RetreatAll®

DIRECTIONS FOR USE

RetreatAll® instruments for endodontic retreatment:

- RetreatAll® files to remove obturation material in the middle/coronal third.
- RetreatAll® files to remove obturation material in the apical third.

COMPOSITION

The cutting surface of these instruments is made of a nickel-titanium alloy.

1) INDICATIONS FOR USE

These instruments have been designed to be used exclusively in a dental clinic or hospital setting by qualified users.
Application field: RetreatAll® are root canal dental instruments used for removing obturation material from the root canal during endodontic retreatment.

2) CONTRAINDICATIONS

- Do not use to remove resin materials.
- Never use RetreatAll® R1 in a curved canal.
- This product contains nickel and should not be used in patients with a known allergy to this material.

3) WARNINGS

- RetreatAll® retreatment files are used to unfill root canals filled with gutta-percha in any of its forms or eugenol-based soluble paste. They cannot be used to unfill resin materials.
- The files are single-use only, so they are not to be reused as this can cause deformation defects (bending, stretching), fractures, corrosion, loss of colour or markings identification, etc., which would mean the instruments cannot meet the level of safety required for the intended use.
- Reuse increases the risk of cross-contamination and breakage.
- There is an increased risk of breakage when used after several disinfection or sterilisation cycles.

4) PRECAUTIONS FOR USE

- These instruments should not be completely immersed in sodium hypochlorite solution
- Instrument decontamination: strictly follow manufacturer's instructions.
- Use a constant rotation speed of:
  - 500 rpm for removing gutta-percha.
  - 250-300 rpm for removing zinc oxide-eugenol based soluble paste.
- For optimal usage, torque control devices are recommended.
- Use R1 file for the coronal and middle thirds of the root canal and, afterwards, R2 file for the apical third.
- This product should be disposed of as medical waste.

5) ADVERSE REACTIONS

- RetreatAll® is not recommended for use in patients with a known allergy to nickel. The use of this product in these patients may cause: difficulty breathing, swelling of the face or eyes, hives or rash. If any of these symptoms occur, the patient should be advised to contact a dental professional immediately.

6) STEP-BY-STEP INSTRUCTIONS FOR USE OF RetreatAll® FILES

Before removing gutta-percha, carrier-based obturators or paste from a root canal:

6.1 Radiographic assessment

- Carefully observe 3 different, horizontally angulated radiographs.
- View the density of the obturation material in terms of width, length and curvature of the canal.

6.2 Access preparation

- Access the pulp chamber and note the circumferential dimensions of the obturation material at the orifice(s).
- Select the best removal technique after radiographic and clinical assessment.

6.3 RetreatAll® OBTURATION REMOVAL TECHNIQUE

Without cutting dentin, remove obturation material using a progressive crown-down technique.

Gutta-percha/carrier-based obturator removal

- When the rotary removal method is utilised, select the lowest speed (500 rpm) that will effectively engage and remove obturation material from the canal.
- Without touching the dentin, gently press the RetreatAll® R1 file into the gutta-percha mass to create friction, generate a heat wave, and extract material out of the canal. Never engage RetreatAll® R1 in a curved canal.
- Remove the R1 file frequently, inspect the flutes and clean off the obturation material and debris.
- Continue with the RetreatAll® R1 file (or the R2 directly in small canals) that fits passively between the dentinal walls until gutta-percha is removed from the coronal third of the canal.
- Select the RetreatAll® R2 file and, using one or more movements, extract obturation material from the middle/apical third of the canal. Use a brushing stroke motion to remove material from the canal walls.
- Continue with the R2 file as long as the flutes of the instrument are full of obturation material when removed.

- When the obturation material is next to the canal terminus, use small-sized hand files with a viscous chelator to negotiate and secure the rest of the canal.
- After ensuring a smooth glide path, use NiTi BlueShaper® file to shape and finish the canal preparation.
- In case of carrier removal, select the appropriate RetreatAll® retreatment file that can reach sufficiently deep into the canal and laterally to the carrier. If it catches on a wide area of the carrier, it will allow for a more effective removal.

