BRASSELER USA	**INSTRUCTIONS FOR PROCESSING OF BRASSELER ENDODONTIC DEVICES***	EN

1. PURPOSE

These instructions are recommended to ensure cleaning, disinfection, and sterilization of select Brasseler Endodontic devices (see section 2) before first use for non- sterile devices and before each reuse for reusable devices. This document aims to help healthcare professionals handle Brasseler Endodontic devices in a safe manner as well as (re)process and maintain them in an appropriate manner, in accordance with the requirements of ISO 17664.

2. SCOPE OF APPLICATION

*These instructions apply to the Brasseler USA Endodontic Devices/Instruments listed here: Gates and Short Gates, Peeso, K-Files, Stiff K-Files, Hedstrom Files, EndoSequence Hand Files, BioRace Rotary Files, BT Race Rotary Files, EndoSequence Controlled Memory Files, EndoSequence Controlled Memory Taper Files, EndoSequence Scout Files, EndoSequence CM Reciprocating Files, ESX Rotary Files, RaCe Files, Razorflex Files, EndoSequence Rotary Files, Scout RaCe Files, XP-3D Shaper, XP-3D Shaper +, XP-3D Finisher, XP-3D Finisher R, XP-3D Scout, XP-3D+ Prokit, Apical Verifiers, BC Paste Filler, Paste Filler Lentulo and Barbed Broaches. Refer to the information on the label or marking on the blister to determine the processing applicable to the device(s):

Sterility	Single use device	Processing required before first use	Processing required after each use
NON STERILE		Yes	No
	No		Yes
STERILE R		No	No
	No		Yes

3. WARNINGS AND PRECAUTIONS

Warnings and precautions for the user:

- The devices covered by these instructions are intended for use in medical or hospital environments by qualified healthcare professionals.
- Use a dental dam when using the device(s) to avoid, for example, aspiration or ingestion by the patient.
- For your own safety, use personal protective equipment required during processing of the devices.
- For your own safety, wear surgical masks, gloves, and safety goggles.
- Carefully read the label or marking on the packaging to ensure you are using the correct device.

Warnings and precautions for the processing of devices:

- Use approved cleaning and disinfecting agents (e.g., approved by the VAH/DGHM or FDA, or bearing the CE marking) and use them according to the recommendations in their respective instruction manual.
- It is the user's responsibility to check the devices before each use in order to identify any possible defects.

Cracks, deformations, signs of corrosion, loss in color or marking are signs that the device is no longer able to achieve the required performance level and should be discarded.

- Do not use hydrogen peroxide (H_2O_2), as it degrades nickel-titanium instruments.
- Do not soak the active part of nickel-titanium devices for more than 5 minutes in a NaOCl solution at more than 5 %.
- Do not exceed a sterilization temperature of 135 °C.

In case of incident:
All serious events occurring in relation to the product must be reported to the manufacturer and the competent authority according to local regulations.

4. LIMITATIONS ON REPROCESSING

Generally speaking, any device showing visible signs of wear and tear or damage should be discarded (see sections 8 and 12).

Single use devices:

Devices labeled for single use only must not be reprocessed for reuse, as they are not designed to perform as intended after first use. Changes in mechanical, physical or chemical characteristics occurring with repeated use and/or (re)processing may compromise the integrity of the design and/or material, thus reducing the safety, performance and/or compliance of the device(s). When single use devices are supplied non-sterile and require sterilization before use, the relevant sections of these instructions are applicable.

Reusable devices with indicator of possible remaining uses:

These devices can be reused up to 8 times depending on the complexity of the canal to be treated. The maximum number of processing cycles depends on the use of the instrument on which it is mounted. Where necessary, refer to the instructions in the device's instructions for use.

Other reusable devices:

Due to the design of the devices and/or materials used and in the absence of contrary indications in the labeling or instructions for use of the device, the total number of uses is 10 (maximum).

5. INITIAL PROCESSING AT THE POINT OF USE FOR REUSABLE DEVICES

After use, follow the steps below:

1. Disassembly: Remove the SMD(s) and/or endo stop(s) from the instrument(s).
2. Pre-cleaning: Within a maximum of 30 minutes after use, remove excess soiling from the device(s) with disposable, lint-free wipes or a soft brush. Immerse the device(s) in a solution of water and neutral detergent.
3. Rinsing: Thoroughly rinse the device(s) with plenty of running water for at least 1 minute.

