



STERILE ENDODONTIC ROTARY FILES

∅	%	L	Stop	Ring	Angles
20	08V	21 - 25 - 31	Yellow	Yellow	CCW 170° CW 60°
25	08V	21 - 25 - 31	Red	Red	CCW 170° CW 60°
35	06V	21 - 25 - 31	Green	Green	CCW 170° CW 60°
45	05V	21 - 25 - 31	White	White	CCW 170° CW 60°

Indication

The product is used for shaping of root canal during non-surgical endodontics treatment. Use by dental professionals only.

Contraindications

Apart from children under 2 years of age (ethylene oxide used in the sterilization process), there is no contraindication to the use of EdgeOne Blaze Utopia™ files for endodontically treating a tooth by orthograde route.

Complications

In cases of complex canal anatomy, per-operative risks (instrumental breakage, ledge, stripping, zipping, false path, perforation, etc.) could occur and lead to a risk of infectious processes.

Warnings/precautions

- The decision to use an endodontic instrument must be relayed to the clinical case expertise, particularly where the canal anatomy is considered to be too complex.
- Patients identified as having a risk of infectious endocarditis.
- Contains Nickel and Titanium and must not be used on patients with known allergic sensitivity to these metals.
- Respect the good dental practice in particular by using a dental dam and gloves.
- Use in continuous rotation at the recommended speed.
- In cases of complex anatomy, the maximum torque may be different from the value recommended by the manufacturer.
- Use according to the recommended procedure (§7).
- Do not use in retreatment.
- Instruments supplied sterile: Check the integrity of the packaging before use. If damaged, do not use the instrument.
- Respect the expiry date.
- Keep the UDI information which is only on the labelling until the last use.
- Year of manufacture: see labelling.

- Do not use if doubt on the respect of storage conditions.
- Single use instrument: Do not reuse the instrument. If you do, there is a risk of decreased performance and security characteristics (fracture of the instrument in the tooth).
- In case of doubt concerning the product identification, do not use.
- Check the condition of the instrument before the use between each canal. If the instrument is damaged or shows signs of wear, do not use.
- Inform the manufacturer and the national regulatory authority of any serious incident relating to the instrument.

Packaging Symbols	STERILEEO	Sterilized by using Ethylene Oxide.		Do not re-use
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Clinical claims

EdgeOne Blaze Utopia™ files in normal conditions.

Clinical performance:

- Shaping ability: adapted debris removal and cutting efficiency
- Respect of canal anatomy
- Geometry adapted to irrigation
- Maintains the apical foramen in its original position

Usability:

- Improved flexibility through heat treatment

Safety:

- Limited risk of breakage
- Limited peroperative risks
- Limited of screwing effects

Characteristics

Instrument in reciprocating motion in type 2 under EN ISO 3630- 1: 2019 standard: rotation angles are explained in the column «CCW» (Counter-clockwise side) and column «CW» (Clockwise side).

Material of operative part: Nitinol.

Use in connection with an endodontic contra-angle according to EN ISO 1797: 2017 (Type 1).

Number of uses: maximum of 4 canals recommended on the same patient

Medical device class according to Directive 93/42 and MDR 2017/745: IIa.

Protocol

EWL: Estimated Working Length

Alternative to other reciprocating instruments.

General information on the protocol for use:

- After opening the access cavity, sodium hypochlorite must be constantly used and renewed before and after each passage of instruments. The sodium hypochlorite must be placed using a syringe in order to be injected as close as possible to the apical region.
- A mineral solvent can be used during glidepath or during the shaping of calcified canals.

Protocol for use:

1. Establish straight-line coronal and radicular access.
2. In the presence of a viscous chelator, use a #10 hand file for scouting the canal and to form an initial glide path and establish working length. In more restrictive canals, use a #6 and/or #8 hand file to length first to create a path for the #10 hand file, then use the #10 hand file and confirm working length.
3. Form the Glide Path with R-Glide or a #15 hand file to working length.
4. ALWAYS initiate Shaping with the R25 Primary in the presence of sodium hypochlorite or other viscous chelation.
5. Use a gentle inward pressure and let the R25 passively progress 2-3mm through the canal. Remove and clean the R25, then irrigate and recapitulate to length with a #10 hand file and re-irrigate.
6. Continue with the R25, advancing 2-3mm at a time repeating the technique in Step 5 to enlarge the coronal 2/3 of the canal using an outward brushing motion.
7. After enlarging the coronal 2/3, reconfirm the working length, confirm patency and verify the Glide Path again with the #10 hand file.
8. Reconfirm the Glide Path with R-Glide or #15 hand file to working length.
9. Take the R25 to the full working length repeating the technique in Step 5.
10. Inspect the apical flutes; if they are loaded with dentinal debris, then the shape is finished*.
11. If the R25 does not progress, then use the R20 in one or more passes to working length and then if need, use the R25 file to working length.
12. When the shape is confirmed, proceed to disinfection.

- If the R20 or R25 is loose at length with no dentinal debris in the apical flutes, continue shaping with the next larger file in the sequence, i.e. R25, R35, R45 until the apical flutes are loaded.

Reprocessing instructions

Not applicable.









Storage and transport conditions


Sterile devices, keep away from sunlight and keep dry:

Disposal

After use, instruments must be placed in a secure container, used to collect cutting or sticking instruments (like needles or disposable bistouries) as per good dentistry practices.

Symbols

	NiTi raw material		Root canal preparation
	Continuous rotation		Assortment <i>when applicable</i>
	normalized handle		Do not use if packaging is damaged
	Medical device		Quantity

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