Revo Condensor

Instructions for use EN

1. **Indication**
REVO Condensor: root canal filling during no surgical endodontic treatments.
For use by a dental professional only.
2. **Contraindications**
There is no contra-indication to the use of REVO Condensor, after decision by the dental professional to perform a no surgical dental root canal treatment.
3. **Complications**
Per-operative risks (instrumental breakage, …) in cases of complex anatomy.
4. **Warning and precaution**
• The decision to use the endodontic instrument must be based on the clinical case expertise, particularly where the canal anatomy is considered to be too complex.
• Patients identified as having a risk of infectious endocarditis.
• Contains nickel and titanium: should not be used in persons with a known allergy to these metals.
• Respect good dental practices, in particular by using a dental dam and gloves.
• Use in continuous rotation at the recommended speed.
• Use according to the procedure recommended (§7).
• Do not use outside of root canal filling step
• Instruments supplied non-sterile: Follow the reprocessing instructions (§8) before use.
• Keep UDI information present on the labelling only until the last use.
• Year of manufacture: see labelling.
• Do not use the instrument if there is any doubt about compliance with the storage conditions.
• If there is any doubt about the identification of the product, do not use it.
• Check the instrument integrity before using between each canal. If the instrument is damaged or shows signs of wear, do not use it.
• Inform the manufacturer and the regulatory authority in the country of any serious incident relating to the instrument.

5. **Clinical claims**
Revo Condensor in normal conditions.

Clinical performance:
• Three-dimensional filling (lateral canal, ishmus…)
• Level of PFGA (% of gutta percha filling) and void
• Filling until the working length
•Prevent the passage of micro-organism and fluid along the root canal system

Safety:
• Limits the risk of fracture

6. **Characteristics**
Type 2 continuous rotating instruments under EN ISO 3630-1: 2019 standard:

	Ø	%	L	Ring color	RPM
revo Condensor	30	4	25		10000-15000
revo Condensor	30	4	29		10000-15000

Material of operative part: Nitinol.
Use in connection with an endodontic contra-angle according to standard EN ISO 1797: 2017 (Type 1).
Number of uses: maximum of 5 canals recommended if the instrument is not visually impaired.
Medical device class according to Directive 93/42/EEC and MDR 2017/745 : IIa.

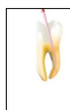
7. **Protocol**

Operative mode
MICRO-MEGA recommends an operative mode for the use of these instruments, but the dentist could decide to use instruments with other sequences, depending of the anatomy of the teeth in conformance with the state of the art for issuing step of filling.

Operating mode : **Thermomechanical condensation technic**

	1	Select the master cone (Gutta percha Point) according to the apical preparation and try it in a humid environment (2.5 % - 5,25% NaOCl). After validation of the master cone, dry the root canal with Paper Points and coat the canal walls with endodontic sealer. Insert the master cone at the WL or the WL -0.5 mm is reached.
	2	Insert the Revo Condensor until friction between the canal walls and the master cone, set the rotation speed at 10,000 – 15,000 rpm, and press against the master cone until its plastification.
	3	Slowly move the Revo Condensor in the root canal performing slight up and down movements to a length between WL-4 and WL-2 mm then slowly remove the Revo Condensor along a canal wall.
	4	Eliminate the excess gutta percha in the pulp chamber with the heated part of a plugger for vertical condensation. Maintain the pressure on the remaining gutta percha with a vertical condensation plugger.

Combined Thermomechanical condensation technic (with Revo Spreader)

	1	Select the master cone (Gutta percha Point) according to the apical preparation and try it in a humid environment (2.5 % - 5,25% NaOCl). After validation of the master cone, dry the root canal with Paper Points and coat the canal walls with endodontic sealer. Insert the master cone at the WL or the WL -0.5 mm is reached.
	2	Condense the master cone laterally with the biggest Revo Spreader (no.020, no.025 or no.030) allowing to reach the WL -2 mm. Repeat this step if necessary, with accessory Gutta Percha points.
	3	Insert the Revo Condensor until friction between the canal walls and the master cone, set the rotation speed at 10,000 – 15,000 rpm, and press against the master cone until its plastification.
	4	Slowly move the Revo Condensor in the root canal performing slight up and down movements until 2/3 of WL then slowly remove the Revo Condensor along a canal wall.
	5	Eliminate the excess gutta percha in the pulp chamber with the heated part of a plugger for vertical condensation. Maintain the pressure on the remaining gutta percha with a vertical condensation plugger.

8. **Reprocessing instructions**

General recommendations	• 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	• 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 ressources, 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	• Gloves, masks, gown 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 15 min. Rinse the products with tap water at 20–40 °C for 1 min. 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. *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 specified by the manufacturer (an excessive concentration may cause corrosion or other 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 1 min with a soft brush until all impurities have been removed. *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 into an ultrasound apparatus beaker. Run ultrasound apparatus for 10–30 min with tap water and 0.5–2.0% neodisher® MediZym. *Remarks: Follow the instructions, observe the water quality, concentrations and cleaning time stated by the manufacturer of the cleaning solution.*
	5	**Rinsing** Rinse the products with tap water at 20–40°C for 1 min. *Remark: It is recommended to use ionized water.*
	6	**Drying** Dry the products with compressed air until products are visibly dry.

automatic	4 5 6	**Cleaning/Rinsing/Drying** Place the instruments in the tray 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 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 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 washer-disinfector 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 using steam vapor: • Apparatus: class B • Minimum temperature: 132°C • Minimum time: 3 min • Absolute pressure: 2.2 bar • Minimum drying time: 20 min 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 regulation.* • *When sterilizing multiple instruments in one autoclave cycle, ensure that the steriliser's maximum load is not exceeded.* • *Place the pouches in the steam sterilizer according to the recommendations given by the sterilizer manufacturer.* • *Use only pre-vacuum air removal steam sterilizers that meet the requirements of EN 13060 (class B, small sterilizer) and EN 285 (full size sterilizer), with saturated steam.*
	10	**Storage** Store the products in a dry, clean and dust-free environment at the temperature specified on the paper-plastic pouch by the steam sterilization 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 rework should be performed.*

9. **Storage and transport conditions**
None

10. **Disposal**
After use, instruments must be placed in a secure container, used to collect cutting or sticking instruments (like needles or disposable bistoury) as per good dentistry practices.

11. **Symbols**

NiTi	Nitinol raw material		Root canal preparation
	Quantity		Assortment
CLASSICS	"CLASSICS" handle	MD	Medical device
134°C	Sterilizable in a steam sterilizer (autoclave) at the temperature specified		

Year of CE marking: 2011
Date of IFU revision: 2023-01-04
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