

**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 *Relieva Stratus* MicroFlow Spacers and the *Relieva Stratus* Deployment Guides are 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.

**DESCRIPTION**

- *Relieva Stratus MicroFlow Spacer (Ethmoid)*
  - is a catheter-based, self-retaining implantable device designed with a microporous reservoir for moistening the ethmoid cells. Two radiopaque markers define the ends of the reservoir. The spacer is delivered to the ethmoid sinus using the appropriate *Relieva Stratus* Deployment Guide (Ethmoid). A suture eyelet is available for additional retention.
- *Relieva Stratus MicroFlow Spacer (Frontal)*
  - is a catheter-based, self-retaining implantable device designed with a microporous reservoir for moistening the frontal sinuses. Two radiopaque markers define the ends of the reservoir. The spacer is delivered to the frontal sinus using the appropriate *Relieva Stratus* Deployment Guide (Frontal). A suture eyelet is available for additional retention.
- *Relieva Stratus Deployment Guide (Ethmoid)*
  - is comprised of two components used to access the ethmoid sinus. The Access Probe has a custom handle and a stainless steel angled distal segment and tip. The Access Probe handle has an upper rail that may be used to attach accessory devices. Additionally, the Access Probe handle has a triangular protrusion that indicates the trajectory of the distal tip (see Figure 1). The Delivery Sheath is a clear shaft that fits over the Access Probe. It is designed to facilitate the delivery of the MicroFlow Spacer. Radiopaque markers are incorporated into the Delivery Sheath to facilitate fluoroscopic visualization.

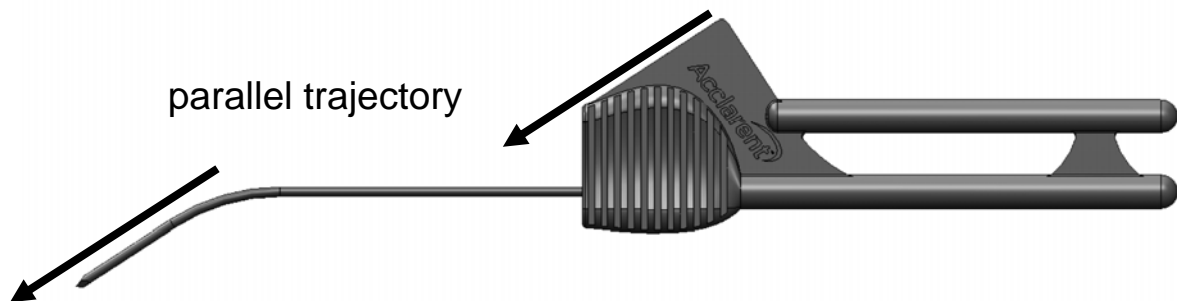


Figure 1. Access Probe

- *Relieva Stratus Deployment Guide (Frontal)*
  - is an alloy cannula comprised of a semi-flexible tube and a tip engineered to aid in accessing the frontal sinus

## INDICATIONS FOR USE

- *Relieva Stratus MicroFlow Spacer (Ethmoid)*
  - The MicroFlow Spacer (Ethmoid) is indicated for use as a postoperative spacer to maintain an opening to the ethmoid sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.
- *Relieva Stratus MicroFlow Spacer (Frontal)*
  - The MicroFlow Spacer (Frontal) is indicated for use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery. The MicroFlow Spacer also helps to prevent obstruction.
- *Relieva Stratus Deployment Guide (Ethmoid)*
  - is intended to provide access to the ethmoid sinuses and to facilitate the delivery of the MicroFlow Spacer.
- *Relieva Stratus Deployment Guide (Frontal)*
  - 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.
- 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 the devices against unknown resistance as this could cause tissue trauma or device damage.
- Do not exceed the maximum volume specified for the MicroFlow Spacer

## PRECAUTIONS

- Before opening any part of the 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(s).

