

Composition

The instrument is made of an Annealed Heat Treated (AHT) nickel-titanium alloy.

EdgeX7 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

- Arubber dam system should be used.
- The EdgeX7 Utopia™ files are sterilized and do not need to be autoclaved before use.
- EdgeX7 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 atleast 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. EdgeX7 Utopia™ files are single patient use devices.
9. Reuse: Once afile is used do not reuse. If a file is reused and used on adifferent 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 afile taken to length increases the risk of canal transportation and file separation.

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**

TheEdgeX7 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 #17/04 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% chlorhexidine 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 EdgeX7 Utopia™ rotary files at the following speed and torque setting:

Speed	Torque
500rpm	410g cm

Recommended File Disposal

Place used files in Biohazard Sharps container.

SYMBOL	MEANING
	Catalogue Number
	Quantity
	Batch code
	Medical device
	Tip diameter
	Taper
	Length
	UDI code (Unique Device Identification)
	Sterilized using irradiation
	Single sterile barrier system
	Do not reuse
	Do not use if package is damaged
	Use-by date
	Clockwise rotation
	Nickel-titanium alloy
	Operating instructions
	Root canal treatment
	Manufacturer
	Authorized representative (authorized representative in the European Union)
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 ¹ Part 801.109 (b) (1))



FKG Dentaire Sàrl
Le Crêt-du-Loche 4
2322 Le Crêt-du-Loche
Switzerland



EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



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