

COMPOSITION

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

EdgeFile® X1 Indications for Use

Endodontics for the removal of dentin and root canal shaping. It is compatible with the WaveOne® reciprocating file system and must be used in the WaveOne® motor and hand piece 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.

Warnings

- A rubber dam system should be used.
- The **EdgeFile® X1** files are non-sterile and must be sterilized before patient use.

Precautions

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 hand piece designed for the WaveOne® instruments.
2. Do not use **EdgeFile® X1** in a traditional rotary hand piece
3. Straight-line access is imperative for proper reciprocating file use and endodontic treatment.
4. Do not force the files down canals, use minimal apical pressure.
5. Clean the flutes frequently and at least after removing the files from the canal.
6. Irrigate and lubricate frequently the canal throughout the procedure.
7. Take each reciprocating file to length only one time and for no more than one second.
8. In apical areas and curved canals exercise caution.
9. **EdgeFile® X1** files are single patient use devices.
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** undergoes 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, the **EdgeFile® X1** will follow and conform to the natural canal anatomy and curvatures.

Adverse Reactions

This product contains Nickel and should not be used for individuals with known allergic sensitivity to this metal.

STEP-BY-STEP INSTRUCTIONS

Sterilization

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

- Scrub the instruments with soap and warm water.
- Rinse thoroughly with distilled or deionized water.
- Allow to air dry.

- Place the instruments, unwrapped, in an autoclave tray.
- Use fresh distilled or deionized water.
- Steam Autoclave at 136° C (plus or minus 2° C) for 20 minutes.
- **EdgeFile® X1** files are for single patient use.
- Recommended File Disposal Place used files 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 Shaping and Cleaning

1. The **EdgeFile® X1** files can only be used in a motor designed for WaveOne® instruments.
2. Place the selected **EdgeFile® X1** file into the hand piece.
3. 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.
4. 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.
5. Repeat steps 3 & 4 until the **EdgeFile® X1** file is to the working length. But 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.
6. 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 Hand piece

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

Obturation of Canal Systems

- When using thermal carrier systems such as **EdgeFile® X1** or **EdgeFile® X1**, 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 reciprocating file does not go to length.

Hand Piece

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

