinfection procedure requires.an additional product- and procedure-specific validation under the responsibility of the user.

[2] If a combined cleaning and disinfectant agent is used for this (e.g. for health and safety reasons), please ensure that this is aldehyde-free (otherwise fixation of blood impurities may occur), has the approved efficiency (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), is suitable for the disinfection of instruments made of metallic or plastic material and is compatible with the instruments (see section "Material Resistance"). Please note that the disinfectant used in the pre-treatment step is only for the protection of personnel and cannot replace the disinfection step, which must be performed later after cleaning.

on “Reusability”). Instruments that are still dirty must be cleaned and disinfected again.

Maintenance

Instrument oils or grease must not be used.

Packaging

Pack the instruments in single-use sterilization packaging (single or double packaging) which fulfills the following requirements (material / process):
- EN ISO/ANSI AAMI ISO 11607
- suitable for steam sterilization (temperature resistance up to at least 142°C (288 °F), sufficient steam permeability)
- sufficient protection of the instruments or sterilization packaging from mechanical damage

Alternatively, suitable sterilization containers can be used to maintain sterility.

Sterilization

Please only use the sterilization procedures listed below for sterilization; other sterilization procedures must not be used.

Steam sterilization
- fractionated vacuum procedure[3,4] (with sufficient product drying[5])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79
- validated according to EN ISO 17665 (applicable IQ/OQ (picking and packing) and product-specific performance qualification (PQ))
- maximum sterilization temperature 138°C (280°F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature) at least 3 min[6] at 132°C (270°F)/134°C (273°F minimum)

The fundamental suitability of the instruments for effective automated cleaning and disinfection was demonstrated by an independent accredited and recognized test laboratory (section 15 (5) MPG) using steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum procedure. Typical conditions in hospital and doctor´s practice as well as the procedure described above were taken into account for this.

The flash/immediate use sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization or plasma sterilization.

The handle and chuck are designed for 50 reprocessing cycles.

Storage

After sterilization, store the instruments in the sterilization packaging / sterilization containers in a dry and dust-free place.

Material Resistance

Please ensure when selecting the cleaning agent or disinfectant that they do not contain the following ingredients:

- organic, mineral and oxidizing acids (minimum permitted pH-value 5.5)
- strong lyes (maximum permitted pH-value 11, weak alkaline cleaner without neutralization recommended)
- oxidizing agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)

Never clean any instruments with metal brushes or steel wool.

Please do not expose any instruments to temperatures higher than 142°C (288 °F)!

Cleaning agents with corrosion inhibitors and rinse aids must not be used!

Reusability

The instruments can be reused, if adequate care is taken and if they are undamaged and clean. The handle and chuck are designed for 50 reprocessing cycles. The use of damaged and dirty instruments is the sole responsibility of the user.
The instruments must not be resharpened or altered by other mechanical processing.

No liability is accepted if this is not complied with.

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3 At least three vacuum steps

4 The less effective gravity displacement procedure should only be used if the fractionated vacuum procedure is not available, it normally requires significantly longer sterilization time and must undergo product-, device- and procedure-specific validation by the user.

5 The drying time actually required depends directly on parameters which are the sole responsibility of the user (load configuration and density, sterilizer condition...) and must therefore be determined by the user. Nevertheless, drying times should not be less than 20 min.

6 or 18 min