Soluble zinc oxide-eugenol based paste removal

- When the rotary removal method is utilised, select the lowest speed (250-300 rpm) that will effectively engage and remove obturation material from the canal.
- Fill the pulp chamber with the appropriate solvent and probe the canal orifice with an explorer to check if the paste has been softened.
- Without engaging dentin, gently press the RetreatAll® R1 file into the material and use a short pecking motion to extract obturation material out of the canal.
- Remove the R1 file frequently, inspect the flutes and clean them of debris.
- Continue with the R1 file that fits passively between the dentin walls, until paste is removed from the coronal third of the canal.
- Select the RetreatAll® R2 file and repeat the same pecking movement to extract obturation material from the middle third of the canal. Use brushing stroke movements to remove material from the canal walls.
- Continue with R2 file until the flutes of the instrument, when removed, are free from obturation material.
- When the obturation material is next to the canal terminus, use small-sized hand files with a viscous chelator to negotiate and secure the rest of the canal.
- After ensuring a smooth glide path, use NiTi BlueShaper® file to shape and finish the canal preparation.

7) CLEANING, DISINFECTION AND STERILISATION

Dental instrument reprocessing procedure.

I - FOREWORD

Instruments marked “sterile” do not require any specific treatment before first use. For the rest of the instruments that are not marked “sterile”, cleaning and sterilisation is necessary before using them for the first time in accordance with section III – STEP-BY-STEP INSTRUCTIONS of these directions for use.

Excluded devices:

Uniclip and Mooser calcinable plastic posts cannot be sterilised and must be disinfected by immersion in NaOCl (2.5 % at least) during 5 minutes at ambient temperature.

II - GENERAL RECOMMENDATIONS

1) Use only a detergent solution with a disinfectant action approved for its effectiveness (VAH/DGHM-listing, CE marking, FDA approval) and follow the instructions of the manufacturer of said product. Anticorrosive cleaning products and disinfectants are recommended for all metal instruments.
2) For your own safety, please use personal protective equipment (gloves, goggles and mask).
3) The user is responsible for the cleaning and sterilisation of the product for the first cycle and each subsequent use, as well as the use of dirty or damaged instruments after sterilisation.

4) The safest option for the professional is to use our instruments only once. After each use, they must be thoroughly inspected before being used again; the presence of defects such as deformations (bent, stretched), fractures, corrosion, loss of colour identification, marking, etc. are indications that the instruments cannot meet the level of safety required for their intended use and should therefore be discarded.
5) Instruments marked as single-use only are not approved for reuse.
6) For the final rinse it is mandatory to use deionised water, either using an automatic washer-disinfector or a manual cleaning method. For the other rinsing steps tap water use is allowed.
7) Instruments with plastic handles, and NiTi instruments should not be used with Hydrogen Peroxide (H2O2) solution which is known to degrade them.
8) Only the active part of the NiTi instrument that is in contact with the patient should be immersed in a NaOCl solution with a concentration NOT greater than 5%.
9) Prevent the instrument from drying out before or during pre-disinfection or cleaning. Dried biological material can be difficult to remove.
10) Do not place identifying labels or markers directly on the instrument.

III - STEP-BY-STEP INSTRUCTIONS

	Operation	Description and Warnings
1	**Disassembling**	• Remove and discard the silicone stoppers.
2	**Rinsing**	• Rinse abundantly (for at least 1 minute) under running water at ambient temperature. While rinsing, use a soft brush (nylon, polypropylene, acrylic) for pre-cleaning until visible impurities are removed.
3a	**Automated cleaning with washer-disinfector**	• Place the instrument in a kit, support, or container made of stainless steel or titanium. • Execute the defined cycle with detergent solution (for example, Metrex EmPowder concentration 1:128 - 1:512) for at least 5 minutes in the washer-disinfector at 20°C - 40°C).
3b.I	**Manual cleaning assisted by an ultrasonic device**	• Place the instrument in a kit, support, or container made of stainless steel, polypropylene, or titanium. • Submerge it in a detergent solution (for example, Metrex EmPowder concentration 1:128) with cleaning properties. If applicable, soak it for at least 15 minutes with the help of an ultrasonic device. • Rinsing: perform a long rinse (at least 1 minute) under running deionised water at a temperature of 20°C - 40°C. • Drying: dry with a single-use non-woven cloth or with a hot air dryer no hotter than 110°C.

