BlueShaper PRO®

DIRECTIONS FOR USE

BlueShaperPRO® instruments for endodontic treatments:

- BlueShaperPRO® Shaping Files (ZX, Z1, Z2)
- BlueShaperPRO® Finishing Files (Z3, Z4, Z5, Z6, Z7)

COMPOSITION

The cutting surface of these instruments is made of a nickel-titanium alloy. DualWire® heat treated.

1) INDICACIONS FOR USE

These instruments have been designed to be used exclusively in a dental clinic or hospital setting by qualified users.
Application field: for the removal of dentin and shaping of the root canal.

2) CONTRAINDICATIONS

- As with all mechanically driven root canal instruments, BlueShaperPRO® files should not be used in cases of severe and sudden apical curvatures due to heightened risk of separation.
- This product contains nickel and should not be used in patients with a known allergy to this material.

3) WARNINGS

- The files are single-use only, so they are not to be reused as this can cause deformation defects (bending, stretching), fractures, corrosion, loss of colour or markings identification, etc., which would mean the instruments cannot meet the level of safety required for the intended use.
- Reuse increases the risk of cross-contamination and breakage.
- There is an increased risk of file separation when used after several disinfection or sterilisation cycles.

4) PRECAUTIONS FOR USE

- Straight-line access is a prerequisite for proper root canal treatment, and with BlueShaperPRO® files there is no exception.

- These instruments should not be immersed in a sodium hypochlorite solution.
- Clean files frequently during instrumentation, inspecting for any signs of distortion or wear, such as missing flutes or nicks.
- Irrigate frequently, recapitulate and irrigate the canal throughout the whole procedure.
- BlueShaperPRO® files should only be used in regions of the canal that have a confirmed and reproducible glide path. Establish a reproducible glide path using hand files of at least an ISO 015 size.
- Use instrumentation files (ZX, Z1 and Z2) with light apical pressure, withdraw it slightly and again apply apical pressure slightly deeper.
- Use BlueShaperPRO® files (Z3, Z4, Z5, Z6 and Z7) without a brushing action.
- Use BlueShaperPRO® files to passively reach working length, and then withdraw immediately.
- BlueShaperPRO® files are manufactured with a process that results in a blue, gold and pink appearance. Due to this process, BlueShaperPRO® files may appear slightly curved. This is not a manufacturing defect. While the file can be easily straightened using only your fingers, it is not necessary to straighten the file prior to use. Once inside the canal, BlueShaperPRO® files will follow the anatomy.
- Always use minimal apical pressure. Never force the files inside the canal.
- This product should be disposed of as medical waste.
- For optimal usage, torque control devices are recommended.
- BlueShaperPRO® rotary files can be used at motor speeds between 300 rpm and 500 rpm.

Recommended motor settings:

BlueShaperPRO®		
File size	**Speed (rpm)**	**Torque (Ncm)**
BlueShaperPRO® ZX-Z7	500	4

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

BlueShaperPRO® 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 BlueShaperPRO® FILES

6.1 Radiographic assessment

Review several horizontal angle radiographs to diagnostically determine the width, length, and curvature of the canals.

6.2 Access preparation
Create a straight-line access to the canal entrance, keeping in mind the taper, flattening, and finishing of the internal axial walls.

6.3 BlueShaperPRO® SHAPING TECHNIQUE:
The crown down technique is the technique of choice for rotary instruments:

- Create straight-line access to the canal entrance orifice.
- In the presence of NaOCl, perform an exploration of the coronal 2/3 with hand files 10 and 15. Gradually work these instruments until a smooth, reproducible glide path is confirmed. Alternatively, mechanised glide path files (such as Z-Glider®) can be used after a 10 hand file.
- In the presence of NaOCl, "float" the Z1 in the canal and passively "follow" the glide path. Before light resistance is encountered, "brush" laterally cutting the dentin on the outstroke to improve straight-line access and apical progression. Always brush away from the furcation.
- Continue shaping with Z1 as described until the depth of a 15 hand file is reached.
- Use the Z2, exactly as described for the Z1, until the depth of a 15 hand file is reached.
- In the presence of a viscous chelator or NaOCl, explore the apical third with hand files 10 and 15 and gradually work them until they are loose at length.
- Establish working length, confirm patency and verify the presence of a smooth and reproducible glide path in the apical third.
- Use Z1 without brushing action until working length is reached.
- Use Z2 without brushing action until working length is reached.
- Reconfirm the working length, irrigate, recapitulate and reirrigate, especially in more curved canals.
- Use Z3 finishing file without brushing action, going deeper with each insertion than the previous insertion until working length is reached, spending the least amount of time possible at this length. Do not leave the file at working length for longer than one second. Reach it and withdraw it.
- Gauge the foramen with a 20 hand file or with a size 25 gutta-percha point. If the instrument has a close fit at length, the canal is properly shaped and ready for obturation.
- If the 20 hand file is loose at length, proceed with the Z4 file and, if necessary, with Z5, Z6 and Z7, using the same movement without brushing to working length, gauging after each finishing file with hand files 25, 30, 40 or 50 respectively.
- If necessary, use the ZX file without brushing motion to move the coronal part of the canal away from the furcal concavities and/or to create more coronal widening.
- ZX can also be used to optimally shape canals in shorter roots.
- The BlueShaperPRO® sequence is the same regardless of the length, diameter or curvature of the canal.

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.

Excluded devices:
Uniclip and Mooser calcinable plastic posts cannot be sterilised and must be disinfected by immersion in NaOCl (2.5 % at least) during 5 minutes at ambient temperature.

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 (H^2O^2) 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**	• Remove and discard the silicone stoppers.
2	**Rinsing**	• 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**	• 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).

	Operation	Description and Warnings
3b.I	**Manual cleaning assisted by an ultrasonic device**	• 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**	• 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:** **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. **5)** The final rinse step should be with deionised water. For other steps follow the water quality defined by the manufacturer. Place the instrument in a kit, support, or container made of stainless steel or titanium to avoid any contact between devices or posts.
3b.III	**Rinsing**	• 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**	Devices should be carefully dried before inspection and packaging • 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.

	Operation	Description and Warnings
4	**Inspection**	• Inspect the operation of the devices. • Inspect devices and identify those with defects. **1)** Dirty devices need to be cleaned again. **2)** Do not reuse the silicone stoppers. **3)** Dispose of any defective devices.
5	**Packaging**	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). **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.
6	**Sterilisation**	• 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.

	Operation	Description and Warnings
7	**Storage**	Keep devices in sterilised packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature. **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
	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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