DIRECTIONS FOR USE

COMPOSITION

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

EdgeFile®X7 Indications for Use

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

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.
• The EdgeFile®X7 files are sterilized and do not need to be autoclaved before use.
• EdgeFile®X7 files are intended for single use only to avoid file separation.
• Do not use if package is damaged.

Precautions for Use

As with all products, use carefully until you become proficient with use. Always determine working length using radio graphs and/or apex locator to properly use rotary files. Important points to remember:
1. Use only in an electric motor and hand piece 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®X7 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. Used files should be disposed of in a Biohazard Sharps container.
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®X7 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®X7 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®X7 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

Electric Handpiece

The EdgeFile®X7 file can only be used in an electric hand piece and motor designed for rotary files. See manufacturer specifications.

EdgeFile®X7 Straight-Line Access and Glide Path Formation

•Prepare straight-line access to all canal orifice.
•With lubrication in the canal form a glide path with a size #10 and #15 hand files or mechanical glide path 2/3 down the length of the canal.

EdgeFile®X7 Size Selection: 20 Series (20/.04), 25 Series (25/.04), 30 Series (30/.04), 35 Series (35/.04), 40 Series (40/.04), and 45 Series (45/.04)

•Take #10 hand file to length.
•Take glide path to length. If glide path feels tight resistance then use the steps below.

•Small Canal: Use a 25/.04 then a 20/.04 and repeat until desired file is to length.
•Medium Canal: Use a 35/.04 then a 30/.04 and repeat until desired file is to length.
•Large Canal: Use a 45/.04 then a 40/.04 and repeat until desired file is to length.

Safe Unwinding

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

EdgeFile®X7 Canal Shaping and Cleaning: 17.04 and 17.06 Files

•With lubricant in the canal and with light apical pressure take the 17/.06 into the canal and follow the glide path using an in-and-out motion while laterally brushing the dentin on the outstroke to enhance the straight-line access of the canal.
•Continue shaping with the S1 until resistance is met or 2/3 down the canal is reached.
•Then use the 17/.04, in the same way until resistance is met or 2/3 down the canal is reached.
•Switch between the 17.04 and 17.06 following the glide path using the same in-and-out as described for both files until 2/3 down the canal is reached.
•Now that the coronal 2/3 of the canal is shaped, form a glide path with the size #10 and #15 hand files or mechanical glide path files into the apical 1/3.
•Establish working length with radiographs and/or an apex locator. Then confirm patency by taking the #10 hand file 1mm past the working length.
•Then, using the same motion as before, switch between the 17/.06 and 17/.04 until reaches the working length.
•If a larger coronal shape is desired, use the 25/.12 at any time after the coronal 2/3 is shaped.

Completing Canal Shaping and Cleaning: 20.06, 25.06, 30.06, and 40.06 Files

•With lubricant in the canal and with light apical pressure complete canal shaping and cleaning by taking the 20/.06 down the canal until the working length is reached.
•Apically gauge the foramen at the working length with a #20 hand file. If the #20 hand file is snug at the working length, the canal is shaped and ready to obturate.
•If the #20 hand file is loose, take the 25/.06 to the working length, then gauge with a #25 hand file. When necessary, the 30/.06 or 40/.06 may need to be used.

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% NaOCI to remove debris and bacteria.
• Rinse the canals for 1 minute with 17% Liquid EDTA to rinse out the 5% NaOCI.
•Rinse the canals for 5 minutes with 2% chlorohexidine or EDTA to kill bacteria.

Obturation of Canal Systems

•When using a 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®X7** 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.

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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)
Rx Only	Caution: Federal law restricts this deivse 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 devise. (FDA 21 CFR¹ Part 801.109 (b) (1))
	Sterile using irradiation (ISO 15223-1)
	Caution (ISO 15223-1)
	Temperature Limit (ISO 15223-1)

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