

Mity VX4 / VX6 & Xtreme VX4 / VX6 NiTi Rotary Files

RX Only - For Dental Use Only



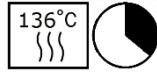
Single
Use
Only



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.

Contraindications

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 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.
- Instruments are single patient use devices.

- 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.

Crown Down Shaping and Cleaning with VX4 (.04 taper)

For smaller canals, start with a 30/04 file. Take the 30/04 to resistance or working length (whichever occurs first). If resistance is encountered before working length is obtained, go to the next smaller instrument following the same protocol until working length is achieved. Between each rotary file recapitulate with a #10 or #15 tip hand file to maintain glide path and help irrigate to the canal terminus. For larger canals, start with a 40/04 and proceed using the Crown Down technique to resistance or working length is achieved.

The same technique applies to the VX6 (.06 taper) instruments

Disposal

Dispose of product in Biohazard Sharps container.

Torque Chart

Size	Mity VX4	Mity VX6	Xtreme VX4	Xtreme VX6
15	30 g-cm	40 g-cm	60 g-cm	80 g-cm
20	30 g-cm	60 g-cm	60 g-cm	100 g-cm
25	60 g-cm	90 g-cm	90 g-cm	150 g-cm
30	90 g-cm	120 g-cm	150 g-cm	200 g-cm
35	100 g-cm	160 g-cm	200 g-cm	250 g-cm
40	130 g-cm	190 g-cm	250 g-cm	300 g-cm

