



Instructions For Use
Balloon Sinuplasty™ System
Relieva™ Devices , ReliENT™ Navigation System, and
OptiLINK™ Extension

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.

PACKAGING

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 *Balloon Sinuplasty™ System Relieva™* devices, the *ReliENT* Navigation System, and *OptiLINK Extension* are intended for single patient use only. Do NOT re-sterilize and / or reuse, as it may result in compromised device performance and risk of improper sterilization and cross contamination.

DESCRIPTION

- *Relieva Sinus Guidewire*
 - is a stainless steel, coated wire with the tip designed to facilitate the location and access of sinus ostia. The *Relieva Sinus Guidewire* is designed in lengths and diameters appropriate for endoscopic surgery.
- *Relieva Sinus Guide Catheter*
 - is an alloy cannula comprised of a semi-flexible tube and a tip engineered to aid in accessing different sinus ostia.
- *ReliENT Adapter and Calibration Device*
 - *ReliENT Adapter*
 - is a customized handle that connects the *Relieva Sinus Guide Catheter* with a receiver for integration with InstaTrak® 3500 Plus navigation systems.
 - *ReliENT Calibration Device*
 - is exclusively designed to calibrate the *Relieva Sinus Guide Catheter's* tip position and trajectory. This device is designed to accommodate specific *Relieva Sinus Guide Catheter* tip shapes.
- *OptiLINK Extension*
 - is a clear, large diameter tube designed to be connected to the proximal end of the *Relieva Sinus Guide Catheter* to extend its overall length.
- *Acclarent Inflation Device*
 - is a high pressure syringe barrel, ergonomic piston handle, and a gauge used to monitor the inflation and deflation of balloon catheters

- *Relieva Sinus Balloon Catheter*

Relieva Sinus Balloon Catheter – Over-the-wire Configuration

- is a sinus remodeling catheter with an integrated shaft system and a high pressure sinus balloon near the distal tip. The shaft is dual lumen tubing. One lumen is used for inflation of the sinus balloon with liquid medium. The second lumen permits the use of a *Relieva Sinus Guidewire* to facilitate advancement of the *Relieva Sinus Balloon Catheter* to the target sinus. The sinus balloon is covered with a coating which enhances the durability of the sinus balloon required for sinus remodeling.
- is a device with several markers. The balloon has radiopaque marker(s) to aid in positioning the sinus balloon in the target sinus. The *Relieva Sinus Balloon Catheter's* proximal shaft has markers which aid in determining the *Relieva Sinus Balloon Catheter* position relative to the entry and exit from the *Relieva Sinus Guide Catheter*.

Relieva Acella™ Sinus Balloon Catheter-- Integrated Guidewire Configuration

- is a sinus remodeling catheter with an integrated guidewire, a single lumen shaft, and a high pressure sinus balloon near the distal tip. The guidewire is designed to facilitate the location and access of sinus ostia. The lumen is used for inflation of the sinus balloon with liquid medium. The sinus balloon is covered with a coating which enhances the durability of the sinus balloon required for sinus remodeling.
- is a device with several markers. The balloon has radiopaque marker(s) to aid in positioning the sinus balloon in the target sinus. The *Acella Sinus Balloon Catheter's* proximal shaft has markers which aid in determining the *Integrated Guidewire Sinus Balloon Catheter* position relative to the entry and exit from the *Relieva Sinus Guide Catheter*. The integrated guidewire has a radiopaque marker in the distal tip to aid in the verification of sinus space access.

- *Relieva Sinus Exchange and Sinus Lavage Catheters*

- are intended to serve as mechanisms for exchanging *Relieva Sinus Guidewires*, irrigation of the sinus or providing additional guidewire support and direction.
- are single lumen, flexible, nylon-blend catheters designed to irrigate, suction or lavage the target sinus. The *Relieva Sinus Exchange Catheter* also facilitates the replacement of a *Relieva Sinus Guidewire*.