- In the case of pre-existing infection, appropriate treatment should be considered.
- Appropriate postoperative care including treatment with antibiotics should be considered,
- In rare instances, the physiochemical condition associated with sinus surgery, both with and without the MicroFlow Spacer, may present a risk of toxic shock syndrome (TSS).

- Refer to the relevant IFU for any attached accessory devices. Note that Acclarent has not performed compatibility testing for accessory devices.
- In rare instances, if the Relieva Stratus MicroFlow Spacer (frontal) is not sutured to the anatomy, it may dislodge and be swallowed by the patient. If the device is swallowed, monitoring to ensure safe passage of the device is recommended.

### **MRI Information**

The Relieva Stratus MicroFlow Spacer was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the Relieva Stratus MicroFlow Spacer is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

### **MRI-Related Heating**

In non-clinical testing, the Relieva Stratus MicroFlow Spacer produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

*Highest temperature change* +1.6°C

Therefore, the MRI-related heating experiments for the Relieva Stratus MicroFlow Spacer at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

### **Artifact Information**

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Relieva Stratus MicroFlow Spacer. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

| Pulse Sequence    | T1-SE               | T1-SE              | GRE                 | GRE                 |
|-------------------|---------------------|--------------------|---------------------|---------------------|
| Signal Void Size  | 394-mm <sup>2</sup> | 45-mm <sup>2</sup> | 517-mm <sup>2</sup> | 163-mm <sup>2</sup> |
| Plane Orientation | Parallel            | Perpendicular      | Parallel            | Perpendicular       |

## **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 manipulation of the devices

- Conduct pre-op planning. Acclarent recommends use of a tri-planar (coronal, axial, sagittal) CT to verify that:
  - the MicroFlow Spacer has the appropriate wing width and device length for the targeted sinuses. If the device is implanted into a location where it is not possible to determine whether the wings will appropriately retain the device, securing the Spacer with suture is recommended.
  - the anatomy will allow for safe implantation without impacting critical structures
- When necessary, 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.
- Some MicroFlow Spacer models contain markers on the catheter shaft that can aid in Spacer positioning and are sinus specific. Select the appropriate spacer for the anatomy to be treated (refer to device label for designation of either “ethmoid” or “frontal” sinus),

## 2. Preparation of the MicroFlow Spacer

- a. Remove the MicroFlow Spacer from its sterile packaging. Inspect the device.

**Note:** Do not remove the wing tube from the distal end of the MicroFlow Spacer catheter. This tube covers the MicroFlow Spacer and keeps the retention wings in place until the MicroFlow Spacer is deployed.

- b. Preparation of the valve: Fill a clean 1 ml luer-compatible syringe with air. Attach the syringe to the luer fitting of the MicroFlow Spacer catheter and inject all of the air into the catheter. There should not be significant resistance during injection.
- c. While stabilizing the wing tube on the catheter, gently wipe both the tube and catheter with sterile saline or water.

## 3. Preparation of the Ethmoid Deployment Guide (ethmoid sinus deployment only)

- a. Remove the Access Probe and Delivery Sheath from its sterile packaging. Inspect both devices.
- b. Remove the protective cover from the Access Probe tip.
- c. Flush the Delivery Sheath with sterile saline or water. Wipe both the Access Probe and Delivery Sheath with sterile saline or water.
- d. Carefully load the Access Probe into the flared, proximal end of the Delivery Sheath. Advance the Access Probe until it can advance no further.

## 4. Loading of the suture

**Note:** Perform step 4 only if you will be using suture as an additional retention mechanism and wish to pre-load the suture prior to deployment.

- a) Slide the wing tube distally to expose the suture eyelet. Take care to keep the retention wings covered and constrained. See Figure 1A.
- b) Thread a minimum 18 inch (45 cm) long 4-0, or 5-0 suture with a straight needle less than 13mm long through the eyelet. See Figure 2A. Even the ends of the suture and place near the proximal end of the catheter.

Slide the wing tube back to its original position. This will cover the eyelet. Take care to keep the distal section of the catheter covered. See Figure 2B.

