

## DIRECTIONS FOR USE

### COMPOSITION

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

### EdgeFile®X1 Indications for Use

These files are used in endodontics for the removal of dentine and root canal shaping. It is compatible with the WaveOne® reciprocating file system and must be used in the WaveOne® motor and handpiece system using the WaveOne® motor setting.

### 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®X1 files are non-sterile and must be sterilised before patient use.
- Do not use the EdgeFile®X1 file in a traditional rotary handpiece.

### 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 reciprocating files. Important points to remember:

1. Use only in an electric motor and handpiece designed for the WaveOne® instruments.
2. Straight-line access is imperative for proper reciprocating 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 reciprocating file to length only one time and for no more than one second.
7. In apical areas and curved canals exercise caution.

8. EdgeFile®X1 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®X1 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®X1 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®X1 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.
- Insert in a steam gravity cycle autoclave at 134°C/137°C with a max temperature of 140°C for a minimum of 3 minutes.
- EdgeFile®X1 files are for single patient use.
- Used files should be disposed of in a Biohazard Sharps container.

### EdgeFile® X1 Straight-Line Access

- Create a glide path and determine the working length prior to EdgeFile®X1 file use by negotiating

all root canals to their terminus with stainless steel #10 and #15 hand files and a lubricant.

- Establish patency by taking a #10 K-File 1mm past the canal terminus, and at least a #15 K-File to the terminus.

### EdgeFile®X1 Size Selection

- If the #10 hand file was tight use the EdgeFile®X1 20/.06
- If the #10 hand file was easy but the #15 hand file was tight use the EdgeFile®X1 25/.06
- If both the #10 and #15 hand files were easy use the EdgeFile®X1 40/.06

### Safe Unwinding

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

### EdgeFile®X1 Canal Shaping and Cleaning

- The EdgeFile®X1 files can only be used in a motor designed for WaveOne® instruments.
- Place the selected EdgeFile®X1 file into the handpiece.
- With lubricant in the canal and light apical pressure, use a gentle inward pecking motion advancing the file 2-3 mm then lifting up 1-2 mm. Keep repeating this motion to passively advance the EdgeFile®X1 file until it does not easily progress.
- Remove the EdgeFile®X1 file from the canal, remove debris and inspect the file, irrigate and recapitulate with a #10 hand file 1 mm past the canal terminus.
- Repeat steps 3 & 4 until the EdgeFile®X1 file is to the working length. If after repeated attempts the EdgeFile®X1 file does not seem to be advancing any further, drop down in EdgeFile®X1 file size and finish the canal.

- Apically gauge the size of the foramen with a hand file the same tip size as the EdgeFile®X1 file taken to length. If the gauging hand file is a snug fit, the preparation is finished. If it is loose, use the next larger EdgeFile®X1 file to finish the preparation. Then obturate the canal.

### Electric HandPiece

The EdgeFile®X1 file can only be used in an electric handpiece and motor designed for WaveOne® instruments using the WaveOne® setting. See manufacturer specifications.

### 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.

### HandPiece

Only use the EdgeFile®X1 in same handpiece and motor that is designed for the WaveOne® instrument using the WaveOne® setting.

### Storage

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