**Product:**
E 01 3526 VenSure®
E 01 3536 VenSure® Light
E 01 3546 VenSure® Nav
E 01 3566 VenSure® 4D
Balloon Dilation Systems

**Manufacturer:**
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info@fiagon.com

For US market only. – This document is intended to provide information to an audience of the US.

**Rx Only**

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

Carefully read all instructions, precautions, and warnings before use. Failure to understand use and observe warnings and precautions may result in complications.
Sterilized with ethylene oxide gas. Do not use if the package is open or damaged.
Store in a cool, dry place.

**Explanation of symbols**

| | | | |
|---|---|---|---|
| | Manufacturer | STERILE EO | Sterilization with ethylene oxide gas |
| REF | Catalog / Reference Number | | Type BF applied part |
| LOT | Lot / Batch Number | -10°C 40°C | Storage Temperature |
| | Content / no. of items in package | | Use by date |
| | Do not reuse | | Keep away from sunlight |
| | Do not re-sterilize | | Keep dry |
| | Consult instructions for use | | Do not use if the package is damaged |
| | Caution | | |

## 1.0 Preface

The VenSure® Balloon Dilation System is for use only by qualified medical professionals. Medical professionals must be trained on the specific surgical procedure for which this equipment is intended.
All physicians who have not completed cadaveric training with Eustachian tube dilation will be required to be trained on the use of the VenSure Balloon Dilation Systems for Eustachian tube dilation in a cadaveric specimen before using the device for Eustachian tube dilation. Please request training at your sales representative.

This manual is intended as a guide for the VenSure®, VenSure® Light, VenSure® Nav, and VenSure® 4D Balloon Dilation Systems.

## 2.0 Indications for Use

- The VenSure® Balloon Dilation System is used to access and treat the frontal ostia/recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.
- To dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in adult patients using a transnasal approach.
  - The VenSure® Nav and the VenSure® 4D Balloon Dilation System is additionally intended for use in conjunction with the Cube Navigation System during sinus procedures when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia.
  - The VenSure® Light Balloon Dilation System is additionally used to locate, illuminate within, and transilluminate across, nasal and sinus structures in adults.

## 3.0 Device description

### VenSure® Balloon Dilation System

The VenSure® Balloon Dilation Systems are sterile, single-patient use balloon device with accessories designed to remodel the bony structures within the sinuses. The VenSure® Balloon Dilation System comes in four versions: navigation-ready versions (VenSure® Nav & VenSure® 4D) that are compatible with the Cube Navigation System, a light-confirmation version (VenSure® Light) and a basic non-navigation version (VenSure®). The four versions include the components described below, each version using the same VenSure Balloon, Inflation device, Extension line, and Bending Tool.

**E 01 3526 VenSure® Balloon Dilation System**

- VenSure Balloon
- Bending Tool
- Inflation Device
- Extension Line

**E 01 3536 VenSure® Light Balloon Dilation System**

- VenSure Balloon with LED Light-Confirmation
- Bending Tool
- Inflation Device
- Extension Line

**E 01 3546 VenSure® Nav Balloon Dilation System**

- VenSure Balloon with Sensor Carrier (Navigation-Ready)
- Bending Tool
- Inflation Device
- Extension Line
- Adhesive Pad*

**E 01 3566 VenSure® 4D Balloon Dilation System**

- VenSure Balloon with Sensor Carrier (Navigation-Ready)
- Bending Tool
- Inflation Device
- Extension Line
- Adhesive Pad*

*Reference the Localizer Adhesive Pad instructions for use (IFU-0011US-EN) for the use of the adhesive pad.

