

DIRECTIONS FOR USE

COMPOSITION

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

EdgeGlidePath™ Indications for Use

• EdgeGlidePath™ Files are used to form the glide path before using any rotary or reciprocating files.

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 EdgeGlidePath™ files are sterilized and do not need to be autoclaved before use.
- EdgeGlidePath™ Files are intended for single use to avoid file separation.
- Rotary Motors: The EdgeGlidePath™ can be used in a reciprocating motor, which moves in the counter-clockwise direction.

Precautions for Use:

Until you become familiar with all new products, exercise caution and follow these important points:

- 1) Use electric handpiece for rotary files.
- 2) Set at 300-500 RPM (Revolutions per Minute).
- 3) Get straight-line access for all rotary files including EdgeFind™ files.
- 4) Do not force files, use minimal pressure down the canal.
- 5) Clean the flutes frequently during use.
- 6) Use copious and frequent irrigation and lubrication during use.
- 7) Use caution in the apical and curved canal regions.
- 8) Rotary files are single-patient use devices.

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

Create Initial Shape Using EdgeGlidePath™

- Establish Straight Line Access.
- Form GlidePath with stainless steel K-File #8 and #10 using EdgeLube™ 17% EDTA and EdgeGel™ 19% EDTA.
- Confirm working length with the #10 K-File using radiograph and/or Apex Locator.
- Start with EdgeFind™ P1-#13, take to working length and irrigate.
- Next use EdgeFind™ P2-#16 take to working length and irrigate.
- Finish with EdgeFind™ P3-#19, take to working length and irrigate.
- Now start canal shaping with EdgeEndo NiTi Rotary Files.

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.

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)
REF	Catalogue Number (ISO 15223-1)
LOT	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))
STERILE R	Sterile using irradiation (ISO 15223-1)
	Caution (ISO 15223-1)
	Temperature Limit (ISO 15223-1)