M3-Path Files

FOR DENTAL USE ONLY

Instruction for use

0) COMPOSITION

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

1) INDICATIONS FOR USE

Applications: catheterization of the root canal.These instruments are to be used only in a clinical or hospital environment, by qualified users.
Users are responsible for checking whether the product can be used for the purpose intended.

2) CONTRAINDICATIONS

None known

3) WARNINGS

This product contains Nickel and should not be used for individuals with known allergic sensitivity to this metal.
In order to prevent infectious agent transfer it is highly recommended to use a rubber dam system during the endodontic procedure.

4) PRECAUTIONS

- Multiple use and re-processing cycles may lead to increased risk of file separation.
- These instruments should not continuously be immersed in a sodium hypochlorite solution.
- Instrument decontamination (Only applicable for the non-sterile version of the instruments): strictly follow decontamination instructions from the manufacturer.
- Irrigate abundantly and frequently.
- Before using the M3-Path Files, establish a glide path using hand files, to at least an ISO size 010.
- Use at constant rotation at a speed of 300 rpm.
- Clean flutes frequently and check for signs of distortion or wear.
- Use the Files with light pressure.
- Use the files to follow the canal to the working length, and then withdraw.

5) ADVERSE REACTIONS

In the present technical state, no adverse reaction has been reported to date.

6) STEP BY STEP INSTRUCTIONS FOR M3-Path Files

1) Establish a manual Glide Path with standard stainless steel K-File # 008, # 010.
2) Identify the working length with the #010 K-File in combination with an Apex Locator.
3) Irigate.
4) Use the M3-Path Files #013 (P1) to working length.
5) Irrigate.
6) Use the M3-Safe Path # 016 (P2) to working length.
7) Irrigate.
8) Use the M3-Safe Path #019 (P3) to working length
9) Irrigate.
10) Before starting the canal shaping with M3 shaping files, confirm your working ength with a K-File #015 combined with an Apex Locator.

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.

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	1 canal max.	2 canals max.	2 canals max.

canals			
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 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.

8) STEP-BY-STEP INSTRUCTIONS

STEP-BY-STEP INSTRUCTIONS

Instruction A

	Operation	Activities	Warning and remarks
1	Disassemblin g	-Disassemble the device, if applicable.	-Remove and discard silicone stops.
2	Pre-Disinfecti on	-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 “Serialization 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	-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

		potential prions.	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).

Manufacturer

United Dental Changzhou
Add:Buliding,B1,No.9
Changyang road,Wujin District,
Changzhou, Jiangsu Province
213145,China.
www.udg-dental.com

EC REP

CE 0197

Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf,
Germany