DIRECTIONS FOR USE

EDGEFILE®X1 Heat Treated Fire-Wire™

Intended Purpose

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.

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

- A rubber dam system should be used.
- Endodontic files are sharp, and caution should be used if touching the blade directly.
- The endodontic files must be sterilized before patient use.
- Endodontic files are for single use only, in order to avoid file separation.
- This device is intended for single patient use only.
- Used files should be disposed of in a Biohazard Sharps container in accordance with local regulations.
- 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.
- Do not use if package is damaged.
- The product and the packaging have 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.
- 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. Use only in an electric motor and hand piece designed for endodontic (rotary/reciprocating) files.
2. Straight-line access is imperative for proper 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 file to length only one time and for no more than one second.
7. In apical areas and curved canals exercise caution.
8. Endodontic 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. 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
- 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

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.

Size Selection: S1, S2, SX, F1, F2, F3 Files

- If the #10 hand file was tight use the **EDGEFILE®X1** 20/.06
- If the #10 hand file was easy but the #15 hand file was tight use the **EDGEFILE®X1** 25/.06
- If both the #10 and #15 hand files were easy use the **EDGEFILE®X1** 40/.06

Straight-Line Access

- Create a glide path and determine the working length prior to **EDGEFILE®X1** 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.

Canal Shaping and Cleaning

EDGEENDO®

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2514 AP The Hague
The Netherlands

US Endodontics, LLC
2809 W. Walnut Street
Johnson City, TN 37604, USA
EdgeEndo.com

CE 0050

- The **EDGEFILE®X1** files can only be used in a motor designed for WaveOne® instruments.
- Place the selected **EDGEFILE®X1** file into the handpiece.
- 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 **EDGEFILE®X1** file until it does not easily progress.
- Remove the **EDGEFILE®X1** 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 **EDGEFILE®X1** file is to the working length. If after repeated attempts the **EDGEFILE®X1** file does not seem to be advancing any further, drop down in **EDGEFILE®X1** file size and finish the canal.
- Apically gauge the size of the foramen with a hand file the same tip size as the **EDGEFILE®X1** 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 **EDGEFILE®X1** file to finish the preparation. Then obturate the canal.

Compatible Hand Pieces

Electric HandPiece

The **EDGEFILE®X1** file can only be used in an electric handpiece and motor designed for WaveOne® instruments using the WaveOne® setting. See manufacturer specifications.

HandPiece

Only use the **EDGEFILE®X1** in same handpiece and motor that is designed for the WaveOne® instrument using the WaveOne® setting

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.

Storage Conditions

- Store at room temperature of 10°C~37.8°C, away from any sunlight. 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)
	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)
	Temperature limit to which the medical device can be safely exposed (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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