Operation		Description and Warnings
3b.II	**Manual disinfection with washer-disinfector**	• Place the instrument in a kit, support, or container made of stainless steel or titanium. • Execute the defined cycle with a mild neutral enzymatic cleaning agent solution (for example, Metrex EmPowder concentration 1:128) for at least 5 minutes in the washer-disinfector at a temperature of >90°C, A0 >3000. • **Note:** **1)** Discard instruments with obvious defects (broken, bent, etc.). **2)** When the instruments are placed in a cleaning kit, support, or container, avoid any contact between them. **3)** Follow instructions and concentrations given by the manufacturer of the detergent solution (see also general recommendations). **4)** Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacture. **5)** The final rinse step should be with deionised water. For other steps follow the water quality defined by the manufacturer. Place the instrument in a kit, support, or container made of stainless steel or titanium to avoid any contact between devices or posts.
3b.III	**Rinsing**	• Rinse abundantly (for at least 1 minute) under running water at ambient temperature. • Use deionised water for rinsing. • If the previously used cleaning solution contains a corrosion inhibitor, rinsing is recommended just before autoclaving.
3b.IV	**Drying**	Devices should be carefully dried before inspection and packaging • Dry with a single-use non-woven cloth or with a hot air dryer at a maximum temperature of 110 °C. • The devices should be dried until visual traces of moisture are eliminated. • Particular attention has to be paid to effectively dry joints or cavities inside the device.
4	**Inspection**	• Inspect the operation of the devices. • Inspect devices and identify those with defects. **1)** Dirty devices need to be cleaned again. **2)** Do not reuse the silicone stoppers. **3)** Dispose of any defective devices.

	Operation	Description and Warnings
5	**Packaging**	Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in “Sterilisation Pouches”. (Use packaging that is resistant to a temperature of 141 °C (286 °F) and that is UNE-EN ISO 11607 compliant). **1)** Avoid any contact between instruments or posts during sterilisation. Use kits, supports or containers. **2)** For sharp devices not contained within a box, silicone tubing should be placed around the devices to prevent puncture of the packaging. **3)** Seal pouches per the pouch manufacturer’s recommendation. If a thermo-sealer is used, the process must be validated. **4)** Check the expiry date of the pouch indicated by the pouch manufacturer to determine the shelf life of the sterile product.
6	**Sterilisation**	• For these devices, steam sterilisation is recommended at 132°C / 273°F for 4 minutes, for the purpose of de-activating potential prions. • Instruments and posts must be sterilised according to the package labelling. • Place pouches in steam steriliser per steriliser manufacturer’s recommendation. • Use only steam sterilisers that meet the requirements of EN 13060 (class B, small steriliser), EN 285 (full size steriliser). • Use a validated sterilisation procedure according to ISO 17665 with a minimum drying time of 20 minutes. • Follow the steriliser maintenance procedure indicated by the steriliser manufacturer. • Control the efficiency and the acceptance criteria of the sterilisation procedure (packaging integrity, no humidity, no colour change of the packaging, positive physicochemical indicators, conformity of actual cycle parameters to reference cycle parameters). • Store traceability records and define shelf life according to packaging manufacturer guidelines. • Shorter sterilisation cycles according to local regulations are possible but are not guaranteed to de-activate prions.
7	**Storage**	Keep devices in sterilised packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature. **1)** Sterility cannot be guaranteed if the packaging is open, damaged or wet. **2)** Check the packaging and medical devices before use (integrity of the packaging, absence of humidity and expiry date).

8) TRANSPORT

- To prevent the medical device from being damaged during transport, the use of specific racks, trays or rigid containers may be recommended.
- When the package is broken, it is no longer sterile. It must be cleaned, disinfected and sterilised before use.

9) STORAGE AND EXPIRY

- Avoid storing in places with high temperatures, humidity and/or direct sunlight. Keep liquids away. Store at ambient temperature.
- Do not damage or puncture the packaging materials.
- This product is subject to improvement without prior notice. Apply the “first in, first out” approach to inventory management.
- Do not store under a germicidal lamp to prevent deterioration.
- The shelf life of endodontic files is 5 years.

10) DISPOSAL

- This product should be disposed of as medical waste.
- For correct disposal, always respect national laws and recommendations from authorities.

11) PACKAGING

- Minimum packaging unit: 4pcs/pack (2 pieces of each size) in aluminium foil box.

12) IDENTIFICATION OF RELATED SYMBOLS

Symbols	Identification
	Product designated for dental use only
	Do not reuse – Single-use only
	Workpiece Material: Nickel Titanium
	Rotating handle
	Medical Device
Heat activation	Pre-bendable
	Recommended rotation speed
	Recommended torque for use
	Batch number
	Sterilised by radiation
	Reference number

Symbols	Identification
	Expiry date
	Consult directions for use
	Authorized representative in the EU
	Manufacturer
	Autoclavable at the specified temperature
	Non-returnable if the seal is broken
	Stopper material: silicone
	Do not use if packaging is damaged. Consult directions for use.
	CE marking

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