

## DIRECTIONS FOR USE

### COMPOSITION

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

### EdgeSequel Utopia™ Indications for Use

These files are used in endodontics for the removal of dentin and root canal shaping. It is compatible with most rotary file systems, electric motors and hand pieces.

### 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 EdgeSequel Utopia™ files are sterilized and do not need to be autoclaved before use.
- EdgeSequel Utopia™ files are intended for single use only to avoid file separation.
- Do not use if package is damaged.

### 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. EdgeSequel Utopia™ 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. Used files should be disposed of in a Biohazard Sharps container.
11. When instrumenting the canal, do not over enlarge the coronal portion of the canal.

12. Too large a file taken to length increases the risk of canal transportation and file separation.
13. EdgeSequel Utopia™ 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, EdgeSequel Utopia™ 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, EdgeSequel Utopia™ files will follow and conform to the natural canal anatomy and curvatures.

### 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:
  - Paino Instrument fracture/breakage
  - Soft tissue damage/bleeding

### Instructions For Use

#### Electric Handpiece

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

#### Simplified Technique Guide

1. Create straight line access to canal orifices.
2. Locate canals and explore using stainless steel hand instruments.
3. Irrigate before each hand or rotary file with liquid NaOCl or 17% EDTA
4. Using a #10 K file or larger file determine the working length with an apex locator and/or radiographs in each canal. This will also form a glide path in each canal.
5. Use #15/04 file in one or more passes, alternating with small-sized hand files if necessary, until working length is reached. If more coronal flare is desired it can be achieved by incorporating the EdgeGlidePath file used in a brushing motion.
6. Next use #25/04 to working length passively; if instrument has not reached working length use smaller additional shaping instrument #20/04 to working length alternating between #20/04 and #25/04.
7. After #25/04 reaches working length if clinician desires a larger apical or canal shape, take a #25/06 or other additional larger 04 or 06 instruments (#30, #35, #40, etc...)

**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% NaOCl to remove debris and bacteria.
- Rinse the canals for 1 minute with 17% Liquid EDTA to rinse out the 5% NaOCl.
- Rinse the canals for 5 minutes with 2% chlorohexidine or EDTA to kill bacteria.

**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 EdgeSequel Utopia™ rotary files at the following speed and torque setting:








Speed	Torque
500rpm	410g cm

**Storage**

- Store at room temperature of 10°C~37.8°C, away from any sunlight.

**Recommended File Disposal**


Place used files in Biohazard Sharps container.

Symbol	Meaning (Standard, If Applicable)
	Manufacturer/Legal Manufacturer (ISO 15223-1)
<b>REF</b>	Catalogue Number (ISO 15223-1)
<b>LOT</b>	Batch Code (ISO 15223-1)
	Used-by Date (ISO 15223-1)
	Do Not Re-use (ISO 15223-1)
	Do not use if package is damaged (ISO 15223-1)
	Consult instructions for use (ISO 15223-1)
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a "dentist/Physician" licensed by the law of the State in which he/she practices to use or order the use of the device. (FDA 21 CFR Part 801.109 (b) (1))
<b>STERILE</b> <b>R</b>	Sterile using irradiation (ISO 15223-1)
	Caution (ISO 15223-1)
	Temperature Limit (ISO 15223-1)

**Manufactured By:**

EMERGO EUROPE  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**Manufactured For:**

 EdgeEndo, LLC  
5600 Wyoming Blvd. NE, Suite 100  
Albuquerque, NM 87109, USA  
EdgeEndo.com 1-855-985-3636