

INSTRUCTION FOR USE

ENGINE ROOT CANAL INSTRUMENTS (CLASS IIa)

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MANUFACTURER

APPLICABLE FOR INDICATIONS FOR USE

Engine root canal instruments
Medical device class IIa

The engine root canal instruments are used to clean, to disinfect and to shape the dental root canals when they are infected by bacterium: it is the endodontic treatment or canal treatment.

1. Only dentists are allowed to use these instruments for the root canal treatment
2. Be sure to sterilize products before first use and re-use.

WARNINGS

DESCRIPTION

All the root canal instruments manufactured under ISO 3630 specifications by FFDM-PNEUMAT are aimed to be used by professionals of dental art only during root canal treatment. Professionals learn to use these instruments and the related medical procedures during their formation.

All instruments are made from high grade stainless steel and machined to ISO standards 3630.



The part ensuring the connection with the contra angle is manufactured according to the ISO norm 1797 (diameter of the contra angle shank: $\varnothing 2.35 \text{ 0} / -0.016 \text{ mm}$)

Easy identification of instruments with color coding or grinded marks according to the ISO norm 3630. Supplied without silicone stopper on the blade.

USING ADVICES

1. It is essential to follow the steps of cleaning, disinfection and sterilization before first use or for reuse (see our recommendations on the label placed on the outer packaging).
2. Only for use by dentists
3. According to its intended use (shaping, filling, enlarging...), choose the most appropriate endodontic instruments (type and ISO number)
4. Before to use the instrument, make sure that it is not damaged: no deformations, no rust, and no scratches.
5. Engine endodontic instruments have to be used by connecting with a contra angle.
6. Please apply the most appropriate engine speed and torque.
7. Irrigate and introduce the endodontic instruments applying reciprocating and vertical filling movements, into the root canal.
8. Use this product carefully to avoid puncturing finger

PACKAGING

Quantity per pack: 6 or 4 units, identical or different (assortment). Plastic box.

MAINTENANCE

1. It is essential to follow the steps of cleaning, disinfection and sterilization before first use or for reuse (see our recommendations on the label placed on the outer packaging).
2. Dispose the product if damaged or decreased in efficiency
3. It is the user's responsibility to sterilize products before first use and re-use.
4. For your safety, we recommend using EPIs (Individual Protective Equipment) - for example: Gloves, eye protection
5. Only use disinfectants with proven effectiveness (EU labeling, FDA approved, ...)
6. After disinfection, put instruments in sterilization sachets. (Check that sachets comply with EN ISO 11607-1 standard)
7. When several instruments are sterilized in a single autoclave cycle, ensure that the maximum load of the autoclave is not exceeded.
8. Follow strictly the instruction manual of the manufacturer of the medical cleaning product

STORAGE

No specific requirements as stainless steel is used, however, it is preferable to store devices in a clean, dry place protected from damp.

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LIFE SPAN

The life span is estimated at 3 years from the date of manufacturing but can vary depending on the use (cutting, conditions), on the frequency of use, and on the quantity of sterilization.

LABEL PLACED ON OUR OUTER PACKAGING

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REUSABLE

DENTAL INSTRUMENTS

CE 0459

It is imperative to respect the stages of cleaning, disinfection and sterilization **before the 1st use and for a re-use..**

CLEANING: Make a brushing of the instrument (nylon brush)

DECONTAMINATION: Ultrasonic sounds with a decontamination solution, rinse abundantly and dry.

STERILIZATION : In a sterilization bag thermo welded.

Autoclave 134 ° during 18 minutes. Store in a dry atmosphere, far from corrosive products.

Precaution of use:

Make sure that the instrument is well fixed by testing the rotation.
Use an alternative contra-angle for the MAD files and a reciprocating contra-angle for flex files.

CE marking obtained In 1996

REV 0 on July 2010

PICTOGRAMS



WARNING - This symbol is used to mean "Attention, see instructions"*



LOT - The symbol must be accompanied by the manufacturer's lot code. Lot code and the symbol must be adjacent.



KEEP DRY - Keep away from rain



STERILIZATION - Autoclave 134° during 18 minutes



MANUFACTURER - The symbol must be accompanied by the name and address of the manufacturer - person who places the device on the market



CONSULT THE MANUAL



NON STERILE



STAINLESS STEEL



NICKEL TITANIUM

CE 0459

Medical devices of class IIa with LNE/GMED certificate