M3-Retreatment Files (M3-RT Files)

FOR DENTAL USE ONLY

DIRECTIONS FOR USE

- M3-RT File #20/07 to unfill the coronal one third
- M3-RT File #25/08 to unfill the middle one third
- M3-RT File #30/09 to unfill the apical one third

0) COMPOSITION

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

1) INDICATIONS FOR USE

These instruments are to be used only in a clinical or hospital environment, by qualified users.
Application field: canal unfilling for endodontic retreatment.

2) CONTRAINDICATIONS

- Do not use to remove resin type pastes.
- Do not use the #20/07 file around a canal curvature.

3) WARNINGS

- This product contains Nickel and should not be used for individuals with known allergic sensitivity to this metal.
- M3 retreatment files are used to unfill root canals filled with gutta percha points, Thermafil obturators or, eugenol based soluble paste. They can't be used to unfill resine type paste.

4) PRECAUTIONS

- Multiple use disinfection and resterilization cycles may lead to increased risk of file separation.
- These instruments should not be immersed in a sodium hypochlorite solution.
- Instrument decontamination: strictly follow decontamination instructions from the manufacturer.
- Use in a constant rotation speed of:
  - 500 rpm for removing gutta percha or Thermafil obturators.
  - 250 – 300 rpm for removing zinc oxide – eugenol based soluble paste.

• For optimal usage, torque control devices are recommended.

5) ADVERSE REACTIONS

In the present technical state, no adverse reaction has been reported so far.

6) STEP BY STEP INSTRUCTIONS FOR PROTAPER FILES

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

- Carefully observe 3 different, horizontally angulated radiographic images.
- Visualize the density of obturation material relative to the width, length, and curvature of the canal.
- 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.
- Without cutting dentin, remove obturation material in a progressive crown-down manner.

Gutta Percha / Carrier-Based Obturator Removal

- When the rotary removal method is utilized, select the lowest speed (500 rpm) that will effectively engage and remove obturation material from the canal.
- Without engaging dentin, gently press the spinning M3 #20/07 file into the gutta percha to create friction, generate a heat wave, and extract material out of the canal. Never engage M3 #20/07 around a canal curvature.*
- Remove the #20/07 file frequently, inspect the blades for obturation material and clean the debris from the flutes.
- Continue with the #20/07 file, or the M3 Retreatment file that fits passively between the dentinal walls, until gutta percha is removed from the coronal one-third of the canal.
- Select the M3 #25/08 file and, using one or more passes, extract obturation material from the middle one-third of the canal. Use a brushing outstroke motion to remove material from the canal walls.
- When appropriate, choose the M3 #30/09 file and lightly press into the more deeply positioned material and auger obturation material out of the apical one-third of the canal.
- Continue with the #30/09 file as long as the flutes of the instrument, upon removal, are loaded with obturation material.
- When the obturation material is short of the canal terminus, use small sized hand files in the presence of a viscous chelator to negotiate and secure the rest of the canal.
- After assessing the glide path, select either manual or rotary NiTi M3 files to shape and finish the canal.

* In the instance of carrier removal, select the appropriately tapered M3 Retreatment file that can be carried sufficiently deep into the canal and lateral to the carrier. A long engagement zone will more effectively auger the entire length of the carrier out of the canal.

Soluble Zinc oxide – Eugenol based Paste Removal

- When the rotary removal method is utilized, select the lowest speed (250-300 rpm) that will effectively engage and remove obturation material from the canal.

- Flood the pulp chamber with the appropriate solvent and probe the canal orifice with an explorer to check if the paste has been effectively softened.
- Without engaging dentin, gently press the spinning M3#20/07 file into the material and use a short pecking motion to extract material out of the canal. Never engage M3#20/07 around a canal curvature.
- Remove the #20/07 file frequently, inspect the blades for obturation material and clean the debris from the flutes.
- Continue with the #20/07 file, or the M3 Retreatment file that fits passively between the dentinal walls, until paste is removed from the coronal one-third of the canal.
- Select the M3#25/08 file and repeat the same pecking action to extract obturation material from the middle one-third of the canal. Use a brushing outstroke motion to remove material from the canal walls.
- When appropriate, choose the M3 #30/09 file and, in the same way auger the more deeply positioned paste material out of the apical one-third of the canal.
- Continue with the #30/09 file as long as the flutes of the instrument, upon removal, are loaded with obturation material.
- When the obturation material is short of the canal terminus, use small sized hand files in the presence of a viscous chelator to negotiate and secure the rest of the canal.
- After assessing the glide path, select either manual or rotary NiTi M3 files to shape and finish the canal.

