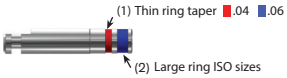
GENERAL INFORMATION

PARAMETERS FOR USE

Recommended speed range : 800-1000 rpm
continuous rotation.
Torque : 1.5 Ncm.

PRODUCT DESCRIPTION

Taper (1) and ISO diameter (2) identification



Depth marks ▲ (in millimeters)
Available on 21 / 25 / 31 mm instruments

Example on 25 / 31 mm instruments

Endo stop - ISO length/active part

INDICATIONS FOR USE

EdgeSequel Utopia™ endodontic instruments are intended for use in medical or hospital facilities, by qualified health professionals.
EdgeSequel Utopia™ instruments are designed for glide path and shaping of root canals.

CONTRAINDICATIONS

Nickel-Titanium instruments must not be used on individuals with a known allergic sensitivity to these metals.

ADVERSE REACTIONS

None known.

NOTICE AND PRECAUTIONS

- Take several radiographs from different angles to determine the anatomy of the root canals (length, width and curvature).
- The number of canals to be treated with a EdgeSequel Utopia™ instrument is limited to a maximum of 8 root canals.
- Irrigate the canal thoroughly and frequently after the EdgeSequel Utopia™ instrument is extracted.
- Regularly inspect the EdgeSequel Utopia™ instrument during use, and discard if it shows any signs of wear (for example : straightening).
- If the EdgeSequel Utopia™ instrument is not progressing easily, remove it from the canal, clean it, inspect its cutting edges, then irrigate the canal and recapitulate with an ISO 010 hand file.
- Always inspect the instrument(s) before use, and discard it (them) if there are any visible defect(s).
- When an instrument reaches the end of its life, please dispose of it in accordance with the applicable laws and regulations.
- These instruments have not been tested on children, pregnant nor breastfeeding women.

PROTOCOL FOR USE

Sequence	Glide path	Shaping	
EdgeSequel Utopia™ 4% sequence	**ESU1** 15/.04	**ESU2** 25/.04	**ESU3** 30/.04
EdgeSequel Utopia™ 6% sequence	**ESU1** 15/.04	**ESU2** 25/.04	**ESU3** 25/.06

1. Create straight-line coronal and radicular access.
2. Use an ISO 010 hand file to explore the canal.
3. Determine the working length using a radiograph. In addition, electronical working length determination can be achieved.
4. Use the EdgeSequel Utopia™ instruments in the order predefined by the chosen sequence. Start with glide path, followed by shaping of the canal.
5. EdgeSequel Utopia™ instruments are to be used with gentle strokes of 2-3 mm, applying very light apical pressure and allowing the instrument to progress passively along the canal. After 3 strokes, remove and clean the instrument, then irrigate ; recapitulate with an ISO 010 hand file.
6. Use the mechanised **ESU1** to perform glide path until the working length is reached.
7. Start the shaping procedure, applying your usual irrigation/ disinfection protocol.
8. Use the **ESU2** until the working length is reached.
9. Use the **ESU3** until the instrument can be inserted to its working length. *If necessary, a brushing motion may be applied to remove coronal interferences and/or ensure uniform shaping of irregular canals.* Once the working length has been reached, remove the instrument to prevent over-enlargement of the foramen.
10. If the preparation is not sufficient for the anatomy of the canal being treated, then continue shaping the canal using the larger sizes of EdgeSequel Utopia™ instruments. *We recommend that 40/.04 or 50/.04 instruments are used for shaping larger canals, following the EdgeSequel Utopia™ 4% sequence. We recommend that 30/.06 or 35/.06 instruments are used for shaping larger canals, following the EdgeSequel Utopia™ 6% sequence.*

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.

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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.

INSTRUCTIONS FOR PROCESSING

WARNINGS AND PRECAUTIONS

Warnings and precautions for the user:

- Use a dental dam when using the device(s) to avoid, for example, aspiration or ingestion by the patient.
- For your own safety, use personal protective equipment required during processing of the devices.
- For your own safety, wear surgical masks, gloves, and safety goggles.
- Carefully read the label or marking on the packaging to ensure you are using the correct device.

Warnings and precautions for the processing of devices:

- Use approved cleaning and disinfecting agents (e.g., approved by the VAH/DGHM or FDA, or bearing the CE marking) and use them according to the recommendations in their respective instruction manual.
- It is the user's responsibility to check the devices before each use in order to identify any possible defects. 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.
- Do not use hydrogen peroxide (H2O2), as it degrades nickel-titanium instruments.
- Do not soak the active part of nickel-titanium devices for more than 5 minutes in a NaOCl solution at more than 5 %.
- Do not exceed a sterilization temperature of 135 °C.

INITIAL PROCESSING AT THE POINT OF USE FOR REUSABLE DEVICES

After use, follow the steps below:

1. Disassembly: Remove the endo stop(s) from the instrument(s).
2. Pre-cleaning: Within a maximum of 30 minutes after use, remove excess soiling from the device(s) with disposable, lint-free wipes or a soft brush. Immerse the device(s) in a solution of water and neutral detergent.
3. Rinsing: Thoroughly rinse the device(s) with plenty of running water for at least 1 minute.

