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

Pay attention to following points during selection of the detergent:

1. fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DIN 6895 or FDA approval/clearance/registration)
2. possibility of an approved program for thermal disinfection (All Values > 3000 or in case of older devices - at least 5 min at 120 °C / 194 °F), in case of chemical disinfection damage of remnants of the disinfectant on the instruments
3. fundamental suitability of the program for instruments as well as their sufficient rinsing steps (in case of a thermal disinfection, the products always meet the maximal degree of safety if the products are oversoaked. These reprocessing instructions apply in principle to all medical devices making up the product range suggested by Jota AG. Any particular features and exclusions that only concern individual items or groups of items are referred to separately.

Fundamental points

All instruments are to be cleaned, disinfected, and sterilized prior to each new application, that is as well as the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

You are responsible for the sterility of the instruments. Therefore, please ensure that only sufficiently dense and product specifically validated procedures will be used for cleaning, disinfection, and sterilization. (All washing agents used for instrument care, washing agents used for instruments made of metallic or plastic material, and be compatible with the instruments (see chapter "material resistance.")

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

Procedure:

1. Transfer the instruments in the WD by use of a small plastic basket.
2. Start the program.
3. Remove the instruments of the WD after the end of the program.
4. Check, maintain, pack, ... (see chapter "check, maintenance, and packaging, if necessary after additional post-drying at a clean place.

The fundamental suitability of the instruments for an automated cleaning and disinfection detergent 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 medical forte (Dr. Weigert GmbH & Co., KG, Hamburg) considering to the specified procedure.

Manual cleaning and disinfection:

Pay attention to following points during selection of the cleaning and disinfection detergent:

1. fundamental suitability for the cleaning and disinfection of instruments made of metallic or plastic material
2. additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAM/DGSM or FDT/FEMA approval/clearance/registration or CE marking) compatible with the used cleaning detergent
3. compatibility of the used detergents with the instruments (see chapter "material resistance.")

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

Procedure:

1. Soak the instruments at least for the given soaking time in the pre-cleaning solution (for example a solution of ultrasonic bath) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by carefully brushing the instruments with a soft brush (at least three times at the beginning of soaking, aids see chapter "specific aspects").
2. Activate ultrasonic treatment for an additional soaking time (but not less than 15 min).
3. Then, remove the instruments of the disinfectant solution and post-rinse them at least three times intensively (at least 1 min) with water.
4. Check the instruments (see chapters "check, maintenance, and packaging.")

Disinfection

5. Soak the 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.
6. Then, remove the instruments of the disinfectant solution and post-rinse them at least five times intensively (at least 1 min) with water.
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 detergent was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the pre-cleaning and cleaning detergent Cediazym/Estrool and the disinfectant Cidex QPA (Johnson & Johnson GmbH, Norderstedt) considering the specified procedure.

Check

Check all instruments after cleaning/dischinfection, respectively, on corrosion, damaged surfaces, and impurities. Do not further disassemble the instruments. Consider a maximum of the number of re-use cycles see chapter "resusability"). Still dirty instruments are to be cleaned and disinfected again.

Manual cleaning and disinfection:

Instruments or grease must not be used with the exception of steel instruments. In that case use only instrument oils (white oil) admitted for instrument care (for example: A4202 or A4250). A temperature of 142 °C (288 °F), satisfactory moisture permeability, and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

For the bur blocks alkaline cleaners must not be applied (maximum admitted pH-value 5.5)

1. Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

Storage

Please store the instruments after sterilization in the sterilization packaging at a dry and dust-free place.

Material resistance

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

- organics, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum admitted pH-value T1, neutral/eutrophic cleaning solution recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- packing agents (for example: hydrogen peroxide)
- halogens (Chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

For the bur blocks alkaline cleaners must not be applied (maximum admitted pH-value 5.5)

1. Do not use any cleaners and bur blocks by use of metallic brushes at steel wool.

2. Do not use any instruments and bur blocks to temperatures higher than 142 °C (288 °F)

Please do not use acidic neutralizing agents or cleaning aids.

Reusability

In case of unusual contamination the instruments can be reused – in case of adequate care and if they are not damaged and cleaned as indicated in chapter "specific aspects", the user is responsible for each further use as well as for the use of damaged and dirty ends.

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Instrument group | brush | specific/additional procedure in case of | pretreatment | manual cleaning/ disinfection | automated cleaning/ disinfection | maintenance | packing | sterilization | maximum admitted cycle number (confirmed by validation, but dependent on specific application) | recommended classification according to KRRK/IKK/BISAm guidance (only German, with respect to intended use)
--- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | ---
stainless steel instruments | standard | standard | standard | lubrication not admitted | standard | standard | standard | 10 | critical B
regular steel instruments | standard | standard | standard | lubrication recommended | standard | standard | standard | 10 | critical B
silicone polisher | standard | standard | standard | lubrication not admitted | standard | standard | standard | 5 | critical B
endodontic instruments without stopper | endodontic brush | standard | standard | lubrication not admitted | use of bur blocks not admitted | use of bur blocks not admitted | 10 | critical B
endodontic instruments with stopper | endodontic brush | mounted | mounted move the stopper at least three times during disinfection | lubrication not admitted | use of bur blocks not admitted | use of bur blocks not admitted | 10 | critical B
all other instruments | standard | standard | standard | lubrication not admitted | standard | standard | standard | 10 | critical B

Additional instructions regarding the use of trepans
- When using trepans, you have to proceed with particular care. For example, if a noticeable, not to exceed the recommended rpm speed range.
- In order to prepare for the actual use of a trepan, it should be set to produce counter-clockwise rotations creating a groove in the bone. Afterwards the trepan can be inserted into this groove and, using clockwise rotations, it can be moved further along.
- Carrying out a prior X-Ray is essential to establish the maximum possible drilling depth and to maintain the necessary distance, for example, to the mandibular nerve. As an additional safety measure to spare the nerve, the axial direction of the trepan counter-clockwise attachment, based on the sagittal level of the ascending branch, must be milled laterally at an angle of approx. 15-20°.

Further comments:
- Due to statutory regulations, returned goods can, on principle, only be accepted if the complete batch number is provided. This number can be found on the product packaging.

**Jota AG products (dental, maxillofacial surgery, general surgery), medical devices, instruments and products are subject to wear. The option of and accountability for multiple use of a product and the frequency of application is solely the decision and own responsibility of the treating clinician based on the application in each case and the possible wear of the products. If in doubt, the products should always be sorted out early and replaced.
- Instruments that are bent and/or do not run true should be out early and replaced.
- Broken off cutting edges of instruments cause vibrations and great forces of pressure, which, in turn, leads to broken prepa-
raters, corners and rough surfaces.
- Bare patches on diamond instruments indicate a lack of abra-
vive particles and can be a sign of blunt instruments. This leads
to excessive temperatures during instrument use.
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Use of pressure
- Users of the instruments should at all times avoid applying excessive pressure. This can damage the working part of the instruments and cause the cutting edges to break off. At the same time, it generates excessive heat.
- The use of excessive pressure when using grinding tools can cause the abrasive particles to break off at the instrument to become clogged and lead to heat generation.
- During polishing, excess pressure can lead to heat generation.
- Due to overheating, excess pressure can damage the dental pulp or, due to broken off cutting edges, it can result in undesired roughness of the cut. In such cases, even instrument breakage cannot be excluded.

Cooling
- In order to avoid excessive heat generation during preparation, a sterile water/sodium chloride solution supplied via a perma-
nent external feeding device should be used to ensure suffici-
cent cooling during use of the instruments.