Acclarent

RELIEVA TRACT™
Balloon Dilation System

Instructions for Use

5x24mm Balloon Catheter and Stylet
7x24mm Balloon Catheter and Stylet
8.5x24mm Balloon Catheter and Stylet
10x40mm Balloon Catheter and Stylet
12x40mm Balloon Catheter and Stylet
14x40mm Balloon Catheter and Stylet
16x40mm Balloon Catheter and Stylet

IFU005161 Rev A

Check www.acclarent.com for the current version of the Instructions for Use

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

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CAUTIONS: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Balloon dilation catheters should be used by or under supervision of physicians thoroughly trained in balloon dilation. A thorough understanding of the technical principles, clinical application, and risk associated with balloon dilation of the nasal passage is necessary before using this device.

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 TRACT™ Balloon Dilation System is 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

The RELIEVA TRACT™ Balloon Dilation System is composed of a balloon catheter and stylet.

- The *Balloon Catheter* includes a luer, an integrated shaft system, and a high-pressure balloon near the distal tip. The shaft is a coaxial catheter. The outer lumen is used for inflation of the balloon with sterile water or saline. The inner lumen permits the use of the stylet to facilitate advancement of the balloon catheter to the target location, such as the nasal passage in the region of the inferior turbinate and nasal septum. The proximal end of the balloon catheter consists of a luer that is used for inflation of the balloon and a secondary luer that is used for stylet access. The balloon is inflated by injecting sterile water or saline through the inflation luer.
- The *Stylet* is intended to facilitate advancement of the balloon catheter. The proximal end has a luer connector that allows the stylet to lock into the stylet port of the balloon catheter. The distal end consists of an atraumatic tip.

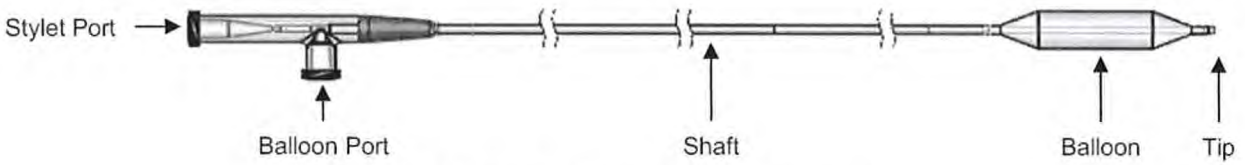


Figure 1. Balloon Catheter Key Components

INDICATIONS FOR USE

The RELIEVA TRACT™ Balloon Dilation System is an instrument intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction by displacing the inferior turbinate and lower nasal septum.

The RELIEVA TRACT™ Balloon Dilation System is intended for use in ages 17 years or older.

CONTRAINDICATIONS

Gross anatomic abnormalities or congenital anomalies involving the central craniofacial skeleton, significant deformities of the caudal septum and dorsal septal deviations contributing to external nasal deformity, deformities of the nasal septum involving excessively thickened or gross excesses of cartilage or bone.

WARNINGS AND PRECAUTIONS

- The device is 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.
- Do not use a device if it becomes damaged or touches a non-sterile object outside of the operating field.
- The device is not indicated for irrigation through the catheter's lumen.
- Do not try to move the balloon catheter while the balloon is inflated. Advancing or retracting the balloon catheter while the balloon is inflated may cause damage to the balloon catheter.
- Never advance or retract the device against unknown resistance, as this could cause tissue trauma or device damage.
- Do not exceed the recommended maximum balloon inflation pressure indicated on the device labeling.
- Check for proper position of the balloon catheter using endoscopic visualization. Balloon inflation in an improper location may lead to patient injury.
- The balloon must be inflated with sterile water or sterile saline. Do not use air or a gas medium to inflate the balloon.
- Use of a balloon catheter that is too large for the targeted anatomy may cause damage to the surrounding anatomy.
- Use of an undersized balloon catheter may result in failure to properly treat the targeted anatomy.
- If the balloon does not deflate when desired, rupture the balloon with a sharp instrument to allow removal.
- Do not insert or inflate the balloon catheter with the protective sheath in place.
- Prior to connecting the balloon catheter to the ACCLARENT® Balloon Inflation Device, the inflation device tubing must be free of air or the efficiency of inflation/deflation may be compromised.
- As standard practice for endoscopic surgery, physical examination and as clinically appropriate radiographic imaging (e.g. CT scan) should be reviewed prior to surgery to assess the patient's individual anatomy and its compatibility with the balloon catheter.

COMPATIBILITY

The RELIEVA TRACT™ Balloon Dilation System is compatible with the ACCLARENT® Balloon Inflation Device.

INSTRUCTIONS FOR USE

General

- Before opening any part of the product'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.
- Visualization of the nasal passage using endoscopy (flexible or rigid) is recommended to

determine the location of the inferior turbinate and existing deformities involving the nasal septum and guide placement of the balloon across the intended site of dilation.

