

NITI Heat Activation

D-SUPER FILES

DENTAL ROOT CANAL INSTRUMENTS



GENERAL INFORMATION: Super rotary files are used for root canal shaping and cleaning during endodontic treatment. Files are offered in either refill or assortment packs.

PRODUCT COMPOSITION: These products contain Brass, Nickel-Titanium and a latex-free silicone stopper.

INDICATIONS FOR USE: The rotary files are instruments used for shaping, cleaning and enlarging root canals.

CONTRAINDICATIONS: Not Applicable

WARNINGS:

1. D-SUPER FILES is a single-use product. Discard after use. Do not re-use. Risk of cross-contamination and breakage.
2. Rotary file is a non-sterile, single use product and must be cleaned and sterilized prior to use.
3. These products should not be used for individuals with sensitivity to brass, nickel or titanium.
4. Use of a rubber dam is recommended when using these instruments for root canal procedures to avoid accidental aspiration or ingestion.
5. In canals with severe or sudden apical curvature additional caution should be exercised due to the heightened risk of file separation.

PRECAUTIONS:

- Rotary file is intended to be used by qualified dental professionals on a general patient population.
- Determining the reference working length with the Endo Stop is imperative to ensure proper instrumentation.
 - Ensure that the rotary file is securely attached to the handpiece prior to use. Refer to the label on the product box for torque and speed recommendations.

ADVERSE EVENTS:

If a medical adverse event occurs, report it to the manufacturer and to the competent authority for that country.

STEP-BY-STEP INSTRUCTIONS

Rotary Files Technique:

1. Locate the canal orifices using straight line access and obtain patency with hand files.
2. Establish working length using hand files, apex locator and radiograph as needed.
3. Establish the glide path using hand files or rotary glide path files.
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 the torque and speed recommended on the label for no longer than 5–7 seconds. The order of using files are K-file #10 or 15, followed by SX and SI for enlargement, hand file of size #15 to probe the working length, followed by S1, S2, F1, F2, F3 to the working length.

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:

1. Use settings for your handpiece according to the label.
2. With the rotary file rotating 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 peck.

3. Wipe the flutes. Irrigate with NaOCl then confirm patency with #10 K-File.
4. Repeat step 2 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.
5. Repeat with next rotary file in the chosen sequence until the 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 are made, and additional care is taken to prevent any adverse events. All measures implemented should be based on individual case requirements.

CLEANING 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 as being capable of preparing a medical device for use.
- Health Care facilities are responsible for calibration of sterilization equipment and training of staff on infection control and sterilization according to the manufacturers' instructions.

Cleaning:

1. Place Rotary Files with silicone stops in an ultrasonic cleaner with room-temperature hospital grade enzymatic solution making sure all devices are fully submerged. Run the ultrasonic cleaner for a minimum of 10 minutes.
2. If any contamination is visible, repeat the cleaning steps until there is no visible contamination.
3. Rinse thoroughly for a minimum of 2 minutes with warm, tap water.
4. Allow the devices to air dry on a clean, disposable lint-free cloth.
5. 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:

Caution: Avoid sterilizing of rotary files in chemical sterilization units to prevent potential corrosion.

- Place the Rotary File(s) in a sterilization pouch which is ISO 11607 compliant.
 - The following moist heat sterilization cycles can be used:
 - Gravity Displacement sterilization cycle at 121 °C (250 °F) for 30 minutes followed by 30 minutes of drying time.
 - Pre-Vacuum sterilization cycle 134 °C (273 °F) for 4 minutes, followed by 20 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. Re-pack 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 regulations for disposal.