

EndoWave NiTi Files

Instructions for use

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Imported by

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EndoWave

Instructions for use

01. Parameters for use

Recommended speed range: 500-600 rpm continuous rotation.
Torque: 1.5 Ncm.

02. Indications for use

EndoWave endodontic instruments are intended for use in medical or hospital facilities, by qualified health professionals. EndoWave instruments are designed for the glide path and shaping of root canals.

03. Contraindications

Nickel-Titanium instruments must not be used on individuals with a known allergic sensitivity to these metals.

04. Warnings and adverse reactions

None known.

05. Notice and precautions

- Use files with a reduction endodontic handpiece, e.g. TriAuto ZX, TriAuto mini or the DentaPort ZX.
- Use the instruments passively with short up and down movements. Ensure that each instrument is used in the canal for as short a time as possible (3-5 seconds). Never force the instrument.
- The most reliable method of preventing material fatigue is to use each instrument only once, particularly with very curved root canals. It is recommended to use EndoWave NiTi files only once.
- These instruments are non-sterile and must be cleaned, disinfected and sterilized before being used for the first time.
- Always inspect the file before use and discard it if there are any visible defect(s).
- EndoWave NiTi files have not been tested on children and on pregnant or breast-feeding women.
- Take several radiographs from different angles to determine the anatomy of the root canals (length, width and curvature).
- When a file reaches the end of its life, please dispose of it in accordance with the applicable laws and regulations.

06. Treatment procedure

- Initial X-ray for diagnosis and assessing the working length. In addition, electronical working length determination can be achieved with e.g. DentaPort ZX, Root ZX.
- Localisation of all root canals.
- Create an access as straight as possible to the canal opening.
- Start with glide path, followed by shaping procedure, applying your usual irrigation/disinfection protocol.

07. Disinfection, cleaning and sterilization

EndoWave instruments have to be cleaned, disinfected and sterilized before being used for the first time and every time after they are used.

07.01. General recommendations

- The temperature of 135 °C must not be exceeded.
- Please only use permissible cleaning agents and disinfectants (listed by VAH/DGHM, CE symbol, FDA approval).
- Please be sure to wear the required personal protective equipment (gloves, face mask, goggles, protective lab coat).
- Do not use hydrogen peroxide (H₂O₂) because it corrodes NiTi instruments.
- Do not immerse nickel-titanium instruments more than 5 minutes in a >5% NaOCL solution.

07.02. Care at the point of use (Pre-desinfection)

Within a maximum of 1 hour after use, remove excess soil with disposable, non-shedding wipes or a soft brush. Thoroughly rinse the device with running water or place it in a solution of water and neutral detergent.

07.03. Preparation for decontamination and cleaning

Device(s) should be reprocessed as soon as is reasonably practical following use. All cleaning agents should be prepared according to the use-dilution recommended by the manufacturer. Purified water may be used to prepare cleaning agents.

07.04. Cleaning and disinfection

Follow one of the two methods provided below (Manual or Automated).

07.04.01 Manual cleaning/disinfection

Equipment: cleaning/disinfecting solution, brush, ultrasonic bath, purified running water, drying towelettes.

Cleaning agent used during the validation of this processing instruction: Helvemed Instrument Forte (2% – 15 min.).

- Disassemble the device(s) (endo stop(s) should be removed).
- Completely immerse the device(s) in a cleaning/disinfecting solution, according to the manufacturer's instructions (dilution, immersion time). If appropriate, use a soft-bristled nylon brush to gently scrub the device(s) until all visible soil has been removed or use ultrasonic equipment.
- Remove the device(s) from the solution and thoroughly rinse under purified running water for a minimum of 1 minute.
- Dry with single use towelettes or filtered compressed air.

07.04.02 Automated cleaning/disinfection

Equipment: Washer/disinfector (compliant to EN ISO 15883), cleaning/disinfecting solution, purified water.

Cleaning agent used during the validation of this processing instruction: Neodisher® Mediclean Forte (washing- 0.5%) and Neodisher® Mediklar Special (thermal disinfection- 0.03%).

Disassemble the device(s), (endo stop(s) should be removed) and place them in a suitable washer/disinfector basket and process using a standard washer/disinfector cleaning cycle for at least 10 minutes at 93°C or A0-value > 3000 completed by hot air drying for at least 15 min. at 110°C.

07.05 Inspection

Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process. Discard device(s) which show any deformation (bent, twisted), damages (broken, corroded) or any other visible defect.

07.06 Packaging

Device(s) should be packed in a medical grade sterilization pouch (compliant to EN ISO 11607-1) or wrapped suitably for the recommended specifications for steam sterilization provided in the section below.

07.07 Sterilization

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated, maintained and checked in accordance with applicable standards (EN 13060 or EN 285).

Sterilization Overview

Exposure Time	3 minutes at a minimum. Exposure time can be extended to 18 minutes to comply with the recommendation from World Health Organization (WHO), Robert Koch Institute (RKI) etc.
Temperature	132 °C – 135 °C (270 °F – 275 °F)
Drying Time	Recommended: 20 minutes (minimum, in chamber)

Order information

Order no.	Conicity	ISO size	Length/mm	Quantity
6820-835	08	35	19	5
6821-425	04	25	21	5
6821-620	06	20	21	5
6821-625	06	25	21	5
6821-630	06	30	21	5
6825-210	02	10	25	5
6825-215	02	15	25	5
6825-220	02	20	25	5
6825-225	02	25	25	5
6825-230	02	30	25	5
6825-235	02	35	25	5
6825-240	02	40	25	5
6825-415	04	15	25	5
6825-420	04	20	25	5
6825-425	04	25	25	5
6825-430	04	30	25	5

Order no.	Conicity	ISO size	Length/mm	Quantity
6825-435	04	35	25	5
6825-440	04	40	25	5
6825-620	06	20	25	5
6825-625	06	25	25	5
6825-630	06	30	25	5
6825-635	06	35	25	5
6825-640	06	40	25	5
6831-220	02	20	31	5
6831-415	04	15	31	5
6831-420	04	20	31	5
6831-425	04	25	31	5
6831-430	04	30	31	5
6831-620	06	20	31	5
6831-625	06	25	31	5
6831-630	06	30	31	5