### *System Components*

#### VenSure® Balloon

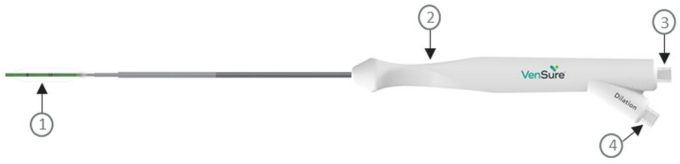
The VenSure® Balloon device (Figure 1) combines features of a malleable suction and a malleable probe with the tissue expansion effect of Balloon dilation. The distal end of the device includes an atraumatic tip and can be shaped to fit the frontal, maxillary, and sphenoid sinuses or to access the Eustachian Tube using the Bending Tool provided with the device. Since the distal end of the device is re-shapeable (maximum of 8 times per unit), one Balloon can be modified to work on multiple sinuses within the same patient.

The device enables a physician to track the device into the sinuses using endoscopic visualization, and after confirmation of placement, the Balloon of the dilation device can be inflated with saline solution using an inflation pump to expand the outflow track of the targeted sinus.

A suction tube may be connected directly to the proximal luer fitting of the VenSure® balloon device to provide active suction (Figure 1). Alternately, an Extension Line connected to a syringe may be connected directly to the proximal luer fitting to provide irrigation. Suction and irrigation are not possible on the VenSure Light, VenSure® Nav, or VenSure® 4D versions.
The VenSure balloons have the following dimensions:

| | |
|---|---|
| **Balloon dimensions** | **Diameter:** 6mm<br>**Length:** 18mm |
| **Balloon Shaft Dimensions** | **Working Length:** 145mm<br>**Distal Tip Diameter:** 1.81mm<br>**Proximal Shaft Diameter:** 2.4mm<br>**Malleability Region:** 40mm |

**Figure 1 VenSure® Balloon**

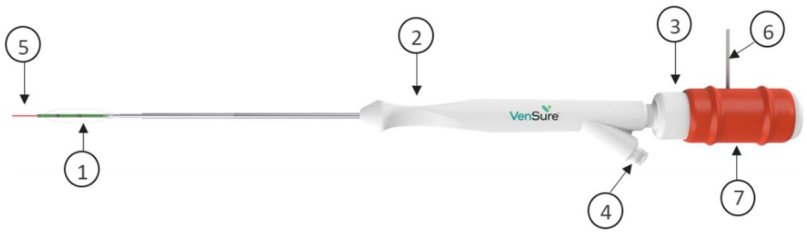



1. Balloon
2. Device Handle
3. Irrigation/Suction Port (luer fitting)
4. Balloon Inflation/Dilation Port (luer fitting)

**VenSure® Light Balloon**

VenSure® Light Balloon device(Figure 2) is an LED light-confirmation version of the VenSure® Balloon device, designed to emit light from the distal end. The device consists of a flexible light fiber, a protective sheath, and an integrated battery-powered LED light source. When activated, the LED Light Fiber fiber will emit red light from the distal tip for over two (2) hours. It has a fiber with a nominal advancement length of 15-20mm from the distal end of the Balloon. The LED Light Fiber is directly integrated into the VenSure® Balloon in the VenSure® Light Balloon version.

**Figure 2 VenSure® Light (Light-Confirmation) Balloon**




1. Balloon
2. VenSure Balloon Handle
3. LED Light Fiber Housing
4. Balloon Inflation/Dilation Port (luer fitting)
5. Light Fiber
6. Pull Tab
7. Light Fiber Advancement Slider

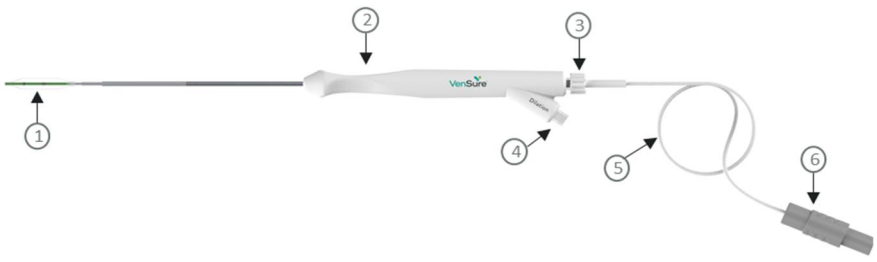
**LED Light Fiber Specifications**

| Item | Specification |
|---|---|
| Weight | 29.80g (1.051oz) |
| Nominal Fiber Working Length | 15-20 mm |
| Light Source Wavelength / Color | 625nm / Red |
| Activation Time | 2 hours |
| Battery Type | CR2 Lithium Manganese Dioxide (Li/MnO2) |
| Power Source | Internal |
| Maximum LED Power Output | 1 W |
| Mode of Operation | Continuous |
| Safe Operating Temperature Range (at Ambient) | 15 to 40°C (59 – 106°F) |
| Safe Storage and Transport Temperature Range | -10 to 40°C |

