



### STERILE ENDODONTIC ROTARY FILES

SHAPING FILES (SX, S1, S2) FINISHING FILES (F1, F2, F3)

	∅	%	L	Stop	Ring	RPM	Maximum Recommended Torque (N.cm)
<b>SX</b>	19	04V	19	<b>Yellow</b>	-	300	5.1
<b>S1</b>	17	02V	21 – 25 – 31	<b>Purple</b>	<b>Purple</b>	300	5.1
<b>S2</b>	20	04V	21 – 25 – 31	<b>White</b>	<b>White</b>	300	2.5
<b>F1</b>	20	07V	21 – 25 – 31	<b>Yellow</b>	<b>Yellow</b>	300	2.5
<b>F2</b>	25	08V	21 – 25 – 31	<b>Red</b>	<b>Red</b>	300	3.1
<b>F3</b>	30	09V	21 – 25 – 31	<b>Blue</b>	<b>Blue</b>	300	3.1

#### 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 EdgeTaper Gold 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 (S7).
- 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		Sterilized by using Ethylene Oxide.		Do not re-use
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#### Clinical claims

EdgeTaper 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**

Type 2 continuous rotating instruments under EN ISO 3630-1: 2019 standard:

- Maximum recommended torque: see table 'Recommended Torque'.

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 EdgeTaper Blaze Utopia™ rotary files are single patient use instruments.

General information on the protocol for use:

- The EdgeTaper Blaze Utopia™ sequence is always the same regardless of the length, diameter or curvature of the canal.
- The crown down technique is the technique of choice for the EdgeTaper Blaze Utopia™ sequence.
- 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.

**Operating procedure:**

1. Realization of an access cavity allowing straight line access to the canal orifice. If necessary, use the EdgeTaper Blaze Utopia™ SX instrument with a brushing motion to move the coronal aspect of the canal away release the coronal constraints from furcal concavities and/or to create more coronal shape. EdgeTaper Blaze Utopia™ SX instrument can also be used to optimally shape canals in shorter roots.
2. Realization of a glidepath of the coronal 2/3 with a #10 and #15 hand instruments. Mechanized glidepath instruments can also be used.
3. After the validation of a smooth reproducible glidepath of the coronal 2/3, use EdgeTaper Blaze Utopia™ S1 to the level of the glidepath carried out previously. In case of resistance, make brushing motion on the safety wall (away from the furcation) to facilitate straight line access and apical progression.
4. Use of EdgeTaper Blaze Utopia™ S2 according to the same recommendations up to the level of the glidepath carried out previously.
5. After shaping the coronal 2/3, realization of a glidepath of the apical 1/3 with a #10 and #15 hand instruments.
6. Establish working length, confirm patency and verify the presence of a smooth reproducible glidepath in the apical

1/3.

7. Use the EdgeTaper Blaze Utopia™ S1 instrument, with a brushing action, until working length is reached. The instrument should never be static in the canal. Then irrigate, verify the apical patency, and irrigate again.
8. Use the EdgeTaper Blaze Utopia™ S2 instrument, with a brushing action, until working length is reached. The instrument should never be static in the canal. Then irrigate, verify the apical patency, and irrigate again.
9. Reconfirm the working length, irrigate, recapitulate and re-irrigate, especially in more curved canals.
10. Use the EdgeTaper Blaze Utopia™ F1 instrument, in a "non-brushing" action, with each insertion deeper than the previous insertion until working length is reached. The instrument should never be static in the canal and should not remain more than one second at working length.
11. Gauge the foramen with a #20 hand instrument. If the instrument is snug at length, the canal is shaped and ready to be obturated. If the #20 hand instrument is loose at length, proceed to the EdgeTaper Blaze Utopia™ F2 and, when necessary the EdgeTaper Blaze Utopia™ F3 with the same protocol to working length, gauging after each Finishing file with 25 or 30 hand instruments, respectively.

**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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