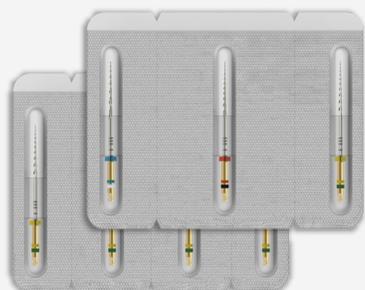


Commercial Presentation of the Product:

Packaged in aluminum blister .



Medical Device Specifications: These devices are designed for cleaning root canals, suitable for all types of root canals with their respective anatomical variations (straight, curved, wide, atretic, flattened), and can be used throughout their entire length. Transient use for up to 60 minutes of continuous operation.

Principle of Operation/Mechanism of Action:

Endodontic files are inserted into the root canal and, through rotational and traction movements, promote debridement and enlargement of the area.

Product Usage:

- The endodontic file can only be used after the sterilization process.
- The use of an endodontic motor with torque control is recommended.
- If any distortion of the blade is observed, it should be discarded immediately.
- Never force the endodontic file apically; insert the file gently and passively.
- Irrigate the root canal frequently during shaping/procedure.
- Dispose of used endodontic files in an appropriate container for biological hazard needles.
- Easy Bassi recommends single-use. Reusing endodontic files significantly increases the risks of cross-contamination, as there is a possibility of use on different patients. Additionally, improper reprocessing can lead to the fracture of the active part of the file or detachment of this part from the handle due to excessive wear. It is crucial to strictly follow all cleaning, disinfection, and sterilization methods. These procedures are essential to ensure that the file is completely free from any type of microorganism before reuse. Failure to comply with these measures can result in serious health risks for the patient, making proper care when reprocessing endodontic files imperative.
- Don't use the endodontic file after the expiration date; the product may perform below specified working standards.
- Product Shelf Life: 3 years from the manufacturing date.

Storage Conditions:

The packaging containing the product must be stored in a well-ventilated, dry place protected from light and adverse weather conditions. Temperature Range: 17°C to 27°C, away from direct sunlight.

Transportation Conditions:

The product must be transported in sealed containers and under conditions that ensure the maintenance of identification and packaging integrity. Temperature Range: 17°C to 27°C, away from direct sunlight.

Handling Conditions:

- Cleaning and disinfection methods:

Cleaning method - all parts must undergo ultrasonic bath with distilled water for 60 minutes at 80°C, as per ultrasonic device instructions. After the ultrasonic bath, they should be rinsed in clean water. Once dry, the files can be placed in sealed paper bags for steam sterilization in an autoclave.

- Recommended sterilization:

Use steam sterilization at 134°C for 7 minutes and 1.20 kgf/cm² (1.15 atm).

- Disposal method:

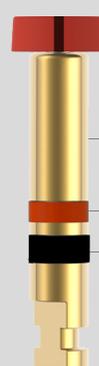
The endodontic file must be disposed of in a suitable container for disposal of infectious sharp materials in watertight, rigid containers, with lids and identification (Descartex type), located at the site of its generation.

Warnings:

- Sodium hypochlorite solution should not be used as a disinfectant.
- Easy Bassi recommends single-patient use as reusing the file can increase the risks of: Cross-contamination, due to the possibility of use on different patients. Fracture of the active part or detachment of the active part from the handle, due to excessive wear.
- Files should be handled by qualified professionals. Instruments must be sterilized before use.
- For an efficient and safe process, the rotary equipment must comply with IEC 60601-1.
- This product contains nickel and should not be used by individuals with known allergic sensitivity to this material.

Precautions:

- Don't use damaged or tampered merchandise.
- Don't use the endodontic file after the expiration date. The product may perform below specified working standards. Don't use the endodontic file after the expiration date. The product may perform less well than specified.



- Gold Handle
- Color Tip
- Color Taper

Taper Tip

.06 -	20 -
.08 -	25 -
.10 -	30 -

Available in lengths: 21 and 25mm

File	NCM	RPM
#.30/10	4	950
#.25/08	4	900
#.20/06	1,5	600



Produced by Easy Equipamentos Odontológicos
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