



## **Instructions for Use**

*Relieva Sidekick*<sup>TM</sup>

Sinus Guide Catheter Handle

*Relieva Sidekick*<sup>TM</sup>

Sinus Guide Catheter Handle (Low Profile)

### 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 Sidekick* Sinus Guide Catheter Handle is sterilized with ethylene oxide gas.

**SINGLE USE:** The *Relieva Sidekick* Sinus Guide Catheter Handle is intended for single patient use only. DO NOT resterilize and/or reuse, as it may result in compromised device performance and risk of improper sterilization and cross contamination.

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

**DESCRIPTION:** The *Relieva Sidekick* Sinus Guide Catheter Handle is a device that attaches to the proximal end of the *Relieva*® family of Sinus Guide Catheters or Frontal Deployment Guide ("Guide"). When attached to the Guide, *Relieva Sidekick* creates an extension from which the user can stabilize the position of the Guide. *Relieva Sidekick* is available in 2 models. Both models consist of a malleable handle and a press-fit connector with a flange feature. One model of the device incorporates a bumper (figure 1), while the Low Profile device does not have a bumper. When used in conjunction with a *Relieva Solo*™ or *Relieva Solo Pro*™ Sinus Balloon Catheter and a *Relieva* Sinus Guide Catheter, the *Relieva Sidekick* bumper helps stabilize the position of the Balloon Catheter in the proper wiring position.

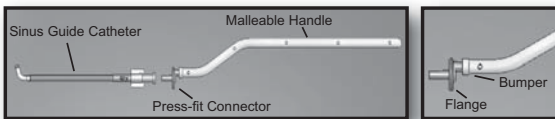


Figure 1

### INDICATIONS FOR USE

The *Relieva Sidekick* Sinus Guide Catheter Handle is intended to create an extension from a Sinus Guide Catheter or Frontal Deployment Guide.

### CONTRAINDICATIONS

None.

### WARNINGS

- Do not use a device where the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Only physicians trained in the use of Balloon Sinuplasty™ technology should use this instrument.

### PRECAUTIONS

- If using the *Relieva Sidekick* with an endoscopic eyepiece only (no camera) take care not to touch the device with the face.

### COMPATIBILITY

Please refer to the appropriate Instructions For Use when using with compatible devices.

Compatible device	Relieva Sidekick™ Sinus Guide Catheter Handle	Relieva Sidekick™ Sinus Guide Catheter Handle (Low Profile)
Relieva Sinus Guide Catheter	Compatible	Non-compatible
Relieva Flex™ Sinus Guide Catheter	Non-compatible	Compatible
Relieva Stratus™ Frontal Deployment Guide	Compatible	Compatible

### INSTRUCTIONS FOR USE

#### 1. General

- Remove the *Relieva Sidekick* from the protective packaging.
- Lightly place the *Relieva Sidekick* fitting into the proximal end of the Guide. Rotate the *Relieva Sidekick* to the desired position relative to the Guide tip.
- Connect the *Relieva Sidekick* to the Guide by firmly pressing the *Relieva Sidekick* fitting into the proximal end of the Guide.
- If desired, bend the *Relieva Sidekick* into the desired shape.

Complete the procedure using compatible instruments following the appropriate Instructions For Use.

#### 2. If using with a *Relieva Solo*™ or *Relieva Solo Pro*™ Sinus Balloon Catheter and a *Relieva* Sinus Guide Catheter:

- When ready to advance the *Relieva Solo* or *Relieva Solo Pro*™ into the desired location, place the index and middle finger under the flange and the thumb above the *Relieva Solo* or *Relieva Solo Pro*™ Balloon Port.
- Using a syringe-like motion, advance *Relieva Solo* or *Relieva Solo Pro*™ into the desired position.

### 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		Upper Limit of Temperature
	Keep dry		Contents of Package/Box
	Keep Away from Sunlight		Manufactured By
	European Authorized Representative		Catalog Number

#### Product Information Disclosure

Acclarent, Inc. has exercised reasonable care in the manufacture of this device. Acclarent, Inc. excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device, as well as factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Acclarent, Inc.'s control, directly affect this device and the results obtained from its use. Acclarent, Inc. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Acclarent, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

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