INDICATIONS FOR USE

- *Relieva Sinus Guidewire*

- is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

- *Relieva Sinus Guide Catheter*

- is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

- *ReliENT Adapter and Calibration Device*

- are intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

- *OptiLINK Extension*

- is intended to extend the length of the *Relieva Sinus Guide Catheter*.



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- **Acclarent Inflation Device**
 - is an instrument intended to inflate, deflate and monitor pressure in balloon catheters used in sinus procedures and dilation of the airway tree..

- **Relieva Sinus Balloon Catheter Over the Wire Configuration**
 - is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

- **Relieva Acella™ Sinus Balloon Catheter-- Integrated Guidewire Configuration**
 - is an instrument intended to provide a means to access the sinus space and to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

- **Relieva Sinus Lavage Catheter**
 - is a tool intended to lavage a target sinus for diagnostic and therapeutic procedures.

- **Relieva Sinus Exchange Catheter**
 - is a tool intended to provide a means of device exchange or to lavage a target sinus for diagnostic and therapeutic procedures.

CONTRAINDICATIONS

Not for use during any other procedure than indicated.

WARNINGS

- Never advance or retract the devices against resistance as this could cause tissue trauma or device damage.
- Intended for single patient use only. DO NOT REUSE.
- Only physicians meeting the *Balloon Sinuplasty™* system qualification objectives may use these products.
- Do not use a device where the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Deflate the sinus balloon fully before withdrawing from the dilated space.
- Do not try to move the Sinus Balloon Catheter while the sinus balloon is inflated.
- Always inflate the sinus balloon with a Sinus Guidewire inserted through the Sinus Balloon Catheter's guidewire lumen.

Note: Not applicable when using the Integrated Guidewire Configuration.

- Do not exceed the recommended maximum sinus balloon inflation pressure of 16 atmospheres (atm).

Note: Do not exceed the recommended maximum sinus balloon inflation pressure of 14 atmospheres (atm) for the Integrated Guidewire Configuration.

- Use only liquid media for inflation. Do not inflate with air.
- Refer to Warnings & Precautions for GE InstaTrak® 3500 Plus Navigation System prior to use of the *ReliENT* Adapter.

PRECAUTIONS

- Patients who are allergic to contrast medium may not be suitable candidates for use of the *Balloon Sinuplasty™* system.
- Prior to use, ensure the connector tubing of the Inflation Device is free of air.
- Before opening any part of the *Balloon Sinuplasty™* system's sterile package, visually inspect the package to ensure that the seals remain intact, the sterile integrity has not been compromised, and that no damage has occurred during shipping and handling.

Note: If during inspection, it is found that the integrity or sterility of the device(s) is compromised, do not use the device.

- Use of a Sinus Balloon Catheter that is too large for the target sinus may cause damage to the sinus balloon and / or surrounding anatomy. Use of an undersized sinus balloon may result in failure to properly treat the target sinus.
- Only move or withdraw the Sinus Balloon Catheter when the sinus balloon is completely deflated. Advancing or retracting the sinus balloon while it is inflated may cause damage to the mucosa or to the *Relieva* devices that are part of the *Balloon Sinuplasty™* system.



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- Due to the variability of sinus development in pediatric patients and as is standard practice for endoscopic sinus surgery, appropriate radiographic imaging (e.g. CT scan) should be reviewed prior to surgery to assess the development of sinus anatomy and compatibility with the Sinus Balloon Catheter.
- When fluoroscopy is used, especially in children, radiation dose to the lens of the eye and other proliferating tissues should be minimized due to the potential of cataract formation or injury to surrounding mid-facial structures.
- When employing fluoroscopy, Acclarent recommends use of self-limiting radiation exposure equipment. It is the responsibility of the user facility and operator to ensure the equipment is calibrated and maintained per the equipment manufacturer's user manual.
- Techniques for reducing fluoroscopic exposure should be exercised. Examples are applying pulsed beam settings, increasing target-to-panel distance, utilizing posterior-anterior projection, or using appropriate lead shield protection. Total fluoroscopy time, especially in children, should be limited to 30 minutes. The operator should make every effort to adhere to the principle of ALARA—"as low as reasonably achievable" for radiation exposure.
- As with any sinus surgery, the *Balloon Sinuplasty™* System should only be used for treatment of pediatric patients who are not responsive to medical therapy.