**VenSure® Nav / VenSure® 4D Balloon**

The VenSure® Nav and the VenSure® 4D Balloon devices (Figure 3) are navigation-ready versions that are compatible with the Cube Navigation System allowing for image-guided visualization when connected to the Cube Navigation System. The VenSure® Nav and the VenSure® 4D contain an integrated sensor carrier that enables the use of image guidance through “plug and play” tracking capability when used with the Cube Navigation System. The sensor carrier detects a signal within a low-energy magnetic field delivered from the navigation unit. The navigation software then displays the location of the balloon device's tip within multiple patient image planes and other anatomic renderings. The VenSure® 4D version additionally gives the ability to show the representation of the bended tip. The sensor carrier is directly integrated into the VenSure® Balloon in the VenSure® Nav and the VenSure® 4D versions.

**Figure 3 VenSure® Nav/VenSure® 4D (Navigation-Ready) Balloon Devices**

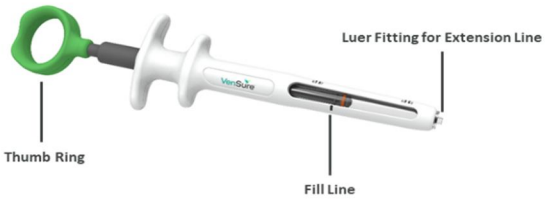



1. Balloon
2. Device Handle
3. Sensor Carrier
4. Balloon Inflation/Dilation Port (luer fitting)
5. Navigation Cable
6. Navigation Connector Plug

**Accessory: Inflation Device**

The Inflation Device (Figure 4) is an accessory to the VenSure® Balloon intended to inflate and deflate the VenSure balloon catheter used in ENT procedures. The extension tubing is 24 inches long and has a male and female luer fitting that is used to connect the Inflation Device to the VenSure balloon. The internal mechanism of the Inflation Device controls the pressure via mechanical force, locking into place when 12 atm has been achieved.

**Figure 4 Inflation Device and 24" Extension Line**




**Accessory: Bending Tool**

The Bending Tool (Figure 5) is an accessory to the VenSure® Balloon used to shape/bend the balloon tip according to the target sinus.

**Figure 5 Bending Tool**


| Bending | Degrees |
|---|---|
| **Sphenoid** | 12.5º |
| **Frontal** | 80º |
| **Maxillary** | 110º or 130º |
| **ET** | 45° |
| **Straight** | 0º |

## 4.0 Contraindications

None known.