6. PREPARATION BEFORE CLEANING

Precautions:

- The device(s) should be reprocessed as soon as possible after use.
- The user should observe the concentrations and soaking times indicated in these instructions. An excessive concentration may cause corrosion or other defects on the devices.
- The disinfectant solution should not contain aldehyde so as to avoid fixation of blood residue.
- Do not use a disinfectant solution containing phenol, aldehyde or substances not compatible with the devices.
- The washer/disinfector must comply with ISO 15883 and undergo regular maintenance and calibration.

7. CLEANING/DISINFECTION

Follow one of the two methods described below (manual or automated) for cleaning and disinfection:

- Manual and mechanized devices before first use (if applicable, see section 2) and before each reuse (if applicable, see section 2).
- SMDs and endo stops before first use and before each reuse.

Manual cleaning/disinfection:

Equipment: Cleaning/disinfectant solution (Helvemed Instrument Forte: 2 % concentration for 15 minutes), brush, ultrasonic bath, purified running water, absorbent cloth.

1. Place the device(s) in a container, limiting any contact between the parts as much as possible.
2. Immerse the device(s) in the recommended cleaning/disinfectant solution. If necessary, use a soft nylon brush to gently scrub the device(s) until all visible soiling has been removed. If needed, use ultrasonic equipment as well.
3. Remove the device(s) from the solution and container and thoroughly rinse them under purified running water for at least 1 minute.
4. Dry the device(s) with single use absorbent cloth.

Automated cleaning/disinfection:

Equipment: Washer/disinfector, purified water, cleaning/disinfectant solution:
- Washing: Neodisher® Mediclean Forte (0.5 % concentration)
- Thermal disinfection: Neodisher® Mediklar Special (0.03 % concentration)

1. Place the device(s) in a washer/disinfector basket, limiting any contact between the parts as much as possible.
2. Process using a standard washer/disinfector cleaning cycle for at least 10 minutes at 93 °C or A_0 value > 3000 and complete with a hot air drying cycle for at least 15 minutes at 110 °C.

8. INSPECTION AND MAINTENANCE

1. Before sterilization, discard any device(s) that has/have the following defects:
   - Plastic deformation
   - Bent device
   - Untwisted device
   - Damaged or blunt cutting edges
   - No marking
   - Corrosion
   - Discoloration
   - Other visible defects
2. Reassemble the SMD(s) and/or endo stop(s) on the appropriate device(s).
3. Thoroughly inspect each device to check that all visible contamination has been eliminated. In case of contamination being observed, repeat the cleaning/disinfection process described above.

9. PACKAGING

Precautions:

- Check the use-by date of the sterilization pouch stated by the manufacturer.
- Use packaging that can withstand temperatures up to 141 °C and complies with ISO 11607 and EN 868.

1. The device(s) should be packed in a medical grade sterilization pouch (compliant with ISO 11607-1). Limit any contact between the devices and seal the pouches in accordance with the manufacturer's recommendations.

10. STERILIZATION

Precautions:

- Autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended.
- Place the pouches in the sterilizer in accordance with the recommendations of the sterilizer's manufacturer.
- The autoclaves should comply with the requirements of the applicable standards (EN 13060 and EN 285) and should be approved, maintained and checked in accordance with these standards and the manufacturer's recommendations.
- Before any sterilization cycle, make sure that the maximum load indicated by the sterilizer's manufacturer is not exceeded.

Device class	Class B
Exposure time	Min. 3 minutes. The exposure time can be extended to 18 minutes to comply with the recommendations of the World Health Organization (WHO), the Robert Koch Institute (RKI), etc. Brasseler USA' medical devices are able to withstand such sterilization cycles.
Temperature	132 °C
Drying time	Recommended: 20 minutes (minimum, in chamber)
Visual inspection	Check the device(s) in accordance with section 8 and verify proper performance of the sterilization cycle (packaging integrity, no humidity, color change of sterilization indicators, physical and chemical integrators, and digital records of various cycle parameters).

11. STORAGE

Precautions:

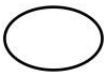
- If the packaging has been opened, damaged or become wet, the sterile state of the devices inside the packaging is not guaranteed. Perform a new complete (re)processing cycle or discard the device(s).

1. Store the device(s) in sterile packaging in a well-ventilated area, protected from dust, moisture, insects and temperature/humidity extremes, and at the temperature specified by the paper-plastic pouch by the manufacturer of the steam sterilizer.
2. The packaging of the sterile devices should be carefully examined before opening (packaging integrity, no humidity, and expiry date) to ensure that the packaging's integrity has not been compromised during storage.