PREPARATION BEFORE CLEANING

Precautions:

- The device(s) should be reprocessed as soon as possible after use.
- The user should observe the concentrations and soaking times indicated in these instructions. An excessive concentration may cause corrosion or other defects on the devices.
- The disinfectant solution should not contain aldehyde so as to avoid fixation of blood residue.
- Do not use a disinfectant solution containing phenol, aldehyde or substances not compatible with the devices.
- The washer/disinfector must comply with EN ISO 15883 and undergo regular maintenance and calibration.

CLEANING/DISINFECTION

Follow one of the two methods described below (manual or automated) for cleaning and disinfection.

Manual cleaning/disinfection:

Equipment: Cleaning/disinfectant solution (Helvemed Instrument Forte: 2 % concentration for 15 minutes), brush, ultrasonic bath, purified running water, absorbent cloth.

1. Place the device(s) in a container, limiting any contact between the parts as much as possible.
2. Immerse the device(s) in the recommended cleaning/disinfectant solution. If necessary, use a soft nylon brush to gently scrub the device(s) until all visible soiling has been removed. If needed, use ultrasonic equipment as well.
3. Remove the device(s) from the solution and container and thoroughly rinse them under purified running water for at least 1 minute.
4. Dry the device(s) with single use absorbent cloth.

Automated cleaning/disinfection:

Equipment: Washer/disinfector, purified water, cleaning/disinfectant solution:

- Washing: Neodisher® Mediclean Forte (0.5 % concentration)
- Thermal disinfection: Neodisher® Mediklar Special (0.03 % concentration)

1. Place the device(s) in a washer/disinfector basket, limiting any contact between the parts as much as possible.
2. Process using a standard washer/disinfector cleaning cycle for at least 10 minutes at 93 °C or A0 value > 3000 and complete with a hot air drying cycle for at least 15 minutes at 110 °C.

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INSPECTION AND MAINTENANCE

1. Before sterilization, discard any device(s) that has/have the following defects:
   - Plastic deformation
   - Bent device
   - Untwisted device
   - Damaged or blunt cutting edges
   - No marking
   - Corrosion
   - Discoloration
   - Other visible defects
2. Reassemble the endo stop(s) on the appropriate device(s).
3. Thoroughly inspect each device to check that all visible contamination has been eliminated. In case of contamination being observed, repeat the cleaning/disinfection process described above.

PACKAGING

Precautions:

- Check the use-by date of the sterilization pouch stated by the manufacturer.
- Use packaging that can withstand temperatures up to 141 °C and complies with EN ISO 11607 and EN 868.

The device(s) should be packed in a medical grade sterilization pouch (compliant with EN ISO 11607-1). Limit any contact between the devices and seal the pouches in accordance with the manufacturer's recommendations.

STERILIZATION

Precautions:

- Autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended.
- Place the pouches in the sterilizer in accordance with the recommendations of the sterilizer's manufacturer.
- The autoclaves should comply with the requirements of the applicable standards (EN 13060 and EN 285) and should be approved, maintained and checked in accordance with these standards and the manufacturer's recommendations.
- Before any sterilization cycle, make sure that the maximum load indicated by the sterilizer's manufacturer is not exceeded.

Device class	Class B
Exposure time	Min. 3 minutes. The exposure time can be extended to 18 minutes to comply with the recommendations of the World Health Organization (WHO), the Robert Koch Institute (RKI), etc.
Temperature	134° C
Drying time	Recommended: 20 minutes (minimum, in chamber)
Visual inspection	Check the device(s) in accordance with section "Inspection and maintenance" and verify proper performance of the sterilization cycle (packaging integrity, no humidity, color change of sterilization indicators, physical and chemical integrators, and digital records of various cycle parameters).

STORAGE

Precautions:

If the packaging has been opened, damaged or become wet, the sterile state of the devices inside the packaging is not guaranteed. Perform a new complete (re)processing cycle or discard the device(s).

1. Store the device(s) in sterile packaging in a well-ventilated area, protected from dust, moisture, insects and temperature/humidity extremes, and at the temperature specified by the paper-plastic pouch by the manufacturer of the steam sterilizer.
2. The packaging of the sterile devices should be carefully examined before opening (packaging integrity, no humidity, and expiry date) to ensure that the packaging's integrity has not been compromised during storage.

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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SYMBOL	MEANING
REF	Catalogue Number
QTY	Quantity
LOT	Batch code
ISO size	Tip diameter
Taper	Taper
Length	Length
STERILE R	Sterilized using irradiation
	Single sterile barrier system
134°C	Sterilizable in a steam sterilizer (autoclave) at temperature specified
	Do not use if package is damaged
	Use-by date
	Clockwise rotation
NiTi	Nickel-titanium alloy
	Operating instructions
	Root canal treatment
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))

Manufactured by:
FKG Dentaire Sàrl
Le Crêt-du-Locle 4
2322 Le Crêt-du-Locle
Switzerland

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