INSTRUCTIONS FOR USE

1. General

- When considering use of this product, preparation of the patient, anesthesia, and postoperative care of the patient should be consistent with standard practice. They should only be altered under the discretion of the operating physician.
- Use of endoscopy and / or fluoroscopy is recommended for visualization during sinus balloon dilation.
- If applicable, prior to the procedure, ensure that a fluoroscopic unit is available, tested, and ready for use. Ensure that the facility staff is properly trained and uses radiation protection techniques to work in an environment where fluoroscopy may be used in accordance with federal and local government standards
- Radiographic imaging (e.g. CT scan) should be assessed prior to performing surgery in pediatric patients to confirm sinus anatomy is developed and can be appropriately dilated with the Sinus Balloon Catheter.

2. Preparation of the Acclarent Inflation Device

- a. If planning to use fluoroscopy, prepare a solution of contrast media in a sterile bowl. The contrast should be diluted with sterile saline or water to achieve an iodine concentration equivalent to 150-180 mg/ml.
- b. Prepare the inflation device according to the appropriate IFU.

3. Preparation of the *Relieva* Sinus Balloon Catheter

- a. A Sinus Balloon Catheter of appropriate size should be chosen for each targeted sinus.

Note: Use of a Sinus Balloon Catheter that is too large for the target sinus may cause damage to the sinus balloon and / or surrounding anatomy. Use of an undersized sinus balloon may result in failure to properly treat the target sinus.

- b. Remove the Sinus Balloon Catheter from the sterile package and remove the protective sheath that covers the balloon. Save the sheath for balloon rewrapping.

Note: DO NOT attempt to insert or re-inflate the sinus balloon with the protective sheath in place.

c. Flush the guidewire lumen with sterile saline or water.

Note: Not applicable when using the Integrated Guidewire Configuration

d. Wipe the surface of the Sinus Balloon Catheter's shaft with sterile saline or water soaked gauze pad.

Note: For the Integrated Guidewire Configuration also wipe the exposed surface of the guidewire with sterile saline or water soaked gauze pad.

4. Attachment of the Acclarent Inflation Device to the *Relieva* Sinus Balloon Catheter

a. Connecting the Sinus Balloon Catheter port to the Inflation Device connecting tube:

- i) For the *Relieva* Sinus Balloon Catheter, connect the balloon port (angled lumen / printed with the word "BALLOON") of the Sinus Balloon Catheter to the connecting tube of the Inflation Device.



- ii) For the Integrated Guidewire Configuration, connect the lumen port of the Sinus Balloon Catheter to the connecting tube of the Inflation Device.



b. Inspect the syringe and connecting tube to ensure that the device has been purged of air bubbles.

c. Hand-tighten the connections. Do not over tighten the connections.

5. Removal of Air from the *Relieva* Sinus Balloon Catheter



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- a. With the gauge held in a downward position, unlock the piston handle. Draw the piston handle all the way back and push the lock lever to the right. This will lock the piston handle in the back position and maintain a vacuum within the closed system.
- b. Wait 10 seconds before inflating balloon.

6. Placement of the *Relieva* Sinus Guide Catheter

- a. Choose an appropriate Sinus Guide Catheter for the target sinus.

Note: *Relieva* Sinus Guide Catheter (M-110S [GC110S]) is not compatible with the 7mm diameter *Relieva* Sinus Balloon Catheter. The F-90S (GC090RS) *Relieva Stratus™* Deployment Guide is not compatible with *Relieva* Sinus Balloon Catheters.

