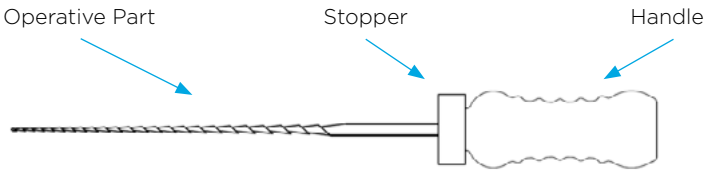
HFile®

DIRECTIONS FOR USE



COMPOSITION

The stainless steel hand use H-Files is composed of handle and operative part.
The cross section of H-Files is round.
The main Materials:

1) Operative part: Stainless steel
2) Handle: White plastic grains (CAN20-037986.002)
3) Stoppers: Colorless translucent rubber (CAN19-259705.001)

1) INDICATIONS FOR USE

The stainless steel hand use H-Files is a hand use root canal instruments for enlarging root canal by the movements of lifting and vertical reciprocation.
It is standard instrument with 2% taper, which is type 1 classification base on ISO 3630-1:2019.

2) CONTRAINDICATIONS

Do not use this product on a patient that has sensitivity or allergic reaction.

3) WARNINGS

- Only skilled dentists are allowed to use this instrument.
- Be sure to sterilize this product before each use.
- Use this product only for the dental service and treatment. Use it in accordance with the intended use.

4) RE-PROCESSING

Our dental root canal instruments are single use and not approved for re-use.

5) SPECIFICATIONS FOR USE

The specification of stainless steel hand use H-Files as the below table (based on ISO 3630-1):

Size	Working length (mm)	Tip diameter (mm)	Taper	Color of handle
006	21 mm (white stopper) 25 mm (yellow stopper) 31 mm (black stopper)	0.06	2%	Pink
008		0.08		Grey
010		0.10		Purple
015		0.15		White
020		0.20		Yellow
025		0.25		Red
030		0.30		Blue
035		0.35		Green
040		0.40		Black
045		0.45		White
050		0.50		Yellow
055		0.55		Red
060		0.60		Blue
070		0.70		Green
080		0.80		Black

- According to its intended use, the dentists can choose the most appropriative type for each case and follow the general method.
- This stainless steel hand use H-Files is under the provisions of ISO 3630 performance test, products' durability for twisting and bending must exceed specified value of our standard.

6) PRECAUTIONS FOR USE

- To prevent infection, pls clean and disinfect the product (please see item 7) and make sure sterilization is completed before using.
- Choose the most appropriative type for each case and follow the general method.
- Before using, make sure the instruments outside of oral cavity that there are no deformations, scratches and cracks.
- If the head of product is thin, long or large, there are possibilities for breaking or twisting. Because of this, be sure to avoid using unreasonable angle and excessive pressure.
- Wear rubber dam etc. to avoid accidental ingestion and falling.
- Do not use this instrument for any purposes except for listed applications above.

- Only for use by dentists.
- This product should be treated as medical waste when disposed.
- Dispose the product if damaged or contaminated.
- After using, wash it with medical cleaning agent and brush, then wash away foreign substances like adherent body fluids and body tissues.
- Set the product to a stand when cleaned by ultrasonic cleaner to avoid deterioration of cutting part.
- Use this product with great care to avoid puncturing fingers because of its possession of sharp-edged part.
- This product has possibility that be corrosive if sunk into NaOC1, EDTA and etc. for a long time.

7) CLEANING, DISINFECTION AND STERILISATION

Dental instrument reprocessing procedure.

I - FOREWORD

Instruments marked "sterile" do not require any specific treatment before first use. For the rest of the instruments that are not marked "sterile", cleaning and sterilisation is necessary before using them for the first time in accordance with section III – STEP-BY-STEP INSTRUCTIONS of these directions for use.

II - GENERAL RECOMMENDATIONS

1) Use only a detergent solution with a disinfectant action approved for its effectiveness (VAH/DGHM-listing, CE marking, FDA approval) and follow the instructions of the manufacturer of said product. Anticorrosive cleaning products and disinfectants are recommended for all metal instruments.
2) For your own safety, please use personal protective equipment (gloves, goggles and mask).
3) The user is responsible for the cleaning and sterilisation of the product for the first cycle and each subsequent use, as well as the use of dirty or damaged instruments after sterilisation.
4) The safest option for the professional is to use our instruments only once. After each use, they must be thoroughly inspected before being used again; the presence of defects such as deformations (bent, stretched), fractures, corrosion, loss of colour identification, marking, etc. are indications that the instruments cannot meet the level of safety required for their intended use and should therefore be discarded.
5) Instruments marked as single-use only are not approved for reuse.
6) For the final rinse it is mandatory to use deionised water, either using an automatic washer-disinfector or a manual cleaning method. For the other rinsing steps tap water use is allowed.
7) Instruments with plastic handles and NiTi instruments should not be used with Hydrogen Peroxide (H^2O^2) solution, which is known to degrade them.
8) Only the active part of the NiTi instrument that is in contact with the patient should be immersed in a NaOCl solution with a concentration NOT greater than 5%.
9) Prevent the instrument from drying out before or during pre-disinfection or cleaning. Dried biological material can be difficult to remove.
10) Do not place identifying labels or markers directly on the instrument.