7) DISINFECTION, CLEANING AND STERILIZATION

Reprocessing procedure for dental instruments.

I - FOREWORD

Devices that are marked as "sterile" do not require any specific treatment before the first use. For all other devices not labelled "Sterile", cleaning and sterilization prior first use is required according to section III - STEP-BY-STEP INSTRUCTIONS part 4 to 8 of this IFU.

For those devices that are not labelled "single use", re-processing of the devices should be carried out as per this IFU. For hygiene and sanitary safety purposes, these instruments must be cleaned and sterilized before each re-use to prevent any contamination.

Excluded devices:

Uniclip and Mooser Calcinable plastic posts cannot be sterilized and must be disinfected by immersion NaOCl (2,5 % at least) during 5 min. at ambient temperature.

II - GENERAL RECOMMENDATION

1) Use only a detergent solution, with disinfecting effect, which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and in accordance with the IFU of the detergent solution manufacturer. For all metal devices, it is recommended to use anticorrosion disinfecting and cleaning agents.
2) For your own safety, please wear personal protective equipment (gloves, glasses, mask).

3) The user is responsible for the cleaning and sterilization of the product for the first cycle and each further usage as well as for the usage of damaged or dirty devices where applicable after sterilization.
4) It is safest for the practitioner to use our devices only once. Should our devices be reused, we recommend that they should not be used more than 5 times. After each processing they should be carefully inspected before use: the appearance of defects such as deformations (bent, unwound), breakage, corrosion, loss of colour coding or marking, indicate that the devices are not able to fulfil the intended use with the required safety level and must therefore be discarded.

   For our root canal shaping instruments we recommend not to exceed the following maximum number of uses;

Type of canal	Stainless Steel instruments with a diameter **≤ISO 015**	Stainless Steel instruments with a diameter **>ISO 015**	NiTi instruments
Extremely curved (>30°) or S-shaped canals	1 canal max.	2 canals max.	2 canals max.
Moderately curved canals (10° to 30°)	1 canal max.	4 canals max.	4 canals max.
Slightly curved (<10°) or straight canals	1 canal max.	8 canals max.	8 canals max.

5) Single use marked devices are not approved for re-use.
6) For the final rinsing step deionised water use is mandatory, whether using an automated washer-disinfector or a manual cleaning method. Tap water is permissible for the other rinsing steps.
7) Instruments with plastic handles, and NiTi instruments should not be used with Hydrogen Peroxide (H_2O_2) solution which is known to degrade them.
8) Only the active part of the NiTi instrument, which is in contact with the patient should be immersed in a NaOCl solution concentrate at NOT more than 5%.
9) Avoid device to dry out, prior to, or during pre-disinfection, or cleaning. Dried biological material can be difficult to remove.
10) Use only device appropriated support for reprocessing.
11) Do not use label systems or identification markers directly on the device.

III - STEP-BY-STEP INSTRUCTIONS

	Operation	***Activities***	***Warning and remarks***
1.	Disassembling	- Disassemble the device, if applicable.	- Remove and discard silicone stops.
2.	Pre-Disinfection	- Soak all devices immediately after use in a disinfection solution. Use a tray made from high density polyethylene or stainless steel.	- Follow instructions and respect concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects on devices). - The pre-disinfection solution should be a specific solution targeted by the supplier for pre-disinfection. It should be used at the dilution specified by the supplier. It should contain, or be combined with a proteolytic enzyme. - The pre-disinfection solution should be aldehyde free (to avoid blood impurities fixation) and without di- or triethanolamines as corrosion inhibitor. Change the pre-disinfection solution regularly i.e. When it becomes soiled, or when efficacy is diminished due to exposure to microbial loads. - Do not use pre-disinfecting solutions containing Phenol or any products, which are not compatible with the devices. - For visible impurities observed on instruments a pre-cleaning is recommended with a soft brush (made from either nylon, polypropylene, acrylic). Manually brush the device until visible impurities are removed.

