K-Files / K-Reamers / H-Files / MME / MMC / H-Files Prime Line / K-Reamers Prime line / K-Files Prime Line

en – Catheterisation and root canal shaping

Instructions for use EN

1. **Indication**

Non-surgical root canal treatment for:

-An irreversibly damaged or necrotic pulp

-Elective devitalization

Intended use: The medical devices (K-Files, Hedstroem Files, K-Reamers) are used for manual catheterism (n°008 to 015) and root canal shaping (all other diameters) during a non-surgical endodontic treatment. The instrument K-Files 008 and 010 are also used in the exploration, initial penetration and root canal permeabilization.

Intended user: For use by dental professionals only.

Intended patient population:

All patients, except:

-Patient which presents a contraindication below

2. **Contraindications**

A non-surgical treatment is not indicated for:

-Teeth that cannot be made functional nor restored.

-Teeth with insufficient periodontal support.

-Teeth with poor prognosis, uncooperative patients or patients where dental treatment procedures cannot be undertaken.

-Teeth of patients with poor oral condition that cannot be improved with a reasonable period.

Precaution to be taken with patient with risk of endocarditis heart disease.

The decision to use the endodontic instrument must be relayed to the expertise of the clinical case, particularly if a root canal anatomy is considered to be too complex or in case of young patient.

3. **Complications**

In cases of complex canal anatomy, per-operative risks (instrumental breakage, ledge, stripping, zipping, false path, perforation, etc.) could occur and lead to a risk of infectious processes.

4. **Characteristics and warnings**

Type 1 manual instruments according to EN ISO 3630-1:2019
Materials of the operative part: Stainless steel
Non-sterile devices.

ø	Maximum recommended number of uses (if the file is not visually damaged)
< 020	2
≥ 020	5

•Respect the good dental practice in particular by using a dental dam and gloves.

•Keep present UDI and packaging information until the last use.

•Do not use if doubt on the respect of storage conditions.

•In case of doubt concerning the product identification, do not use.

•Check the condition of the instrument's blade and its fit with the handle before use. If the instrument is damaged or shows signs of wear, do not use it.

•Inform the manufacturer and the national regulatory authority of any serious incident relating to the instrument.

•Be sure to respect the maximum recommended number of uses.

•Follow the reprocessing instructions (§6) before first use and reuse.

Medical device class according to MDR 2017/745: Ir.

5. **Clinical claims**

There are no specific clinical claims for the devices other than the achievement of the indication for use that corresponds to paragraph 1.

6. **Reprocessing instructions**

General recommendations	• For your own safety, please wear personal protective equipment (gloves, glasses and mask). • Do not use cleaning or disinfecting agents containing phenol, aldehyde and alkaline composition. • Always respect the instructions for use provided by the manufacturer of the products.
Limitations on reprocessing	• Due to the product design and the materials used, no definite limit to the maximum number of performable processing cycles can be specified. The service life of the medical devices is determined by their function and careful handling. Multiple use disinfection and re-sterilisation cycles may lead to increased risk of file separation. • The user must ensure that the processing method used, including re-sources, materials and personnel, is appropriate and meets the applica-ble requirements. • The state of the art and national laws require that validated procedures be followed.
Material needed	• Gloves, masks, gown, dental dam, as recommended by the cleaning agents manufacturers • Running Tap water, deionized water or purified water according to European Pharmacopoeia • Cleaning agent (neodisher® Septo Active and neodisher® MediZym) • Small soft brushes • Container • Ultrasonic tub or washer-disinfector • Class B sterilization apparatus according to EN ISO 17665. *Remark: All material used should be cleaned and replaced regularly. Identify material used for each step of the process (initial treatment, cleaning or rinsing).*

