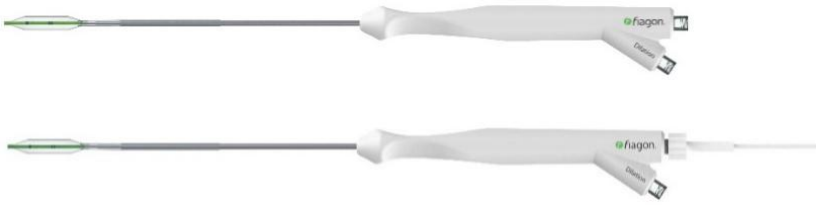
Product:
E 01 3506 VenSure™

E 01 3516 VenSure™ Nav

For use with the Fiagon Navigation System



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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
	Date of Manufacture
REF	Reference number/Order number
LOT	Production lot/ batch
	Content / no. of items in package
	Do not reuse
	Do not re-sterilize
	Consult instructions for use
STERILE EO	Sterilization with ethylene oxide gas
	Use by date
	Keep away from sunlight
	Keep dry
	Do not use if the package is damaged
	Caution

1.0 Preface

The Fiagon balloon devices, VenSure™ and VenSure™ Nav are for use only by qualified medical professionals. Medical professionals must be trained on the specific surgical procedure for which this equipment is intended.

This manual is intended as a guide for the two variants of the balloon devices, VenSure™ and VenSure™ Nav.

2.0 Indications for Use

The VenSure™ Balloon Device and VenSure™ Nav Balloon Device are used to access and treat the frontal 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.

The VenSure™ Nav Balloon Device is intended for use in conjunction with the Fiagon 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 Fiagon Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Fiagon Navigation system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery can be identified relative to a CT or MR based model of the anatomy.

3.0 Device description

Fiagon's VenSure™ and VenSure™ Nav balloon devices (Figure1 and Figure 2, respectively) are sterile, single-patient use devices designed to remodel the bony structures within the sinuses. The device comes in two versions a navigation ready version (VenSure™ Nav) that is compatible with the Fiagon electromagnetic navigation system, and a basic non-navigation ready version (VenSure™).

The VenSure™ and VenSure™ Nav devices, combine 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 using the Bending Tool provided with the device. Since the distal end of the device is re-shapeable (maximum of 6 time per unit), one balloon can be modified to work on multiple sinuses within the same patient.

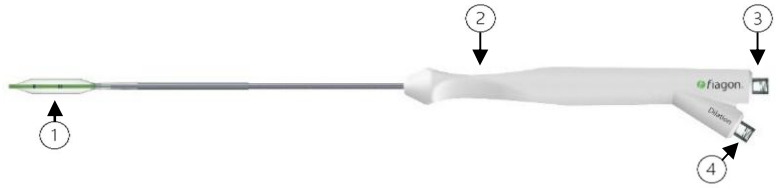
Both versions enable a physician to track the device into the sinuses using endoscopic visualization; while the VenSure™ Nav allows for image-guided visualization when connected to the Fiagon Navigation System. The VenSure™ Nav contains an integrated sensor carrier that enables the use of image guidance through "plug and play" tracking capability when used with the Fiagon 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. 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 basic 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™ Nav.

The VenSure™ balloons have the following dimensions:

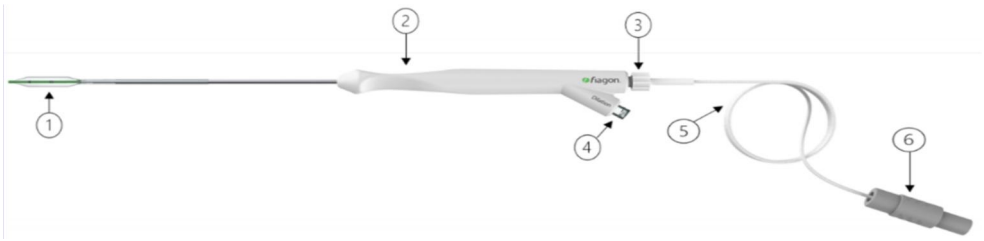
Balloon dimensions	Diameter - 6mm Length - 18mm
Balloon Shaft Dimensions	Working Length – 145mm Distal Tip Diameter – 1.63mm Proximal Shaft Diameter – 2.4mm Malleability Region – 40mm

Figure 1 E 01 3506 VenSure™ (Basic) Balloon Device



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

Figure 2 E 01 3516 VenSure™ Nav (Navigation-Ready) Balloon Device



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

4.0 Contraindications

None known.

