

FOR DENTAL USE ONLY

INSTRUCTIONS FOR USE – EdgeDiamond Utopia™

EN

GENERAL INFORMATION

COMPOSITION

The instrument is made of a nickel-titanium blade, handle, the silicone endo stop, and the color-coded band

PARAMETERS FOR USE

Continuous rotation

Recommended speed: 350 - 500 rpm

Torque: 3.5 Ncm

Possibility of use in optimized non-continuous rotation (+340° / -20°)

Recommended speed: 350 - 500 rpm

Torque: 3.5 Ncm

INDICATIONS FOR USE

EdgeDiamond Utopia™ files are endodontic instruments used for performing root canal treatment to mechanically shape and prepare the root canals during endodontic therapy. The device is intended to be used sterile and single use only.

CONTRAINDICATIONS

- Mechanically driven endodontic instruments 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.

ADVERSE REACTIONS

- Device fracture/breakage
- Complications usually associated with endodontic procedures including:
 - Pain
 - Instrument fracture/breakage
 - Soft tissue damage/bleeding
- Infection – Do not use if package is damaged or open, due to risk of infection occurring.

NOTICE AND PRECAUTIONS

- Take several radiographs from different angles to determine the anatomy of the root canals (length, width and curvature).
- Use only in an electric motor and hand piece designed for rotary file instruments.
- Straight-line access is imperative for proper rotary file use and endodontic treatment.
- Do not force the files down canals, use minimal apical pressure.
- Clean the flutes frequently and at least after removing the files from the canal.
- Irrigate and lubricate the canal frequently throughout the procedure.
- Take each rotary file to length only one time and for no more than one second.
- In apical areas and curved canals exercise caution.
- EdgeDiamond Utopia[™] files are single patient use devices.
- When an instrument reaches the end of its life, please dispose of it in accordance with the applicable laws and regulations.
- When instrumenting the canal, do not over enlarge the coronal portion of the canal.
- A too large file taken to length increases the risk of canal transportation and file separation.

PROTOCOL FOR USE

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 Slider file in one or more passes, alternating with small-sized hand file, if necessary, until working length is reached.
6. Next use Shaper, F1, F2, F3 to working length passively; if instrument has not reached working length use smaller additional shaping instrument F1 to working length alternating between F1 and F3.
7. If F3 is not sufficient, FX and FXL can be used.

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.

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.
- Use personal protective equipment required during processing of the devices.
- 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:

- The EdgeDiamond Utopia[™] files are sterilized and no need to be autoclaved before use.
- The EdgeDiamond Utopia[™] files are intended for single use only to avoid file separation.
- Do not use if package is damaged.

STERILIZATION

- Files are single use only and not meant for reprocessing.
- Due to basic sterilization, no need for autoclave sterilization before use.

PACKAGING

The packaging of the sterile instruments 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.













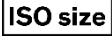





STORAGE

The shelf-life is 5 years for the sterile instruments. The use-by date is indicated on the packaging. Sterility is preserved and guaranteed for the whole shelf life unless the packaging is broken, or the storage conditions are not respected.

DISPOSAL

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

SYMBOL TABLE

SYMBOL	MEANING
	Catalogue Number
	Quantity
	Batch code
	Root canal treatment
	Operating instructions
	Do not use if package is damaged
	Sterilized using irradiation
	Single sterile barrier system
	Use-by date
	UDI code (Unique Device Identification)
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.
	Caution
	Nickel-titanium alloy
	Tip diameter
	Taper
	Length
	Do not reuse
	Optimized non-continuous rotation
	Clockwise rotation