## 5.0 Warnings & Precautions

- 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.
- Do not use if package is opened or damaged since the sterility and functionality of device may be compromised. Do not use after expiration date.
- Do not open sterile barrier until surgical use.
- Never advance or withdraw the Balloon Device against any resistance. Do not use excessive force or torque to advance Balloon Device when positioned in any paranasal, nasopharynx space or in the Eustachian tube. Such actions could lead to tissue trauma, bleeding, or device damage.
- Due to the variability of anatomy, review appropriate radiographic imaging (e.g. CT scan) prior to treatment.
- Do not exceed the maximum recommended balloon inflation pressure of 12 atm. Over-inflation of the Balloon can result in serious adverse events.
- Do not use suction during inflation.
- Only use sterile saline or sterile water as inflation solution.
- Fully deflate the Balloon prior to removal from anatomy.
- Only use device in conjunction with endoscopic visualization.
- Only physicians with experience in sinuplasty procedures should use VenSure® balloon dilation systems.
- Do not try to move the device while the Balloon is inflated.
- Prior to irrigation, ensure that the Balloon is fully deflated so that sinus contents and irrigation fluid can exit the sinus cavity.
- Do not remove the device from the target area while irrigation is occurring.
- Do not use the VenSure device to dilate Eustachian tubes in patients with a history of patulous Eustachian tubes or evidence of internal carotid artery dehiscence.
- Do not irrigate or suction in the Eustachian tube or in the presence of a bony dehiscence or defect in any sinus wall as it can lead to inadvertent fluid extravasation, such as into the orbit.
- Do not over-tighten or apply too much torque to the VenSure® to Inflation Device connection. Over-tightening can cause damage or leaking, and/or improper inflation.
- Do not under-tighten the connection between VenSure® and Inflation Device. Under-tightening can cause leaking and/or improper inflation.
- Use the supplied Bending Tool to angle the distal tip of the VenSure® accurately for target structure.
- Do not attempt to irrigate or suction with VenSure® Nav, VenSure® 4D or VenSure® Light product variant. Use the VenSure® variants without image-guided capability.
- No modification of this device is allowed.
- *For VenSure Light*: Do not activate the Light until just prior to use. Once activated the fiber will emit continuous light for over two (2) hours. There is no on/off switch.
- *For VenSure Light* Do not stare directly at tip of VenSure Light device while illumination is active.
- *For VenSure Light*: Do not point with the device directly at anyone's eyes while illumination is active.

- *For VenSure Light*: Do not advance the fiber when the Balloon is inside of the Eustachian tube.
- Do not incinerate the device except for disposal in a controlled incinerator.
- Dispose of device according to Federal, State, and Local regulations, and appropriate environmental health safety guidelines.

## 6.0 Compatibility

- The VenSure® Nav and the VenSure® 4D may only be used as accessories in connection with the Cube Navigation System.
- Consult the instructions for use for the Cube Navigation System if using the VenSure® Nav or VenSure® 4D versions of the device.
- Be aware of the image-guidance (stereotaxic navigation) system's technological principles and limitations including: Electromagnetic-based navigation systems are subject to interference from metallic objects or other emitters that can impact navigational accuracy or may interfere with other devices and/or implants. If you suspect interference, move equipment further apart, use a radio frequency barrier, or do not use the stereotaxic navigation system if it is not operating as intended.
- Before using VenSure® Nav or VenSure® 4D, the patient registration must be completed. The navigation system does not navigate until patient registration is performed.
- To avoid problems with the interpretation of the navigation display, pay attention to the position of the calibrated navigation point. The displayed navigation point corresponds to the tip of the balloon device.
- Do not start using the navigation system information before you have checked, calibrated, and verified it. Make sure that the Luer Lock connector for the sensor carrier is securely fixed. Check the displayed position of the instrument on several anatomical structures after connecting the instrument. If the deviation is significant do not use the instrument.

## 7.0 Instructions for Use

***System Preparation***

1. Remove the sterile pouch containing the balloon dilation device system from the carton. Discard the carton
2. Inspect the protective packaging (Tyvek pouch) for any obvious signs of damage or sterile barrier breach.
3. While maintaining the sterile field, open the sterile pouch to remove the tray containing the balloon dilation device system. Discard the empty pouch.
4. Open the tray by removing the retaining lid to remove the Inflation Device, the extension line, Balloon Device, and Bending Tool onto the sterile field.
5. Remove the clear balloon sheath protector covering the Balloon. Discard the clear balloon sheath protector.
6. Inspect for any obvious signs of damage.
7. Fill a sterile container with sterile saline or sterile water.
8. Place distal end of the inflation device into the sterile container such that the tip remains submerged in saline.
9. Push the syringe handle all the way in before pulling it all the way back until the handle reaches a hard stop.
10. Connect female luer fitting of the extension tubing onto the distal end of the Inflation Device by twisting it until sufficiently tight (**Figure 6a**).
11. Place distal end of the extension tubing into the sterile container such that the male connector remains submergedin saline (**Figure 6b**).
12. To draw saline into the syringe barrel, point the distal tip of the Inflation Device upwards, push the syringe handle all the way in before pulling it all the way back until the handle reaches a hard stop.
13. To purge air bubbles from the syringe barrel, push and pull the syringe handle all the way in and out with the maleconnector fully submerged in the saline. Repeat until all air bubbles have been visually removed from the syringe barrel and extension tubing.
14. After air bubbles have been purged, align the orange O-ring with the fill line on the Inflation Device (**Figure 6c**).