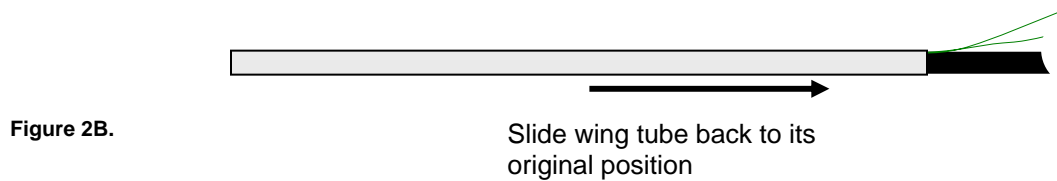
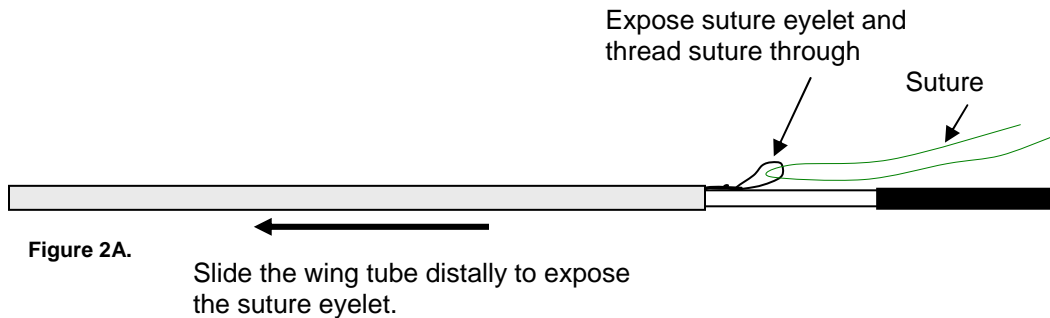


Figure 2. Loading the suture onto the MicroFlow Spacer

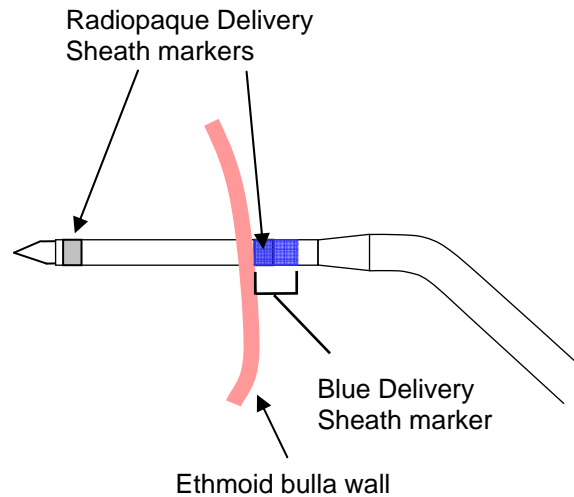
### 5. Deployment of the MicroFlow Spacer (Ethmoid Sinus)

- a. Using an endoscope, locate the anterior wall of the ethmoid bulla.
- b. Advance the Access Probe with Delivery Sheath through the nose. Place the point of the Access Probe at the ethmoid bulla.

**Note:** Confirm that the Access Probe is pointing towards the targeted ethmoid sinus.

- c. Using endoscopy and/or fluoroscopy, advance the Access Probe with Delivery Sheath small distances at a time to puncture the ethmoid cell(s). Continue until the distal edge of the blue marker and distal edge of the proximal radiopaque marker reach the anterior bulla wall. This placement ensures that upon deployment, the spacer's retention wings will be distal to the anterior bulla wall. Using endoscopy, confirm proper position of the Delivery Sheath by viewing the blue Delivery Sheath marker proximal at the anterior bulla wall. See Figure 3.

**Note:** Use fluoroscopy, endoscopy, and/or the Access Probe handle features to check the angle at which the Access Probe with Delivery Sheath will be advanced and that the path is clear of critical structures. Advance the Access Probe with Delivery Sheath along the trajectory of the distal section of the Access Probe.



