EdgeOnyx™

Dental Root-Canal Instruments

FOR DENTAL USE ONLY

BEFORE USING THE FILES PLEASE SEE THE eIFU BELOW

ELECTRONIC INSTRUCTIONS FOR USE

EdgeOnyx Dental Root-Canal Instruments are single use medical devices that are supplied non-sterile but are intended to be used in a clean, disinfected and sterile state and therefore will require processing prior to use. This device must not be reprocessed after clinical use. Re-use may result in infection and patient injury.

1) INDICATIONS FOR USE

- EdgeOnyx instruments are indicated for use on any patient demographic exhibiting pulp or periapical diseases that require root canal treatment.
- Intended use: Used to explore, shape, and clean the root canal system during dental treatment.
- Expected users: Endodontic instruments are to be used only in a clinical or hospital environment by qualified dental professionals such as general practitioners as well as endodontic specialists.
- The instruments shall be used in combination with a handpiece.

2) CONTRAINDICATIONS

- It is forbidden for those who are allergic to nickel-titanium alloy.

3) STRUCTURE, COMPOSITION, SPECIFICATION AND RECOMMENDED ROTARY AND TORQUE

- It consists of an operating part, a shank, and a rubber limit block.
- There is a cutting edge on the operating part.
- The operating part is made of nickel-titanium alloy (NiTi).
- The shank is made of Nickel plated copper (C3604).
- The rubber limit block is made of silicone rubber.
- Single or mixed packaging, non-sterile supply.
- Main material: Nickel-titanium alloy (NiTi).
- Specification:

Product Name	Size	Taper	Length	Torque	Speed
X-Find	09	.09	15mm	2.5N/cm	300-500 RPM
X-Follow	15	.04	21mm/ 25mm		
X-follow	17				
X-Finish	20				
X-Finish	25				
X-Finish	30				
X-Finish	35				
X-Finish	40				
X-Finish	45				

3) WARNINGS

- Single-use products shall not be re-processed nor reused. Reusing these products increases the risk of cross-contamination and/or breakage.

4) PRECAUTIONS

- Safety and effectiveness of use have not been established in pregnant or breastfeeding women or in children.
- For your safety, wear personal protective equipment (gloves, glasses, mask).
- Inspect the packaging before use and do not use the instruments if the packaging is damaged.
- Do not use the instruments after the expiration date.
- Check the instrument before each use for signs of defects such as deformations (bent, unwound), breakage, corrosion, damaged cutting edges, and loss of color coding or marking. With these indications the devices are not able to fulfil the intended use with the required safety level, instruments should be discarded.
- Before using it, make sure it is well connected to the contra-angle.
- Check instrument and clean working part frequently during instrumentation, inspecting for signs of distortion, elongation or wear, such as uneven flutes, or dull spots. Given these indications that the devices are unable to fulfil the intended use with the required safety level, the instruments should be discarded.
- The instrument should not be completely immersed in sodium hypochlorite solution (NaOCl). Only the working part of the nickel titanium instrument in contact with the patient can be immersed in a sodium chloride solution with a concentration not exceeding 5% for no more than 5 minutes.
- Caution in the apical area and around significant curvatures.
- Irrigate abundantly and frequently the canal throughout the procedure.
- Always use minimal apical pressure. Never force the files down the canal.
- When instrument does not easily progress, clean and inspect the cutting flutes, then irrigate, recapitulate with a manual file and re-irrigate.
- For shaping extremely curved canals it is safer to use the file only to shape one canal in order to reduce the risk of breakage. Pay attention to the following:
  - Use a new file and discard it after the canal was treated (single canal use).
  - Use manual instead of rotary files.
  - Use small size, flexible or/and NiTi files.

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- Visually inspect the working part for all the defects listed in the former paragraph during use.
- Avoid the standard reaming continual rotational motion and instead use small angle motions (filing motion, watch winding oscillation motion, or balanced force technique) in order to limit the rotational bending fatigue on the instruments and improve their expected life.

5) ADVERSE REACTIONS

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

6) STORAGE CONDITIONS

- Keep the product in a dry and clean place away from light.

7) STEP-BY-STEP INSTRUCTIONS

1. Clean, disinfect and sterilize (see section 8, silicone rubber can be sterilized and disinfected).
2. Preliminary confirmation of the working length based on image radiology judgment.
3. Use ISO 010 or ISO 015 type K file to advance with a slight thrust of 2-3mm, reaching the working length one or more times; Irrigate thoroughly with sodium hypochlorite.
4. Widen the orifice of root canal by Opener.
5. Glide path preparation with instrument sequentially from small to large.
6. Check with corresponding files until the shaping of the root canal is completed.

8) CLEANING, DISINFECTION AND STERILIZATION

Device:	**Dental Root-Canal Instruments**
Advice:	Dental root-canal instruments are single-use medical devices that are supplied non-sterile but are intended to be used in a clean, disinfected and sterile state and therefore will require processing prior to use. This device must not be reprocessed after clinical use. Re-use may result in infection and patient injury.

Processing Instructions	
Pre-Cleaning of dental root-canal instruments:	Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution. Clean the surfaces with a soft bristle brush.
Cleaning:	Regarding cleaning/ disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the dental root-canal instruments into the machine on a tray and start the program: • 4 min pre-washing with cold water (<40°C); emptying • 5 min washing with a mild alkaline cleaner at 55°C - emptying • 3 min neutralising with warm water (>40°C); emptying • 5 min intermediate rinsing with warm water (>40°C); emptying The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert). Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.

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Disinfection:	Automated thermal disinfection in washer-disinfector under consideration of national requirements in regards to A0 value (see EN ISO 15883). A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an A0 value of >3000. Here we suggest a disinfection cycle of 5 min disinfection time at 93°C.
Drying:	Automated Drying: Drying the instruments through drying cycle of washer-disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.
Functional Testing Maintenance:	Visual inspection for cleanliness of the products. After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use. Check that the product has no dents, cracks, deformations, scratches or corrosion; Check all markings on the product for clear visibility. Defective device should be immediately discarded. The defects include: material deformation and corrosion. Before packaging and autoclaving, make sure that these devices have been maintained acc. to manufacturer's instruction.
Packaging:	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO11607.

Sterilization:	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/ EN 13060/EN ISO 17665) under consideration of the respective country requirements. Minimum requirements: 3 min at 134° (in EU: 5 min at 134°) Drying time: For steam sterilization, we recommend a drying time of 20 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. After sterilization: a. Remove the product from the autoclave. b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. Check that the sterilization wraps or pouches are not damaged.
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

9) SERIOUS INCIDENT REPORTING

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

10) SYMBOLS GLOSSARY

Symbols	EN	Symbols	EN
	Consult instructions for use		Use-by-date
	Manufacturer		Date of manufacture
	Caution		Medical device
	Batch code		Silicone

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NiTi	Nickel titanium		Handle Right angle RA
xxx-xxxmin⁻¹	Recommened Rotation Speed	xxx°C	Autoclave at the specified temperature
	Do not use if package is damaged and consult instructions for use		Keep dry
NON STERILE	Non-sterile		Do not re-use
	Temperature Limit	REF	Catalogue number
QTY	Quantity	%	Humidity Limitation
Rx Only	Caution : Federal law restricts this device to sale by or on the order of a dentist		

Production Date: See product package

- Useful Life: Five years
- Effective Date: 30th, Jan 2026

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 Instuctions for use for Product Name "EdgeOnyx" 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.

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