- b. Remove the Sinus Guide Catheter from the sterile package.
- c. If using the *OptiLINK™* Extension, remove it from the sterile package. Attach the Sinus Guide Catheter extension to the Sinus Guide Catheter’s luer connector.
- d. Flush the Sinus Guide Catheter and Sinus Guide Extension with sterile saline or water. Wipe the surface with sterile saline or a water-soaked gauze pad.
- e. If using image guidance, refer to the following instructions for preparation of the Sinus Guide Catheter Adapter System

Note: Refer to InstaTrak® 3500 Plus Users Manual for detailed instructions for InstaTrak® 3500 Plus operation, indications, contraindications, warnings and precautions.

Note: Confirm that the InstaTrak® 3500 Plus System is set-up and operational.

<i>Relieva</i> Sinus Guide Catheter	<i>ReliENT</i> Navigation System
F-70 GC070	RNA70110
M-110 GC110	RNA70110

Table 1: *Relieva* Sinus Guide Catheter Tip Shape and *ReliENT* Navigation System Compatibility

(The *Relieva* Sinus Guide Catheter (M-110S [GC110S]) is not compatible with the *ReliENT* Navigation System)

Note: Do not shape the sinus guide catheter’s malleable shaft if you intend to use it with the *ReliENT* Navigation System.

- i) Remove the *ReliENT* Adapter and Calibration Device from the sterile package.
- ii) Open the hinge on the Adapter and place the Sinus Guide Catheter’s luer connector into the groove designed to accommodate the luer. Close the hinge.
- iii) Press and turn the black thumbscrew clockwise to securely tighten.

Note: The Sinus Guide Catheter may not be positioned correctly in the Adapter if there is a visible gap along the length of the Adapter. Reposition the Sinus Guide Catheter and re-tighten the black thumbscrew.

- iv) Verify that the Sinus Guide Catheter is securely positioned in the Adapter by applying side to side force to the Sinus Guide Catheter. If the fit is not secure, tighten the thumbscrew. The Sinus Guide Catheter must be completely secure and immobile in the Adapter.
- v) Snap the Adapter onto the InstaTrak® 3500 Plus Receiver and gently press until the receiver is locked into the back end of the Adapter. The InstaTrak® 3500 Plus system will automatically detect that the Adapter is attached to a receiver.
- vi) Confirm that the receiver cable is securely connected to the InstaTrak® 3500 Plus system.

Note: “RELIEVA SINUS GUIDE” will be displayed on the InstaTrak® 3500 Plus monitor.

- vii) On the Calibration Device identify the corresponding calibration track for the selected Sinus Guide Catheter.
- viii) Carefully slip the tip of the Sinus Guide Catheter into the calibration cup and then snap the Sinus Guide Catheter in place along the appropriate calibration track.
- ix) Confirm that the Sinus Guide Catheter is securely captured in the Calibration Device.
- x) Locate the calibration tip closest to the blue tip of the Sinus Guide Catheter. Place this calibration tip in the center dimple of the InstaTrak® 3500 Plus Transmitter.

Note: When calibrating, gently rest the calibration tip on the transmitter dimple. Do not apply excessive force that can cause the sinus guide catheter or assembly to flex.

- xi) Proceed with following the InstaTrak® 3500 Plus protocol for calibration.
- xii) Do not remove the Sinus Guide Catheter from the Calibration Device. Flip the Sinus Guide Catheter and the Calibration Device.
- xiii) Place the calibration tip farthest away from the blue tip of the Sinus Guide Catheter in the center dimple of the InstaTrak® 3500 Plus Transmitter.
- xiv) Proceed with following the InstaTrak® 3500 Plus protocol for calibration.
- xv) After completing the calibration with both tips, remove the Calibration Device from Sinus Guide Catheter.

Note: Stabilize the Sinus Guide Catheter’s shaft and gently push the Calibration Device away from the Sinus Guide Catheter by applying pressure on the raised tabs.

- xvi) Proceed with following the InstaTrak® 3500 Plus protocol for verification of the Sinus Guide Catheter’s tip.

Note: Perform periodic verification assessment following the InstaTrak® 3500 Plus methods for verification modes.