3.	Rinsing	- Abundant rinsing (at least 1 min) under running water (ambient temperature).	- Use tap water for rinsing. - If a pre-disinfectant solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the cleaning step.
4a.	Automated Cleaning with washer- disinfector	- Place the devices in a kit, support, or container (made from stainless steel or titanium) to avoid any contact between devices or posts. - Place the devices in the washer-disinfector and execute the defined cycle (Ao value > 3000 or, at least 5 min at 90°C (194°F)). - Use a detergent solution with cleaning properties (we recommend Neodisher Mediclean Forte at 0.4%).	- Discard any devices with defects (broken, bent,…). - Avoid any contact between instruments or posts when placing in the washer-disinfector use kits, supports or containers. - Follow instructions and concentrations given by the manufacturer of the detergent solution. - Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacturer. - The final rinse step should be with deionised water. For other steps follow the water quality defined by the manufacturer. - Use only approved washer-disinfector according to EN ISO 15883, maintained and validated regularly. - It is recommended to use an alkaline detergent with tensides, which has grease removal, disinfection (against bacteria/ fungi) and corrosion inhibition properties. The detergent should be approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and used in accordance with its DFU The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.
OR			
4b.i	Manual Cleaning assisted by an ultrasonic device	- Place the devices in a kit, support or container (made from stainless steel, polypropylene or titanium) to avoid any contact between devices. - Immerse in the detergent solution with cleaning properties, assisted by an ultrasonic device if suitable for at least 15 min.	- No visible impurities should be observed on the devices. - If visible impurities are observed on the devices, the device must be manually brushed with a soft brush (made from either nylon, polypropylene, acrylic) until visible impurities are removed. - Discard any devices with defects (broken, bent, and unwound). - Follow instructions, observe water quality, concentrations and cleaning time stated by the manufacturer of the cleaning solution. - It is recommended to use an alkaline detergent with tensides, which has grease removal, disinfection (against bacteria/ fungi) and corrosion inhibition properties. The detergent should be approved for its efficacy (VAH/DGHM-listing, CE marking, FDA approval) and used in accordance with the DFU of the detergent solution manufacturer). - The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.
4b.ii	Rinsing	- Abundant rinsing (at least 1 min) under running water (ambient temperature).	- Use deionised water for rinsing. - If the previously used cleaning solution contains a corrosion inhibitor, it is recommended to do the rinsing step just before starting the autoclaving.
4b.iii	Drying	- Devices should be thoroughly dried before inspection and packaging.	- Dry with a single use non-woven cloth. - Devices should be dried until visual traces of moisture are eliminated. - Particular attention has to be paid to effectively dry joints or cavities within a device.
5.	Inspection	- If applicable assemble the devices (including the placement of new silicon stops). - Inspect the devices functionality. - Visually inspect devices with naked eye under appropriate lighting (min 500 lux) and sort out those with defects.	- Dirty devices must be cleaned again. - Do not re-use silicon stops. - Discard devices, which show any defect as described in the General Recommendation above (point 4).

6.	Packaging	- Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in "Sterilization pouches".	- Device must be double-packaged using paper-plastic pouches for steam sterilization prior sterilization. Ensure that the pouches are suitable for steam sterilization and were validated and manufactured as per ISO 11607 and EN 868-5. - Use an appropriate packaging, moist-heat resistant (141°C, 286°F) and compliant with ISO 11607. - Avoid any contact between instruments or posts during sterilization. Use kits, supports or containers. - For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing. - Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated and the thermosealer must be calibrated and qualified. - Check the validity period of the pouch given by the pouch manufacturer to determine the shelf life.
7.	Sterilization	- The following sterilization cycles can be used: • 132°C (269.6°F), 4 minutes; • 134°C (273.2°F), 3 minutes; • 134°C (273.2°F), 18 minutes. We recommend a steam sterilization at 134°C / 273.2°F during 18 minutes for the purpose of de-activating potential prions.	- The instruments and posts must be sterilized according to the packaging labelling. - When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded. - Place the pouches in the steam sterilizer according to the recommendation given by the sterilizer manufacturer. - Use only Pre-Vacuum air Removal steam sterilizer that are matching the requirements of EN 13060 (class B, small sterilizer) and EN 285 (full size sterilizer), with saturated steam. - Use a validated sterilization procedure according to ISO 17665 with a minimum drying time of 20 min. - Respecting the maintenance procedure of the sterilizer is under the responsibility of the the owner and should be performed following the requirements for medical devices sterilization (examples: planning of maintenance, qualification, acceptance criteria of condensate and water as per EN 285, annex 2). - Control the efficiency and acceptance criteria of the sterilization procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical indicators, conformity of actual cycle parameters, to reference cycle parameters). A special attention should be paid to the packaging integrity if the sterilization cycle 134°C (273.2°F), 18 minutes was used. - Store traceability records and define shelf-life according to packaging manufacturer guidelines. - Shorter sterilization cycles according to local regulations are possible but are not guaranteed to de-activate prions.
8.	Storage	- Keep devices in sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature (typically 15 - 25°C (59 - 77°F)).	- After sterilization, the product should be manipulated with care in order to keep the integrity of the packaging (sterile barrier). - Sterility cannot be guaranteed if packaging is open, damaged or wet. - Check the packaging and the medical devices before using them (packaging integrity, no humidity and use by date). In case of damage, a complete rework should be performed.

Manufacturer

EC REP

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