**Figure 3. Placement of the Ethmoid Deployment Guide**

- d. Maintain the position of the Delivery Sheath, and remove the Access Probe.
- e. Confirm that the wings of the MicroFlow Spacer are still confined with the wing tube.
- f. Grasp the MicroFlow Spacer at the proximal-most section of the wing tube. Insert the wing tube and the MicroFlow Spacer catheter as a unit into the Delivery Sheath.
- g. Continue to grasp the wing tube, and advance the unit until the wing tube stops. (The proximal end of the wing tube will visibly extend outside of the Delivery Sheath).
- h. Grasp the proximal section of the MicroFlow Spacer catheter. Advance the MicroFlow Spacer catheter through the Delivery Sheath. If using fluoroscopy, continue until the MicroFlow Spacer's proximal radiopaque marker is just distal to the Delivery Sheath's proximal radiopaque marker. If using endoscopy, advance until the distal edge of the MicroFlow Spacer shaft marker abuts the proximal edge of the Wing Tube. This ensures that the MicroFlow Spacer is correctly positioned.

**Note:** Ensure that the Delivery Sheath remains steady and has not moved from the desired location. Use endoscopy to confirm that the distal edge of the blue marker is at the anterior bulla wall.

- i. Stabilize the MicroFlow Spacer catheter and retract the Delivery Sheath to deploy the retention wings. Using fluoroscopy and/or endoscopy, confirm that the retention wings have deployed inside the ethmoid bulla.

**6. Deployment of the MicroFlow Spacer (Frontal Sinus)**

- a. Flush the Frontal Deployment Guide with sterile saline or water.

- b. Attach Relieva Sidekick, if desired. Refer to the Relieva Sidekick IFU for instructions.
- c. Insert the MicroFlow Spacer into the Frontal Deployment Guide using the grip on the Wing Tube. Advance the MicroFlow Spacer until the Wing Tube stops advancing,
- d. Grasp the MicroFlow Spacer and advance until the distal tip of the reservoir is just proximal to the distal tip of the Frontal Deployment Guide,
- e. Gently place the Frontal Deployment Guide tip across the ostium of the target sinus. Radiopaque and endoscopically-visible markers at the distal tip of the Frontal Deployment Guide can facilitate placement and confirmation of Deployment Guide tip.

**Note:** Ensure that the targeted frontal sinus opening is of sufficient size to accommodate the tip of the Frontal Deployment Guide.

**Note:** Take care to position the Frontal Deployment Guide in the desired location within the frontal sinus using fluoroscopy and/or endoscopy for confirmation. The Retention Wings will deploy as soon as the spacer exits the Frontal Deployment Guide. If desired, advance Relieva Luma or a Sinus Guidewire through the Deployment Guide and into the desired sinus prior to inserting the MicroFlow Spacer to confirm appropriate sinus targeting. Relieva Luma or the Sinus Guidewire must then be removed prior to inserting the MicroFlow Spacer.

- f. Advance the MicroFlow Spacer out the end of the Frontal Deployment Guide. The Frontal MicroFlow Spacer model contains markers on the catheter shaft that can aid in Spacer positioning.
- g. Confirm that the Retention Wings are correctly deployed superior to the frontal ostium.

**Note:** Take care not to move the Frontal Deployment Guide catheter prior to injection of fluid. This will protect the MicroFlow Spacer catheter and minimize the risk of device kinking.

## 7. Injection of Saline (ethmoid and frontal sinuses)

- a. Fill a 1 ml luer-compatible syringe with 0.31 ml of sterile saline.
- b. Attach the syringe to the luer fitting of the MicroFlow Spacer catheter taking care not to move the spacer.
- c. Inject the entire 0.31 ml of sterile saline into the catheter in one rapid motion. Remove the syringe.

