

# paradigm™

## Rotary & Reciprocating Endodontic Files, Rx Only

### INTENDED USE

The Paradigm endodontic files are intended for the removal of pulp/dentin and shaping of the root canal. Devices are intended to be used by trained endodontists and dentists.

### CONTRAINDICATIONS

This device should not be used in cases with severe and sudden apical curvatures due to increased risk of separation.

### ⚠️ WARNINGS

Files are non-sterile and must be sterilized before use. Files contain nickel and should not be used by those with known allergic sensitivities. Do not use if packaging is damaged.

### PRECAUTIONS

Caution must be taken with any mechanically driven endodontic system. Paradigm™ files are designed to be used as specified in rotary or reciprocating methods using a torque-controlled motor. Recommended operating parameters are given in **Error! Reference source not found..** Straight-line access is vital for proper endodontic treatment with Paradigm endodontic files. Frequent cleaning of the file flutes is recommended during use. Minimal apical pressure is recommended. Endodontic files are single-use only, consult this document in its entirety prior to use.

Table 1: File Specifications & Operating Parameters

	Size	Length (mm)	Tip Size (mm)	Torque (g-cm)	Speed (RPM)
paradigm BX™ (Rotary)	AX	19	018	500	300
	A1	25	017	500	300
	A2	25	018	150	300
	M1	25	020	150	300
	M2	25	025	300	300
	M3	25	030	300	300
paradigm QUANTUM™ (Reciprocating)	M4	25	040	300	300
	M5	25	045	300	300
	SM	25	020	200-300	350
	PR	25	025	200-300	350
	MD	25	035	200-300	350
	LG	25	045	200-300	350

### INSTRUCTIONS FOR USE

The Paradigm endodontic files are single-use devices. The following steps should be taken by a healthcare professional:

#### 1. STERILIZATION

Files must be sterilized prior to use. ANSI/ADA Specification 28 recommends the following:

- Scrub files with soap and warm water.
- Rinse thoroughly with distilled or deionized water.
- Allow to air dry.
- Place files, unwrapped, in the autoclave tray.
- Use fresh distilled water or deionized water.
- Steam Autoclave at 276.8°F (136°C) (plus or minus 3.6°F (2°C)) for 20 minutes.

#### 2. OPERATION






paradigm BX™	paradigm QUANTUM™
<ul style="list-style-type: none"> <li>- Create straight-line access.</li> <li>- Lubrication using a viscous chelator is important throughout the procedure.</li> <li>- Establish a glidepath to working length using #10 and #15 hand files.</li> <li>- Confirm patency and verify the presence of a glide path in the apical 1/3</li> <li>- Shape and finish the canal using the crown-down technique using a progression of available sizes to their respective working lengths, recapitulating with hand files as needed.</li> <li>- Disinfect and obturate canals.</li> </ul>	<ul style="list-style-type: none"> <li>- Create straight-line access.</li> <li>- Lubrication using a viscous chelator is important throughout the procedure.</li> <li>- Establish a glidepath to working length using #10 hand files.</li> <li>- Set range of motion to 150CCW-30CW to 170CCW-50CW.</li> <li>- Shape the canal with the Primary size using a gentle inward pecking motion (2-3mm strokes) and a partial reciprocating motor, recapitulating with hand files as needed.</li> <li>- Confirm patency and verify the presence of a glide path</li> <li>- Advance the Primary size file to working length. If the file does not progress, use the Small size. If the apical flutes are not loaded with debris, increase size to Medium or Large</li> <li>- Disinfect and obturate canals.</li> </ul>

#### 3. DISPOSAL

Dispose of file after single-use. It is recommended to dispose of used files in a Biohazard Sharps container.



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SYMBOL	EN
	Single-use only.
	Consult instructions for use or consult electronic instructions for use.
	Do not use if package is damaged.
	Sterilize before use. Non-sterile product. Autoclave before use at 273.2°F (134°C) for 20 min.
	Manufacturer.