- Select the appropriate balloon size such that the full inflation diameter can effectively dilate the target anatomy to the desired dimensions. The nasal passage region can be assessed by direct visualization (e.g. endoscope) with CT scan imaging as clinically indicated.

Preparation

1. Remove the balloon catheter and stylet from the sterile package.
2. If using with the stylet, insert stylet into the stylet port of the balloon catheter (see *Figure 2*). The stylet may be locked into place by connecting the male luer on the stylet with the female luer on the balloon catheter.
   - Note: Once locked into place, the stylet tip will extend 13 mm past the distal end of the balloon catheter.
3. Remove the protective sheath that covers the balloon.
4. Wipe the surface of the balloon and catheter shaft with sterile saline.
5. Prepare the ACCLARENT® Balloon Inflation Device.
   - Note: For steps requiring use of the Acclarent® Balloon Inflation Device, refer to the appropriate IFU. Use the table below to aspirate fluid into the inflation device targeting the approximate syringe volumes to meet but not exceed recommended maximum pressures (see table below).

Table 1. Acclarent Balloon Inflation Device Syringe Volume

Balloon Size (Diameter x Length)	Inflation Device Syringe Volume
5 x 24 mm	6 – 8 cc
7 x 24 mm	6 – 8 cc
8.5 x 24 mm	12 cc
10 x 40 mm	12 cc
12 x 40 mm	12 cc
14 x 40 mm	12 cc
16 x 40 mm	16 cc

6. Connect the balloon port (printed with the letter "B", see *Figure 2*) to the connecting tube of the inflation device.

Figure 2. Stylet Port and Balloon Port Locations

7. Prepare the balloon catheter by applying a vacuum with the inflation device to ensure that all air is removed from the balloon catheter and the inflation device.
8. Locate the site of the desired dilation using endoscopy (flexible or rigid).

9. Under endoscopic visualization, insert balloon through the corresponding nostril maintaining contact with the nasal floor and the lower septum. The proximal end of the balloon should be evenly positioned with the head of the inferior turbinate.

Inflation

10. Stabilize the shaft of the balloon catheter prior to inflation and maintain control of the catheter during the entire procedure.
11. Under endoscopic visualization, slowly inflate (approximately 1atm per second) the balloon to the desired pressure by monitoring pressure on the inflation device. During inflation, endoscopically visualize the diameter, shape, and position of the balloon. Ensure the balloon portion of the catheter is not positioned across the nostril and that it remains in close proximity to the nasal floor adjacent to the inferior turbinate and the lower half of the nasal septum. As dilation takes place, the pressure reading may fluctuate. Adjust the balloon pressure as necessary to maintain the desired pressure.
    - **Warning:** If the balloon moves proximally, distally, or superiorly during inflation or at any time during the procedure, do not hold the balloon against resistance. Deflate the balloon, reposition it and re-inflate.
    - Note: If at any time during the inflation process it is noted that the balloon has ruptured (identified by a rapid decrease in pressure on the inflation device or visually noted under endoscopic visualization), gently remove the balloon.
    - Note: Do not exceed the maximum pressure of the chosen balloon catheter. The maximum pressures for balloon sizes are listed in the table below.

Table 2. Maximum Pressures

Balloon Size (Diameter x Length)	Maximum Pressure
5 x 24 mm	16 atm
7 x 24 mm	16 atm
8.5 x 24 mm	12 atm
10 x 40 mm	12 atm
12 x 40 mm	10 atm
14 x 40 mm	10 atm
16 x 40 mm	8 atm

Removal

12. Once desired dilation is achieved, completely deflate the balloon.
13. Once the balloon is fully deflated, gently remove the balloon catheter from the nasal passage.
    - Note: Only advance or withdraw the balloon catheter when the balloon is completely deflated. Advancing or retracting the balloon while it is partially or fully inflated may cause serious damage to surrounding anatomical structures or the device.
14. Confirm under endoscopic visualization that the nasal passage has been sufficiently dilated to address the existing deformity. Inspect the nasal cavity after dilation and position the anatomy (i.e. septum or inferior turbinate) to the desired location, if necessary.
15. If additional dilations are required, reposition the balloon and repeat the steps for balloon

dilation.

16. After use, dispose of the device in accordance with accepted hospital biohazard procedures.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING

Catalogue number

Batch code


Date of manufacture


Use-by date


Packaging unit

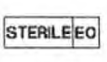

Manufacturer


Do not re-use


Consult instructions for use
www.acclarent.com

On order of physician only

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner



Sterilized using ethylene oxide


Do not use if package is damaged


Keep away from sunlight


Keep dry

Maximum pressure


Balloon diameter


Balloon length


Catheter OD


Catheter length

Acclarent, Inc.
33 Technology Drive
Irvine, CA 92618 USA
www.acclarent.com
+1-877-775-2789 | +1-650-687-5888

For patent information refer to www.acclarent.com/patentmarking