M3-Pro Gold 2018

FOR DENTAL USE ONLY

Instruction for use

M3-Pro Gold 2018 INSTRUMENTS FOR ENDODONTIC TREATMENT:

- **M3-Pro Gold 2018 Orifice opener: #17/12, 19mm**
- **M3-Pro Gold 2018 Glider path: #12/02, 21mm-25mm-31mm**
- **M3-Pro Gold 2018 Glider path: #16/02, 21mm-25mm-31mm**
- **M3-Pro Gold 2018 Small: #25/04, 21mm-25mm-31mm**
- **M3-Pro Gold 2018 Prime: #25/06, 21mm-25mm-31mm**
- **M3-Pro Gold 2018 Medium:#35/04,21mm-25mm-31mm**

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: for the removal of dentin and shaping of the root canal.

2) CONTRAINDICATIONS

As with all mechanically driven root canal instruments, M3-Pro Gold 2018 files should not be used in cases of severe and sudden apical curvatures due to heightened risk of separation

3) WARNINGS

This product contains nickel and should not be used for individuals with known allergic sensitivity to this material

4) PRECAUTIONS

Working length determination is imperative to ensure proper instrumentation using any mechanized or hand instrument. The use of radiographs in combination with an apex locator is a recommended method of working length determination. These instruments are to be used only in a clinical or hospital environment by qualified users following good dental practice (using gloves, glasses, a mask and a rubber dam etc.). While we have implemented safeguards against possible misuse, there are several important points to remember:

• Inspect the packaging before use and do not use the instruments if the packaging is damaged;
• For optimal usage, torque controlled motors are recommended;
• Before using any instrument, make sure it is well connected to the contra-angle head;
• Take caution in the apical area and around significant curvatures;
• These instruments should not be immersed in a sodium hypochlorite solution;
• Clean the flutes frequently during instrumentation, inspecting for signs of distortion, elongation or wear, such as uneven flutes, dull spots;
• Frequently irrigate, recapitulate and irrigate the canal throughout the procedure, after using each file;
• M3-Pro Gold files should only be used in regions of the canal that have a confirmed and reproducible glide path;
• Use the appropriate finishing files to passively follow the canal to the working length as recommended in the step-by-step instructions (part 6), and then withdraw immediately;
• The maximum preparation size for the M3-Pro Gold is given by the MEDIUM size instrument but if a larger preparation is needed we recommend refining the apical area with the necessary NiTi hand files;
• The M3-Pro Gold 2018 files are intended for Single Use only (on one patient during a single procedure).

5) ADVERSE REACTIONS

As with all mechanically driven root canal instruments, M3-Pro Gold 2018 files should not be used in cases of severe and sudden apical curvatures due to heightened risk of separation

6) STEP BY STEP INSTRUCTIONS FOR M3-Pro Gold 2018 FILES

•Step by step instructions (see also the illustrated Step by step card):

•Step 1:Determine length and negotiate canal by using #10 stainless steel K file.

•Step 2: Open 1/3 upper part of canal orifice by using orifce fle #17/12 with Speed 300 rpm, Torque 3.0 N.cm

•Step 3:Build a glide path by using path fle #12/02vt and #16/02vt with Speed 350 rpm, Torque 1.5 N.cm.

•Step 4:Use file #18/05, #25/06, #35/04 to prepare root canal with:
#18/05, #35/04 with Speed 350 rpm, Torque 1.5 N.cm. #25/06 with Speed 350 rpm, Torque 2.0 N.cm. Using brushing motion to prepare 1/3 to 2/3 middle part of canal,until working length is reached.

•Step 5: Do not leave the file at working length for longer than one second during root canal preparation, and process of irrigate, recapitulate and re-irrigate shall be repeated after each step.

•Step 6:Using M3 Max file to clean prepared canal before obturation is recommended to remove possible remaining debris.

7) DISINFECTION, CLEANING AND STERILIZATION

Reprocessing procedure for dental instruments.

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.

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 sterilization or disinfection 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.

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 washerdisinfector 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 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.

STEP-BY-STEP INSTRUCTIONS

Instruction A

	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(See general recommendations). -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

4	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 washerdisinfector and execute the defined cycle (Ao value > 3000 or, at least 5 min at 90°C). -Use a detergent solution with cleaning properties	-Discard any devices with large obvious 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(see also general recommendations). -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 IFU The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.

