Processing (cleaning, disinfecting, and sterilizing) of medical devices

The medical devices are reusable unless their label contains explicit information to the contrary. However, as a rule, it is the sole responsibility of the doctor/expert using the devices to decide whether, depending on the respective case and the potential wear and tear of the products, he can reuse the products and how frequently he uses them. In case of doubt, it is always advisable to discard the products early and to replace them. The manufacturer cannot guarantee the faultless function and performance of the products combined with a maximum degree of safety if the products are overused.

These reprocessing instructions apply in principle to all medical devices. Any particular features and/or exclusions that only concern individual items or groups of items are referred to separately. As to the general application and safety instructions concerning the use of the products, we would advise you to consult the application and safety instructions for the medical products.

General Principles

All products are to be cleaned, disinfected, and sterilized prior to each application; this is required in particular for the first-time use after delivery of the unsterile instruments (cleaning and disinfecting after the removal of transport packaging; sterilization after removing wrapping). An effective cleaning and disinfection are an indispensable requirement for an effective sterilization of the instruments.

As you are responsible for the sterility of the products during use, please ensure that only sufficient device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization:

- that the used devices (disinfector, sterilizer) are maintained and checked at regular intervals and
- that the validated parameters are adhered to during each cycle.

Please ensure to avoid a higher contamination of the complete sterilization tray during application by separate collection of contaminated instruments (without laying back into the sterilization tray). Pre-clean the contaminated instruments, then sort them back into the sterilization tray and clean, disinfect and sterilize the completely equipped sterilization tray.

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 (not relevant for USA).

As the products are destined to be used for surgical, periodontological or endodontic procedures such as root canal debridement, they may penetrate the skin or the mucosa and come into contact with blood, internal tissues or organs (including wounds). Therefore, we recommend that they be assigned to risk group Critical B if used for their intended purpose. Attention: In the case of some instruments, there are additional or deviating procedures required (see chapter “Specific aspects”).

Cleaning and disinfecting

Basic rules:
If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. 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. The pre-treatment step is to be performed in both cases.

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Pre-treatment:

Abrasive impurities need to be removed from the products directly after use (within two hours maximum).

Procedure:

1. Disassemble the instruments as possible. Remove contaminated instruments of the sterilization tray (see chapter "Specific aspects").
2. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F). If applicable (see chapter "Specific aspects"). Rinse all lumens of the instruments at least three times at the beginning and at the end of the soaking time with a syringe (minimum volume 5-10 ml). Sway movable parts at least three times during pre-rinsing.
3. Soak the disassembled instruments for the given soaking time in the pre-cleaning solution[1] so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush[2] (at beginning of soaking, see chapter "Specific aspects") and subsequent ultrasonic treatment (after brushing, for the minimum soaking time, but not less than 5 min). Sway movable parts at least three times during pre-cleaning. If applicable (see chapter "Specific aspects"). Rinse all lumens of the instruments at least three times at the beginning and at the end of the soaking time with a syringe (minimum volume 5-10 ml).
4. If applicable (see chapter "Specific aspects"). Rinse all lumens of the instruments at least three times at the beginning and at the end of the soaking time with a syringe (minimum volume 5-10 ml).
5. Check the instruments on visible remnants. In case of still remaining remnants (e.g., bone or dentin particles) repeat steps 2 to 5, otherwise discard the instruments.

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml), as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

1. In case of application of a 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 clearance or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material and be compatible with the instruments (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.
2. Never clean products, bur blocks and sterilization trays using metal brushes or steel wool.

Automated cleaning/disinfection (disinfector/ WD (Washer-Disinfector)):

Please consider the 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 clearance).
- possibility for an approved program for thermal disinfection (A0 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 instruments).
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program.
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water.
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying.

If a WD is built in accordance with DIN EN ISO 15883 and regularly tested and maintained during its service life, it meets the above-mentioned requirements with regard to water and air quality.

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When choosing an appropriate cleaning and disinfecting agent you need to ensure:

- fundamental suitability for the cleaning of instruments made of metallic or plastic 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 clearance or CE marking) compatible to the used cleaning detergent.
- compatibility of the used detergents with the instruments (see chapter "material resistance").

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

Procedure:

1. Disassemble the instruments as possible. Only pre-cleaned instruments can be sorted into the sterilization tray (e.g., bur blocks made of stainless steel (see chapter "Specific aspects")).
2. Transfer the disassembled instruments in the WD (pay attention that the instruments have no contact). If applicable (see chapter "Specific aspects"). Connect the instruments to the rinsing port of the WD.
3. Start the program.
4. Disconnect (if applicable) and remove the instruments of the WD after end of the program.
5. Check and pack the instruments 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 instruments for an effective automated cleaning and disinfection was demonstrated by an independent, governmentally 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 pre-cleaning and cleaning detergent Neodisher mediclean forte (5 min at 95° C) (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

Manual cleaning and disinfection:

When choosing an appropriate cleaning and disinfecting agent you need to ensure

- fundamental suitability for the cleaning and disinfection of instruments made of metallic or plastic material.
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development).
- application of a disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA clearance or CE marking) compatible with the used cleaning detergent.
- compatibility of the used detergents with the instruments (see chapter "material resistance").

