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.

EdgeOne Fire™ Indications for Use

These files are used in 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.
• 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.
• EdgeOne Fire™ files are non-sterile and must be sterilised before patient use.
• Do not use the EdgeOne Fire™ file in a traditional rotary hand piece.

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® 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. EdgeOne Fire™ files are single patient use devices.
9. Once file is used do not reuse. If 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. EdgeOne Fire™ 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, EdgeOne Fire™ 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, EdgeOne Fire™ 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 temp of 140°C for a minimum 3 minutes.
•EdgeOne Fire™ files are for single patient use.
•Used files should be disposed of in a Biohazard Sharps container.

EdgeOne Fire™ Straight-Line Access

•Create a glide path and determine the working length prior to EdgeOne Fire™ 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.

EdgeOne Fire™ Size Selection

•If the #10 hand file was tight use the EdgeOne Fire™ 20/06

•If the #10 hand file was easy but the #15 hand file was tight use the EdgeOne Fire™ 25/06

•If both the #10 and #15 hand files were easy use the EdgeOne Fire™ 40/06

Safe Unwinding

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

EdgeOne Fire™ Canal Shaping and Cleaning

•The EdgeOne Fire™ files can only be used in a motor designed for WaveOne® instruments.

•Place the selected EdgeOne Fire™ 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 EdgeOne Fire™ file until it does not easily progress.

•Remove the EdgeOne Fire™ 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 EdgeOne Fire™ file is to the working length. If after repeated attempts the EdgeOne Fire™ file does not seem to be advancing any further, drop down in EdgeOne Fire™ file size and finish the canal.

•Apically gauge the size of the foramen with a hand file the same tip size as the EdgeOne Fire™ 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 EdgeOne Fire™ file to finish the preparation. Then obturate the canal.

Electric Hand Piece

The EdgeOne Fire™ 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 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.

Hand Piece

Only use the EdgeOne Fire™ in same hand piece 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.