EDGEENDO®

DIRECTIONS FOR USE

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

EdgeOne Fire GlidePath™ Indications for Use
•EdgeOne Fire GlidePath™ Files are used to form the glide path before using any rotary or reciprocating files.

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 EdgeOne Fire GlidePath™ files are non-sterile and must be sterilized before patient use.
• EdgeOne Fire GlidePath™ Files are intended for single use to avoid file separation.
• Rotary motors: The **EdgeOne Fire GlidePath™** can be used in a reciprocating motor, which moves in the counter-clockwise direction.

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. EdgeOne Fire GlidePath™ 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. EdgeOne Fire GlidePath™ 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 GlidePath™ 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 GlidePath™ 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:
- o   Pain
- o   Instrument fracture/breakage
- o   Soft tissue damage/bleeding

INSTRUCTIONS FOR USE

Sterilization
Files must be cleaned and sterilized before use.
•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.

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•Use fresh distilled or deionized water.
•Insert in a steam gravity cycle autoclave at 136° C (plus or minus 2° C) for 20 minutes.
•EdgeOne Fire GlidePath™ files are for single patient use.
•Used files should be disposed of in a Biohazard Sharps container.

Electric Handpiece

The EdgeOne Fire GlidePath™ file can only be used in an electric hand piece and motor designed for rotary files. See manufacturer specifications.

EdgeOne Fire GlidePath™ Straight-Line Access and Glide Path Formation
•Prepare straight-line access to 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.

EdgeOne Fire GlidePath™ Size Selection: S1, S2, SX, F1, F2, F3 Files
•Established canal patency by taking #10 1mm past working length.
•Take a #15 hand file to working length. Shape and Finish Canal.
•Fill chamber with EDTA liquid
•Take S1 to working length. Rinse with EDTA liquid.
•Recapitulate #10 hand file to working length.
•Take S2 to working length. Rinse with EDTA liquid.
•Recapitulate #10 hand file to working length. Take F1 to working length.
•Rinse with EDTA liquid.
•Recapitulate # 10 hand file to working length.
•If a larger file is needed then use F2 or F3. Disinfect and Obturate Canals with Gutta Percha Points.
•Fill chamber with EDTA liquid.
•Take # 10 hand file 2/3 down canal.
•Fill chamber with EDTA liquid.
•Take SX tip size 19 rotary file to length form glide path in Apical 1/3.
•Fill chamber with EDTA liquid.
•Take #10 hand file to estimated working length.
•Establish working length with Apex Locator using hand file or X-ray.

Optional Steps: S1, S2, F1, F2, F3 Files
•Established canal patency by taking #10 1mm past working length.

•Take a #15 hand file to working length Shape and Finish Apical 1/3.
•Fill chamber with EDTA liquid.
•Take S1 to working length. Rinse with EDTA liquid.
•Recapitulate #10 hand file to working length.
•Take S2 to working length. Rinse with EDTA liquid.
•Recapitulate #10 hand file to working length. Take F1 to working length.
•Rinse with EDTA liquid. Recapitulate #10 hand file to working length.
•If a larger file is needed then use F2 or F3.
•Disinfect and obturate canals with gutta percha points.

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

EdgeOne Fire GlidePath™ Canal Shaping and Cleaning: SX, S1 and S2 Files
•With lubricant in the canal and with light apical pressure take the S1 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 S2 17/.04, in the same way until resistance is met or 2/3 down the canal is reached.
•Switch between the S1 and S2 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 S1 17/.06 and S2 17/.04 until S2 reaches the working length.
•If a larger coronal shape is desired, use the SX 25/.12 at any time after the coronal 2/3 is shaped.

Completing Canal Shaping and Cleaning: F1, F2, F3, F4 Files.
•With lubricant in the canal and with light apical pressure complete canal shaping and cleaning by

taking the F1 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 F2 25/.06 to the working length, then gauge with a #25 hand file. When necessary, the F3 30/.06 or F4 40/.06 may need to be used.

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 **EdgeOne Fire GlidePath™** reciprocating files at the following speed and torque settings:

Speed	Torque
300-500 rpm	300 g-cm

Storage Information

•Product is to be stored in an environment with a temperature range of 10 Degrees Celsius to 37.8 Degrees Celsius.

EDGEENDO

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