

Apical Shaper®

DIRECTIONS FOR USE

ApicalShaper® files are used to enlarge root canals by inserting them into the contra-angle of an endodontic motor to make lifting and vertical reciprocating movements. They are taper instruments with a taper of more than 2%, which classifies them as type 2 in ISO3630-1: 2019.

They are non-sterile instruments.

COMPOSITION

ApicalShaper® files contain an active part, stopper and shank.
The main materials are as follows:

- 1) Active part: Nickel Titanium
- 2) Handle: Brass C3604
- 3) Stopper: colourless translucent rubber (CAN19-259705.001)



1) INDICATIONS FOR USE

ApicalShaper® files are indicated for root canal enlargement.

These instruments have been designed to be used exclusively in a dental clinic or hospital setting by qualified users, following dentistry best practices (use of gloves, goggles, rubber dam, etc.).

2) CONTRAINDICATIONS

This product should not be used in patients with a known sensitivity or allergy to the materials.



3) WARNINGS

- For use by dentists only.
- Be sure to sterilise this product before each use.
- Do not use this product for any other use except dental service and treatments. Use it in accordance with its intended use.

4) PRECAUTIONS FOR USE

- To prevent infection, clean and disinfect the product (see item 7) and ensure sterilisation is completed before using.
- Choose the most appropriate type for each case and follow the general method.
- Before using, outside the oral cavity, make sure the instruments do not have any deformations, scratches and cracks.
- If the head of the product is thin, long or large, there is a possibility of breakage or twisting. Because of this, be sure to avoid using unreasonable angles and excessive pressure.
- A rubber dam should be used to prevent accidental ingestion or falling.
- Do not use this instrument for any purposes except for those applications listed above.
- For use by dentists only.
- This product should be disposed of as medical waste.
- Dispose of the product if damaged or contaminated.
- After using, wash it with a medical cleaning agent and brush, then wash away foreign substances like adherent bodily fluids and bodily tissues.
- Place the product in a support when cleaning with an ultrasonic cleaner to avoid deterioration of the cutting area.
- Use this product with great care to avoid puncturing fingers with the sharp-edged part.
- This product has the possibility of being corrosive if immersed in NaOCl, EDTA, etc. for a long time.

Recommended motor settings:

ApicalShaper®		
File size	Speed (rpm)	Torque (Ncm)
ApicalShaper® Z30, Z35, Z40, Z50	150 - 350	2 - 2.5

The speed and torque settings indicated in the table above are demonstrative and can be modified according to user preferences and equipment possibilities.

5) ADVERSE REACTIONS

ApicalShaper® is not recommended for use in patients with a known allergy to nickel. The use of this product in these patients may cause: difficulty breathing, swelling of the face or eyes, hives or rash. If any of these symptoms occur, the patient should be advised to contact a dental professional immediately.



6) STEP-BY-STEP INSTRUCTIONS FOR USE OF APICALSHAPER® FILES

6.1 The following table shows the specifications for ApicalShaper® (based on ISO 3630-1 and ISO3630-5):

Size	Working length (mm)	Tip diameter (mm)	Taper (%)	Ring Colour
030	21	0.30	3	Blue
035		0.35	3	Green
040	25	0.40	3	Black
050	31	0.50	3	Yellow

6.2 Before using ApicalShaper®, establish a reproducible glide path using K-File hand files that start from #08 to #015 (no bigger than #15) or Z-Glider® files.

6.3 Choose the most appropriate size for each case and follow the general method.

6.4 Recommended rotary speed: 150-350 rpm/min, Torque: 2.0- 2.5N.cm.

6.5 ApicalShaper® is under the provisions of the ISO 3630 performance test, product durability for twisting and bending must exceed the specified value of our standard.

7) CLEANING, DISINFECTION AND STERILISATION

Dental instrument reprocessing procedure.

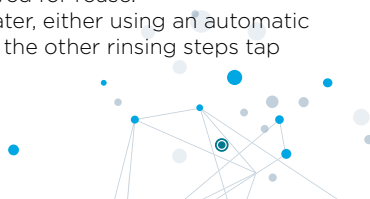
I - FOREWORD

Instruments marked “sterile” do not require any specific treatment before first use.

