

DIRECTIONS FOR USE

COMPOSITION

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

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

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™ Sapphire 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™ Sapphire 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™ Sapphire 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™ Sapphire 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:
 - Pain
 - Instrument fracture/breakage
 - Soft tissue damage/bleeding

INSTRUCTIONS FOR USE

Electric Handpiece

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

EdgeSequel™ Sapphire Straight-Line Access and Glide Path Formation

- Prepare straight-line access to all 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.

EdgeSequel™ Sapphire Size Selection: 20 Series (20/.04), 25 Series (25/.04), 30 Series (30/.04), 35 Series (35/.04), 40 Series (40/.04), and 45 Series (45/.04)

- Take #10 hand file to length.

- Take glide path to length. If glide path feels tight resistance then use the steps below.
- Small Canal: Use a 25/.04 then a 20/.04 and repeat until desired file is to length.
- Medium Canal: Use a 35/.04 then a 30/.04 and repeat until desired file is to length.
- Large Canal: Use a 45/.04 then a 40/.04 and repeat until desired file is to length.

Safe Unwinding

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

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™ Sapphire 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) |
|  | Catalogue Number (ISO 15223-1) |
|  | 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 devise. (FDA 21 CFR Part 801.109 (b) (1)) |
|  | Sterile using irradiation (ISO 15223-1) |
|  | Caution (ISO 15223-1) |
|  | Temperature Limit (ISO 15223-1) |