



Instructions for Use

Relieva Vigor™

Sinus Guidewire

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.

STERILITY: The *Relieva Vigor* Sinus Guidewire is sterilized with ethylene oxide gas.

SINGLE USE: The *Relieva Vigor* Sinus Guidewire is intended for single patient use only. DO NOT resterilize and/or reuse.

STORAGE: Store in a cool, dry place.

DESCRIPTION

The *Relieva Vigor* Sinus Guidewire is a 0.035"- compatible Sinus Guidewire with a pre-shaped radiopaque distal tip and lubricious coating. The *Relieva Vigor* Sinus Guidewire may also have one or more shaft marker bands.

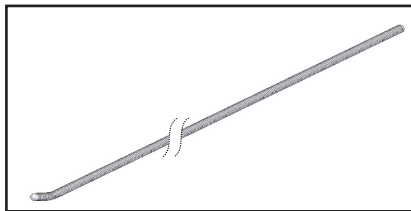


Figure 1

INDICATIONS FOR USE

The *Relieva Vigor* Sinus Guidewire is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

CONTRAINDICATIONS

Not for use during any other procedures 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 a Sinus Guidewire against unknown resistance as this could cause tissue trauma or device damage.

PRECAUTIONS

Do not attempt to alter the pre-shaped distal tip of the *Relieva Vigor* Sinus Guidewire, as this may result in device damage.

COMPATIBILITY

The *Relieva Vigor* Sinus Guidewire is compatible with the *Balloon Sinuplasty™ System Relieva®* devices.

INSTRUCTIONS FOR USE

- Flush the protective hoop with sterile saline or water.
- Remove the *Relieva Vigor* Sinus Guidewire from the protective hoop.

If used in conjunction with a Sinus Guide Catheter:

- Insert the *Relieva Vigor* Sinus Guidewire through the Sinus Guide Catheter and advance into the target sinus until some light resistance is felt. **DO NOT USE EXCESSIVE FORCE.**
- If significant resistance is encountered, retract the *Relieva Vigor* Sinus Guidewire and slightly change the position (rotate in either direction). Again advance the *Relieva Vigor* Sinus Guidewire in a gentle, probing motion.
- Confirm placement and position of the *Relieva Vigor* Sinus Guidewire with endoscopic and/or fluoroscopic visualization.

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		Diameter Compatibility
	Length		Tip Shape
	Keep dry		Maximum Temperature
	Keep Away from Sunlight		0123 CE Mark
	European Authorized Representative		Manufactured By

Product Information Disclosure

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U.S. Patent Nos. 7,500,971 and 7,462,174 and other U.S. and foreign patents pending.