5.0 Warnings

- 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.
- The VenSure™ and VenSure™ Nav devices are not indicated for Eustachian Tube Dilation.
- 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 VenSure™ 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.
- 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 VenSureTM sinus dilation devices.
- 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 sinus area while irrigation is occurring.

- Do not irrigate in the presence of a bony dehiscence or defect in any sinus wall as it can lead inadvertent fluid extravasation, such as into the orbit.

VenSure™ Nav specific warnings:

- Do not attach the VenSure™ Nav to other image guidance systems as use with other systems may result in inaccurate device positioning. Refer to Section 8.1 System Preparation Step 5 on how to connect the VenSure™ Nav to the Navigation System. The navigation only works in connection with Fiagon Navigation Systems.
- 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.
- Do not attempt to irrigate or suction with VenSure™ Nav product variant. Use the VenSure™ variant without image-guided capability.
- 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.

6.0 Precautions

- 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.
- Consult the instructions for use of the compatible Inflation Device.
- Use the supplied Fiagon Bending Tool to angle the distal tip of the VenSure™ accurately for target sinus.

Precautions specific to VenSure™ Nav

- Consult the instructions for use for the Fiagon Navigation System if using the VenSure™ Nav version of the device.
- Before using VenSure™ Nav, the patient registration must be completed. The Navigation System does not navigate until patient registration is performed.
- The patient registration must be done according to the instructions of use for the Fiagon Navigation System. Consult the instructions for use of the appropriate navigation application for necessary steps to perform the registration.
- 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.

7.0 Compatibility

- The balloon tip is shaped/bent according to target sinus using the supplied Fiagon Bending Tool.
- The bending angles of the Bending Tool are as follows:

Target Sinus	Degrees
Sphenoid	12.5º
Frontal	80º
Maxillary	130º
Straight	0º

- The balloon can be dilated using the following inflation pump:

- REF: E 01 3591, Disposable Inflation Device
- The VenSure™ Nav may only be used as an accessory in connection with the Fiagon Navigation System.

8.0 Instructions for Use

8.1 System Preparation

1. Remove the sterile pouch containing the balloon device from the carton and place onto the sterile field. Discard the carton.

2. While maintaining the sterile field, open the sterile pouch to remove the balloon dilation device and the bending tool. Discard the empty pouch.

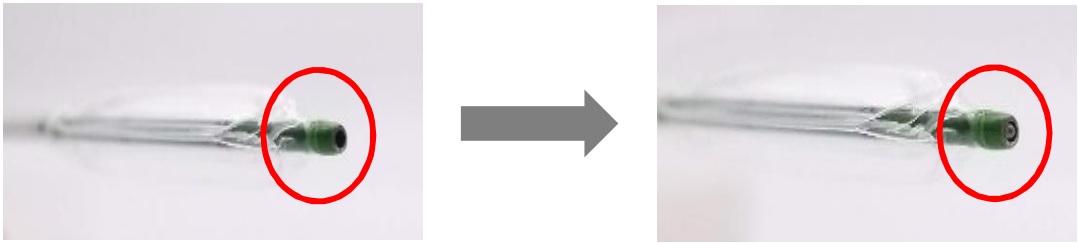
Note: Skip to step 9, if using *E 01 3506 VenSure™*

Engage Sensor Carrier

3. To ensure a stable connection of the sensor carrier to the balloon device.

   Secure the sensor carrier to the device by pushing the white proximal connector of the sensor carrier towards the distal tip of the device until the sensor carrier Luer fitting connector can be locked.

