



## **Instructions For Use**

***Relieva Flex™  
Sinus Guide Catheter***

***Relieva®  
Sinus Guide Catheter***

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## 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:** Sterilized with ethylene oxide gas. Do not use if the package is open or damaged.

**STORAGE:** Store in a cool, dry place.

**SINGLE USE:** The sinus guide catheter is intended for single patient use only. Do NOT resterilize and / or reuse, as it may result in compromised device performance or cross contamination as a result of improper sterilization.

## DESCRIPTION

All of the devices in the Relieva® family of sinus guide catheters are delivered in a single use sterile package.

### *Relieva Sinus Guide Catheter*

The *Relieva Sinus Guide Catheter* consists of a distal angled tip, a semi-malleable shaft and a proximal luer hub. A radiopaque marker band is embedded under the blue tip to allow for fluoroscopic visualization. The shaft consists of a steel tube and a lubricious inner liner. The colored band indicates the target sinus and the tip angle. The luer hub allows for flushing of the device before use. The wings of the hub are aligned with the distal angled tip.

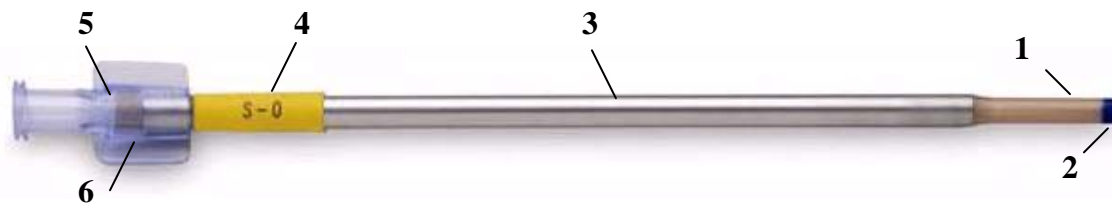


Figure 1: *Relieva Sinus Guide Catheter*

- 1) Distal angled tip
- 2) Radiopaque marker band
- 3) Steel shaft
- 4) Colored band
- 5) Luer hub
- 6) Wings

### *Relieva Flex Sinus Guide Catheter*

The *Relieva Flex Sinus Guide Catheter* incorporates an atraumatic, radiopaque, distal angled tip that is shaped to facilitate access to a targeted sinus. Certain designs incorporate a bevel to aid in sinus access. The distal shaft contains a lubricious inner liner. The suction hub enables the user to maneuver the sinus guide catheter. The hub incorporates a suction control port which allows the user to increase and decrease the amount of suction through the sinus guide catheter. A barb fitting on the hub anchors the suction tube to the hub. The suction tube connects the sinus guide catheter to a vacuum source. The hub contains a coated valve, which seals around a sinus balloon catheter or sinus irrigation catheter to maintain suction. It also maintains the sinus balloon catheter position during wiring by applying a retention force to the shaft of the sinus balloon catheter system.

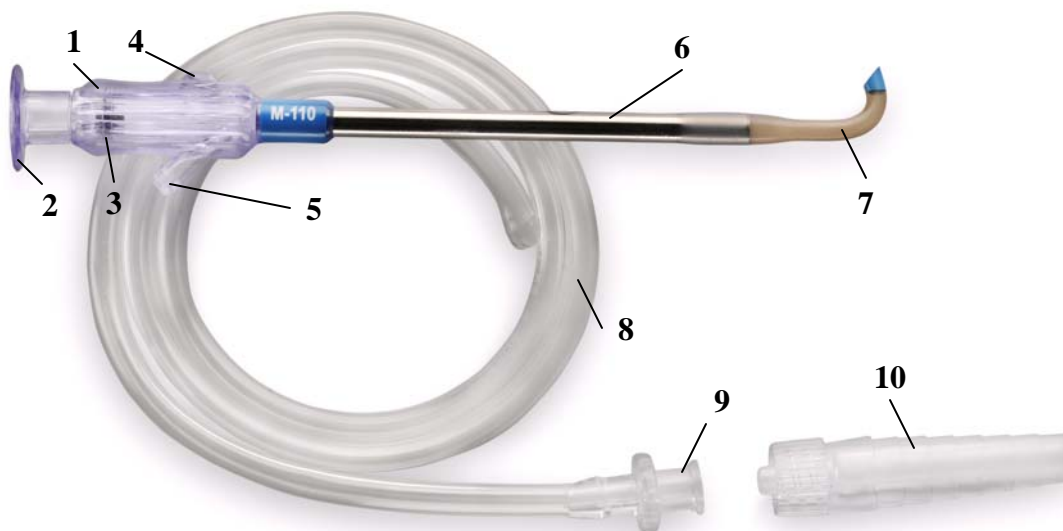


Figure 2: *Relieva Flex Sinus Guide Catheter*

- 1) Suction hub
- 2) Flange
- 3) Coated valve
- 4) Suction control port
- 5) Barb fitting
- 6) Steel shaft
- 7) Distal tip
- 8) Suction tube
- 9) Suction tube luer
- 10) Suction tube connector

## INDICATIONS FOR USE

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

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

## CONTRAINDICATIONS

Not for use during any other procedure than indicated.

## WARNINGS

- Intended for single patient use only. **DO NOT REUSE.**
- Only physicians meeting the *Balloon Sinuplasty™* system qualifications may use these products.
- Do not use a sinus guide catheter if the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Never advance or retract a sinus guide catheter against unknown resistance, as this could cause tissue trauma or device damage.
- Do not try to move a sinus guide catheter while a sinus balloon catheter is inflated.

