

## Processing (cleaning, disinfection, and sterilization) of GOMINA saw blades

### Fundamental points

All saw blades are to be cleaned, disinfected, and sterilized prior to each application; this is required in particular when using the unsterile saw blades for the first time after delivery (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). Effective cleaning and disinfection is an indispensable requirement for sterilization to be effective.

You are responsible for the sterility of the saw blades. Therefore, please ensure that

- only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization,
- the used devices (WD, sterilizer) will be maintained and checked regularly,
- the validated parameters will be applied for each cycle.

Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the doctor's practice or of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions.

### Transport

To protect the medical device, the environment and the medical personnel, you must ensure a safe transport of the used instruments to the processing site. Accordingly, collect them up after use and place side by side in a sealed container.

### Cleaning and disinfection

#### Basics

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the saw blades. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered<sup>1</sup>.

The pre-treatment step is to be performed in both cases.

#### Pre-treatment

Please remove coarse impurities of the saw blades directly after application (within a maximum of 2 h).

Pay attention to following points during selection of the cleaning detergent<sup>2</sup>:

- fundamental suitability for the cleaning of instruments made of metallic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the used detergents with the saw blades (see chapter „material resistance,“)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions.

<sup>1</sup> In case of application of a manual cleaning and disinfection procedure a product and procedure specific validation under responsibility of the user is required.

<sup>2</sup> In case of application of a combined cleaning and disinfection detergent for this (e.g. in consequence of personnel's safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the saw blades (see chapter „material resistance,“). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel's safety, but cannot replace the disinfection step later to be performed after cleaning.

### Manual Cleaning

#### Procedure:

1. Rinse the saw blades for at least 1 minute under running drinking-quality tap water (temperature < 35 °C/95 °F).
2. Place the saw blades in a small parts basket for the required exposure time in an ultrasonic bath with the cleaning solution, so that the saw blades are sufficiently submerged. Ensure that the blades do not touch.  
Remove all visible contamination (particularly from the serration) manually using a clean soft brush intended solely for this purpose, but never a metal brush or steel wool.
3. Additionally activate the ultrasonic cleaning for the required exposure time.
4. Rinse again for at least 1 minute under running drinking-quality tap water.
5. Repeat Steps 2 to 4 until no contamination is visible (particularly bone residues in the serration).

### Automated cleaning/disinfection (WD (Washer-Disinfector))

Please pay attention to following points during selection of

#### the WD:

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- possibility for an approved program for thermal disinfection (A<sub>0</sub> value > 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the saw blades)
- fundamental suitability of the program for saw blades as well as sufficient rinsing steps in the program
- the quality of water used must meet the requirements of DIN EN ISO 15883 (fully deionized water / pH value between 5–8)
- only uses filtered air (oil-free, low contamination with microorganisms and particles) for drying
- a validated procedure must be used for the implementation with the WD
- regularly maintenance and check/calibration of the WD

Please pay attention to following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the saw blades (see chapter „material resistance,“)

Please pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

#### Procedure:

1. Transfer the disassembled saw blades using a small pieces basket in the WD (pay attention that the blades do not touch)
2. Start the program.
3. Remove the saw blades of the WD after end of the program.
4. Check and pack the saw blades immediately after the removal (see chapters „check,“, „maintenance,“, and „packaging,“, if necessary after additional post-drying at a clean place)

The fundamental suitability of the saw blades for an effective automated cleaning and disinfection was demonstrated by an independent accredited and recognized (§ 15 (5) MPG) test laboratory by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the cleaning detergent Neodisher mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

## Check

Check all saw blades after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities (especially including bone remnants). Do not further use damaged saw blades (for limitation of the numbers of re-use cycles see chapter „reusability,“). Still dirty saw blades are to be cleaned and disinfected again.

## Maintenance

Instrument oils or grease must not be used.

## Packaging

Please pack the cleaned and disinfected saw blades in single-use sterilization packagings (single or double packaging), which fulfil the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the saw blades as well as of the sterilization packagings to mechanical damage

## Sterilization

Please use only the listed sterilization procedures for sterilization; no other sterilization procedures may be applied.

### Steam sterilization

- fractionated vacuum/dynamic air removal procedure<sup>34</sup> (with sufficient product drying<sup>5</sup>)
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMIST79
- validated according to EN ISO 17664 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 138 °C (280 °F; plus tolerance according to EN ISO 17664)
- sterilization time (exposure time at the sterilization temperature) at least 3 min<sup>6</sup> at 132 °C (270 °F)/134 °C (273 °F)
- water for the vacuum pump (tap water: hardness: 7–20° f, 4–11 dH, 0.7–2 mmol/L, temperature: max. 20 °C)
- water for steam generation (osmosis water or demineralized water: according to DIN EN 285 Appendix B, Table B1)

<sup>3</sup> at least three vacuum steps

<sup>4</sup> The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure, normally requires a significantly longer sterilization time, and is to be validated by the user under consideration of product, device, and procedure.

<sup>5</sup> The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions...) and by this is to be determined by the user. Nevertheless, drying times of less than 20 min must not be applied.

<sup>6</sup> respectively 18 min

The fundamental suitability of the saw blades for an effective steam sterilization was demonstrated by an independent accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum/dynamic air removal procedure. For this, typical conditions in clinic and doctor's practice as well as the specified procedure were considered.

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

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

The saw blades are intended for 5 reprocessing cycles.

## Storage

Please store the saw blades after sterilization in the sterilization packaging in a dry and dust-free place.

The duration of the storage of the prepared instruments varies due to the different process parameters and cannot be definitively specified. The responsibility for this lies with the user.

## Material resistance

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:

- organic, mineral, and oxidizing acids (minimum admitted pH-value 5,5)
- strong lyes (maximum admitted pH-value 11, weak alkaline cleaner without neutralization recommended)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)

Please do not clean any saw blades by use of metal brushes or steel wool.

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

Cleaning detergent with corrosion inhibitors as well as rinsing aids must not be used!

## Reusability

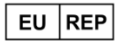
The saw blades can be reused – in case of adequate care and if they are undamaged and clean – 5 times. The user is responsible for each further use as well as for the use of damaged and dirty saw blades. The saw blades must neither be sharpened nor changed through other mechanical processing (no liability in case of disregard).

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