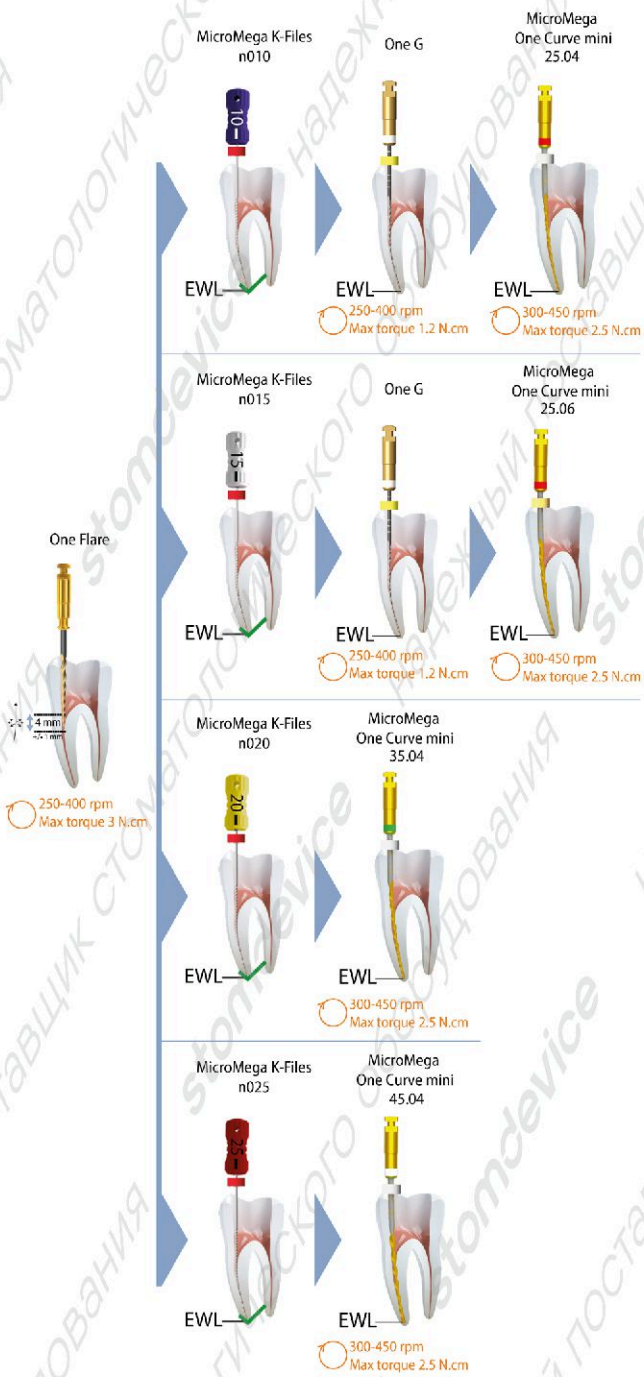
MicroMega One Curve mini - MicroMega One Curve mini Procedure Pack - MicroMega One Curve mini Assorted

NiTi Root Canal Instruments

Protocol MicroMega One Curve mini



	Ø	%	L	Stop	Ring	RPM	Recommended Torque (N.cm)
One Flare	25	9	17	-	-	250-400	3
One G	14	3	21 - 25 - 29	●	○	250-400	1.2
MicroMega One Curve mini N25 4%	25	4	21 -25 - 31	○	●	300-450	2.5
MicroMega One Curve mini N25 6%	25	6	21 -25 - 31	●	●	300-450	2.5
MicroMega One Curve mini N35 4%	35	4	21 -25 - 31	○	●	300-450	2.5
MicroMega One Curve mini N45 4%	45	4	21 -25 - 31	○	○	300-450	2.5

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1. **Indication**

One Flare: flaring during non-surgical endodontics treatment.
MicroMega One Curve mini: shaping of root canal during non-surgical endodontics treatment.
One G, MicroMega K-Files: glide path of root canals during non-surgical endodontic treatment.
For use by a dental professionals only.

2. **Contraindications**

Apart from children under 2 years of age (ethylene oxide used in the sterilization process), there is no contraindication to the use of MicroMega One Curve mini for endodontically treating a tooth by orthograde route.

3. **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.

4. **Warnings/precautions**

- The decision to use an endodontics 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 it.
- Inform the manufacturer and the national regulatory authority of any serious incident relatcginged to the instrument.

Packaging symbol	STERILE EO	Sterilised by using Ethylene Oxide. Do not re-use

5. **Clinical claims**

MicroMega One Curve mini 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

Note: MicroMega K-Files and One G are glide path files used before shaping operations. One Flare is a flaring instrument used at the start of the shaping.

6. **Characteristics**

MicroMega K-Files:
- Diameters 10 (purple handle), 15 (white handle), 20 (yellow handle), 25 (red handle)
- Taper .02 (red stop)
- Material of operative part: Stainless steel
- Lengths: 25 mm

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:
- No. 25. 06, 35 .04, 45 .04: maximum of 5 canals recommended on the same patient and on the same tooth if the instrument is not visually damaged;
- No. 25 .04: maximum of 2 canals recommended on the same patient and on the same tooth if the instrument is not visually damaged.

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

7. **Protocol**

EWL: Estimated Working Length

Operating procedure:

The instruments must be used in a back-and-forth motion without any apical pressure.

Remove and clean the instrument and irrigate the canal when apical resistance or a slight apical pull is encountered.

Note: It is necessary to irrigate abundantly between each instrument passage and to clean the turns of the instrument after each introduction into the channel. Check the instrument between each canals (see §4).

8. **Reprocessing instructions**

Not applicable.

9. **Storage and transport conditions**

Sterile devices:

10. **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.

11. **Symbols**

NiTi	NiTi raw material		Root canal preparation
SSt	Stainless steel material		Assortment
CLASSICS	'CLASSICS' handle		Do not use if packaging is damaged
MD	Medical device		Quantity
	Continuous rotation		

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