

INSTRUCTION FOR USE

DENTAL BURS (CLASS IIa)

MANUFACTURER

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APPLICABLE FOR

Dental burs

Medical device class IIa

List:

Cavity bur / Fissure bur / Vulcanite bur / Stump bur / Special steel bur / Surgical bur / Twisted drill

INDICATIONS FOR USE

The burs are rotary grinding instruments used to work hard tissue (such as tooth and bones) and resine.

WARNINGS

1. Only dentists are allowed to use the dental burs for dental treatments
2. Be sure to sterilize products before first use and re-use.

The burs are rotary grinding instruments used to work hard tissue and resin.

They are made of stainless steel or carbon steel.

Our vulcanite and special burs can also be used by dental prosthetist to work ceramic, plastic and other materials.

Products examples

Vulcanite bur with HP connection. HP : Hand Piece



Round bur with RA connection. RA : Right Angle



DESCRIPTION

All the burs manufactured under ISO 3823 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.

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

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, choose the most appropriate bur (type and ISO number) and use it to work hard tissues.
4. Before to use the bur, make sure that it is not damaged: no deformations, no rust, and no scratches.
5. The burs have to be used by connecting with a contra angle.
6. Please apply the most appropriate engine speed and torque.
7. Use this product carefully to avoid puncturing finger

PACKAGING

Plastic box by pack of 6 or by unit

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

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load of the autoclave is not exceeded.

8. Follow strictly the instruction manual of the manufacturer of the medical cleaning product

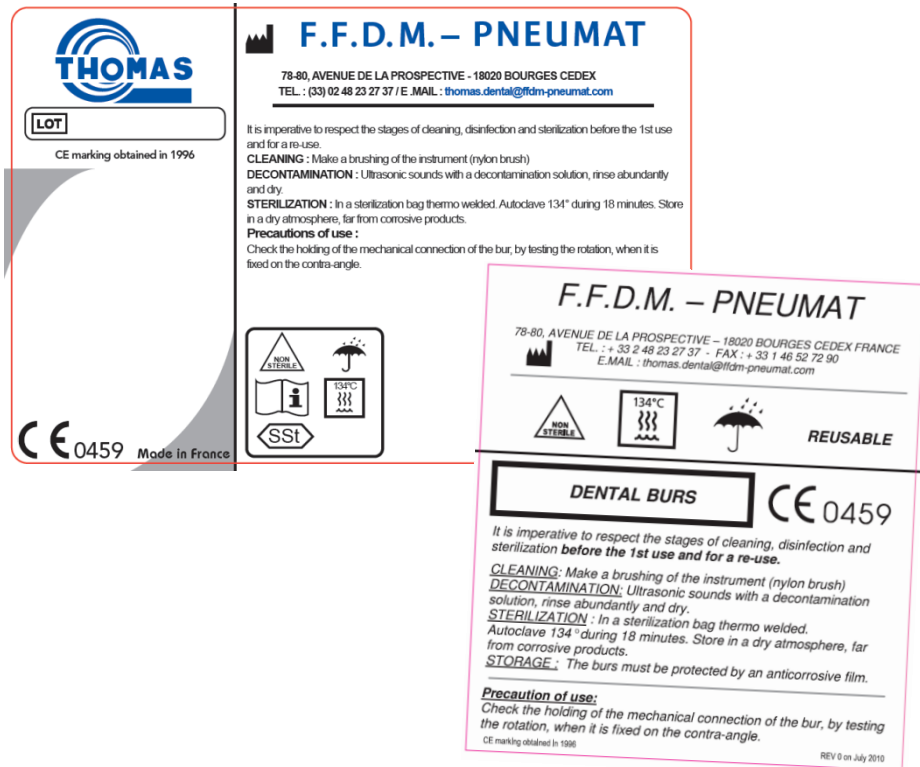
STORAGE

It is preferable to store devices in a clean, dry place protected from damp.

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



LABEL PLACED ON THE BOXES

Examples



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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



CARBON STEEL



Medical devices of class IIa with LNE/GMED certificate