

## DIRECTIONS FOR USE

### COMPOSITION

The instrument is made of an Annealed Heat Treated (AHT) nickel-titanium alloy brand named Fire-Wire<sup>™</sup>.

### EdgeFile<sup>®</sup>X1 Indications for Use

These files are used in endodontics for the removal of dentin and root canal shaping. It is compatible with the WaveOne<sup>®</sup> reciprocating file system and must be used in the WaveOne<sup>®</sup> motor and hand piece system using the WaveOne<sup>®</sup> 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<sup>®</sup>X1 files are sterilized and do not need to be autoclaved before use.
- Do not use if package is damaged.
- EdgeFile<sup>®</sup>X1 files are for single use only, in order to avoid file separation.

### 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 hand piece designed for the WaveOne<sup>®</sup> 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<sup>®</sup>X1 files are single patient use devices.
9. Reuse: Once 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. Used files should be disposed of in a Biohazard Sharps container.
11. When instrumenting the canal, do not over enlarge the coronal portion of the canal.
12. Too large a file taken to length increases the risk of canal transportation and file separation.
13. EdgeFile<sup>®</sup>X1 files undergo our proprietary Annealed Heat Treatment (AHT) forming our branded Fire-Wire<sup>™</sup> NiTi which increases cyclic fatigue resistance and torque strength. With this proprietary processing, EdgeFile<sup>®</sup>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<sup>®</sup>X1 files will follow and conform to the natural canal anatomy and curvatures.

### Adverse Reactions

- Device fracture/breakage
- Infection – Do not use if package is damaged or open, due to risk of infection occurring.
- Complications usually associated with endodontic procedures including:
  - Pain
  - Instrument fracture/breakage
  - Soft tissue damage/bleeding

## INSTRUCTIONS FOR USE

### Hand Piece

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

### EdgeFile<sup>®</sup> X1 Straight-Line Access

- Create a glide path and determine the working length prior to EdgeFile<sup>®</sup>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<sup>®</sup>X1 Size Selection

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

### Disinfecting:

- After each canal is fully shaped, rinse the canals for 1 minute with 17% Liquid EDTA to remove the canal Smear Layer.
- Rinse the canals for 5 minutes with 5% NaOCl to remove debris and bacteria.
- Rinse the canals for 1 minute with 17% Liquid EDTA to rinse out the 5% NaOCl.
- Rinse the canals for 5 minutes with 2% chlorohexidine or EDTA to kill bacteria.

### 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 hand piece with the same speed and torque settings you are currently using with your rotary system. Or if you wish, you can use all **EdgeFile®X1** rotary files at the following speed and torque setting:











Speed	Torque
500rpm	410g cm

### Storage

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

### Recommended File Disposal

Place used files in Biohazard Sharps container

Symbol	Meaning (Standard, If Applicable)
	Manufacturer/Legal Manufacturer (ISO 15223-1)
	Catalogue Number (ISO 15223-1)
	Batch Code (ISO 15223-1)
	Used-by Date (ISO 15223-1)
	Do Not Re-use (ISO 15223-1)
	Do not use if package is damaged (ISO 15223-1)
	Consult instructions for use (ISO 15223-1)
<b>Rx Only</b>	Caution: Federal law restricts this device to sale by or on the order of a "dentist/Physician" licensed by the law of the State in which he/she practices to use or order the use of the device. (FDA 21 CFR <sup>1</sup> Part 801.109 (b) (1))
	Sterile using irradiation (ISO 15223-1)
	Caution (ISO 15223-1)
	Temperature Limit (ISO 15223-1)