



Instructions for Use

Relieva Vortex™

Sinus Irrigation Catheter

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

STERILE: The *Relieva Vortex* Sinus Irrigation Catheter is sterilized with ethylene oxide gas.

STORAGE: Store in a cool, dry place.

DESCRIPTION

The *Relieva Vortex* Sinus Irrigation Catheter (figure 1) has both forward and side-facing distal openings to facilitate irrigation delivery and a radiopaque marker band to aid in placement.

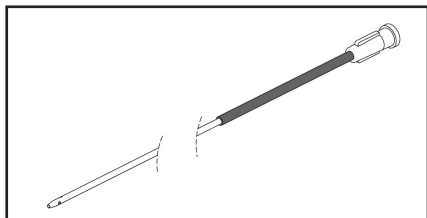


Figure 1

INDICATIONS FOR USE

The *Relieva Vortex* Sinus Irrigation Catheter is intended to provide a means to irrigate from within a target sinus for diagnostic and therapeutic procedures.

CONTRAINDICATIONS

Not for use during any other procedure than indicated.

WARNINGS

- Do not use a device where the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Never advance or retract against unknown resistance, as this could cause tissue trauma or device damage.

COMPATIBILITY

The *Relieva Vortex* Irrigation Catheter is compatible with the *Balloon Sinuplasty™* System *Relieva®* Devices. Please refer to the appropriate Instructions for Use when using with compatible devices.

INSTRUCTIONS FOR USE

1. Remove from packaging and flush Sinus Irrigation Catheter with sterile saline or water.
2. Pass the Sinus Irrigation Catheter over the Sinus Guidewire into the target sinus. Confirm placement with endoscopic and/or fluoroscopic visualization.
3. Remove the Sinus Guidewire from the Sinus Irrigation Catheter.
4. Irrigate and/or suction through the Sinus Irrigation Catheter using standard syringes and suction devices.

Note: Flush the Sinus Irrigation Catheter after use in each sinus to ensure that material does not dry on the inner surface.

GRAPHIC SYMBOLS CONTAINED ON DEVICE LABELING

	Batch Code		On Order of Physician Only
	Sterilized Using Ethylene Oxide		Date of Manufacture
	Use By		Consult Instructions For Use
	Do Not Re-Use		Compatible Sinus Guidewire size
	Maximum Catheter Outer Diameter		Manufactured By
	Keep dry		Maximum Temperature
	Keep Away from Sunlight		0123 CE Mark
	European Authorized Representative		

Product Information Disclosure

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