

Mity Roto 360° & Xtreme 360° NiTi Rotary Files

RX Only - For Dental Use Only



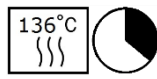
Single
Use
Only



Consult
Instructions
For Use



Sterilize
Before
Use



Autoclave
Temperature
and Time



Contains
Nickel
Titanium

Composition

Operative portion of file is composed of nickel titanium alloy.

Indications for Use

Files are used for the removal of dentin and shaping of the root canal.

Contradictions

None known.

Warnings

Files are provided non-sterile and must be sterilized before use. Single use only as re-use increases risk of fracture. This product contains nickel and should not be used for individuals with known allergic sensitivity to this material.

Adverse Reactions

Files contain nickel which may cause allergic reactions.

Precautions

- As with all new products, you must exercise caution until you become proficient in its use.
- A slow-speed hand piece is required for rotary file use.
- Operate the hand piece at 250-300 RPM (Revolutions per minute) with torque settings per torque chart.
- Straight-line access is a prerequisite for proper endodontic treatment.
- Always utilize minimal apical pressure. Do not force the files down the canal.
- Clean file flutes after each insertion into the root canal and inspect flutes for distortion or wear. Discard if visible.
- Frequently irrigate and lubricate the canal throughout the procedure.
- Take each file to length only one time and for no more than one second.
- Exercise caution in the apical area and around significant curvatures.

- If the file is too large and taken to length it will increase the risk of canal transportation and file separation.

Sterilization

Files must be sterilized before use. ANSI/ADA Specification 28 recommends:

- Scrub the files with soap and warm water
- Rinse thoroughly with distilled or deionized water
- Allow to air dry
- Place the files, unwrapped, in the autoclave tray
- Use fresh distilled or deionized water
- Steam Autoclave at 136°C (+/-2°C) for 20 minutes
- Instruments are single patient use only

Step-by-Step IFU

Straight-Line Access

- Create straight line access to canal orifices.
- Locate canals and explore using small stainless steel hand file. Minimum size #15 K-File required prior to rotary use. Apex Access Kit rotary files size 15 and 20 can also be used after #10 K-File in lieu of additional hand instruments.

Step-Back Method

- Start with a #15 engine file. Take the #15 to resistance or working length (whichever occurs first). Proceed with the #20 and then the #25.
- If this is the tip size you desire, then take the next file size 1mm shorter and continue taking the following sizes 1mm shorter than previous until desired flaring is accomplished. Between each rotary file recapitulate with a #10 or #15 hand file to maintain glide path and help lubricate to the canal terminus.
- If not, take the next larger file to length. Keep taking the next larger size to length until you achieve the tip size you desire then repeat step 2.

Disposal

Dispose of product in Biohazard Sharps container.

Torque Chart

Sizes	Torque	
15 - 20	20 g-cm	0.2 Ncm
25 - 30	40 g-cm	0.4 Ncm
35 - 40	80 g-cm	0.6 Ncm
45 - 50	150 g-cm	1.5 Ncm
55 - 60	190 g-cm	1.9 Ncm
70 - 80	350 g-cm	3.5 Ncm

