

MM Nerve Broaches

Instructions for use

EN

1. Indication

Pulp tissues removal during a non-surgical endodontic treatment. For use by a dental professional only.

2. Contraindications









There is no contraindications to the use for endodontically treating a tooth by orthograde route.

3. Complications

In cases of complex anatomy, per-operative risks (instrumental breakage) could occur and induce a risk of infectious processes.

4. Characteristics and warnings

Color code:

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- 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).
- Check the condition of the instrument's blade and its fit with the handle before use. 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.

Number of uses: single use.

Medical device class according to MDR 2017/745: I.

Packaging symbol			Non-sterile, Do not re-use
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5. Clinical claims

There are no specific clinical claims for the devices other than the achievement of the indication for use that corresponds to paragraph 1.

6. Reprocessing instructions

General recommendations	<ul style="list-style-type: none"> • For all metal devices, the use of anticorrosion disinfecting and cleaning agents is recommended. • 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	<ul style="list-style-type: none"> • 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 applicable requirements. • The state of the art and national laws require that validated procedures be followed.
Material needed	<ul style="list-style-type: none"> • Gloves, masks, gown as recommended by the manufacturer of cleaning agent and detergent • Tap or deionized water • Disinfectant (neodisher® Septo Active) • Detergent (neodisher® MediZym) • Small soft brushes • Container • Ultrasonic tub or washer-disinfector • Class B sterilisation apparatus <p><i>Remark: All material used should be cleaned and replaced regularly. Identify material used for each step of the process (initial treatment, cleaning or rinsing).</i></p>

1	<p>Initial treatment</p> <p>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 15 min.</p> <p>Rinse the products with tap water at 20-40 °C for 1 min.</p> <p>If there is waiting time before the next step, make sure the device stays moist by placing it in a wet wipe. Do not exceed 1 hour waiting time.</p> <p><i>Remarks:</i></p> <ul style="list-style-type: none"> • Do not use fixing 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 specified by the manufacturer (an excessive concentration may cause corrosion or other defects on devices).
2	<p>Preparation before cleaning</p> <p>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.</p> <p><i>Remark: Follow instructions and respect concentrations and immersion times specified by the manufacturer (an excessive concentration may cause corrosion or others defects on devices).</i></p>
3	<p>Visual inspection</p> <p>Inspect the used products and discard damaged products (broken, untwisted or abnormally bent).</p>

manual	4	<p>Cleaning</p> <p>Insert the products into an ultrasound apparatus beaker.</p> <p>Run ultrasound apparatus for 10-30 min with tap water and 0.5-2.0% neodisher® MediZym.</p> <p><i>Remarks: Follow instructions, observe water quality, concentrations and cleaning time specified by the manufacturer of the cleaning solution.</i></p>
	5	<p>Rinsing</p> <p>Rinse the products with tap water at 20-40°C for 1 min.</p> <p><i>Remark: It is recommended to use deionized water.</i></p>
	6	<p>Drying</p> <p>Dry the products with compressed air until products are visibly dry.</p>
automatic	4	<p>Cleaning/Rinsing/Drying</p> <p>Place the instruments in the tray of the washer/disinfector's sliding trolley.</p> <p>Perform cleaning cycle with 0.2-1.0% neodisher® MediZym.</p> <p>Perform drying.</p> <p><i>Remarks:</i></p> <ul style="list-style-type: none"> • Disinfection (thermal or chemical-thermal) is not required since the products are sterilised after cleaning. • Follow instructions and concentrations specified by the manufacturer of the detergent solution. • Follow the instructions of the washer-disinfector and verify that the success criteria have been met after each cycle as specified 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 that comply with EN ISO 15883, and are maintained and validated regularly.
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7	<p>Visual inspection</p> <p>Inspect the used products.</p> <p>Re-do steps 4-5-6 if the product is visibly not clean or discard any damaged products.</p>	
8	<p>Packaging</p> <p>Place the instruments in a paper-plastic pouch for steam sterilisation in compliance with ISO 11607 and EN 868 standards.</p> <p><i>Remarks:</i></p> <ul style="list-style-type: none"> • For sharp devices that are not contained within a box, silicon tubes should be placed around the devices to prevent the packaging from being pierced. • Seal the pouches as recommended by 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	<p>Sterilisation</p> <p>Sterilise the products using steam:</p> <ul style="list-style-type: none"> • Apparatus: class B • Minimum temperature: 132°C • Minimum time: 3 min • Absolute pressure: 2.2 bar • Minimum drying: 20 min <p>Control the physico-chemical indicators and cycle parameters.</p> <p>The temperature settings at 134°C and duration of 18 min are mandatory for prion inactivation according to French regulations.</p> <p><i>Remarks:</i></p> <ul style="list-style-type: none"> • 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 a pre-vacuum air removal steam steriliser that meets the requirements of EN 13060 (class B, small steriliser) and EN 285 (full-size steriliser), with saturated steam. 	
10	<p>Storage</p> <p>Store the products in a dry, clean and dust-free environment at the temperature specified by the paper-plastic pouch by the steam steriliser manufacturer.</p> <p><i>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.</i></p>	








7. Storage and transport conditions

None.

8. 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.

9. Symbols

	Stainless steel material		Root canal preparation
	Quantity		Assortment
	Nerve Broaches		Medical device
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified		

Year of CE marking: 1998
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