

ELECTRONIC INSTRUCTIONS FOR USE

EdgeUtopia K and C Sterile Stainless Steel Hand Files are single use medical devices that are supplied sterile. This device must not be reprocessed after clinical use. Re-use may result in infection or patient injury.

TYPE/MODEL: EdgeUtopia K-File, Sterile, Stainless Steel

SPECIFICATIONS: ISO Tip sizes - 6, 8, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 10-35 (10, 15, 20, 25, 30, 35) 21mm and 25mm lengths

TYPE/MODEL: EdgeUtopia C-File, Sterile, Stainless Steel

SPECIFICATIONS: ISO Tip sizes - 6, 8, 10, 15 21mm and 25mm lengths

1) INDICATIONS FOR USE

- EdgeUtopia K and C Sterile Hand Files are indicated for use on any patient demographic exhibiting various pulpitis, pulp necrosis of root canal disease.
- Intended use: Used for the removal of dentin and root canal shaping during root canal therapy.

2) CONTRAINDICATION

- The product contains nickel and chromium and should not be used on individuals with known allergic sensitivity to these metals.

3) STRUCTURE AND COMPOSITION

- The handuse files are made of stainless steel. The working end has flutes and blades, to cut and prepare smooth root canal.
- Non-active device, supplied sterile, ready-to-use.

4) WARNINGS

- Single-use products shall not be re-processed nor reused. Reusing these products increases the risk of cross-contamination and/or breakage.
- This product is used by professional dentists only.
- Do not use this product for any purpose other than dental treatment or service.
- Follow dental practice, to use rubber dams during operation.

5) PRECAUTIONS

- For your own safety, wear personal protective equipment (gloves, glasses, mask).
- The disposable sterile root canal files must not be reused. Before using, the packaging and the instruments should be inspected. If any defects or damages are found in the packaging or the root canal files that prevent their normal use, they should be replaced immediately.

- Retain UDI information on the label.
- This product is sharp. When handling and using, take proper protective measures for yourself and be careful to avoid being punctured or stabbed.
- The used products should be discarded as medical waste.

6) ADVERSE REACTIONS

- In the present technical state, no adverse reaction has been reported so far.

7) STORAGE CONDITIONS

- Handle with care during transportation and storage; do not stack to avoid damage.
- Avoid storing in areas with high temperature, high humidity, or direct sunlight.
- The product should be stored at room temperature.

8) SHELF LIFE

- 5 years from the date of manufacture (refer to packaging label) when stored under the recommended conditions.













9) STEP-BY-STEP INSTRUCTIONS

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 NaClO.
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 NaClO 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.

10) SERIOUS INCIDENT REPORTING

- Any serious incident in relation to this product should be reported to the manufacturer and the competent authority according to local regulations.

11) SYMBOLS GLOSSARY

Symbols	EN	Symbols	EN
	Batch code		Stainless Steel
	Date of Manufacture		Quantity
	Use-by-date		Consult Instruction for Use
	Caution		Do not use if package is damaged and consult instructions for use
	Sterilized using irradiation		Do not reuse
	Medical Device		Catalogue number

HOW TO ORDER A FREE PAPER COPY OF THIS ELECTRONIC INSTRUCTIONS FOR USE (eIFU)

By Phone: To order a free paper copy, you need access to a telephone.

1) Call 855.985.3636 and follow the operator instructions.

2) Request paper copy of the Instructions for use for "EdgeUtopia K and C Sterile Hand Files" and provide the address you would like to receive the paper copy of the Instructions for Use. The paper copy will be delivered to the indicated address within seven (7) calendar days without any additional cost.