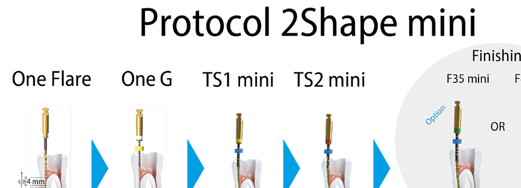
2Shape mini / 2Shape mini Procedure Pack / 2Shape mini assorted NiTi Root Canal Instruments

Protocol 2Shape 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	● (yellow)	○	250 - 400	1.2
2Shape TS1 mini	25	4	21 - 25 - 31	● (blue)	● (yellow)	250 - 400	TS1 : 2 TS2 : 2.5
2Shape TS2 mini	25	6		● (blue)	● (red)		
2Shape F35 mini	35	6	21 - 25 - 31	● (blue)	● (green)	250 - 400	F35 : 2.5 F40 : 2
2Shape F40 mini	40	4		● (blue)	● (black)		

Instruction for use EN

1. **Indication**

One Flare: flaring during non-surgical endodontics treatment.

2Shape mini: shaping of root canal during non-surgical endodontics treatment.

One G, K files: glide path of root canals during non-surgical endodontic treatment.

Use by a dental professional 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 2Shape mini for endodontically treating a tooth by orthograde route.

3. **Complications**

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

4. **Warning and precaution**

- The decision to use an endodontics instrument must be relayed to the clinical case expertise in particular for a canal anatomy considered as too complex.
- Patients identified as having a risk of infectious endocarditis.
- Contains Nickel and Titanium and should not be used on patient 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 can be different from the value recommended by the manufacturer.
- Use according to the procedure recommended (§7).
- Do not use in retreatment.
- Instruments supplied non-sterile/Reusing instruments supplied sterile: Follow the reprocessing instructions (§8) 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 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. Otherwise the risk is a decrease of performances and security characteristics (fracture of the instrument in the tooth).
- In case of doubt concerning the product identification, do not use.
- Check the instrument state before the use between each canal. If the instrument is damaged or shows signs of wear, do not use the instrument.
- Inform the manufacturer and the country regulatory authority of any serious incident related to the instrument.

Packaging symbol	STERILE EO	(do not re-use symbol)	Sterile using Ethylene Oxide. Do not re-use
Packaging symbol	NON STERILE	(do not re-use symbol)	Not Sterile, Do not re-use
Packaging symbol	NON STERILE	-	Not Sterile
Packaging symbol	STERILE EO	-	Sterile Ethylene Oxide

5. **Clinical claims**

2Shape 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

Note: K Files and One G are glide path files used before shaping operation. One Flare is a flaring instrument occurring in the beginning of the shaping.

6. **Characteristics**

K Files:

- Diameters 10 (purple handle),
- Taper .02 (red stop)
- Material of operative part: Stainless steel
- Lengths: 21 – 25 – 29 mm

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

- Maximum recommended torque (not required): see table "Recommended Torque".

TS2 mini and F35 mini have a smaller wire diameter than TS2 and F35 which results in less damage to the coronal part of the tooth.

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

7. **Protocol**

Cf Protocol.

Operating procedure :

Progressive movement in three waves (3 up-and-down movements) with upward circumferential filing movement. Insert the rotating instrument into the root canal until a resistance can be felt. Perform a circumferential brushing movement when feeling the resistance in order to eliminate the primary constraints. Remove the file from the root canal, clean the grooves and irrigate the root canal. Then continue the progressive downward movement. On average, 2 to 3 passages are required before reaching the apex.

8. **Reprocessing instructions**

General recommendations	• For all metal devices, it is recommended to use anticorrosion disinfecting and cleaning agents. • For your own safety, please wear personal protective equipment (gloves, glasses and mask). • Do not use cleaning or disinfecting agents containing phenol, aldehyde and alkaline composition. • Always respect the instructions for use provided by the manufacturer of the products.
Limitations on reprocessing	• Due to the product design and the materials used, no definite limit to the maximum number of performable processing cycles can be specified. The service life of the medical devices is determined by their function and careful handling. Multiple use disinfection and re-sterilisation cycles may lead to increased risk of file separation. • The user must ensure that the processing method used, including re-sources, materials and personnel, is appropriate and meets the applica-ble requirements. • The state of the art and national laws require that validated procedures be followed.
Material needed	• Gloves, masks, blouse as recommended by the manufacturer of cleaner and detergent • Running or deionized water • Disinfectant (neodisher® Septo Active) • Detergent (neodisher® MediZym) • Small soft brushes • Container • Ultrasonic tub or washer-disinfector • Class B sterilisation apparatus *Remark: All material used should be cleaned and replaced regularly. Identify material used for each step of the process (initial treatment, cleaning or rinsing).*