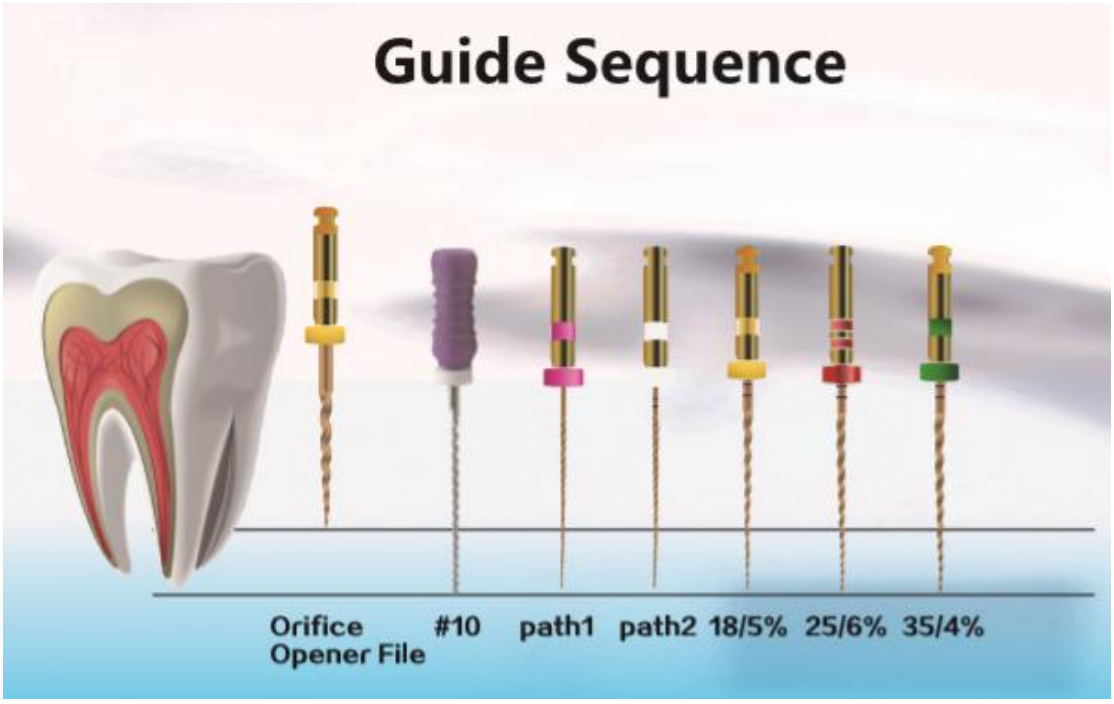
Instruction B

1	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.	-No visible impurities should be observed on the devices. -If visible impurities are observed on the devices, the device must be manually brushed t with a soft brush (made from either nylon, polypropylene, acrylic) until visible impurities are removed. -Discard any devices with large obvious defects (broken, bent, and unwound). -Follow instructions, observe water quality, concentrations and cleaning time stated by the manufacturer of the cleaning solution (see also general recommendations). -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 IFU of the detergent solution manufacturer). -The detergent should be aldehyde free and without di- or triethanolamines as corrosion inhibitor.

2	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.
3	Drying	- Devices should be thoroughly dried before inspection and packaging.	-Dry on a single use non-woven cloth, or with a hot air drier at not more than 110°C. -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
4	Inspection	-If applicable assemble the devices (including the placement of new silicon stops). -Inspect the devices functionality. -Inspect devices 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 .
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 which are resistant up to a temperature of 141°C (286°F) and in accordance with EN 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. -Check the validity period of the pouch given by the pouch manufacturer to determine the shelf life.
6	Sterilization	- Steam sterilisation at 134°C / 273°F during 18 min is recommended for these devices, for the purpose of de-activating potential prions.	-The instruments and posts must be sterilized according to the packaging labelling. -Place the pouches in the steam steriliser according to the recommendation given by the steriliser manufacturer. -Use only steam steriliser that are matching 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 min. -Respect the maintenance procedure of the steriliser given by the steriliser manufacturer. -Control the efficiency and acceptance criteria of the sterilisation procedure (packaging integrity, no humidity, no colour change of packaging, positive physico-chemical 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 sterilization packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature.	-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).



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