	1	**Initial treatment** • Initial treatment • Place used products in a container or a wipe with running water at 20-40 °C and 1.0 % neodisher® Septo Active for 5 to 15 min. Rinse the products with running tap water at 20-40 °C for 1 min. • If there is time before the next step, make sure the device remains moist by placing it in a wet wipe. Do not exceed 1 hour. *Remarks:* *Do not use fixing agents or hot water (> 40 °C), as this causes fixation of residues and can impair successful cleaning.* *Follow instructions and respect the concentrations and immersion times given by the manufacturer (an excessive concentration may cause corrosion or other defects on devices).*
	2	**Preparation before cleaning** If the devices have visible impurities, it is recommended to manually pre-clean by brushing under tap water at 20-40°C for at least 1 min with a soft brush until all impurities have been removed. *Remark: Follow instructions and respect concentrations and immersion times specified by the manufacturer (an excessive concentration may cause corrosion or others defects on devices).*
	3	**Visual inspection** Inspect the used products and discard damaged products (broken, untwisted or abnormally bent).
manual	4	**Cleaning** Insert the products into an ultrasound apparatus beaker. Run ultrasound apparatus for 10-15 min with tap water and 0.5-2.0% neodisher® MediZym. *Remarks: Follow instructions, observe water quality, concentrations and cleaning time specified by the manufacturer of the cleaning solution.*
manual	5	**Rinsing** Rinse the products with purified water according to European Pharmacopoeia at 20-40°C for 1 min. *Remark: It is recommended to use deionized water.*
manual	6	**Drying** Dry the products with compressed air until products are visibly dry.
automatic	4 5 6	**Cleaning/Rinsing/Drying** Place the instruments in the tray of the on the slide-in trolley of the washer/disinfector. Ensure that the cleaning agent and water can reach all area of the instrument's blade. Pre-cleaning: cold tap water, 4 min Run cleaning cycle with 0,5-1,0% neodisher® MediZym at 50°C for 10min Final rinsing with purified water according to European Pharmacopoeia for 3 min Perform drying. *Remarks:* *•Follow instructions and concentrations given by the manufacturer of the detergent solution.* *•Follow the instructions of the washer-disinfector and verify the success criteria after each cycle have been met as stated by the manufacturer.* *•Use only approved washers-disinfectors according to EN ISO 15883, maintained and validated regularly.*
	7	**Visual inspection** Inspect the used products. Re-do steps 4-5-6 if the product is visibly not clean or discard any damaged products.
	8	**Packaging** Place the instruments in a paper-plastic pouch for steam sterilisation in compliance with ISO 11607 and EN 868 standards. *Remarks:* • *Seal the pouches as recommended by of the pouch manufacturer. If a thermo-sealer is used, the process must be validated and the thermo-sealer must be calibrated and qualified.*
	9	**Sterilisation** Sterilize the products with steam vapor The following sterilization cycles can be used: •Apparatus: class B •132°C (269,6°F), 4 min •134°C (273,2°F), 3 min •134°C (273,2°F), 18 min •Minimum drying: 20 min Control the physico-chemical indicators and cycle parameters. We recommend a steam sterilization at 134°C and duration of 18 min for prion inactivation accor-ding to French regulations. *Remarks:* • *When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser's maximum load is not exceeded.* • *Place the pouches in the steam steriliser according to the recommendations given by the steriliser manufacturer.* • *Use only a pre-vacuum air removal steam steriliser that meets the requirements of EN 13060 (class B, small steriliser) and EN 285 (full-size steriliser), with saturated steam.* • *Use only validated sterilizer according to EN ISO 17665, maintained and validated regularly.*
	10	**Storage** Store the products in a dry, clean and dust-free environment at the temperature specified by the paper-plastic pouch by the steam steriliser manufacturer. *Remark: Check the packaging and the medical devices before using them (packaging integrity, no humidity and use-by date). In case of damage, a complete rerun should be performed.*

7. **Storage and transport conditions**

Keep away from sunlight and keep dry.

Keep the initial packaging close until the reprocessing step (§6).

Close immediately the initial packaging after removing an instrument.

8. **Disposal**

After use, instruments must be placed in a secure container, used to collect cutting or sticking instruments (like needles or disposable bistouries) as per good dentistry practices.

9. **Symbols**

SSt	Stainless steel material		Root canal preparation
	Quantity	134°C	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
NON STERILE	Non-sterile		Assortment
	Keep away from sunlight	LOT	Batch code
	Keep dry	MD	Medical device
	Legal manu-facturer		Date of manufacture
	Distributor	REF	Catalogue number
UDI	Unique Device Identifier		Consult instructions for use

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