For more information visit
www.BrasselerUSA.com

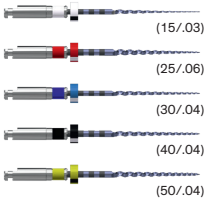
BRASSELER USA®
One Brasseler Blvd, Savannah, Georgia 31419

EndoSequence Reciprocating CM Files Instructions for Use

REF. - 99.7AA.10.22A.EN - n°301 - 2020/06

EndoSequence Reciprocating CM Files

Description



ISO diameter (1) identification



Depth marks ▲ (in millimetres)
Available on 21 / 25 / 31 mm instruments

Example on 25 / 31 mm instruments



General Instructions

ESRCM instruments must only be used in reciprocating (counterclockwise) mode.

Intended Use

ESRCM endodontic instruments are intended for use in medical or hospital facilities, by qualified health professionals.

ESRCM Scout instrument is designed for glide path of root canals in reciprocating mode.

ESRCM #25/#30/#40/#50 instruments are designed for shaping and cleaning root canals in reciprocating mode.

STERILE R

Notice and precautions

- Take several radiographs from different angles to determine the anatomy of the root canals (length, width and curvature).
- Irrigate the canal thoroughly and frequently after the ESRCM Scout instrument or ESRCM single-file shaping instrument is extracted.
- If the ESRCM Scout or an ESRCM single-file shaping instrument is not progressing easily, remove it from the canal, clean it, inspect its cutting edges, then irrigate the canal and recapitulate with an ISO 010 hand file.
- Single use instruments must not be retreated for subsequent use. This could compromise their integrity.
- Always inspect the instrument(s) before use, and discard (it) them if there are any visible defect(s).
- When an instrument reaches the end of its life, please dispose of it in accordance with the applicable laws and regulations.

Instructions for Use

1. Create straight-line coronal and radicular access.
2. Use an ISO 010 hand file to explore the canal.
3. Determine the working length using a radiograph and/or an apex locator.
4. Use the mechanised **ESRCM Scout** instrument, applying gentle strokes of 2-3 mm to establish a glide path until the working length is reached. After 3 strokes, remove and clean the instrument, then irrigate; recapitulate with an ISO 010 hand file.
5. Select the ESRCM single-file shaping instrument which is best suited to the anatomy of the canal being treated. In most cases, and depending on your approach to apical preparation, the **ESRCM #25** or **ESRCM #30** will be appropriate. *If the radiographs do not allow you to clearly identify the anatomy of the canal, it can be gauged using hand files.*
6. Start the shaping procedure, applying your usual irrigation/disinfection protocol.
7. Use gentle strokes of 2-3 mm, applying very light apical pressure and allowing the ESRCM single-file shaping instrument to progress passively along the canal. After 3 strokes, remove and clean the instrument, then irrigate; recapitulate with an ISO 010 hand file.
8. Repeat the previous step until the ESRCM instrument has reached its working length. *If necessary, a brushing motion may be applied to remove coronal interferences and/or ensure uniform shaping of irregular canals.* Once the working length has been reached, remove the instrument to prevent over-enlargement of the foramen.

Once all the canals have been shaped, proceed with the cleaning of the canals. *For an optimal result, the use of XP-3D Finisher is recommended.*

Once the cleaning of the canals is completed, proceed to the next phase of treatment:

9. Obturate with gutta-percha and sealer. *EndoSequence BC points and EndoSequence BC sealer are recommended.*

Made in CH

Warnings

EndoSequence Reciprocating CM Files are intended for single use only, e.g. 1 tooth (up to 1 molar). *The reuse of instruments labeled as single use increase the risks of breakage and cross contaminations.*

- Do not soak nickel-titanium instruments more than 5 minutes in a solution of NaOCl at more than 5%.
- Hydrogen peroxide (H2O2) degrades the instruments.
- Operating an Endodontic File with too high of an RPM may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, and patient burns.
- 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.
- 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 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 Endodontic Files to avoid possible aspiration or swallowing of the file.
- Do not apply excessive pressure on the Endodontic 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.
- Do not use Endodontic Files that are worn-out, dull or that exhibit “unwinding” as this could cause undesirable heat or may cause the file to fail.
- 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 Endodontic File, or damage to the preparation site due to vibration of a worn chuck or turbine.
- Ensure the Endodontic 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 Endodontic File.
- Never force a file into a handpiece as this could cause damage to the handpiece collet.
- Eye protection must be worn to protect against ejected particles.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated.
- This product contains nickel, a chemical known in the state of California to cause cancer, birth defects or other reproductive harm.

SYMBOL	MEANING	SYMBOL	MEANING
	Reciprocating motion (counterclockwise)		Do not use if package is damaged
REF	Catalogue Number		Consult instructions for use
LOT	Lot Number	NiTi	Nickel Titanium
QTY	Quantity in the package		Warning
STERILE R	Sterilized by irradiation	Rx Only	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
	Expiry date		
	Do not re-use (max. 4 canals)		

Contraindications

This product contains nickel and should not be used for individuals with known allergic sensitivity to this metal.

Precautions

Sterile products - Use

1. Open the individual blister pack.
2. Extract the instrument (use of gloves imperative) and attach it to the contra-angle.
3. Use the instrument according to the protocol on front page.

4. Always check expiry date.

5. If file sterility is compromised prior to use, please clean and sterilize according to the following protocol:

1. Pre-disinfection or decontamination
- Immerse the instruments as soon as possible after use in a disinfectant solution.
- Thoroughly rinse instruments in water after disinfection.

2. Manual cleaning & disinfection
- Soak all instruments in a disinfectant/detergent solution and, if appropriate, use an ultrasonic washing device.

(Remove the silicone stops if necessary).

3. Rinsing & drying

Rinse the instruments thoroughly with clean water and dry them.

4. Inspection
- Check the status of instruments and eliminate those with defects.
- If the instruments are still dirty, clean them again.
- If necessary, reassemble the instruments (Mount silicone stops).

5. Packaging
- Place the instruments in «bags for sterilization», as soon as possible after cleaning.

6. Sterilization*

Sterilize with steam at 134°C (273°F) / 2,1 bars / 18 min. for endodontic instruments and filling.
- Check the success of the sterilization cycle (cycle parameters consistent with the data validation).
- Use a physicochemical indicator for each sterilization cycle.

***Precautions:**
- The methods of sterilization via chemiclave and hot air have not been validated.
- REPROCESSING LIMITS: A process of repeated sterilization has little effect on the instruments. The lifetime of the instruments is determined by wear and damage after use.

BRASSELER USA®

Distributed by
Brasseler U.S.A Dental, LLC
One Brasseler Blvd
Savannah, GA 31419 USA