Note: It will be necessary to re-calibrate if:

- (1) the receiver pack is removed from the Adapter
- (2) the receiver cable is unplugged from the InstaTrak® 3500 Plus system
- (3) the Sinus Guide Catheter is removed from the Adapter

- f. After initial endoscopic examination, position the tip of the Sinus Guide Catheter near the targeted sinus ostium.
 - i) When using image guidance, confirm the position of the Sinus Guide Catheter on the InstaTrak® 3500 Plus monitor.

Note: Image guidance may be used to track the Sinus Guide Catheter’s tip location and the trajectory of the Sinus Guide Catheter’s tip shape.

Note: Do not ignore any field distortion messages. When the field is distorted or excessive metal is detected (i.e. the presence of fluoroscopic imaging equipment in close proximity), accuracy may be affected.

- g. Determine the position by using endoscopy to visualize the blue band at the tip of the Sinus Guide Catheter. Fluoroscopy may also be used to confirm placement by visualizing the radiopaque marker located 2mm proximal from the tip of the Sinus Guide Catheter.

Note: To disconnect the InstaTrak® 3500 Plus Receiver, locate the press tab on the bottom of the Adapter. Gently press the tab and grasp the receiver to separate it from the Adapter.

7. Placement of the *Relieva* Sinus Guidewire

- a. After the Sinus Guide Catheter is positioned, select the type of Sinus Guidewire that is compatible with the intended *Relieva* Sinus Balloon Catheter and appropriate for the patient’s nasal anatomy.

- b. Remove the Sinus Guidewire protective hoop from the sterile package. Flush the protective hoop with sterile saline or water.
- c. Remove the Sinus Guidewire from the protective hoop.
- d. Carefully shape the Sinus Guidewire or the Integrated Guidewire Configuration's tip to facilitate wire manipulation.
- e. Once the Sinus Guide Catheter is properly positioned, insert the Sinus Guidewire through the Sinus Guide Catheter. Advance the Sinus Guidewire through the Sinus Guide Catheter, across the sinus ostium, and into the target sinus.
 - i) When using image guidance, gently advance the Sinus Guidewire through the Sinus Guide Catheter, across the sinus ostium, and into the target sinus while observing the trajectory of the Sinus Guide Catheter on the InstaTrak® 3500 Plus monitor.

Note: Steps 'a', 'b', 'c' and 'e' are not applicable to the use of the Integrated Guidewire Configuration

8. Advancement and Visualization of the *Relieva* Sinus Guidewire or Integrated Guidewire Configuration Sinus Balloon Catheter

- a. Entry into the target sinus is marked by smooth passage through the sinus ostium. Advance the Sinus Guidewire or the Integrated Guidewire Configuration into the target sinus until some light resistance is felt. **DO NOT USE EXCESSIVE FORCE.**
- b. If significant resistance is encountered, retract the Sinus Guidewire or the Integrated Guidewire Configuration. Slightly change the position (rotate in either direction). Again advance the Sinus Guidewire or the Integrated Guidewire Configuration in a gentle, probing motion.
- c. Confirm placement and position of the Sinus Guidewire or the Integrated Guidewire Configuration with endoscopic and / or fluoroscopic visualization.

9. Placement of the *Relieva* Sinus Balloon Catheter

- a. Advance the Sinus Balloon Catheter over the Sinus Guidewire, through the Sinus Guide Catheter, and across the targeted sinus ostium.

Note: For the Integrated Guidewire Configuration Sinus Balloon Catheter, advance the Sinus Balloon Catheter through the Sinus Guide Catheter and across the targeted sinus ostium.

- b. Position the sinus balloon across the area to be dilated and confirm its position using fluoroscopic and / or endoscopic visualization.

10. Visualization of the *Relieva* Sinus Balloon Catheter

- a. Using the marker(s) on the shaft of the Sinus Balloon Catheter, visually confirm that the Sinus Balloon Catheter has exited the Sinus Guide Catheter.
- b. Under fluoroscopic visualization, radiopaque markers within the sinus balloon indicate the proximal and distal ends of the sinus balloon.