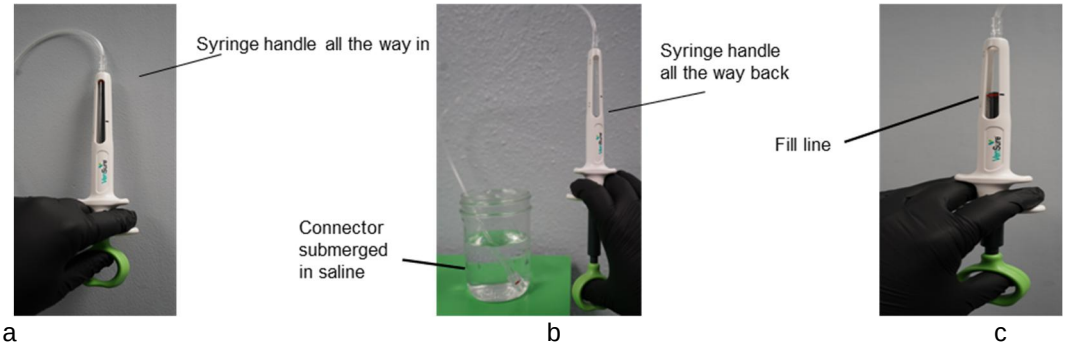



**Figure 6 Filling Inflation Device with Saline**

**NOTE:** If leak is detected and syringe cannot be fully purged of air bubbles, first verify that the connections are sufficiently tightened and repeat steps to prime the Inflation Device. If air bubbles persist, discard tray contents and get new sealed Inflation Device.

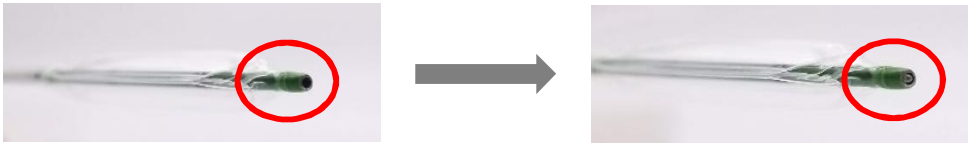
***VenSure® Nav (E 01 3546) and VenSure® 4D (E 01 3566) Preparation***

**NOTE: Skip to step 21, if using *E 01 3536 VenSure® Light and Skip to step 27, if using E 01 3526 VenSure® ***

***Sensor Carrier Check***

15. Ensure a stable connection of the sensor carrier to the balloon device.
    Confirm the white proximal connector of the sensor carrier is securely locked to the balloon


16. Confirm the sensor distal tip is visible and inline with the distal tip of the balloon device.
17. If the sensor tip is not visible turn the white proximal end of the navigation sensor carrier CLOCKWISE to securely tighten the sensor to the device. Continue turning until the sensor distal tip is in line with the distal tip of the device.



**CAUTION:** Do not overtighten or apply too much torque to the connector of the device. Over-tightening can cause damage to the device and/or inaccurate navigation of the tip of the device.

**CAUTION:** Do not under tighten the connector of the device. Under-tightening can cause inaccurate navigation of the tip of the device.

18. Insert the plug of the navigation sensor carrier into the appropriate socket (green socket for 'Instrument') on the navigation unit. Note that the arrow marking at the plug aligns with the marking at the socket.

