



INSTRUCTIONS FOR USE

EN

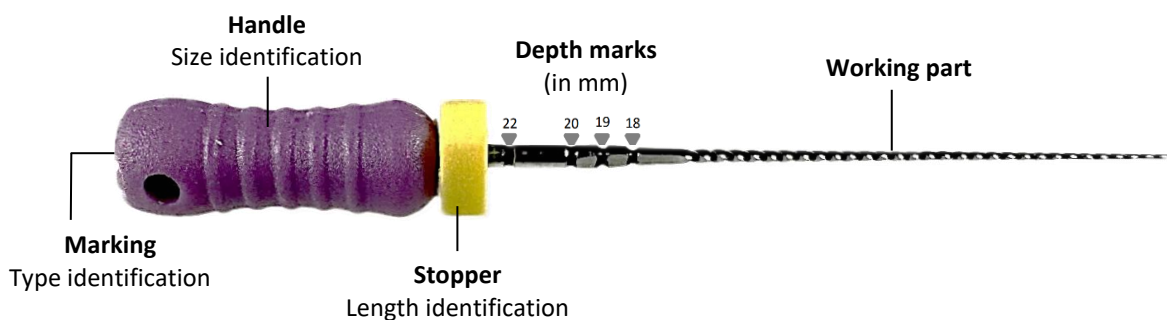
FOR DENTAL USE ONLY

INSTRUCTIONS FOR USE – EDGEUTOPIA K-FILES™, EDGEUTOPIA H-FILES™, EDGEUTOPIAC-FILES™

1) GENERAL DESCRIPTION

Composition:

The hand root canal file consists of working part made of stainless steel, a plastic handle and a Stopper made of silicone.



Type marking:

Product Name	Type	Marking
EDGEUTOPIA  K-FILE™	K-File	□
EDGEUTOPIA  C-FILE™	C-File	C
EDGEUTOPIA  H-FILE™	H-File	○

Tip size color code:

06	08	10	12	15	20	25	30	35	40	45	50	55	60	70	80
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Length color code:

21	25	31
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Specifications:

A. EdgeUtopia K-Files

ISO Tip size: 6, 8, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80.

Length: 21mm, 25mm and 31 mm.

Taper: .02

B. EdgeUtopia H-Files

ISO Tip size: 15, 20, 25, 30, 35, 40, 45, 50

Length: 21mm, 25mm and 31 mm.

Taper: .02

C. EdgeUtopia C-Files

ISO Tip sizes: 6, 8, 10, 12, 15

Length: 21mm and 25mm

Taper: .02



2) INTENDED USE

The EdgeUtopia K-File™, EdgeUtopia H-File™ and EdgeUtopia C-File™ are used for the removal of dentin and root canal shaping during root canal therapy.

3) INDICATIONS FOR USE

EdgeUtopia K-File, EdgeUtopia H-File and EdgeUtopia C-File are indicated for the treatment of various pulpitis and root canal diseases with dental pulp necrosis.

4) CONTRAINDICATIONS AND ADVERSE REACTIONS

None known.

5) WARNINGS AND PRECAUTIONS

1. These devices can be used and reprocessed up to 10 times
2. This product can only be used by professional dentists
3. Carefully read the label, marking on the packaging and this instruction for use to ensure the correct identification and use of device
4. Ensure that the product is disinfected every time it is used
5. Do not use this product for any purpose other than dental treatment and service
6. Use a dental dam when using endodontic instruments to avoid inhalation or ingestion by the patient
7. The product contains Nickel and chromium should not be used on individuals with known allergic sensitivity to these metals
8. For your own safety, wear personal protective equipment (masks, gloves, and goggles) during the treatment and reprocessing of the instrument
9. Do not use the instruments after expiration date
10. For sterile version, do not use if packaging seal is broken, damaged or wet
11. Always inspect the instrument(s) before use, and discard (it) them if there are any visible defect(s)
12. Cracks, deformations, signs of corrosion, loss in color or marking are signs that the device is no longer able to achieve the required performance level and should be discarded
13. All serious events occurring in relation to the product must be reported to the manufacturer and the competent authority according to local regulations

6) PERFORMANCE CHARACTERISTICS

EdgeUtopia K-File, EdgeUtopia H-File and EdgeUtopia C-File hand files are compliant with all applicable testing requirements of the ISO 3630 series of standards.



7) PROTOCOL FOR USE

1. Open the cavity of crown, using diamond burs.
2. Use #6, #8 or #10 files to explore the root canal, to follow the root canal by rotating in a back-and-forth motion, to rinse the root canal with NaOCl.
3. Use #15 file to further clear the root canal, and then determine the working length.
4. Rinse again and use #15 file to remove the debris to avoid obstruction.
5. Use #20 file, to pull up and down. Each time, prepare apically for 2-3mm, then clean debris and prepare gradually to the apex.
6. Use #25 file to finish the root canal. If resistance is encountered during preparation, do not force the file apically. Irrigate with NaOCl throughout the procedure to prevent debris from being packed toward the apex, which could compromise the obturation.
7. For large canals, select appropriate files and prepare the canal sequentially to the desired master apical size for obturation.

8) CONDITIONS AND TERM OF STORAGE, SHELF-LIFE

The shelf-life is 5 years. The use-by date is indicated on the packaging.

9) REPROCESSING

1. Reprocess immediately after use to prevent debris from drying on the device.
2. Non-sterile files must be sterilized before their first use and after each use. Recommended method: sterilization cycles with the Pre-Vacuum air Removal steam sterilizer (saturated steam and compliant with EN 13060 (class B, small sterilizer) and EN 285 (full size sterilizer): 134°C (273°F) with at least 18 min holding time, 20 min drying time (According to ISO 17665).
3. After use, immerse the device in a enzymatic cleaning and disinfecting solution, observing the concentration, temperature and contact time specified by the solution manufacturer, and ensure that the solution is compatible with stainless steel dental instruments.
4. Rinse thoroughly with water and dry.
5. Sterilize according to 2.

10) DISPOSAL

When a device reaches the end of its life, make sure that it is discarded in accordance with the applicable laws and regulations.

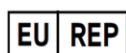


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11) SYMBOLS

Symbol	Description	Symbol	Description
	Batch code		Stainless Steel
	Date of Manufacture		Quantity
	Use-by-date		Consult Instruction for Use
	Caution		Do not use if package is damaged
	Sterilized using irradiation		Non sterile
	Unique Device Identification		Autoclavable
	Medical Device		Catalogue number
	Manufacturer		Authorized Representative in the European Union
	Endodontic Instrument		



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