HINWEISE ZUR WIEDERAUFBEREITUNG & ALLGEMEINE ANWENDUNGS- UND SICHERHEITSHINWEISE

INSTRUCTIONS FOR PROCESING & GENERAL APPLICATION AND SAFETY INSTRUCTIONS

Instructions for the processing
(Cleaning, disinfection, and sterilization)
of instruments from Jota AG
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The medical devices produced and sold by Jota AG are re-usable 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 re-use 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 Jota AG 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 making up the product range supplied by Jota AG. Any particular features and/or exclusions that only concern individual items or groups of items are referred to separately.

Fundamental points

All instruments are classified as semi-critical instruments and are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for 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 are indispensable requirements for an effective sterilization of the instruments.

You are responsible for the sterility of the instruments. Therefore, please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD, sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Please pay attention to avoid a higher contamination of the complete bur block during application; otherwise, it is necessary to clean and disinfect the bur block as well as all instruments inside (after removal).

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). It also refers to country specific specification of workplaces for cleaning and disinfection.

Some instruments require additional aspects. For this, pay attention-on to chapter “Specific aspects”.

Cleaning and disinfecting

Basic:
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.

Pre-treatment:
Please remove coarse impurities of the instruments directly after application (within a maximum of 1 h).

Procedure:

1. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F).
2. Soak the instruments at least for the given soaking time in the pre-cleaning solution (e.g. ID 212 forte, 2% for 5 Minutes; by the use of an ultrasonic bath) 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 (at least three times after beginning of soaking, aids see chapter “Specific aspects”).
3. Then activate ultrasonic treatment for an additional soaking time (but not less than 5 min).
4. Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with cold tap water.
5. In case of still visible contamination repeat steps 2, 3, and 4, otherwise discard the instrument. This is especially relevant for diamond instruments.

Pay attention to following points during selection of cleaning detergent 1):

› fundamental suitability for the cleaning of instruments made of metallic or plastic material
› suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
› compatibility of the cleaning detergent with the instruments (see chapter „material resistance„)

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 demineralized 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 approval/clearance/ registration 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.

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

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 (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 demineralized 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
› regularly maintenance and check/calibration of the WD

Pay attention to following points during selection of the cleaning deter-gent:

› fundamental suitability for the cleaning of instruments made of metallic or plastic material
› additional application – in case of non-application of a thermal dis-infection – 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 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. Transfer the pre-cleaned instruments in the WD by the use of a small piece’s basket or tray.
2. Start the program:
   3 min pre-rinsing with cold tap water (<30°C)
   drain
   10 min cleaning at 50 - 60°C with 0.2-1% Neodisher® Mediclean Dental
   drain
   1 min rinsing with demin. water (40-45°C)
   drain
   1 min rinsing with cold demin. water (<30°C)
   drain
   5 min thermal disinfection for 5 min at 90-92°C with demin. water
   drain
   30 min automatic drying at 100°C
   (wd program)
3. Remove the instruments of the WD after end of the program.
4. 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 7835 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the pre-cleaning and cleaning detergent neodisher® Mediclean Dental (Dr. Weigert GmbH & Co. KG, Hamburg) con-sidering to the specified procedure.

Manual cleaning and disinfection (not recommended):

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

› fundamental suitability for the cleaning and disinfection of instruments made of metallic or plastic material
› in case of application of an ultrasonic bath: 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 approval/clearance/registration 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 demineralized 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.

Manual Procedure after Pre-treatment:

Manual Cleaning

1. Soak the instruments for the given soaking time in the cleaning solution (e.g. ID 212 forte, 2% for 5 Minutes; by the use of a ultrasonic bath) 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 (at least three times after at beginning of soaking, aids see chapter “Specific aspects”).
2. Then activate ultrasonic treatment for an additional soaking time (but not less than 15 min).
3. Then, remove the instruments of the cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water.
4. Check the instruments (see chapters „check„ and „maintenance„).

Manual Disinfection

5. Soak the instruments for the given soaking time in the disinfectant solution (e.g. ID 212 forte, 2% for 1 Minutes; by the use of a ultrasonic bath) 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 was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the pre- cleaning and cleaning detergent and the disinfectant ID 212 forte (Dürr Dental SE, Bietigheim-Bissingen) considering the specified procedure.

Check
Check all instruments after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities. Do not further use damaged instruments (for limitation of the numbers of re-use cycles see chapter „reusability„). Still dirty instruments or instruments with visible residuals (under regular light conditions) are to be cleaned and disinfected again.

Maintenance
Instrument oils or grease must not be use except for steel instruments. In that case use only instrument oils (white oil) admitted to steam sterilization considering the maximum possible sterilization temperature, with approved biocompatibility and without mono-, di, or triethanolamine as corrosion inhibitor.

Packaging
Please insert the cleaned and disinfected instruments in the corresponding bur blocks (if required) and pack them in single-use sterilization packaging (single or double packaging), 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 142 °C (288 °F), sufficient steam permeability)
› sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage

Sterilization
Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

› fractionated vacuum/dynamic air removal procedure[2, 3] (with sufficient product drying5)
› 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 perfo mance qualification (PQ))
› maximum sterilization temperature 138 °C (280 °F; plus tolerance according to EN ISO 17665)
› sterilization time (exposure time at the sterilization temperature):

Area	fractionated vacuum/dynamic air removal	gravity displacement
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min[4]	not recommended
other countries	at least 3 min[5] at 132 °C (270 °F) / 134 °C (273 °F), drying time at least 20 min[4]	not recommended

[2] at least three vacuum steps
[3] The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure, will require significantly longer sterilization times and is to be validated dependent on product, packaging, sterilizer, program, and parameters under sole responsibility of the user.
[4] 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.
[5] 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 EHS 3870 (Tuttnauer, Breda Netherlands) 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
Please store the instruments after sterilization in the sterilization packaging’s 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:
› organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
› strong lyes (maximum admitted pH-value 11, neutral/enzymatic or alkaline cleaner recommended)[6]
› organic solvents (for example: acetone, ether, alcohol, benzine)
› oxidizing agents (for example: hydrogen peroxide)
› halogens (chlorine, iodine, bromine)
› aromatic, halogenated hydrocarbons

[6] For the bur blocks alkaline cleaners mast not applied (maximum admitted pH-value 9).

Please do not clean any instruments and bur blocks by use of metal brushes or steel wool.

Please do not expose any instruments and bur blocks to temperatures higher than 142 °C (288 °F)!
Please do not apply acidic neutralizing agents or cleaning aids.

Reusability
The instruments can be reused – in case of adequate care and if they are undamaged and clean as indicated in chapter “Specific aspects”. 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).

Attachment A: 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. Repeat procedure, if visible residuals are given

Bur blocks/instrument trays:

› Cleaning and disinfecting only without products being loaded (pro-ducts must not be cleaned and disinfected whilst they are in the bur block/ instrument tray)

DE	Das Dokument in der jeweils aktuellsten und gültigen Version sowie in anderen Sprachen finden Sie auf unserer Webseite **www.jota.ch**.
EN	The document in other languages as well as the latest and applicable version you find on the website **www.jota.ch**.
FR	Vous trouverez les documents dans d'autres langues ainsi que la dernière version sur notre site **www.jota.ch**.
ES	Documentos en otras lenguas, así como también la versión más reciente encontrase en nuestra página web **www.jota.ch**.

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