**CAUTION:** Note that you are inserting the plug of the device into a non-sterile device.

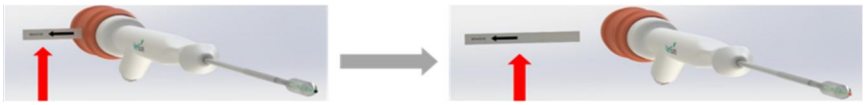
19. Once the instrument is connected, you will hear a confirmation tone and the status display of the instrument is displayed in color. The number of remaining uses is displayed in the status indicator of the instrument on the navigation screen. The instrument is accepted and registered to the navigation system. The navigation screen will display the position of the VenSure® Nav tip ("navigation point"). In case of the VenSure® 4D, the representation of the bended tip is shown.

***VenSure® Light (E 01 3536) Preparation***

20. Ensure the LED Light Fiber is securely connected to the luer fitting of the VenSure Balloon Device
21. If needed tighten the LED Light Fiber by rotating clockwise until the LED Light Fiber housing is flush with the handle of the VenSure device


**NOTE:** Do not over tighten.

22. To activate the LED Light Fiber, remove the pull tab. This will turn on the red light and unlock the slider.



**NOTE:** Do not remove the pull tab until ready to use the device. Do not try to reinsert the pull tab once removed.

23. Confirm that light is being transmitted through the LED Light Fiber.

***LED Light Fiber Operation***

24. Under endoscopic visualization, locate the target treatment area
25. Use the LED Light Fiber Slider to advance and retract the Light Fiber


**WARNING:** Make sure the pull tab has been fully removed.
**WARNING:** Do not advance the LED Light Fiber fiber against resistance.
**NOTE:** The LED Light Fiber fiber can advance up to 15-20mm.

***Balloon Preparation***

26. Connect the inflation device extension line to the luer fitting marked “Dilation“ (the bottom of the two luer fittings when the device is oriented to read the text right-side-up) by turning CLOCKWISE until the line is sufficiently tight.

**CAUTION:** Do not overtighten or apply too much torque to the connection to the device. Over-tightening can cause damage to the device, leaking of the device, and/or improper inflation.
**CAUTION:** Do not under tighten the connection to the device. Under-tightening can cause leaking of the device and/or improper inflation.
**CAUTION:** Do not connect the inflation device extension line to the balloon until the day of its intended use. Connecting the extension line to the balloon prior to the day it is intended to be used could cause corrosion of the internal balloon shaft.

27. With the Inflation Device connected to the balloon system and pointed down, pull the syringe handle all the way back such that the syringe handle is locked in place. Verify there is no leak in the system. (e.g., continuous formation of air bubbles).

**NOTE:** If leak is detected and cannot be resolved, the balloon system may be compromised and a new system may be necessary.

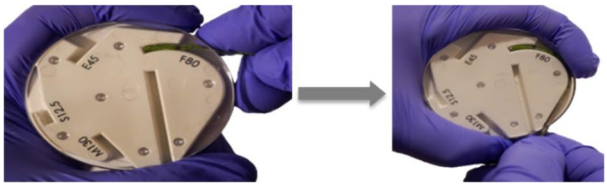
***Shaping the Balloon Tip***

28. Insert the distal tip of the device into the desired bending slot of the bending tool

**NOTE:** The Balloon is delivered in a straight bend configuration, and it is recommended to complete the balloon dilation of the sphenoid and/or frontal sinus(es) before the treatment of the maxillary sinus(es).
**NOTE:** The VenSure® tip can be shaped a maximum of eight (8) times.
**NOTE:** The bending angles of the bending tool are as follows:

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Straight** | 0º | **Sphenoid** | 12.5º | **Frontal** | 80º | **Maxillary** | 110º **or** 130º | **Eustachian Tube** | 45° |

29. While holding the bending tool in one hand, grab the metal shaft of the VenSure®, closest to the bending tool edge, and begin to bend downwards until the desired angle is achieved. The balloon tip is shaped/bent according to the target sinus and the Eustachian tube using the supplied Bending Tool. If the angle is too acute, the user may stop the bend before reaching the full bend on the Bending Tool.



30. Inspect the device to ensure no damage incurred and the desired bend angle was achieved.
31. Test the Balloon by inflating the Balloon to 12 atm to confirm successful inflation without leaks or damage to the Balloon.

