Vortex Blue® Rotary Files

US

RX ONLY
FOR DENTAL USE ONLY

DIRECTIONS FOR USE
STERILE ENDODONTIC ROTARY FILES

1) INDICATIONS FOR USE
For the removal of dentin and shaping of the root canal.

2) CONTRAINDICATIONS
None known.

3) WARNINGS
- Rotary files contain nickel and should not be used for individuals with known allergic sensitivity to this metal.
- It is highly recommended to use a rubber dam system during the endodontic procedure.

Vortex Blue® files are provided sterile and cannot be reused. Re-use would increase the risk of cross contamination or breakage.

4) PRECAUTIONS
As with all new products, you must exercise caution until you become proficient in its use. Length determination is imperative to ensure proper instrumentation using any rotary or hand instrument. The use of radiographs and an apex locator are two acceptable methods of length determination. These instruments are to be used only in a clinical or hospital environment by qualified users following good dental practice (using gloves, glasses and a dental dam etc.). 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 hand piece at a speed of 500 RPM (Revolutions Per Minute).
3) Straight-line access is a prerequisite for proper root canal treatment, Vortex Blue® files are no exception.
4) Always use minimal apical pressure. Never force the files down the canal.
5) Clean the flutes frequently during instrumentation, inspecting for signs of distortion or wear, such as uneven flutes, dull spots.
6) Frequently irrigate, recapitulate and re-irrigate the canal throughout the procedure, minimally after using each file.
7) To promote the mechanical preparation objectives, take any Vortex Blue® 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) 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.

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

5) ADVERSE REACTIONS

None known.

6) STEP BY STEP INSTRUCTIONS FOR Vortex Blue® Files

Vortex Blue® rotary files are single patient use instruments.

Recommended File Disposal: Place used files in a Biohazard Sharps container.

6.1 CREATE STRAIGHT-LINE ACCESS

Establish working length and create a glide path for Vortex Blue® 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.

6.2 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 a small hand instrument to maintain a glide path to working length.
- In the coronal portion of moderate to mild curvatures, you can utilize an .06 taper instrument.
- Past the mid root in moderate to severe curvature .04 taper Vortex Blue® files are recommended.

6.3 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.
- A Vortex obturator the same tip/taper as the size verifier taken to working length can be used to obturate the canal.

7) CLEANING, DISINFECTION AND STERILIZATION

- Not applicable; the Vortex Blue® files are provided sterile and intended for Single Use only.
- Disinfection, cleaning and sterilization procedures are not recommended.
- Re-use of Vortex Blue® files can increase the risk of cross contamination and breakage.

Symbols	EN
	Do not re-use
	Expiry date
	Manufacturer date
	Batch number
	dentsplysirona.com Electronic instructions for use
	Sterilized using irradiation
	Do not use if package is damaged
	Opened packages are not replaced
	500 min. $^{-1}$ Speed of rotation

Manufactured for:

DENTSPLY Tulsa Dental Specialties
DENTSPLY International Inc.
608 Rolling Hills Dr.
Johnson City, TN 37604
Phone: 1.800.662.1202
Fax: 1.800.597.2779
dentsplysirona.com
Made in USA