

	One Flare	One G	TS1	TS2	F35	F40		Cleaning/Rinsing/Drying Place the instruments in the tray of the washer-disinfector. Perform cleaning cycle with 0.2-1.0% neutralizer solution. Perform drying.
								Remarks: - Disinfection (thermal or chemical) must be required since the products are sterilized by autoclave. - Follow instructions and concentrations specified by the manufacturer of the detergent solutions used. - Follow the instructions of the washer-dryer and verify the success criteria have been met each cycle as specified by the manufacturer. - The final rinse step should be well deionized water. - For the last step, follow the water quality defined by the manufacturer. - Use only approved washers-disinfectors comply with EN ISO 15858, and are maintained and validated regularly.
	230-400 rpm Max torque 1 N.cm	230-400 rpm Max torque 1.2 N.cm	250-400 rpm Max torque 2 N.cm	270-400 rpm Max torque 2.5 N.cm	250-400 rpm Max torque 2.5 N.cm	250-400 rpm Max torque 2 N.cm		
	Ø	%	L	Stop	Ring	RPM	Recommended torque (N.Cm)	
One Flare	25	9	17	-	•	250 400	1.3	7
One G	14	3	21 - 25 + 31	●	○	250 400	2	
ZShape KFile	25	4		●	●		2	
ZShape TS2	25	6		●	●		2.5	
ZShape F35	35	6		●	●		2.5	
ZShape F40	40	4		●	●		2	
Instruction for use	EN Medical device class according to Directive 93/42/EEC and MDR 2017/745/EU							
1. Indication	One Flare: Irrigation during non-surgical endodontic treatment. ZShape: Initial shaping of root canal during non-surgical endodontic treatment. One G, Micro Mega K-Files: glide path of root canal during non-surgical endodontic treatment.							
2. Contraindications	For use by dental professionals only. Apart from children under 2 years of age (ethylene oxide used in the sterilization process), there are no contraindications to the use of ZShape for endodontically treating a tooth by peroperative risks.							
3. Complications	In cases of complex canal anatomy, entrapment risks (instrumental breakage, ledge, stripping, zipping, flare, false perforation etc.) could occur and lead to a risk of infectious processes.							
4. Warnings/precautions	The decision to use an endodontics instrument must be based on the clinical case expertise, particularly where the canal anatomy is considered to be too complex. Patients identified as having a risk of infectious endocarditis. Contacts Nickel and Titanium and should not be used on patients with known allergic sensitivity to these metals. Respect the good dental practice, in particular the use of a dental dam and gloves. Use in continuous rotation at the recommended speed. In cases of complex anatomy, the maximum torque may differ from the value recommended by the manufacturer. Do not exceeding the recommended procedure (S7). Using ultrasonic devices. Instruments supplied non-sterile/Reusing instruments supplied sterile-Follow the reprocessing instructions (S8) before use. Instruments supplied sterile-Check the integrity of the packaging before use. If damaged, do not use the instrument. If applicable, respect the expiry date. Keep the UDI information which only appears on the labelling until the last use. Year of manufacture see Labelling. Do not use if doubtful on the aspect 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 condition of the instrument before use between each call. 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 relating to the instrument.							
Packaging symbol	STERILE EO	Sterilised using Ethylene Oxide. Do not re-use	Non-Sterile	Non-sterile	Non-Sterile	Non-sterile	Non-Sterile	Non-Sterile
Packaging symbol	NON THERM STERILIZED	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Packaging symbol	NON THERM STERILIZED	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Packaging symbol	STERILE EO	Sterilised using Ethylene Oxide	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile
5. Clinical claims	ZShape in painful maxilla lesions conditions.							
Clinical performance	Shaping ability, debris removal and cutting efficiency. Respect of canal anatomy. Geometry adapted to irrigation. Maintains the apical forces in its original position.							
Usability:	Improved flexibility thanks to heat treatment							
Safety:	Limited risk of breakage Limited risk of scraping Limited risk of piercing soft tissue Micro Mega K-Files and One G and Glane guide files used without shaping operations. One Flare is a flaring instrument after the start of the shaping step.							
6 Characteristics	Micro Mega K-Files: Diameter 10 (purple handle) Taper .02 (.red step) Material: stainless steel; Plain-stainless steel Lengths: 21 – 25 mm							
Type 2 retaining Instruments under EN ISO 3630-1:2019 standard.	Maximum recommended torque (not required); see table "Retaining Torque".							
Material of operative part: Nitinol	Used in connection with an endodontic crown-angle according to EN ISO 7917 (Type 1).							
Preparation before cleaning	If the devices have visible impurities, it is recommended to manually pre-clean by brushing under tap water at 20-40°C for at least 1 min with a soft brush until all impurities have been removed. Remark: Follow instructions regarding concentration and immersion times given by the manufacturer (an excessive concentration may cause corrosion or other defects on devices).							
Visual inspection	Inspect the used products and discarded damaged products (broken, untwisted or abnormally bent).							
Cleaning	Insert the products into an ultrasound apparatus bucket. Run ultrasound apparatus for 10 to 30 min with tap water and 0.5-2.0% neutraliser Medizym. Remark: Follow instructions, observe water quality, concentrations and cleaning time specified by the manufacturer of the cleaning solution.							
Rinsing	Rinse the products with tap water at 20-40°C for 1 min. Remark: It is recommended to use deionized water.							
Drying	Dry the products with compressed air until completely dry.							
Storage	Store the products in a dry, clean and dust environment at the temperature specified by the steam sterilisation pouches by the steam manufacturer. Remark: Check the packing and the moisture barrier before using them (packaging integrity, humidity and use-by date). In case of damage, complete re-run should be performed.							
7 Disposal	After use, instruments must be placed in a secure container, collect cutting or sticking instruments like needles or disposables in a good dentistry practice.							
8 Symbols	NITI raw material	CLASSICS handle	ASSORTMENT	DO NOT USE IF PACKAGING IS DAMAGED	STERILIZABLE IN STEAM STERILIZATION AUTOCLAVE AT THE TEMPERATURE SPECIFIED	QUANTITY		
Year of CE marking: 2017								

[illegible]