12. DISPOSAL

When a device reaches the end of its life, make sure that it is discarded in accordance with the applicable laws and regulations.

	Symbol	Designation	Description	Reference / ISO registration number
Identification of economic operators		Manufacturer	Identifies the manufacturer of the medical device (name and address). Note: If a date is next to this symbol, this corresponds to the date of manufacture. Date format: YYYY-MM-DD.	ISO 15223-1 (ISO no. 7000-3082)
		Importer	Identifies the importer of the medical device (name and address).	ISO no. 7000-3725
		Distributor	Identifies the distributor of the medical device (name and address).	ISO no. 7000-3724
General symbols		Medical device	Indicates that this is a medical device.	(EU) 2017/745 Annex I, Article 23.2(q)
	 brasselerusa.com/eIFU	Operating instructions	Indicates the need for the user to consult the operating instructions and/or the processing instructions for Brasseler Endodontic devices, as well as this document, made available on Brasseler's website.	ISO 15223-1 (ISO no. 7000-1641)
	Rx Only	Prescription device	Caution : Federal law restricts this device to sale by or on the order of a "dentist/physician" licensed by the law of the State in which he/she practices to use or order the use of the device	21 CFR 801.109
		Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions to be taken that cannot be presented on the medical device itself.	ISO 9687 (ISO no. 7000-0434A)
Product identification and other information specific to each batch		Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 (ISO no. 7000-2493)
		Batch code	Indicates the manufacturer's batch code so that the batch can be identified.	ISO 15223-1 (ISO no. 7000-2492)
		UDI code (Unique Device Identification)	Indicates the UDI code and UDI carrier specific to the device.	(EU) 2017/745 Annex I, Article 23.2(h)
		Quantity	Indicates the quantity contained in the packaging.	Not applicable
		Use-by date	Indicates the date after which the medical device is not to be used. Date format: YYYY-MM-DD.	ISO 15223-1 (ISO no. 7000-2607)
		Date of manufacture	Indicates the date on which the medical device is manufactured. Date format: YYYY-MM-DD.	ISO 15223-1 (ISO no. 7000-2497)

Symbol		Designation	Description	Reference / ISO registration number
Other symbols relating to product identification and specifications		Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 (ISO no. 7000-1051)
		Indicator of number of possible remaining uses	Indicates the number of possible remaining uses of the instrument.	Not applicable
		Clockwise rotation	Indicates that an instrument is intended to be used in a clockwise direction. This symbol is accompanied by a rotational speed expressed in revolutions per minute [rpm].	ISO 21531 (ISO no. 7000-0258)
		Reciprocating movement (counterclockwise)	Indicates that an instrument is intended to be used in a reciprocating movement with a counterclockwise result.	Not applicable
		Material symbol	Indicates the material from which the device is made: NiTi Nickel-titanium alloy SSt Stainless steel Sil Silicone P Plastic Al Aluminum	ISO 9687 (ISO no. 7000-2793)
		Tip diameter	Indicates the tip diameter of an instrument, expressed in hundredths of a millimeter.	Not applicable
		Taper	Indicates the taper of an instrument, expressed in millimeters per millimeter of length (e.g., .02 corresponds to 2 %)	Not applicable
		Length	Indicates the usable length of the device.	Not applicable
		Thickness	Indicates the thickness of the device.	Not applicable
		Width	Indicates the width of the device.	Not applicable
Information relating to sterility and (re)sterilization		Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1 (ISO no. 7000-2502)
		Single sterile barrier system	Indicates that the device is packaged in a single sterile barrier system.	(EU) 2017/745 Annex I, Article 23.3(a) (ISO no. 7000-3707)
		Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 (ISO no. 7000-2606)
		Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1 (ISO no. 7000-2609)
		Sterilizable in a steam sterilizer (autoclave) at temperature specified	Indicates that the medical device is sterilizable in a steam sterilizer (autoclave) at the temperature specified.	ISO 9687 (ISO no. 7000-2868)

Symbol		Designation	Description	Reference / ISO registration number
Identification of the intended use		Accessory	Indicates that this is an accessory.	Not applicable
		Root canal treatment	Indicates that this is a device used for root canal treatments.	ISO 21531 (ISO no. 7000-2861)
Other symbols		Empty alveolus	Indicates that the blister alveolus is empty	Not applicable

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