11. Dilation of the *Relieva* Sinus Balloon Catheter

- a. Inflate the balloon catheter following the Inflation Device instructions.
- b. As the sinus balloon is inflating, monitor the diameter, shape, and position of the sinus balloon under fluoroscopic and / or endoscopic visualization.
- c. Inflate the sinus balloon until desired results are achieved.

Note: DO NOT EXCEED 16 ATM (Maximum Pressure) for the *Relieva* Sinus Balloon Catheter and 14 ATM (Maximum Pressure) for the Integrated Guidewire Configuration.

- d. Once desired results are achieved, deflate the sinus balloon. Confirm the deflation under fluoroscopic and / or endoscopic visualization.

Note: Only move or withdraw the Sinus Balloon Catheter when the sinus balloon is completely deflated. Advancing or retracting the sinus balloon while it is inflated may cause serious damage to surrounding anatomical structures or to the Relieva devices that are part of the Balloon Sinuplasty™ system.

e. Once the Sinus Balloon Catheter is fully deflated, remove the entire system from the patient.

Note: If planning to use either a Sinus Exchange Catheter and / or a Sinus Lavage Catheter, the Sinus Guide Catheter and Sinus Guidewire should be left in place. This should be performed by backing the Sinus Balloon Catheter out of the Sinus Guide Catheter, leaving the Sinus Guide Catheter and Sinus Guidewire in place. Refer to sections 13 and 14 for use of these two products.

Note: The Integrated Guidewire Configuration Sinus Balloon Catheter is not directly compatible with the Sinus Lavage Catheter. Insert an appropriate sized Sinus Guide Catheter and Sinus Guidewire if the use of the Lavage Catheter is desired.

f. If additional inflations are required, reposition the sinus balloon and repeat the steps for sinus balloon dilation.

g. If at anytime during the inflation process it is noted that the sinus balloon has ruptured (identified by a rapid decrease in pressure on the Inflation Device or visually noted under fluoroscopic or endoscopic visualization), remove the entire system as a unit and inspect each device to ensure that all parts have been removed. Flush the sinus with sterile saline or water to remove any remaining contrast media, if using. Verify removal of all device parts and contrast media under fluoroscopy and endoscopy.

Note: After use, the Inflation Device may be a potential biohazard. Handle and dispose of in accordance with accepted hospital procedures.

12. If dilating additional sinus ostia, re-prepare the *Relieva* Sinus Balloon Catheter

Note: If the Sinus Balloon Catheter and the Inflation Device have been disconnected, clean the catheter and inflation device connectors by rinsing in sterile saline or water prior to re-establishing the connection. Follow the Preparation and Attachment of the Inflation Device and Sinus Balloon Catheter (steps 2 and 4).

Note: After removal from the nose, if excess resistance is felt when retracting a Sinus Balloon Catheter through a Sinus Guide Catheter, gently compress the Sinus Balloon Catheter and push it retrograde through the Sinus Guide Catheter.

a. Lock Inflation Device and inflate balloon to 2 atm.

b. Rinse sinus balloon with sterile saline or water.

c. Pull a negative vacuum to fully deflate the sinus balloon. This will create three wings on the sinus balloon.

Note: If three wings do not form on the sinus balloon, re-inflate the sinus balloon to 2 atm. Place three fingers equally centered on the sinus balloon to serve as a guide to form the wings. Release the lock lever on the Inflation Device and pull a negative vacuum to fully deflate the sinus balloon.

d. Gently re-wrap the wings of the sinus balloon back around the Sinus Balloon Catheter in a clockwise motion, patting the sinus balloon from the distal to proximal end.

Note: Use care not to twist the catheter shaft.

- e. Slide the protective sheath back over the balloon to restore the sinus balloon to a tight profile. Remove the protective sheath.

Note: DO NOT attempt to insert or re-inflate the sinus balloon with the protective sheath in place.

- f. Wipe down the Sinus Balloon Catheter and flush with sterile saline or water.

