DIRECTIONS FOR USE

EDGEONE PLATINUM™ 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.
- The endodontic files must be sterilized before patient use.

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.

Adverse Reactions

- Device fracture/breakage
- Complications usually associated with endodontic procedures including:
  - Pain
  - Instrument fracture/breakage
  - Soft tissue damage/bleeding

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

- Files are single use only and not meant for reprocessing.
- Autoclaving should be performed immediately before use.
- Place the instruments unwrapped in an autoclave tray.
- Use fresh distilled or deionized water.
- Insert in a steam gravity cycle autoclave at 134°C-137°C with a max temp of 140°C for a minimum 3 minutes.
- Aseptic transport to the point of use should follow autoclaving.
- Storage of the sterilized device is not recommended.

EDGEONE PLATINUM™ Instruments

- VERIFILE™
- Small
- Primary
- Medium
- Large

Finishing Canal

- If the VERIFILE™ goes down to working length without resistance, finish with either the Medium or Large file.
- If the VERIFILE™ goes down to working length with moderate resistance, finish with the Primary.
- If the VERIFILE™ goes down to working length with tight resistance, finish with the Small.

EDGEENDO®

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If the VERIFILE™ goes not go down to working length, alternate between the Small and VERIFILE™ until the Small is to working length.

GlidePath:

- Fill the chamber with EDGELUBE™ EDTA Liquid.
- Take #10 hand file to the estimated working length.
- Establish the working length with Apex Locator or X-ray.
- Established canal patency by taking the #10 hand file 1mm past the working length.
- Expand the GLIDEPATH™ by taking a #15 hand file or EDGEGLIDEPATH™ rotary or EDGEFIND™ rotary files to working length.

Initial Shaping:

- Fill chamber with EDGELUBE™ EDTA liquid.
- Always use the EDGEONE PLATINUM™ VERIFILE™ as your first file for initial shaping of the canal by taking it to length with small in-and-out motions advancing the file apically 1-3mm per stroke.

After the VERIFILE™, rinse with EDGELUBE™ EDTA liquid and recapitulate with a #10 hand file.

Compatible Hand pieces

These files are used in endodontics for the removal of dentin and root canal shaping. It is compatible with the **WaveOne Gold®** reciprocating file system and must be used in the **WaveOne Gold®** motor and hand piece system using the **WaveOne Gold®** motor setting.

Hand Piece

Only use the EDGEONE PLATINUM™ in same hand piece and motor that is designed for the **WaveOne Gold®** instrument using the **WaveOne Gold®** setting.

Electric Hand Piece

The EDGEONE PLATINUM™ file can only be used in an electric hand piece and motor designed for **WaveOne Gold®** instruments using the **WaveOne Gold®** 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% 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

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)
	Do not reuse: Indicates a medical device that is intended for one single use only (ISO 15223-1)
	Non-Sterile: medical device that has not been subjected to a sterilization process (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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