DIRECTIONS FOR USE

Sterile, reciprocating (150° anticlockwise/30° clockwise), shaping files for endodontic use.

Excalibur® Shaping Files:
- Excalibur® File E20 Small (№ 020/.05)
- Excalibur® File E25 Regular (№ 025/.05)
- Excalibur® File E35 Medium (№ 035/.05)
- Excalibur® File E45 Large (№ 045/.05)

COMPOSITION
The cutting surface of these instruments is made of a nickel-titanium alloy.

1) INDICATIONS FOR USE
Excalibur® shaping files are used in endodontics for the shaping and cleaning of root canals.
These instruments should only be used in a clinical or hospital setting, by qualified personnel, following good dental practices (use of gloves, goggles, rubber dam, etc.).

2) CONTRAINDICATIONS
- Excalibur® shaping files should not be used in cases of severe and abrupt curvatures when mechanically driven.
- These instruments contain nickel and should not be used by individuals with a known allergic sensitivity to this metal.

3) WARNINGS
- The use of a rubber dam system during the endodontic procedure is highly recommended.
- 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 identification or level of safety required for the proper 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

- A prerequisite for proper root canal treatment is direct access, and with Excalibur® files there is no exception.
- Clean files frequently during instrumentation, inspecting for any signs of distortion or wear, such as missing flutes or nicks.
- Irrigate copiously and frequently after removing any Excalibur® shaping files from a canal.
- Be especially careful with canals that split and/or have abrupt curvatures or recurvatures.
- For your own safety, wear personal protective equipment (gloves, goggles, mask).
- Excalibur® shaping files should not be completely immersed in sodium hypochlorite (NaOCl) solution.
- Irrigate the canal abundantly and frequently during the procedure.
- Apply the reciprocating motion with light apical pressure.
- Use a gentle inward pecking motion, with short strokes, to advance the Excalibur® shaping file through a smooth and reproducible patency.
- Remove the Excalibur® file when it does not advance easily. Clean and inspect cutting flutes, re-irrigate, recapitulate with size 010 file and re-irrigate.
- Excalibur® shaping files are recommended to be used mechanically (by hand on severe curvatures) with a motor that has the recommended settings for Excalibur®.
- Excalibur® files use a unique approach during manufacturing that increases resistance to cyclic fatigue compared to standard NiTi. Due to this, Excalibur® shaping files may appear slightly curved. This is not a manufacturing defect. It is not necessary to straighten the file before use. Once inside the canal, Excalibur® files will follow the glide path, adapting to natural curvatures.
- Before using Excalibur®, explore the canal with hand files, at least up to ISO size K 010.
- Always start the Excalibur® file shaping procedure in the presence of sodium hypochlorite.
- This product should be disposed of as medical waste.

Recommended motor settings:

Excalibur®		
File size	**Speed (rpm)**	**Torque (Ncm)**
Excalibur® E20 Small, E25 Regular, E35 Medium y E45 Large	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

Excalibur® 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 EXCALIBUR® 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 Excalibur® shaping technique:

1) Create a straight-line access to the canal entrance.
2) Use a size 010 hand file to check for patency to working length. In more restrictive canals, use a size 010 hand file anywhere in the canal to create a glide path.
3) Expand this glide path to at least 0.15mm using a hand or mechanical file, such as the Z-Glider® file.
4) Always initiate the shaping procedure with the file E25 Regular (025/.05 red) in the presence of sodium hypochlorite.
5) Use gentle inward pressure and let file E25 Regular passively progress through any area of the canal that has a confirmed glide path. After shaping 2-3 mm of any given canal, remove and clean the file E25 Regular, then irrigate, recapitulate with a 010 hand file and re-irrigate.
6) Continue with the file E25 Regular, in 2-3 passes, to pre-enlarge the coronal two thirds of the canal.
7) In more restrictive canals, use a 010 hand file to the terminus of the canal. Work gently with this file until it is completely loose at length.
8) Establish working length, confirm patency and verify the glide path.
9) Expand this glide path to at least 0.15 mm using a hand or mechanical file.
10) Carry the file E25 Regular to the full working length in one or several passes. When length is reached, remove the file to avoid excessively enlarging the foramen. Inspect the apical flutes on the file, and if they are full of debris, then the shaping is finished.
11) If the file E25 Regular does not advance, use a 010 hand file or a mechanical file such as the Z-Glider® in one or more passes until working length is reached, then use the Excalibur® E25 Regular file until working length is reached to optimise the shape.
12) Once the shape is confirmed, proceed with 3D disinfection protocol.

* If Excalibur® E25 Regular is loose at working length and does not have debris on the apical flutes of the file, continue with Excalibur®E35 Medium (035/.05 green) and/or E45 Large (045/.05 white) until the apical flutes are full of debris.

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) 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%.
8) Prevent the instrument from drying out before or during pre-disinfection or cleaning. Dried biological material can be difficult to remove.
9) 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).
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.

Operation		Description and Warnings
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.
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.

	Operation	Description and Warnings
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.
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
FOR DENTAL USE ONLY	Product designated for dental use only
	Do not reuse – Single-use only
NiTi	Workpiece Material: Nickel Titanium
	Rotating handle
MD	Medical Device
Heat activation	Pre-bendable
XXXXXX – XXXXXX min⁻¹	Recommended rotation speed
XXX mNm	Recommended torque for use
LOT	Batch number
STERILE R	Sterilised by radiation
REF	Reference number

Symbols	Identification
	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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