	1	**Initial treatment** Place used products in a container or a wipe with tap water at 20-40 °C and 1,0 % neodisher® Septo Active for 5 to 15min. Rinse the products with tap water at 20-40 °C for 1 min. If there is waiting time before next step, make sure the device stays moist by packing it in a wet wipe. Do not exceed 1 hour waiting time. *Remarks:* • *Do not use fixating agents or hot water (> 40 °C), as this causes fixation of residues and can impair successful cleaning.* • *Follow instructions and respect concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects on devices).*
	2	**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 at least 1min with a soft brush until the disappearance of impurities. *Remark: Follow instructions and respect concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or others defects on devices).*
	3	**Visual inspection** Inspect the used products and discard the damaged products (broken, untwisted or abnormally bent).
manual	4	**Cleaning** Insert the products in the ultrasound apparatus beaker. Run ultrasound apparatus for 10-30min with tap water and 0.5-2.0% neodisher® MediZym *Remarks: Follow instructions, observe water quality, concentrations and cleaning time stated by the manufacturer of the cleaning solution.*
manual	5	**Rinsing** Rinse the products with tap water at 20-40°C for 1min. *Remark: It is recommended to use deionized water.*
manual	6	**Drying** Dry the products with compressed air until products are visibly dried.
automatic	4 5 6	**Cleaning/Rinsing/Drying** Place the instruments in the tray of the on the slide-in trolley of the washer/disinfector. Perform cleaning cycle with 0.2-1.0% neodisher® MediZym Perform drying. *Remarks:* • *Disinfection (thermal or chemical-thermal) is not required since the products are sterilised after the cleaning.* • *Follow instructions and concentrations given by the manufacturer of the detergent solution.* • *Follow the instructions of the washer-disinfector and verify the success criteria have been met after each cycle as stated by the manufacturer.* • *The final rinse step should be with deionized water. For other steps follow the water quality defined by the manufacturer.* • *Use only approved washers-disinfectors according to EN ISO 15883, maintained and validated regularly.*
	7	**Visual inspection** Inspect the used products. Re-do steps 4-5-6 if the product is visibly not clean or discard any damaged products.
	8	**Packaging** Place the instruments in a paper-plastic pouch for steam sterilisation compliant with ISO 11607 and EN 868. *Remarks:* • *For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent packaging piercing.* • *Seal the pouches according to the recommendation of the pouch manufacturer. If a thermo-sealer is used, the process must be validated and the thermo-sealer must be calibrated and qualified.*
	9	**Sterilisation** Sterilise the products with steam vapor • Apparatus: class B • Minimum temperature: 132°C • Minimum time: 3min • Absolute pressure: 2,2 bar • Minimum drying: 20min Control the physico-chemical indicators and cycle parameters. *Remarks :* • *The settings temperature at 134 °C and duration of 18 min are recommended for prion inactivation according to French regulations.* • *When sterilising multiple instruments in one autoclave cycle ensure that the steriliser's maximum load is not exceeded.* • *Place the pouches in the steam steriliser according to the recommendations given by the steriliser manufacturer.* • *Use only pre-vacuum air removal steam steriliser that are matching the requirements of EN 13060 (class B, small steriliser) and EN 285 (full size steriliser), with saturated steam.*
	10	**Storage** Store the products in a dry, clean and dust-free environment at the temperature specified by paper-plastic pouch for steam sterilisation manufacturer. *Remark: Check the packaging and the medical devices before using them (packaging integrity, no humidity and use-by date). In case of damage, a complete rerun should be performed.*

9. **Storage and transport conditions**

Store sterile instruments in their original packaging, protected from sunlight and heat, in a clean and dry place.

There are no special storage and transport conditions for non-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	(symbol)	Root canal preparation
SSt	Stainless steel material	(symbol)	Assortment
CLASSICS	'CLASSICS' handle	(symbol)	Do not use if packaging is damaged
MD	Medical device	(symbol)	Quantity
(symbol)	Continuous rotation		

Year of CE marking: 2017

Instructions d'utilisation FR

1. **Indication**

One Flare : Evasement coronai[...]

2Shape mini / 2Shape mini procedure pack / 2Shape mini assorted NiTi Root Canal Instruments

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