

DIRECTIONS FOR USE

COMPOSITION

The instrument is made of an Annealed Heat Treated (AHT) nickel-titanium alloy brand named Fire-Wire™. All files are constant tapered.

EdgeFile®X5 Indications for Use

These files are used in endodontics for the removal of dentine and root canal shaping. It is compatible with most rotary file systems, electric motors and handpieces.

Contraindications

- Like all mechanically driven endodontic instruments they should not be used in cases with very severe and sudden curvatures.
- This product contains nickel and should not be used for individuals with known allergic sensitivity to this metal.

Warnings

- A rubber dam system should be used.
- EdgeFile®X5 files are non-sterile and must be sterilised before patient use.
- Do not use the EdgeFile®X5 file in a traditional rotary.
- Rotary motors handpiece: The **EdgeFile®X5** can be used in a clockwise rotary motor but not in the reciprocating motor, using the reciprocating setting, which moves in the counter-clockwise direction.

Precautions for Use

As with all products, use carefully until you become proficient with use. Always determine working length using radiographs and/or apex locator to properly use rotary files. Important points to remember:

1. Use only in an electric motor and handpiece designed for rotary file instruments.
2. Straight-line access is imperative for proper rotary file use and endodontic treatment.
3. Do not force the files down canals, use minimal apical pressure.
4. Clean the flutes frequently and at least after removing the files from the canal.
5. Irrigate and lubricate the canal frequently throughout the procedure.
6. Take each rotary file to length only one time and for no more than one second.

7. In apical areas and curved canals exercise caution.
8. EdgeFile®X5 files are single patient use devices.
9. Reuse: Once a file is used do not reuse. If a file is reused and used on a different patient infection can be introduced. Performance of the file can also be reduced.
10. When instrumenting the canal, do not over enlarge the coronal portion of the canal.
11. Too large a file taken to length increases the risk of canal transportation and file separation.
12. EdgeFile®X5 files undergo our proprietary Annealed Heat Treatment (AHT) forming our branded Fire-Wire™ NiTi which increases cyclic fatigue resistance and torque strength. With this proprietary processing, EdgeFile®X5 files may be slightly curved. This is not a manufacturing defect. While the file can be easily straightened with your fingers, it is not necessary as once they are inside the canal, EdgeFile®X5 files will follow and conform to the natural canal anatomy and curvatures.

Adverse Reactions

- Device fracture/breakage
- Infection
- Complications usually associated with endodontic procedures including:
 - Pain
 - Instrument fracture/breakage
 - Soft tissue damage/bleeding

INSTRUCTIONS FOR USE

Sterilisation

Files must be cleaned and sterilised before use.

- Scrub the instruments with a long-handled bristle brush in water and a suitable detergent (specified for the purpose).
- Rinse thoroughly with distilled, deionized, or RO water.
- Allow to air dry.
- Place the instruments, wrapped or unwrapped, in an autoclave tray.
- Use fresh distilled or deionized water.
- Insert in a steam gravity cycle autoclave at 134°C-137°C with a max temp of 140°C for a minimum 3 minutes.
- EdgeFile®X5 files are for single patient use.
- Used files should be disposed of in a Biohazard Sharps container.

Electric Handpiece

The EdgeFile®X5 file can only be used in an electric handpiece and motor designed for rotary files. See manufacturer specifications.

EdgeFile®X5 Straight-Line Access and Glide Path Formation

- Create a glide path and determine the working length prior to EdgeFile®X5 file use by negotiating all root canals to their terminus with stainless steel #10 and #15 hand files and a lubricant.

Safe Unwinding

- As a safety feature the files are designed to unwind. They may be used until the files unwind backwards.

EdgeFile®X5 Canal Shaping and Cleaning: 20 Series (20/.04 & 20/.06)

- For all canals no matter the canal size, start with a 20/.06 rotary File.
- Between each rotary file recapitulate with a #10 or #15 tip hand file to maintain glide path and help lubricate the canal terminus.
- Take the 20/.06 to resistance or working length (whichever occurs first). If resistance is met before reaching the working length then go to a 20/.04.
- Take the 20/.04 to resistance or working length (whichever occurs first). If resistance is met before reaching the working length then repeat going from the 20/.06 to 20/.04 until one of them goes to the working length.
- If the file that goes to length first contains debris on the last flute, then the canal is a size 20 tip and can be obturated to that corresponding tip and taper with a thermal carrier or gutta percha, (see Obturation of Canal Systems).
- If the file did not contain debris on the last flute and was the 20/.04, then finish shaping the canal with the lubricant by using the 20/.06 then 20/.04 until the 20/.06 reaches the working length, then go to the 30 series.

EdgeFile®X5 Canal Shaping and Cleaning: 30 Series (30/.04 & 30/.06) 40 Series (40/.04 & 40/.06)

- Take a 30/.06 to resistance or working length (whichever occurs first). If resistance is met before reaching the working length then go to a 30/.04.

- Take the 30/.04 to resistance or working length (whichever occurs first). If resistance is met before reaching the working length then repeat going from the 30/.06 to 30/.04 until one of them goes to the working length.
- If that file contains debris on the last flute, then the canal is a size 30 tip and can be obturated to that corresponding tip and taper with a thermal carrier or gutta percha, (see Obturation of Canal Systems).
- If the file does not contain debris on the last flute, then the canal is larger than a size 30 tip and a 40 tip size is needed.
- Take the 40 and alternate between the 40/.06 and 40/.04 until one of them is to length and then obturate.

Obturation of Canal Systems

- When using thermal carrier system use size verifiers to determine the proper sized carrier.
- When using a master gutta percha cone that matches the largest file taken to length, remember sometimes you may need to drop down in cone tip size if the corresponding gutta percha to your final rotary file does not go to length.

Speed and Torque

- Use the same handpiece with the same speed and torque settings you are currently using with your rotary system. Or if you wish, you can use all **EdgeFile®X5** rotary files at the following speed and torque settings:

Speed	Torque
300-500 rpm	300 g-cm

Storage

Store at room temperature of 10°C~37.8°C, away from any sunlight.