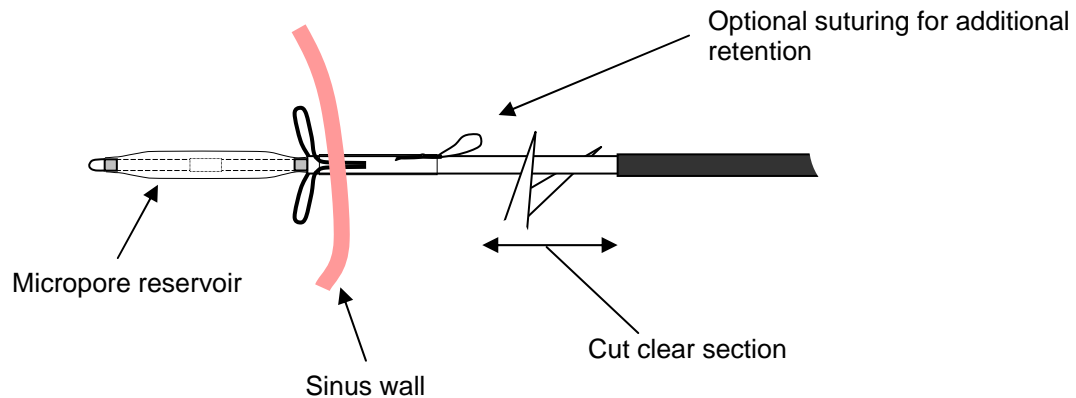
## 8. Securing the MicroFlow Spacer

- a. For frontal sinuses only, cut the proximal luer connector on the MicroFlow Spacer, remove Relieva Sidekick (if necessary) and retract the Frontal Deployment Guide.

**Note:** Take care not to dislodge the deployed MicroFlow Spacer during Frontal Deployment Guide retraction.

### For ethmoid and frontal sinuses:

- b. Using an endoscope, cut the clear section of the catheter shaft. The exact cut location on the clear section of the catheter is at the discretion of the physician. See Figure 4.
- c. If the retention suture is utilized, secure to the nasal septum or inferior vestibule. Cut and remove excess suture. Take care not to dislodge the Spacer during suturing.



**Figure 4. Cutting of the MicroFlow Spacer catheter in the clear section**

- d. Remove the trimmed proximal MicroFlow Spacer catheter shaft.
- e. The MicroFlow Spacer may be left in place for up to 14 days. The microporous reservoir allows saline to moisten the area around the MicroFlow Spacer.

**Note:** Take care not to dislodge the deployed MicroFlow Spacer while performing procedures during the implant period such as removal of a splint.

## 9. Removal of the MicroFlow Spacer

- a. To remove the MicroFlow Spacer, cut and remove the suture, if previously utilized. Using standard instruments, remove the MicroFlow Spacer by grasping the shaft and pulling it through the sinus opening. The MicroFlow Spacer's retention wings will fold to facilitate removal.

Discard the MicroFlow Spacer as you would biohazardous material.

## 10. Preparation of the Delivery Sheath for a second MicroFlow Spacer deployment (ethmoid only)

- a. If deployment of a second MicroFlow Spacer in the same patient is intended, remove the wing tube from the Delivery Sheath before reloading the Delivery Sheath onto the Access Probe.
- b. Flush the lumen of the Delivery Sheath with saline or water. Flush sufficiently to ensure that no material on the internal surface of the Delivery Sheath will be deposited onto the subsequent Spacer.
- c. Inspect the Delivery Sheath to ensure it is not damaged prior to using for a second deployment.

## 11. Preparation of the Frontal Deployment Guide for a second MicroFlow Spacer deployment (frontal only)



**Instructions For Use**  
**Relieva Stratus™ MicroFlow Spacers**  
**Relieva Stratus™ Deployment Guides**

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- a. If necessary, remove the wing tube from the first MicroFlow Spacer from the Deployment Guide and discard.
- b. Flush the lumen of the guide with sterile saline or water. Flush sufficiently to ensure that no material on the internal surface of the Frontal Deployment Guide will be deposited onto the subsequent Spacer.
- c. Inspect the Frontal Deployment Guide to ensure it is not damaged prior to using for a second deployment.

**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.

U.S. Pat. Nos. 7,361,168, 7,410,480 and 7,419,497 and other U.S. and Foreign Patents Pending.

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