For the rest of the instruments that are not marked “sterile”, cleaning and sterilisation is necessary before using them for the first time in accordance with section III - STEP-BY-STEP INSTRUCTIONS of these directions for use.

II - GENERAL RECOMMENDATIONS

- 1) Use only a detergent solution with a disinfectant action approved for its effectiveness (VAH/DGHM-listing, CE marking, FDA approval) and follow the instructions of the manufacturer of said product. Anticorrosive cleaning products and disinfectants are recommended for all metal instruments.
- 2) For your own safety, please use personal protective equipment (gloves, goggles and mask).
- 3) The user is responsible for the cleaning and sterilisation of the product for the first cycle and each subsequent use, as well as the use of dirty or damaged instruments after sterilisation.
- 4) The safest option for the professional is to use our instruments only once. After each use, they must be thoroughly inspected before being used again; the presence of defects such as deformations (bent, stretched), fractures, corrosion, loss of colour identification, marking, etc. are indications that the instruments cannot meet the level of safety required for their intended use and should therefore be discarded.
- 5) Instruments marked as single-use only are not approved for reuse.
- 6) For the final rinse it is mandatory to use deionised water, either using an automatic washer-disinfector or a manual cleaning method. For the other rinsing steps tap water use is allowed.



- 7) Instruments with plastic handles and NiTi instruments should not be used with Hydrogen Peroxide (H₂O₂) solution, which is known to degrade them.
- 8) Only the active part of the NiTi instrument that is in contact with the patient should be immersed in a NaOCl solution with a concentration NOT greater than 5%.
- 9) Prevent the instrument from drying out before or during pre-disinfection or cleaning. Dried biological material can be difficult to remove.
- 10) Do not place identifying labels or markers directly on the instrument.

III – STEP-BY-STEP INSTRUCTIONS

Operation		Description and Warnings
1	Disassembling	<ul style="list-style-type: none"> Remove and discard the silicone stoppers.
2	Rinsing	<ul style="list-style-type: none"> Rinse abundantly (for at least 1 minute) under running water at ambient temperature. While rinsing, use a soft brush (nylon, polypropylene, acrylic) for pre-cleaning until visible impurities are removed.
3a	Automated cleaning with washer-disinfector	<ul style="list-style-type: none"> Place the instrument in a kit, support, or container made of stainless steel or titanium. Execute the defined cycle with detergent solution (for example, Metrex EmPowder concentration 1:128 - 1:512) for at least 5 minutes in the washer-disinfector at 20°C - 40°C).
3b.I	Manual cleaning assisted by an ultrasonic device	<ul style="list-style-type: none"> Place the instrument in a kit, support, or container made of stainless steel, polypropylene, or titanium. Submerge it in a detergent solution (for example, Metrex EmPowder concentration 1:128) with cleaning properties. If applicable, soak it for at least 15 minutes with the help of an ultrasonic device. Rinsing: perform a long rinse (at least 1 minute) under running deionised water at a temperature of 20°C - 40°C. Drying: dry with a single-use non-woven cloth or with a hot air dryer no hotter than 110°C.
3b.II	Manual disinfection with washer-disinfector	<ul style="list-style-type: none"> Place the instrument in a kit, support, or container made of stainless steel or titanium. Execute the defined cycle with a mild neutral enzymatic cleaning agent solution (for example, Metrex EmPowder concentration 1:128) for at least 5 minutes in the washer-disinfector at a temperature of >90°C, A0 >3000. Note: <ol style="list-style-type: none"> 1) Discard instruments with obvious defects (broken, bent, etc.). 2) When the instruments are placed in a cleaning kit, support, or container, avoid any contact between them. 3) Follow instructions and concentrations given by the manufacturer of the detergent solution (see also general recommendations). 4) Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacture.