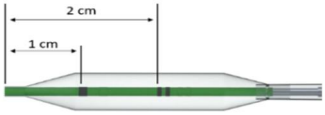
**CAUTION:** Do not use VenSure® device if leaks or damage to the Balloon is detected
**NOTE:** For improved visualization, it is recommended to wipe the Balloon with a sterile wipe/gauze in between balloon dilations and bending.

***System Operation***

32. Under endoscopic visualization and/or image guidance or light confirmation, locate the target treatment area.
33. With endoscopic visualization, advance the device forward to position the Balloon within the target structure.

**WARNING:** Never advance or withdraw the VenSure® Balloon against any resistance. Do not use excessive force or torque to advance VenSure when positioned in any paranasal or nasopharynx space. Such actions could lead to tissue trauma, bleeding, or device damage.

**NOTE:** Underneath the outer balloon surface are 2 reference markings located 10mm and 20mm (1cm and 2cm) from the distal tip of the device**.**




**CAUTION:** Do not forcefully advance the Balloon against resistance

34. Discontinue use of suction prior to inflating Balloon.

**WARNING:** To avoid barometric trauma to tissue, do not use the VenSure® in suction mode while Balloon is inflated.

35. Once the device is in the desired position for the user, Inflate the Balloon with the inflation device to 12 atm by slowly depressing the syringe plunger until you hear a click. Then release the plunger and it will click once more to lock the plunger in place. The click and locking of the syringe plunger indicates 12 atm of pressure is reached.

**WARNING:** For Eustachian Tube Dilation, to avoid barometric trauma to tissue, if using the VenSure® Light, VenSure® Nav, or VenSure® 4D. Balloon detach and remove the LED Light Fiber or Sensor Carrier from the Balloon prior to inflating the Balloon in the Eustachian Tube.

36. As the Balloon is inflating, monitor the diameter, shape, and position of the Balloon under endoscopic visualization. The Balloon should be inflated for **3-5 seconds** for **Sinus Dilation** and for **approximately 2 minutes** for **Eustachian tube Dilation.**
    To unlock the syringe plunger and deflate the Balloon depress the syringe plunger until it clicks again then release and fully retract the syringe plunger to deflate the Balloon.

**NOTE:** Do not continue applying pressure to the syringe plunger after it is locked in place.

**WARNING**: Over-inflation of the Balloon can result in serious adverse events. DO NOT EXCEED 12 atm when dilating.

**WARNING**: Do not try to move the device while the Balloon is inflated.

**CAUTION:** Do not use air or any gaseous medium to inflate the Balloon, only use sterile saline or sterile water.

37. If multiple inflations are needed to achieve the desired result, deflate Balloon, and repeat the steps of performing a dilation.
38. Once desired results are achieved, deflate the Balloon completely using the inflation device.

**WARNING**: Fully deflate the Balloon prior to removal from anatomy.

39. Remove the device after fully deflating the Balloon.

**NOTE:** Irrigation/suction are not possible with VenSure® Light, VenSure® Nav, or VenSure® 4D.

If physician wishes to irrigate the sinus cavity after dilation:

40. Remove the inflation device by turning the connection to the device COUNTERCLOCKWISE.
41. Connect a sterile saline or sterile water filled syringe with extension line to the luer fitting connection of the irrigation/suction port on the balloon device to irrigate through the balloon device

**NOTE:** Before irrigating it is recommended to ensure with endoscopic visualization that the Balloon is fully deflated.

**CAUTION:** Do not remove the device from the target sinus area while irrigation is occurring.

42. If the surgeon wishes to suction using the device, press-fit a sterile tube that can attach to the luer fitting of the irrigation/suction port of the device
43. After the operation, disconnect the device from the navigation system (if applicable) by pulling the plug directly.

**CAUTION:** Do not pull the cable or the bend protection. This may damage the cable of the device.

44. After procedure, dispose of device according to Federal, State, and Local regulations, and appropriate environmental health safety guidelines. Do not incinerate except for disposal in a controlled incinerator.