

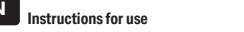


# Endodontic Hand File

K-File, K-Reamer,  
Hedstroem File



MD



EN

Instructions for use

## 1. Indication

The medical devices (K-File, K-Reamer and Hedstroem File, K-reamer) are used for canal treatment, irrigation and root canal filling during a non-surgical endodontic treatment. K-File 008 and 010 are also used in the exploration, initial penetration and root canal permeabilization.

## 2. Contraindications

Apart from children under 2 years of age (ethylene oxide used in the sterilization process), there are no contraindications to the use for endodontically treating a tooth by orthograde route.

## 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

<b>Ø</b>	Maximum recommended number of uses (if the file is not visually damaged)
< 020	2
> 020	5

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

Medical device class according to Directive 93/42/EEC and MDR 2017/745: Is.

Packaging symbol **STERILE|EO** Sterilised using Ethylene Oxide.

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

• For all medical devices, the use of antimicrobial disinfecting agents and cleaning agents is recommended.  
• For own safety, please wear personal protective equipment (gloves, glasses and mask) and avoid contact.  
• Do not use cleaning or disinfecting agents containing phenol, hydrochloric acid and chlorine compounds.

• All instruments for use provided by the manufacturer of the products.

• Due to the product design and the materials used, no performance processing can be specified. The service life of the medical devices is determined by their function and careful handling. Multiple use disinfection and re-sterilization cycles may lead to increased risk of failure.

• The user must ensure that the processing method used, including in-source materials and personnel, is appropriate and meets the applicable requirements.

• The state of the art and national laws require that validation of the process be followed.

• Gloves, mask, gown as recommended by the manufacturer of cleaning agent and detergent  
• Tap or deionized water  
• Disinfectant (ORB-Sept IND REF 262557)  
• Root Canal Cleaner (ORB-Sept TC Thermo Cleaner (REF 303410))  
• Small soft brushes  
• Contaminant  
• Ultrasonic bath or washer-disinfector  
• Ultrasonic sterilization apparatus  
• All material used should be cleaned and replaced regularly. Material used for each step of the process (final treatment, cleaning and rinsing).

Initial treatment  
Place used products in a container or a wipe with tap water at 20-40 °C and 1 % ORB-Sept IND (REF 262557) for 5 to 10 minutes.

• If there is waiting time before the next step, make sure the device stays moist by placing it in a wet wipe. Do not exceed 1 hour waiting time.

• Do not fix fixtures or hot water (> 40 °C), as this causes fixation of residues and can impair successfull sterilization.  
• Follow instructions and respect concentrations and immersion times specified by the manufacturer (an excessive concentration may cause corrosion or other defects on devices).

Preparation before cleaning  
If the devices show 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 are removed. Forming of the Nurzirkon (alle anderen Darmescess) eingesetzt. The K-File 008 and 010 werden durch eine Exploration, einer ersten Penetration und zur Permeabilisierung des Wurzelkanals eingesetzt.

• Preparation before cleaning  
Die Medizinprodukte (K-File, Hedstroem File, K-Reamer) werden im Rahmen einer nicht operativen Endodontie (Kathetertreatment) mit einem Wurzelkanal ausgestattet. Der Katheter wird unter 20-40 °C und 1 % ORB-Sept IND (REF 262557) und 1 % ORB-Sept TC Thermo Cleaner (alle anderen Darmescess) eingesetzt. Die K-File 008 und 010 werden durch eine Exploration, einer ersten Penetration und zur Permeabilisierung des Wurzelkanals eingesetzt.

• Preparation before cleaning  
If the devices show 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 are removed. Forming of the Nurzirkon (alle anderen Darmescess) eingesetzt. The K-File 008 and 010 werden durch eine Exploration, einer ersten Penetration und zur Permeabilisierung des Wurzelkanals eingesetzt.

Nur für den zahnärztlichen Gebrauch.

