

File Organizer

DIRECTIONS FOR USE

1) INDICACIONES FOR USE

The File Organizer is used as a file holder with ruler for measuring the length of root canal files during the endodontic instrumentation which helps to set a precise working time. It's a measuring device and file holder used for measuring length of files or gutta percha points during the treatment.

2) PRODUCT STRUCTURE AND MATERIALS

The File Organizer is made of durable plastic (Polyethersulfone, PES).

3) WARNINGS

- Use only by professionals.
- This device is not sterilized. Be sure to sterilize this product before each use.
- Use this product only for dental service and treatment. Use it in accordance with the intended use.

4) CONTRAINDICATIONS

No contraindications known.

5) STEP-BY-STEP INSTRUCTIONS FOR USE OF THE FILE ORGANIZER

This instrument is to be used only in a clinical or hospital environment, by qualified users.

Measuring the length of files

When the dentist needs to measure the length of files or gutta percha points, the scale side of the File Organizer may be used as on the picture below:





Used as a disinfection holder of files

After cleaning the file, put it into the File Organizer, disinfect or sterile according to the instruction specified in the IFU of each rotary file.

6) CLEANING, DISINFECTION AND STERILISATION

Dental instrument reprocessing procedure.

- 1) Remove the packaging of gauge before sterilization. Pay attention on the special characteristic material of gauge. The sterilize temperature should not exceed 132°.
- 2) If the disinfection solution contains corrosion inhibitor, it is recommended to wash the instruments before the high-pressure steam curing.
- 3) Put the File Organizer in the disinfection bag and sterilize at 132°C / 269.6°F and 210Kpa for 4 minutes with steam sterilization. The drying time is 20 minutes.
- 4) Put the gauge in a sterile package and place it in a dry and clean environment.

7) STORAGE AND EXPIRY












- Avoid storing in places with high temperatures, humidity and/or direct sunlight. Keep liquids away. Store at ambient temperature.
- Do not damage or puncture the packaging materials.
- This product is subject to improvement without prior notice. Apply the “first in, first out” approach to inventory management.
- Do not store under a germicidal lamp to prevent deterioration.

8) PACKAGING


- Minimum packaging unit: 1pcs/pack




9) IDENTIFICATION OF RELATED SYMBOLS

Symbols	Identification
 FOR DENTAL USE ONLY	Product designated for dental use only
	Batch number
	Non-Sterile
	Materials includes Plastic
	Reference number
	Expiry date
	Consult directions for use
	Authorized representative in the EU
	Manufacturer
	Autoclavable at the specified temperature
	CE marking

 SHENZHEN DENCO MEDICAL CO.,LTD
Room 301.No.8 1st of road of Xiawei Industrial Zone,
Zhangkengjing Community Guanhu Street,
Longhua District, 518110, Shenzhen China
hola@zarc4endo.com • www.zarc4endo.com

 Wellkang Ltd
Enterprice Hub, NW Business Complex,
Baraghmore Rd, Derry, BT48 8SE,
Northern Ireland, UK
T. +44 (20) 3287 6300, AuthRep@CE-marking.eu

 **Importer for the EU:**
IPG Dental Group S.L.
C/ Marqués de San Esteban nº8, 1ª A y B,
33206 Gijón, Asturias (Spain)