DIRECTIONS FOR USE

EDGEONE FIRE GLIDEPATH™ Heat Treated Fire-Wire™

Intended Use

Endodontic files and reamers are single use surgical instruments used for performing root canal treatment to mechanically shape and prepare the root canals during endodontic therapy or to remove the root canal obturating material when performing retreatment. The device is intended to be used sterile and single use only.

Intended Users

The device is designed to be used by a Dental or Endodontic specialist trained in endodontic techniques. No additional training is required for the safe use of the device by the treating physician.

Intended Patient Population

Adolescent to adult population. People with permanent teeth in need of endodontic pulpectomy.

COMPOSITION

The instrument is made of a nickel-titanium blade, handle, the stop, and the color-coded band.

Contraindications

- Mechanically driven endodontic instruments 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

- Endodontic files are for single use only, in order to avoid file separation.
- The product has not been designed or tested for reuse. The ability to effectively clean and re-sterilize this single use device and subsequent reuse may adversely affect the clinical performance, safety and/or sterility of the device.
- Endodontic files are sharp, and caution should be used if touching the blade directly.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
- If the packaging is damaged, please dispose of the damaged product and utilize an undamaged product instead as the former may be contaminated.

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 endodontic files. Important points to remember:

1. A rubber dam system should be used.
2. Use only in an electric motor and hand piece designed for endodontic (rotary/reciprocating) files.
3. Straight-line access is imperative for proper 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 the canal frequently throughout the procedure.
7. Take each file to length only one time and for no more than one second.
8. In apical areas and curved canals exercise caution.
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. Do not exceed the handpiece recommended maximum torque or speed. Exceeding settings may cause the device to fail.
13. Endodontic 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, the 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, endodontic files will follow and conform to the natural canal anatomy and curvatures.
14. Do not use after the expiration date on the label.

Adverse Reactions

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

Safe Unwinding

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

INSTRUCTIONS FOR USE

Sterilisation

No sterilisation steps are needed for product provided sterile.

EdgeOneFire GlidePath™

- Shaping files from the canal.
- Use a reciprocating motion with light apical pressure.
- Use a gentle inward-outward motion, with short up and down strokes, to passively advance the EdgeOneFire GlidePath™ & Shaping files.
- Remove EdgeOneFire GlidePath ™ & shaping file when it does not easily progress. Clean and inspect the cutting flutes, then irrigate, recapitulate with a size #10 file and re-irrigate.
- EdgeOneFire GlidePath ™ & Shaping files may appear slightly curved. This is not a manufacturing defect. It is not necessary to straighten the file prior to use. Once inside the canal they will follow the natural canal curvatures.

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- Before using EdgeOneFire GlidePath ™ file, scout the canal with hand files, to at least a #10 K-file with a lubricant such as EdgeLube®.

STEP-BY-STEP INTRUCTIONS
Radiographic evaluation:

Review different horizontally angulated radiographs to diagnostically determine the width, length, and curvature of any given root canal.

Access preparation:

Create straight-line access to the canal orifice(s) with emphasis on flaring, flattening, and finishing the internal walls.

EdgeOneFire GlidePath ™ file technique:

1. Prepare straight line access to canal orifice.
2. In the presence of EdgeLube™, explore the canal up to a #10 hand file.
3. Determine working length with the help of a per-op radiograph and an apex locator.
4. Irrigate with EdgeLube™.
5. With gentle inward pressure, let the EdgeOneFire GlidePath ™ file passively progress in the canal. Use the EdgeOneFire GlidePath™ file in one or more passes until the full working length is reached.
6. Irrigate, recapitulate and irrigate again.
7. Reconfirm the working length, before shaping the canal with the EdgeCoil™ Fire shaping files.

Shaping files technique:

1. Establish straight-line coronal access.
2. In the presence of EdgeLube™, use a #10 hand file to verify a glide path to length.
3. Expand this glide path to at least 0.15 mm using either a hand file or mechanical file, such as EdgeFind™ or EdgeOneFire GlidePath™ file.
4. Initiate the shaping procedure with the shaping file in the presence of EdgeLube™.
5. Use gentle inward pressure and let the shaping file passively progress. After shaping 2-3 mm of any given canal, remove and clean the file, then irrigate, recapitulate with a #10 hand file and re-irrigate.
6. Continue with the shaping file, in 2-3 passes, to enlarge the coronal two thirds of the canal.
7. Utilize a brushing motion on the outstroke to eliminate coronal interferences or to enhance shaping.
8. In more restrictive canals, use a #10 hand file, in the presence of EdgeLube™, to the terminus of the canal. Gently work this file until it is completely loose at length.
9. Establish working length, confirm patency and verify the glide path.
10. Expand this glide path to at least 0.15 mm using a hand or mechanical glide path file.
11. Carry the shaping file to the full working length in one or more passes. Upon reaching length, remove the file, inspect the apical flutes; if they are loaded with dentinal debris, then the shape is finished*.
12. If the shaping file doesn't progress then re-use the EdgeOneFire GlidePath™ file and take it 1.0 mm past the working length. Then take the shaping file to the working length.
13. When the shape is confirmed, proceed with disinfection.
14. After sterilizing the canal use EdgeBioCeramic™ Sealer to fill the canal. then place the largest gutta percha or thermal carrier that goes to length.

Motor Settings

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: 300-500 RPM
- Torque: 300 g-cm

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 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.

Disposal

- Recommended file disposal: Place used files in Biohazard Sharps container.

Reporting of Incidents to manufacturer and competent authorities

- In case any patient/user faces a serious incident, the entirety of the incident will be reported to the following:
  - The manufacturer of the device: US ENDODONTICS
  - The competent authority of the country where the user/patient resides

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Symbol Table

Symbol	Meaning (Standard, if Applicable)
	Manufacturer: Indicates the medical device manufacturer (ISO 15223-1)
	Authorized Representative: Indicates the AR in the EU
	Importer: Indicates the entity importing the medical device into the locale (ISO 15223-1)
	Conformité Européene. EU mandatory conformity marking.
	Translation: Indicates that the original information has been translated and replaced (ISO 15223-1)
	Medical Device: Indicates the item is a medical device (ISO 15223-1)
	Catalogue number: indicates the Medical Device SKU (ISO 15223-1)
	Batch Code: Manufacturer's batch code so batch or lot can be identified (ISO 15223-1)
	Indicates the date after which the medical device should not be used (ISO 15223-1)
	Do not reuse: Indicates a medical device that is intended for one single use only (ISO 15223-1)
	Do not resterilise: Indicates medical devices that is not to be resterilised (ISO 15223-1)
	Medical device sterilized using irradiation and packaged with a single outer sterile barrier system (ISO 15223-1)
	Medical device should not be used if package is damaged and consult instructions for use (ISO 15223-1)
	Consult IFU: consult the Instructions For Use, and eIFU website listed (ISO 15223-1)
	Caution is necessary when operating device. Align cautions (ISO 15223-1)
	Unique Device Identifier: Indicates a carrier that contains UDI information (ISO 15223-1)
	Date and Country of Manufacture: To identify the country of manufacture of products next to date of manufacture (ISO 15223-1)
Rx ONLY	Prescription Use Only: Caution: Federal law restricts this device to sale by or on the order of a dentist (21CFR 801.109)

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