Combined cleaning/disinfection detergents should not be used. Only in case of extremely low contamination (no visible impurities) combined cleaning/disinfection could be used. 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 as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

Procedure: Cleaning

1. Disassemble the instruments as possible. Only pre-cleaned instruments can be sorted into the sterilization tray (see specific dismantling instructions).
2. Soak the disassembled instruments for the given soaking time in the cleaning solution so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush[1] and subsequent with ultrasonic treatment (after brushing, for the minimum soaking time, but not less than 5 min). Sway movable parts at least three times during cleaning. If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 5-10 ml).
3. Then, remove the instruments of the cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Sway movable parts at least three times during post-rinsing. If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 5-10 ml).
4. Check the instruments (see chapters "check" and "maintenance").

1. Never clean products, bur blocks and sterilization trays using metal brushes or steel wool.

Disinfection

5. Soak the disassembled instruments for the given soaking time in the disinfectant solution so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Sway movable parts several times during disinfection. If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 5-10 ml).
6. Then, remove the instruments of the disinfectant solution and post-rinse them at least five times intensively (at least 1 min) with water. Sway movable parts at least three times during post-rinsing. If applicable (see specific dismantling instructions): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 5-10 ml).
7. Dry and pack the instruments immediately after the removal (see chapter "packaging", if necessary, after additional post-drying at a clean place).

The fundamental suitability of the instruments for an effective cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the cleaning detergent Gigazyme (5 min with 5% solution) and the disinfectant Gigasept Instru AF (15 min with 3% solution) (Schülke & Mayr GmbH, Norderstedt) considering the specified procedure.

Checking

After all products have been cleaned and/ or cleaned/disinfected, check them for corrosion, damaged surfaces/ bare patches, broken/chipped-off edges, deformations (e.g., bent rather than round) and impurities and eliminate damaged products (limited numbers for re-use see chapter on 'Re-use'). Products that are still contaminated need to be cleaned and disinfected once more.

Maintenance

- Re-assemble disassembled products (see specific instructions).
- Instrument oils must not be used.

Packaging

Please insert the cleaned and disinfected products in the dedicated bur block/sterilization tray. Please pack the instruments or the sterilization trays single-use sterilization packaging (single or double packaging) and/or sterilization containers, which fulfill 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 138 °C (280 °F), sufficient steam permeability).
- sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage.
- regular maintenance according to the instructions of the manufacturer (sterilization container).
- Individual packaging: the packaging must be sufficiently large to ensure that the sealing is tension-free.

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Sterilization

We only recommend the use of the sterilization procedures listed below.

Steam sterilization:

- fractionated vacuum/dynamic air removal procedure[1] (with sufficient product drying[3]).
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance).
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ)).
- maximum sterilization temperature 134 °C (273 °F; plus, tolerance according to EN ISO 17665).
- sterilization time (exposure time at the sterilization temperature):

Cycle Type	Exposure time at 132° C 270°F)	Minimum Drying Times
Fractionated Vacuum / Dynamic Air-Removal	4 minutes	20-30 minutes

[1] at least three vacuum steps

[2] 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 less than 20 min must not be applied.

[3] respectively 18 min (inactivation of prions, not relevant for USA).

The fundamental suitability of the instruments for an effective steam sterilization was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer Systec V-150 (Systec GmbH Labor-Systemtechnik, Wettenberg) 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, and ethylene oxide sterilization, as well as plasma sterilization.

Storage

Prior to the first use of the device, the product should be stored in its original packaging at room temperature in dust- and humidity-free conditions. Subsequently, the products should be stored in appropriate hygienically maintained containers (protected from dust, humidity, and recontamination). After sterilization, the products need to be stored in sterilization wrapping in a dry and dust-free place. Please note the shelf-life resulting from the validation of the sterilization wrapping.

Material resistance

When choosing the cleaning and disinfecting agents ensure that they do not contain the following ingredients:

- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- strong lye (maximum admitted pH-value 11, neutral/enzymatic, weak alkaline or alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

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Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments. Please do not clean any instruments and sterilization trays by use of metal brushes or steel wool. Please do not expose any instruments and sterilization trays to temperatures higher than 138 °C (280 °F)!

Re-use

The instruments can be reused – in case of adequate care and if they are undamaged and clean. For bur blocks – in case of adequate care and if they are undamaged and clean – a reuse up to 100 times is possible. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

Specific aspects

Diamond products and ceramic grinding tools:

- Use particular care during the cleaning of the grinding surfaces and ensure that all residues are removed

Products equipped with a conduit to supply a cooling medium and other products with lumens (canals, drillings etc.):

- Actively rinse the lumen during pre-cleaning and manual cleaning and disinfection process
- Products containing lumens without feed-through channels must not be re-used

Supports:

- Disassemble instrument completely prior to cleaning and disinfecting
- Wrapping and sterilization only in disassembled state

The above instructions have been validated by the manufacturer of the medical devices who found them to be SUITABLE for preparing a medical device for re-use. It is up to the person in charge of the reprocessing to ensure that, based on the use of the correct equipment, material and personnel in the reprocessing facility, the actual reconditioning process produces the desired results. Normally, this requires the validation and routine monitoring of the procedure. Equally, each deviation from the instructions provided should be carefully checked for effectiveness and potential adverse consequences by the person in charge of reprocessing.

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Fabriqué pour :

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