

# ZenFlex™

## Rotary Files

### Instructions for Use

**Kerr Corporation**  
1717 West Collins Ave.  
Orange, CA 92667 USA  
1-800-KERR-123 | kerrdental.com

077-0645 Rev01  
2020-10



### SYMBOLS DESCRIPTION

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

	Caution
	Batch code
	Manufacturer
	Date of manufacture
	Catalogue number
	Consult instructions for use
	Do not re-use
	Non-sterile
	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Gravity Displacement Sterilizable in a steam sterilizer (autoclave) at 121 °C (250 °F).
	Pre-Vacuum Sterilizable in a steam sterilizer (autoclave) at 132 °C (270 °F).
	Ultrasonic bath

### GENERAL INFORMATION

ZenFlex™ rotary files are used for root canal shaping and cleaning during endodontic treatment. Files are offered in either refill or assortment packs of 20, 25, 30, 35, 40, and 45 tips. Additional refills are available in 50 and 55 tips.

### PRODUCT COMPOSITION

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

### INDICATIONS FOR USE

ZenFlex™ rotary files are instruments used for shaping, cleaning and enlarging root canals.

### CONTRAINDICATIONS

None known.

### WARNINGS

- ZenFlex™ is a single use product. Discard after use. Do not re-use. Risk of cross-contamination and breakage.
- ZenFlex™ is non-sterile, single use product and must be cleaned and sterilized prior to use.
- These products should not be used for individuals with sensitivity to brass, nickel

or titanium.

- Use of a rubber dam is recommended when using these instruments for 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

- ZenFlex™ 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.
- ZenFlex™ is made to be used with an 8:1 Endodontic handpiece. Ensure that the rotary file is securely attached to the handpiece prior to use. Refer to Table 1 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

- Locate the canal orifices using straight line access and obtain patency with hand files.
- Establish working length using hand files, apex locator and radiograph as needed.
- Establish the glide path using hand files or rotary glide path files.
- Take the first rotary file in the sequence (20 tip) to resistance, repeating as needed for difficult, curved or narrow canals.
- Take each instrument to resistance at the torque and speed recommended in the Table 1. for no longer than 5-7 seconds.
- 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

- Use settings for your handpiece according to Table 1. below.
- 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.
- Wipe the flutes. Irrigate with NaOCl then confirm patency with #10 K-File.
- 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.
- 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 are made, and additional care is taken to prevent any adverse events. All measures implemented should be based on individual case requirements.

**TABLE 1. TORQUE AND SPEED RECOMMENDATIONS FOR ZENFLEX™**

File Type	Speed (RPM)	Torque (g-cm)	Torque (N-cm)
ZenFlex 04 taper, 20 & 25 tip	500	100	1.00
ZenFlex 04 taper, 30, 35, 40, 45, 50 & 55 tip	500	300	2.94
ZenFlex 06 taper, 20 & 25 tip	500	200	1.96
ZenFlex 06 taper, 30, 35, 40, 45, 50 & 55 tip	500	350	3.43

### 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**

**Note:** Do not sterilize the Rotary Files in a chemical sterilization unit as it might corrode.

- Place the Rotary File(s) in a sterilization pouch which is FDA-cleared or 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 132 °C (270 °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.

### **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.