13. If use of the *Relieva* Sinus Exchange Catheter is desired

Note: This is not applicable when using the Integrated Guidewire Sinus Balloon Catheter

- a. Remove the Sinus Exchange Catheter from its sterile package. Flush the Sinus Exchange Catheter with sterile saline or water. Wipe the surface of the catheter with sterile saline or a water-soaked gauze pad.
- b. Position the Sinus Exchange Catheter by passing it over the Sinus Guidewire and through the Sinus Guide Catheter. Place the Sinus Exchange Catheter across the target sinus ostium.

Note: Once in position, the Sinus Exchange Catheter may be used for:

- (1) **Guidewire exchange:** Remove the current Sinus Guidewire through the Sinus Exchange Catheter. Advance a new Sinus Guidewire through the Sinus Exchange Catheter. Confirm the position of the new Sinus Guidewire through endoscopic and / or fluoroscopic visualization. While maintaining the position of the new Sinus Guidewire, remove the Sinus Exchange Catheter.
- (2) **Irrigation of the target sinus:** Remove the Sinus Guidewire from the Sinus Exchange Catheter. Attach a syringe to the Sinus Exchange Catheter to irrigate the target sinus.
- (3) **Additional support and direction during *Relieva* Sinus Guidewire placement:** Pass the Sinus Exchange Catheter over the Sinus Guidewire and through the Sinus Guide Catheter. Place the Sinus Exchange Catheter close to the target sinus. Insert the Sinus Guidewire through the Sinus Exchange Catheter and across the targeted sinus ostium. While maintaining the position of the Sinus Guidewire, remove the Sinus Exchange Catheter.

14. If use of the *Relieva* Sinus Lavage Catheter is desired

Note: The Integrated Guidewire Configuration Sinus Balloon Catheter is not directly compatible with the Sinus Lavage Catheter. Insert an appropriate sized Sinus Guide Catheter and Sinus Guidewire if the use of the Lavage Catheter is desired.

- a. Remove the Sinus Lavage Catheter from its sterile package. Flush the Sinus Lavage Catheter with sterile saline or water. Wipe the surface of the catheter with sterile saline or a water-soaked gauze pad.
- b. Pass the Sinus Lavage Catheter over the Sinus Guidewire, through the Sinus Guide Catheter and into the target sinus.
- c. Confirm placement of the Sinus Lavage Catheter with endoscopic and / or fluoroscopic visualization.
- d. Remove the Sinus Guidewire from the Sinus Lavage Catheter, maintaining catheter position.
- e. While using the Sinus Lavage Catheter, alternate between suction and irrigation. This action will drain the target sinus of any purulent material, mucoid debris or fluids.

Note: If the OptiLINK Extension is connected to the Sinus Guide Catheter, remove the Extension prior to inserting the Sinus Lavage Catheter. During Extension removal, take care to avoid kinking or displacing the Sinus Guidewire.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING

	Sterilized Using Ethylene Oxide		Keep Away from Sunlight
	Batch Code		Do Not Re-Use
REF	Catalog Number	Rx ONLY	On Order of Physician Only
	Manufactured By		Date of Manufacture
	Use By		Consult Instructions For Use
	European Authorized Representative		CE Mark
	Contents of Package/Box		Guide Tip Angle
	Catheter Outer Diameter (OD)		Catheter Inner Diameter (ID)
	Balloon Length		Balloon Diameter
	Guide Catheter Inner Diameter (ID)		Minimum Guide Catheter Inner Diameter (ID)
	Guidewire Tip Shape		Maximum Guidewire Diameter
	Upper Limit of Temperature		Maximum Pressure
	Type BF Applied Part		Integrated Guidewire Length
	Integrated Guidewire Diameter		

Note: CE Mark applies to products that bear CE Mark on pouch and carton labeling only.



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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.

United States Patent Nos. 5,264,260; 5,599,576; 5,766,158; 7,462,175; 7,500,971. Other United States and Non-United States Patents Pending.

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