

M3-Opener 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

For the removal of dentin and shaping of the orifice in the coronal 2-3mm of the root canal.

2) CONTRAINDICATIONS

None known

3) WARNINGS

M3-Opener Files are non-sterile products and must be sterilized before use.

This product contains Nickel and should not be used for individuals with known allergic sensitivity to this metal. It is recommended that diagnostic radiographs be taken from multiple angles to evaluate root canal curvature prior to rotary instrumentation.

Straight-line access and a reproducible glide path are prerequisites for proper endodontic treatment.

4) PRECAUTIONS

As with all new products, you must exercise caution until you become proficient in their use. While we have implemented safeguards against possible misuse, there are several important points to remember:

1. An Endo motor is required for rotary file use
2. Operate the handpiece at 300 RPM (Revolutions per minute) and torque with 3 N.cm.
3. M3-Opener Files are designed to shape the coronal portion or orifice of the canal to enhance straight line access to the apical foramen. The files can be used for lateral or vertical cutting. Always use light apical pressure when advancing the instrument into the canal, and cutting the dentin away from the furcation.
4. Clean the flutes frequently during instrumentation (after the file is removed from the canal).
5. Irrigate and lubricate the canal frequently throughout the procedure.
6. M3-Opener Files are single patient use devices. They can become less efficient after multiple uses causing undue stress to the file. This can lead to file separation.
7. Select appropriately sized instruments when opening the canal orifice, as choosing an overly large file can lead to dangerous over-enlargement of the coronal portion of narrow root forms. M3-Opener Files are not designed for instrumentation of the apical third of roots and should

never be taken to working length.

8. Avoid deep penetration into the orifice of the canal when coronal curvatures are present. Furthermore, anticipate the presence of these curvatures in teeth that have both buccal and lingual (palatal) canals in the same root.

5) ADVERSE REACTIONS

None known.

6) STEP BY STEP INSTRUCTIONS FOR M3-Safe Opener Files

M3-Opener Files are designed for orifice management and shaping of the coronal portion of the canal and should be used in conjunction with a supplemental instrument set for apical preparation. The clinician can choose a torque setting within the operating range of their torque controlled motor, based on their experience.

7) DISINFECTION, CLEANING AND STERILIZATION

Files must be sterilized before use.

- Scrub the instruments with soap and warm water
- Rinse thoroughly with distilled or deionized water
- Allow to air dry.
- Place the instruments, unwrapped, in the autoclave tray.
- Use fresh distilled or deionized water
- Steam Autoclave at 136 (\pm 2)C for 20 minutes.
- M3-Opener Files are single patient use instruments.
- Recommended file disposal: Place used files in a biohazard sharps container.

Manufacturer



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

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Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf,
Germany