Instructions for processing & 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 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 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 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).

Some instruments require additional aspects. For this, pay attention 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 2 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[1] (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 at beginning of soaking, aids see chapter "Specific aspects").
3. 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 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 the 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 (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 detergent:
- 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 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 instruments in the WD by the use of a small pieces basket.
2. Start the 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 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the pre-cleaning and cleaning detergent Neodisher mediclean 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 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.

Procedure:
Cleaning
1. Soak the instruments for the given soaking time in the cleaning solution (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. 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„).

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 was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the pre-cleaning and cleaning detergent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt) 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 are to be cleaned and disinfected again.

Maintenance
Instrument oils or grease must not be use with the exception of 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 packagings (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 packagings 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 drying[5])
- 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 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 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 and ethylene oxide sterilization, as well as plasma sterilization.

Storage
Please store the instruments after sterilization in the sterilization packagings 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 be 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

Instrument group	brush	specific/additional procedure in case of						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	packing	sterilization		
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

General application and safety instructions

for the medical device from Jota AG

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- Jota AG products (dental, maxillary surgery, general surgery,) must only be used by dentists, doctors and/or the respective experts who, due to their training and experience, are intensely familiar with the use of these products and who have the corresponding expertise in the respective specialist fields. The use of surgical products requires relevant expertise and experience in dental implantology, maxillary surgery and/or other surgical fields including diagnosis, preoperative planning and surgical techniques.
- It is the sole responsibility of the doctor in charge who, depending on the respective situation (indication), decides on the actual use of the Jota AG products for each individual case
- All JOTA AG products have been developed for specific applications. Therefore, inappropriate use can result in the premature wear and tear of the products and put patients and users at risk.

Application

- In order to avoid damaging the instruments, they must be removed from the blister pack by pulling off the back-sheet.
- It is essential to only use turbines as well as hand and angle pieces that are technicaly and hygienically faultless, maintained and cleaned.
- The instruments must be rotating when applied on material. They should not be placed on material and then brought to rotation.
- Rotating instruments need to be clamped as far down as possible with their speed set before applying them on the object. are used with the rotary instruments.
- Using the instruments for canting or leveraging should be avoided as it increases the risk of breakage.
- Depending on the application, it is recommended to use protective goggles while using the instruments. Users of diamond disks should use a disk protection device.
- Inappropriate use of the products leads to badly executed work and increased risk.
- When working with dry materials, it is recommended to use a suction cleaning device.
- In particular,users of hand tools should take care to use them gently and with consideration.
- The user must at all times avoid touching the instruments and parts without protection (protective gloves should be worn).
- Thermal bone damage caused by rotating and oscillating tools (e.g. pilot burr, conical burr, expansion burr) must at all times be avoided (user training, working at low speed and with sufficient cooling).
- During intraoral application attention has to be made to the fact that the products are protected against aspiration or falling on the floor.

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 or 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 rough surfaces. In such cases, even instrument breakage cannot be excluded.

Cooling

- In order to avoid excessive heat generation during preparation, a sterilewater/sodium chloride solution supplied via a permanent external feeding device should be used to ensure sufficient cooling during use of the instruments.
- When using FG instruments that are more than 22 mm long or whose head diameter exceeds 2 mm, additional external cooling is required.
- Insufficient cooling will lead to irreversible damage to the bone and/or the adjacent tissue.

Storage, disinfection, cleaning and sterilization

- Unless there is explicit information to the contrary, all Jota AG products are supplied in non-sterile packaging and, depending on the application, they need to be sterilised prior to use. Prior to their first use on the patient and immediately after each use, all products need to be disinfected and sterilised. Inappropriate cleaning and sterilising of the instruments can result in the patient being infected with harmful bacteria.
- You will find detailed instructions for the disinfecting, cleaning and sterilising of products in the Instructions for the processing of instruments produced by Jota AG on the previous page. We would also be happy to provide you with these instructions at your request. They are also available on the internet at www.jota.ch.
- The products should be stored in appropriate, hygienically maintained containers. The same applies to sterilised instruments. The stored products must be protected from dust, humidity and recontamination. Instructions as to maximum storage duration must be adhered to.

Speed recommendations for rotary instruments

- Following the instrument-specific speed recommendations produces the best results.
- Exceeding the maximum admissible speed (rpm) when using long and pointed instruments tends to produce vibrations that can lead to the destruction of the instrument.
- When using working parts with diameters exceeding the thickness of the shaft, excessive speed can release great centrifugal forces that may cause the shaft to bend and/or the instrument to break. Therefore, the maximum admissible rpm must never be exceeded.
- Please consult the manufacturer's information (see catalogue or www.jota.ch) for the recommended and the maximum admissible speed ranges. Non-compliance with the maximum admissible speed puts safety at risk.
- Generally, the following rules apply:
  - The larger the working part of an instrument the lower the speed
  - Surgical instruments: suitable for geared down micro-motor hand and angle pieces 10:1 with stable ball bearings. Speed 600 to 800 rpm with physical and, possibly, sterile external cooling or internal cooling when using the respective hand piece.

Discarding worn instruments and parts

- Jota AG products can principally be reused several times – unless specifically indicated and labelled otherwise. Rotating instruments 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.
- Broken off cutting edges of instruments cause vibrations and great forces of pressure, which, in turn, leads to broken preparation corners and rough surfaces.
- Bare patches on diamond instruments indicate a lack of abrasive particles and can be a sign of blunt instruments. This leads to excessive temperatures during instrument use.
- Instruments that are bent and/or do not run true should be discarded forthwith.
- With the reuse of disposable products the risk of infection cannot be excluded and a risk-free functional safety cannot be guaranteed.

Additional instructions regarding the use of trepans

- When using trepans, you have to proceed with particular care. For example, it is advisable not to exceed the recommended rpm speed ranges.
- 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 down.
- 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 countersink attachment, based on the sagittal level of the ascending branch, must be milled laterally at an angle of approx. 15-20°.

Ø < 045 

Ø ≥ 045 

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.