III- STEP-BY-STEP INSTRUCTIONS

Operation		Description and Warnings
1	**Disassembling**	• Remove and discard the silicone stoppers.
2	**Rinsing**	• Rinse abundantly (for at least 1 minute) under running water at ambient temperature. While rinsing, use a soft brush (nylon, polypropylene, acrylic) for pre-cleaning until visible impurities are removed.
3a	**Automated cleaning with washer-disinfector**	• Place the instrument in a kit, support, or container made of stainless steel or titanium. • Execute the defined cycle with detergent solution (for example, Metrex EmPowder concentration 1:128 - 1:512) for at least 5 minutes in the washer-disinfector at 20°C - 40°C).
3b.I	**Manual cleaning assisted by an ultrasonic device**	• Place the instrument in a kit, support, or container made of stainless steel, polypropylene, or titanium. • Submerge it in a detergent solution (for example, Metrex EmPowder concentration 1:128) with cleaning properties. If applicable, soak it for at least 15 minutes with the help of an ultrasonic device. • Rinsing: perform a long rinse (at least 1 minute) under running deionised water at a temperature of 20°C - 40°C. • Drying: dry with a single-use non-woven cloth or with a hot air dryer no hotter than 110°C.
3b.II	**Manual disinfection with washer-disinfector**	• Place the instrument in a kit, support, or container made of stainless steel or titanium. • Execute the defined cycle with a mild neutral enzymatic cleaning agent solution (for example, Metrex EmPowder concentration 1:128) for at least 5 minutes in the washer-disinfector at a temperature of >90°C, A0 >3000. • **Note:** **1)** Discard instruments with obvious defects (broken, bent, etc.). **2)** When the instruments are placed in a cleaning kit, support, or container, avoid any contact between them. **3)** Follow instructions and concentrations given by the manufacturer of the detergent solution (see also general recommendations). **4)** Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacture. **5)** The final rinse step should be with deionised water. For other steps follow the water quality defined by the manufacturer. Place the instrument in a kit, support, or container made of stainless steel or titanium to avoid any contact between devices or posts.

	Operation	Description and Warnings
3b.III	Rinsing	• Rinse abundantly (for at least 1 minute) under running water at ambient temperature. • Use deionised water for rinsing. • If the previously used cleaning solution contains a corrosion inhibitor, rinsing is recommended just before autoclaving.
3b.IV	Drying	Devices should be carefully dried before inspection and packaging • Dry with a single-use non-woven cloth or with a hot air dryer at a maximum temperature of 110 °C. • The devices should be dried until visual traces of moisture are eliminated. • Particular attention has to be paid to effectively dry joints or cavities inside the device.
4	Inspection	• Inspect the operation of the devices. • Inspect devices and identify those with defects. **1)** Dirty devices need to be cleaned again. **2)** Do not reuse the silicone stoppers. **3)** Dispose of any defective devices.
5	Packaging	Place the devices in a kit, support or container to avoid any contact between instruments or posts and pack the devices in “Sterilisation Pouches”. (Use packaging that is resistant to a temperature of 141 °C (286 °F) and that is UNE-EN ISO 11607 compliant). **1)** Avoid any contact between instruments or posts during sterilisation. Use kits, supports or containers. **2)** For sharp devices not contained within a box, silicone tubing should be placed around the devices to prevent puncture of the packaging. **3)** Seal pouches per the pouch manufacturer’s recommendation. If a thermo-sealer is used, the process must be validated. **4)** Check the expiry date of the pouch indicated by the pouch manufacturer to determine the shelf life of the sterile product.
6	Sterilisation	• For these devices, steam sterilisation is recommended at 132°C / 273°F for 4 minutes, for the purpose of de-activating potential prions. • Instruments and posts must be sterilised according to the package labelling. • Place pouches in steam steriliser per steriliser manufacturer’s recommendation. • Use only steam sterilisers that meet the requirements of EN 13060 (class B, small steriliser), EN 285 (full size steriliser). • Use a validated sterilisation procedure according to ISO 17665 with a minimum drying time of 20 minutes.

	Operación	Descripción y advertencias
6	**Sterilisation**	• Follow the steriliser maintenance procedure indicated by the steriliser manufacturer. • Control the efficiency and the acceptance criteria of the sterilisation procedure (packaging integrity, no humidity, no colour change of the packaging, positive physicochemical indicators, conformity of actual cycle parameters to reference cycle parameters). • Store traceability records and define shelf life according to packaging manufacturer guidelines. • Shorter sterilisation cycles according to local regulations are possible but are not guaranteed to de-activate prions.
7	**Storage**	Keep devices in sterilised packaging in a clean environment, away from sources of moisture and direct sunlight. Store at ambient temperature. **1)** Sterility cannot be guaranteed if the packaging is open, damaged or wet. **2)** Check the packaging and medical devices before use (integrity of the packaging, absence of humidity and expiry date).

8) TRANSPORT

- To prevent the medical device from being damaged during transport, the use of specific racks, trays or rigid containers may be recommended.
- When the package is broken, it is no longer sterile. It must be cleaned, disinfected and sterilised before use.

9) STORAGE AND DURATION OF USE

- 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.
- The shelf life of endodontic files is 5 years.

10) DISPOSAL

For correct disposal, always respect national laws and recommendations from authorities.

11) PACKAGING

- Minimum packaging unit: 6pcs/pack in aluminium foil box.
- Assortment: 1 piece of each size in a single pack.

12) IDENTIFICATION OF RELATED SYMBOLS

Símbolo	Explicación
FOR DENTAL USE ONLY	Product designated for dental use only
	Do not reuse – Single-use only
SSt	Workpiece Material: Stainless Steel
MD	Medical Device
LOT	Batch number
	Identification symbol for H-files
STERILE R	Sterilised by radiation
REF	Reference number
	Expiry date
	Consult directions for use
EC REP	Authorized representative in the EU
	Manufacturer
132°C	Autoclavable at the specified temperature
	Assortment
6	6 pcs/pack
CE	CE marking

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