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STERILIZE BEFORE USE    Single Use Only    Rx Only    For Dental Use Only

### Indications for Use:

For the removal of dentin and shaping of the root canal.

### Contraindications:

None known.

### Warnings:

Rotary files are non-sterile products and must be sterilized before use.

### Precautions:

As with all new products, you must exercise caution until you become proficient in its use. While we have implemented safeguards against possible misuse, there are several important points to remember:

1. A slow-speed handpiece is required for rotary file use.
2. Operate the handpiece at 500 RPM (Revolutions per minute).
3. Straight-line access is a prerequisite for proper endodontic treatment, Profile® Vortex® files are no exception.
4. Always utilize minimal apical pressure. Don't force the files down the canal.
5. Clean the flutes frequently during instrumentation (after the file is removed from the canal).
6. Frequently irrigate and lubricate the canal throughout the procedure.
7. To promote the mechanical preparation objectives, take any Profile Vortex instrument to length only one time and for no more than one second.
8. Exercise caution in the apical area and around significant curvatures.
9. Rotary files are single patient use devices.
10. When instrumenting the canal, select appropriately sized instruments as choosing an overly large file can lead to dangerous over-enlargement of the coronal portion of narrow root forms. Additionally, too large a file taken to length increases the risk of file separation.

### Adverse Reactions:

None known.

## Step-By-Step Instructions

### Sterilization

Files must be sterilized before use. ANSI/ADA Specification 28 recommends:

- Scrub the instruments with soap and warm water.
- Rinse thoroughly with distilled or deionized water.
- Allow to air dry.
- Place the instruments, unwrapped, in the autoclave tray.
- Use fresh distilled or deionized water.
- Steam Autoclave at 136° C (plus or minus 2° C) for 20 minutes.
- Profile Vortex rotary files are single patient use instruments.
- Recommended File Disposal: Place used files in a Biohazard Sharps container.

### Create Straight-Line Access

Establish working length and create a glide path for Profile® Vortex® rotary files to follow:

- Negotiate all root canals to their terminus with stainless steel Lexicon® K-files, in the presence of ProLube® root canal conditioner.
- Establish patency by taking a #10 K-File past the canal terminus, and at least a #15 K-File to the terminus.

### Shape Canal— Crown Down

Initiate Crown Down cleaning and shaping technique

- In small canals (mesials/buccals of molars, small premolars and lower anteriors) start with a 30/.04 rotary file. Take 30/.04 to resistance or working length (whichever occurs first). If resistance is encountered before working length is obtained, go to next smaller instrument following the same protocol until working length is achieved. Between each rotary file recapitulate with a #10 or #15 tip hand file to maintain glide path and help irrigate (NaOCl) to the canal terminus.
- In larger canals (palatal/distals of molars, larger premolars, upper anteriors) begin with a 40/.04 rotary file. Use the crown down technique to resistance or working length. If resistance is encountered before working length is achieved, move on to smaller sized instruments until working length is achieved. Between instruments, recapitulate with small hand instrument to maintain a glide path to working length.

	FILE SIZE	SPEED (rpm)	TORQUE (g-cm)
Profile Vortex .04	15/.04 & 20/.04	500	75
	25/.04 & 30/.04	500	104
	35/.04 & 40/.04; 45/.04 & 50/.04	500	132
Profile Vortex .06	15/.06 & 20/.06	500	195
	25/.06 & 30/.06	500	290
	35/.06 & 40/.06; 45/.06 & 50/.06	500	368

See motor and contra-angle requirements per motor manufacturer specifications.

### Obturation of Canal Systems

- When using centrally condensed warm gutta percha techniques such as Vortex® Obturators, rely on size verifiers to determine proper fit and length control of filling materials.