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## PRECAUTIONS

- When using the *Relieva Flex Sinus Guide Catheter*, do not attempt to bend the non-malleable shaft
- The *Relieva Flex Sinus Guide Catheter* is designed to remove non-viscous fluids from the surgical field such as blood. Attempting to remove viscous material from the surgical field, such as thick mucus, could lead to device clogging.

## COMPATABILITY

Compatible device	<i>Relieva Sinus Guide Catheter</i>	<i>Relieva Flex Sinus Guide Catheter</i>
<i>ReliENT™ Adapter and Calibration Device</i>	Compatible (F-70 GC070 and M-110 GC110 only)	Non-compatible
<i>Relieva Sidekick™ Sinus Guide Catheter Handle</i>	Compatible	Non-compatible
<i>Relieva Sidekick™ Sinus Guide Catheter Handle (Low Profile)</i>	Non-compatible	Compatible

Please refer to appropriate IFUs when using other devices.

## INSTRUCTIONS FOR USE

### 1. Preparation and inspection

- a. Before each use, inspect the device and package.
  - i. Ensure that the sterility of the device has been maintained by examining the package.
  - ii. Ensure that the device has not been damaged during shipping or storage.
- b. Remove the sinus guide catheter from the package.
- c. Sterile suction tubing is pre-attached to the *Relieva Flex Sinus Guide Catheter*. If it will not be used during the procedure, the tube may be disconnected.
- d. Flush the sinus guide catheter by injecting sterile saline or water through the proximal hub.
  - i. Note: Avoid activating suction before flushing the *Relieva Flex Sinus Guide Catheter*. If suction is engaged before flushing the sinus guide catheter, it is possible the suction will prevent the sterile saline or water from entirely flushing the sinus guide catheter.
- e. Wipe the surface of the sinus guide catheter with a sterile saline or water soaked gauze pad.
- f. Should the physician elect to use suction with the *Relieva Flex Sinus Guide Catheter*, connect the suction tube connector to a vacuum source.
- g. Attach *Relieva Sidekick™ Sinus Guide Catheter Handle* if desired.

### 2. Accessing the sinus space











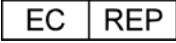




- a. The sinus guide catheter of appropriate angle should be chosen for each targeted sinus.
- b. Under direct visualization, gently position the tip of the sinus guide catheter near the targeted sinus ostium, but without engaging the ostium directly.
- c. Verify the sinus guide catheter tip position by endoscopic or fluoroscopic visualization.
- d. When the sinus guide catheter is in position, stabilize the catheter and introduce other devices into the inner lumen to access the targeted sinus.

### 3. Using suction with the *Relieva Flex Sinus Guide Catheter*

- a. Even with the control port open, the *Relieva Flex Sinus Guide Catheter* will maintain slight suction when the suction tube is connected to a vacuum source.
- b. To increase the amount of suction through the *Relieva Flex Sinus Guide Catheter* with no devices loaded, cover the back of the proximal hub with one finger and the control port with a

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- second finger.
- c. Using suction with only the *Relieva Luma® Sinus Illumination System* or a sinus guidewire loaded:
    - i. Insert the *Relieva Luma Sinus Illumination System* or sinus guidewire into the inner lumen of the *Relieva Flex Sinus Guide Catheter*.
    - ii. To increase the amount of suction through the *Relieva Flex Sinus Guide Catheter* with only the *Relieva Luma Sinus Illumination System* or a sinus guidewire loaded, cover the back of the proximal hub with one finger and the control port with a second finger.
  - d. Using suction with a sinus balloon catheter system pre-loaded:
    - i. Insert the sinus balloon catheter into the inner lumen of the *Relieva Flex Sinus Guide Catheter* and advance the sinus balloon catheter to the distal shaft marker.
    - ii. To increase the amount of suction, cover the control port with one finger.
    - iii. To achieve maximum suction, retract the sinus balloon catheter proximally up to 3mm.
  - e. Clearing the lumen of the *Relieva Flex Sinus Guide Catheter*
    - i. Disconnect the suction tube from the suction source. Unscrew the suction tube connector from the suction tube luer. Flush the *Relieva Flex Sinus Guide Catheter* thoroughly with sterile saline or water through the suction tube luer.
    - ii. If flushing through the suction tube does not clear the blockage, disconnect the suction tube from the barb fitting and flush the *Relieva Flex Sinus Guide Catheter* thoroughly with sterile saline or water through the barb fitting.
    - iii. If necessary, remove all devices from the inner lumen and flush thoroughly with sterile saline or water.
- 4. Advancing *Relieva Solo™ Sinus Balloon Catheter* or *Relieva Solo Pro™ Sinus Balloon Catheter* while using the *Relieva Flex Sinus Guide Catheter***
- a. When ready to advance the *Relieva Solo Sinus Balloon Catheter* or *Relieva Solo Pro Sinus Balloon Catheter* into the desired position, place the index and middle finger under the flange on the *Relieva Flex Sinus Guide Catheter* and the thumb above the *Relieva Solo Sinus Balloon Catheter* or *Relieva Solo Pro Sinus Balloon Catheter* balloon port.
  - b. Using a syringe-like motion, advance *Relieva Solo Sinus Balloon Catheter* or *Relieva Solo Pro Sinus Balloon Catheter* into the desired position.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING

	Sterilized Using Ethylene Oxide		Keep Away from Sunlight
	Batch Code		Do Not Re-Use
	Catalog Number	<b>Rx ONLY</b>	On Order of Physician Only
	Keep dry		Date of Manufacture
	Use By		Consult Instructions For Use
	Upper Limit of Temperature		European Authorized Representative
	Contents of Package/Box		Manufacturer
	Tip Angle		Min Guide Catheter ID

**Product Information Disclosure**

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Patents pending

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