

SYMBOLS DESCRIPTION

Full explanation of symbols used on Kerr packaging located at: <http://www.kerndental.com/symbols-glossary>

en - ENGLISH	
TF™, K3™, K3™XF and Quantec™ Endodontic rotary files GENERAL INFORMATION Endodontic rotary files are used for root canal shaping and cleaning during endodontic treatment. Files are offered in either retrofit or as assortment packs.	
PRODUCT COMPOSITION These products contain Brass, Stainless Steel, Nickel-Titanium and a latex-free silicone stopper.	
INDICATIONS FOR USE Rotary files are instruments used for shaping, cleaning and enlarging root canals.	
CONTRAINDICATIONS None known.	
WARNINGS • Rotary files are single use products. Discard after each use. Do not re-use. Risk of cross-contamination and breakage. • Rotary files are non-sterile, single use products and must be cleaned and sterilized prior to use. • These products should not be used for individuals with sensitivity to brass, nickel-titanium, or stainless steel. • Use of a rubber dam is recommended when using these instruments to root canal procedures to avoid accidental aspiration or ingestion. • In canals with severe or sudden apical curvature additional caution should be exercised due to the heightened risk of file separation.	
PRECAUTIONS • This product is intended to be used by qualified dental professionals on a general patient population. • Determining the reference working length with the silicone stopper is imperative to ensure proper instrumentation. • Rotary files are made to be used with a slow speed handpiece. Ensure that the rotary file is securely attached to the handpiece prior to use.	
Do not re-use	
Non Sterile	

Authorized representative in your country

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

STEP-BY-STEP INSTRUCTIONS	
Rotary Files Technique:	
1. Rotate the canal offices using straight line access and obtain patency with hand files.	
2. Begin crown down by taking a coronal shaper to resistance.	
3. Establish working length using hand files, apex locator and radiograph as needed.	
4. Take the first rotary file in the sequence to resistance, repeating as needed for difficult, curved or narrow canals.	
5. Take each instrument to resistance at a torque and speed required for your clinical situation.	
6. Additional Clinical Tips:	
• Irrigate the canal using NaOCl (Sodium hypochlorite), 17% EDTA or a suitable lubricant agent to facilitate debris removal.	
• Use light pressure and avoid force. When the instrument no longer advances apically, proceed to a smaller file.	
• Prior to use, check instruments for defects, including deformation, breakage, fractures, corrosion, handle damage, and loss of color coding or size marking. Discard any product with defects.	
• Use personal protective equipment such as gloves and safety glasses.	
Shaping Technique:	
NOTE: Users of e-motion™ or elements™ motors must preset settings for each appropriate file. Take each instrument to resistance at the torque and speed recommended for your clinical setting.	
1. With the rotary file engaged as you enter the canal, slowly advance the rotary file with a single controlled motion until the file engages dentin, then completely withdraw the rotary file from the canal. Do not force the rotary file apically. Do not peek.	
2. While the flutes, irrigate with NaOCl then coronal patency with #10 F file.	
3. Repeat step 1 using the rotary file you started with until you are not able to passively advance or working length is achieved. Never apply pressure on the rotary file.	
4. Repeat with next rotary file in chosen sequence until final working length and desired shape are achieved.	
NOTE: Techniques suggested are guidelines for the average case. It is imperative that clinical judgment always be exercised, appropriate setting adjustments be made, and additional steps taken to prevent any adverse events. No claims are implemented should be based on individual case requirements.	

ALLIANCE AND STERILIZATION INSTRUCTIONS

NOTE: Rotary files are non-sterile, single use products and must be cleaned and sterilized prior to use.
• The instructions provided in the section "Cleaning and Sterilization Instructions" have been validated by the manufacturer of the medical device and are intended to be used in accordance with the instructions provided.
• Health Care facilities are responsible for calibration of sterilization equipment and training of staff on infection control and sterilization according to the manufacturer's instructions.

Cleaning

- Place use files with silicone tips in an ultrasonic cleaner with room-temperature hospital grade enzymatic solution following all device use as fully submerged. Run the ultrasonic cleaner for a minimum of 10 minutes.
- If any contamination is visible, repeat the cleaning steps until there is no visible contamination.
- Rinse thoroughly for a minimum of 2 minutes with warm, tap water.
- Allow the device to air dry on a clean, disposable lin-free cloth.
- Inspect the files for any signs of damage. Discard files if there are visible signs of deformation, breakage, fractures, corrosion, handle damage, loss of color coding or size marking. Discard any product with defects.

STERILIZATION

- Do not sterilize the Rotary File in a chemical sterilization unit or in a night container.
- Use the Rotary File(s) in the sterilization pouch which is FDA-cleared to ISO 11607 compliant.
- The following most heat sterilization cycles are listed:
 - Gratly Autoclavation: sterilization cycle at 121° (250° F) for 30 minutes followed by 30 minutes of drying time.
 - Gratly Autoclavation: sterilization cycle at 132° (270° F) for 30 minutes followed by 30 minutes of drying time.
- Inspect the pouch for damage and if found, do not use the product as the product's sterilization could be compromised. Repack the product and repeat the sterilization procedure.

STORAGE AND DISPOSAL

After sterilization, place the pouches containing the files in a dry and dark place. Follow pouch manufacturer instructions for storage conditions and maximum storage time. Follow local and national regulatory for disposal.

DISCLAIMER

The instructions provided above have been validated by Kerr Corporation. Any deviation by the dental professional / user from the instructions provided above will be done at your own risk. Kerr Corporation will not be able to address any requests for refund or exchanges under guarantee of any products that have not been handled or reprocessed in accordance with the above instructions.

ENDODONTIC ROTARY FILES

TF™, K3™, K3™XF and Quantec™

Instructions for Use

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