

## Brasseler USA ESR™ EndoSequence® Reciprocating File

ESR™ EndoSequence® Reciprocating Files are available in sterile blister packs with various ISO tip sizes and working lengths. The devices are for single patient use only.

### Intended Use

ESR™ EndoSequence® Reciprocating Files fit into a reciprocating dental handpiece allowing the user to perform root canal debridement.

### Warnings

Warning: Attention should be paid to the speed of work (RPM) and range of motion

-  RPM range (300-350 RPMs). Use of the file beyond the RPM range may cause the file to break and result in patient or user harm. Operating an ESR File with too high of an RPM may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- The instruments perform best within the following reciprocating range of motion (150CCW-30CW to 170CCW-50CW). Operating the ESR File outside of these ranges could cause insufficient cleaning of the root canal and result in procedural delays.

- Failure to follow these instructions may cause the following: apex perforation, insufficient cleaning of the root canal, preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the file.
- The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
-  ESR™ EndoSequence® Reciprocating Files are for single patient use only. Use on more than one patient may cause file failure or infection/cross-contamination.
- Irrigation with ultrasonics is recommended. Inadequate use of irrigation may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Always clean the ESR File after every three (3) engagements. Failure to clean the file may cause the file to break or unwind causing patient or user harm or may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Use a rubber dental dam while using ESR Files to avoid possible aspiration or swallowing of the file.
- Do not apply excessive pressure on the ESR Files as this could cause undesirable heat or may cause the file to fail and cause patient or user injury.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause patient or user injury.
- Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.

### Contraindications

-  ESR™ EndoSequence® Reciprocating Files contain nickel and should not be used for individuals with known allergic sensitivity to this metal as it may cause hypersensitivity.

### Precautions

-  Do not use if the package is damaged. ESR Files may become damaged or contaminated if the packaging is compromised.
- Use on more than three canals (single patient) may cause the ESR File to break or unwind and cause patient or user injury.

- Do not use ESR Files that are worn-out, dull or that exhibit “unwinding” as this could cause undesirable heat or may cause the file to fail.
- Move the ESR File continuously when in use to avoid localized heating and/or damage to the file. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to patient discomfort, injury of the patient or user, aspiration or swallowing of the ESR File or damage to the preparation site due to vibration of a worn chuck or turbine.
- Ensure the ESR File is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the file to “walk out” of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the file.
- Never force an ESR File into a handpiece as this could cause damage to the handpiece collet.
- Eye protection must be worn to protect against eject particles.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated.

### General Instructions

- ESR™ EndoSequence® Reciprocating Files are used in a reciprocating motion at 300-350 RPM. The instruments perform best within the following reciprocating range of motion (150CCW-30CW to 170CCW-50CW). As with all reciprocating files it is important to frequently irrigate and clear the cutting flutes during clinical use. For maximum safety the ESR Files should be used in a Crown Down\* manner using the Rhythm Motion \*\*.

Note: Regardless of the canal size, the preparation is complete when working length is reached with resistance and the cutting flutes are clear of pulp and contain clean dentin shavings.

### Shaping and Cleaning

#### Standard canals:

1. Following straight line access and the removal of coronal pulp, use a #10 hand file to establish preliminary canal patency based on the Estimated Working Length (EWL.)
2. Use the ESR #25 Primary File with 1 Rhythm Motion to remove some coronal and mid-root dentin.
3. Establish Working Length (WL) with a hand file or Scout File.
4. Use the ESR #25 Primary File with 1-2 Rhythm Motions until WL is achieved.
5. Fill with matching ESR BC Points and BC Sealer using Hydraulic Condensation or your desired obturation technique (applies to all canal sizes).

#### Large canals:

- After Step 4, if additional debris remains in the canal or wider shaping is required, use the ESR #35 Medium File and/or ESR #45 Large File(s) with the same motion, until all debris is removed. If still wider diameters are present consider using the XP-3D Finisher™ to reach larger diameters without removing dentin.

#### Small canals:

- After Step 3, use the ESR #25 Primary File for 2 gentle Rhythm Motions making sure not to push on the file.

Note: In tight canals WL should not be reached with the initial 2 Rhythm Motions of the #25.

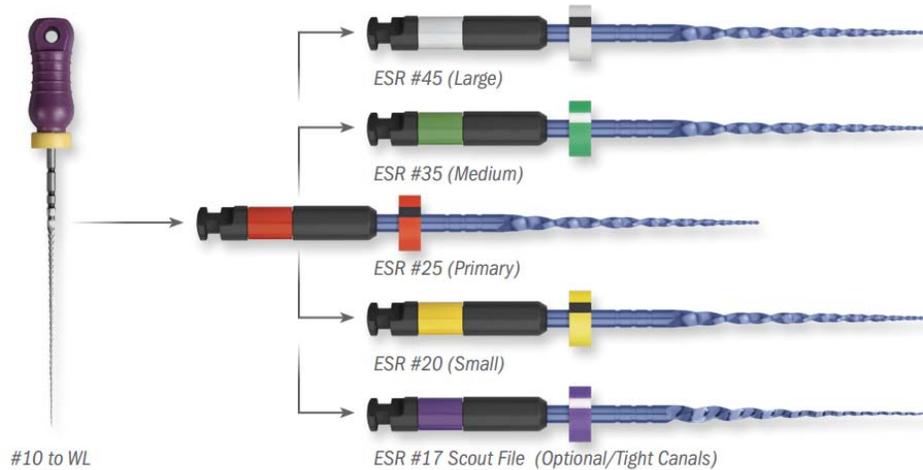
- Next use the ESR #20 Small File with 2 gentle Rhythm Motions or until WL is reached with resistance. If the flutes of the #20 file still contain pulp tissue finish the preparation to #25.

Note: The ESR #17 Scout File may be incorporated into the crown down technique and/or used after initial patency is established with a #10 K-File.

*\*Crown Down protocol involves using the larger file in a series followed by the smaller files in descending sequence of use while monitoring the files movement towards the working length.*

*\*\*Each Rhythm Motion (RM) consists of three, light strokes to engagement, followed by removing the file completely and cleaning the debris out of the file flutes. The canal is then irrigated thoroughly with EDTA prior to the start of the next Rhythm Motion.*

RM = 3 strokes+wipe+irrigate



### Obturation

Obturate the canals using BC Sealer™ and the corresponding ESR Series BC Point™.

- Select the ESR Series BC Point that matches the last rotary file taken to working length.
- Deliver BC Sealer throughout the canal using a small file.
- Coat the selected ESR Series BC Point with BC Sealer and slowly seat the BC Point to full working length.

SYMBOL	MEANING (STANDARD, IF APPLICABLE)
	Manufacturer/Legal Manufacturer (ISO 15223-1)
<b>REF</b>	Catalogue Number (ISO 15223-1)
<b>LOT</b>	Batch Code (ISO 15223-1)
<b>QTY</b>	Quantity (N/A)
	Use-by date (ISO 15223-1)
	Do not re-use (ISO 15223-1)
	Do not use if package is damaged (ISO 15223-1)
	Consult instructions for use (ISO 15223-1)
	Caution (ISO 15223-1)
<b>STERILE R</b>	Sterile using irradiation (ISO 15223-1)
<b>Rx Only</b>	Caution: Federal law restricts this device to sale by or on the order of a "dentist/physician" licensed by the law of the State in which he/she practices to use or order the use of the device. (FDA 21 CFR <sup>1</sup> Part 801.109 (b)(1))
	Revolution (RPM) (ISO 21531)
	Material Symbol (ISO 21531)


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