Operation		Description and Warnings
3b.II	Manual disinfection with washer-disinfector	<p>5)The final rinse step should be with deionised water. For other steps follow the water quality defined by the manufacturer.</p> <p>Place the instrument in a kit, support, or container made of stainless steel or titanium to avoid any contact between devices or posts.</p>
3b.III	Rinsing	<ul style="list-style-type: none"> • Rinse abundantly (for at least 1 minute) under running water at ambient temperature. • Use deionised water for rinsing. • If the previously used cleaning solution contains a corrosion inhibitor, rinsing is recommended just before autoclaving.
3b.IV	Drying	<p>Devices should be carefully dried before inspection and packaging</p> <ul style="list-style-type: none"> • Dry with a single-use non-woven cloth or with a hot air dryer at a maximum temperature of 110 °C. • The devices should be dried until visual traces of moisture are eliminated. • Particular attention has to be paid to effectively dry joints or cavities inside the device.
4	Inspection	<ul style="list-style-type: none"> • Inspect the operation of the devices. • Inspect devices and identify those with defects. <p>1) Dirty devices need to be cleaned again. 2) Do not reuse the silicone stoppers. 3) Dispose of any defective devices.</p>
5	Packaging	<p>Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in “Sterilisation Pouches”. (Use packaging that is resistant to a temperature of 141 °C (286 °F) and that is UNE-EN ISO 11607 compliant).</p> <p>1) Avoid any contact between instruments or posts during sterilisation. Use kits, supports or containers. 2) For sharp devices not contained within a box, silicone tubing should be placed around the devices to prevent puncture of the packaging. 3) Seal pouches per the pouch manufacturer’s recommendation. If a thermo-sealer is used, the process must be validated. 4) Check the expiry date of the pouch indicated by the pouch manufacturer to determine the shelf life of the sterile product.</p>



	Operation	Description and Warnings
6	Sterilisation	<ul style="list-style-type: none"> • For these devices, steam sterilisation is recommended at 132°C / 273°F for 4 minutes, for the purpose of de-activating potential prions. • Instruments and posts must be sterilised according to the package labelling. • Place pouches in steam steriliser per steriliser manufacturer's recommendation. • Use only steam sterilisers that meet the requirements of EN 13060 (class B, small steriliser), EN 285 (full size steriliser). • Use a validated sterilisation procedure according to ISO 17665 with a minimum drying time of 20 minutes. • Follow the steriliser maintenance procedure indicated by the steriliser manufacturer. • Control the efficiency and the acceptance criteria of the sterilisation procedure (packaging integrity, no humidity, no colour change of the packaging, positive physicochemical indicators, conformity of actual cycle parameters to reference cycle parameters). • Store traceability records and define shelf life according to packaging manufacturer guidelines. • Shorter sterilisation cycles according to local regulations are possible but are not guaranteed to de-activate prions.
7	Storage	<p>Keep devices in sterilised packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature.</p> <ol style="list-style-type: none"> 1) Sterility cannot be guaranteed if the packaging is open, damaged or wet. 2) Check the packaging and medical devices before use (integrity of the packaging, absence of humidity and expiry date).

8) TRANSPORT

- To prevent the medical device from being damaged during transport, the use of specific racks, trays or rigid containers may be recommended.
- When the package is broken, it is no longer sterile. It must be cleaned, disinfected and sterilised before use.

9) STORAGE AND EXPIRY

- Avoid storing in places with high temperatures, humidity and/or direct sunlight. Keep liquids away. Store at ambient temperature.
- Do not damage or puncture the packaging materials.
- This product is subject to improvement without prior notice. Apply the “first in, first out” approach to inventory management.
- Do not store under a germicidal lamp to prevent deterioration.
- The shelf life of endodontic files is 5 years.

10) DISPOSAL




















- This product should be disposed of as medical waste.
- For correct disposal, always respect national laws and recommendations from authorities.




11) PACKAGING


- Minimum packaging unit: 6pcs/pack in aluminium foil box.
- Assortment: 1 piece of each size in a single pack.

12) IDENTIFICATION OF RELATED SYMBOLS

Symbols	Identification
 FOR DENTAL USE ONLY	Product designated for dental use only
	Do not reuse – Single-use only
	Workpiece Material: Nickel Titanium
	Rotating handle
	Medical Device
Heat activation	Pre-bendable
	Recommended rotation speed
	Recommended torque for use
	Batch number
	Sterilised by radiation
	Reference number
	Expiry date
	Consult directions for use
	Authorized representative in the EU
	Manufacturer
	Autoclavable at the specified temperature
	Non-returnable if the seal is broken
	Stopper material: silicone
	Do not use if packaging is damaged. Consult directions for use.
	CE marking

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