4. 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.

5. 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 is in the 12 o'clock position.

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

6. 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.

NOTE: To connect the VenSure™ Nav to the Navigation System via a longer distance use the Fiagon extension cable instrument or the Fiagon double instrument support cable, which are accessories to the Fiagon Navigation System.

NOTE: If the VenSure™ Nav does not register with the navigation system, it cannot be used for navigation. Open a new Navigation-Ready balloon device to register, or use the VenSure™ device without navigation.

CAUTION: The extension cable and double instrument support are non- sterile. Do not place the connected parts on the instrument table.

7. Perform patient registration in accordance with the ENT application described in the Fiagon Navigation System Instructions for Use (IFU).

8. After connecting the VenSure™ Nav to the Navigation System and registering the patient, the navigation screen will display the position of the VenSure™ Nav tip ("navigation point").

9. Remove the clear balloon sheath protector covering the sinus balloon. Discard the clear balloon sheath protector.

8.2 Inflation Device Preparation

10. Remove from packaging and fill the inflation device with sterile saline or sterile water as instructed in the Instructions for Use for the inflation device being used.

11. After preparing the inflation device, 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 cannot be turned further.

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**.**

8.3 Shaping the Balloon Tip

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

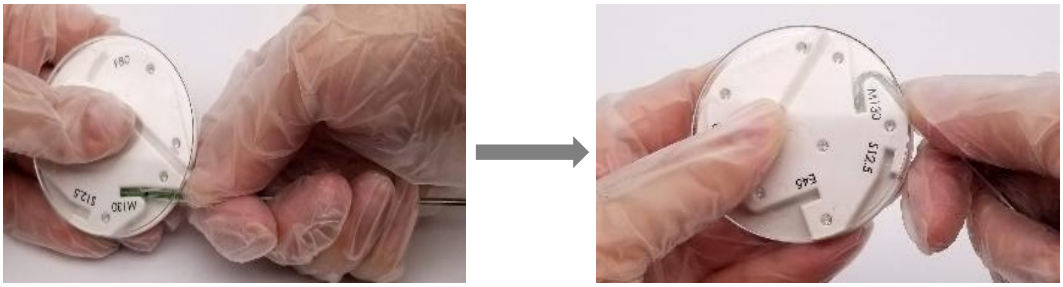
NOTE: The balloon is delivered in a straight bend configuration and it is recommended to complete the balloon dilation of the sphenoid and/or frontal sinus(es) before the treatment of the maxillary sinus(es).

NOTE: The VenSure™ tip can be shaped a maximum of six (6) times.

NOTE: The bending angles of the bending tool are as follows:

Straight	0º	**Sphenoid**	12.5º	**Frontal**	80º	**Maxillary**	130º

13. 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.



14. Inspect the device to ensure no damage incurred and the desired bend angle was achieved.

15. 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.

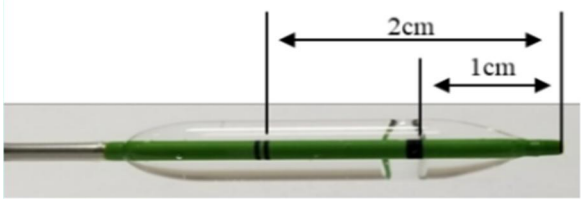
8.4 System Operation

16. Under endoscopic visualization and/or image guidance, locate the target treatment area.

WARNING: Never advance or withdraw the VenSure™ 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.

17. With endoscopic visualization, advance the device forward to position the balloon within the sinus opening.

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.

18. 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.

19. Once the device is in the desired position for the user, Inflate the inflation device per the Instructions for use of the inflation device.

    As the balloon is inflating, monitor the diameter, shape, and position of the balloon under endoscopic visualization.

    Slowly inflate the balloon with sterile saline or sterile water up to **12 atm**. The balloon should be inflated for up to 5 seconds.

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.

20. If multiple inflations are needed to achieve the desired result, deflate balloon, and repeat the steps of performing a sinus dilation.

21. Once desired results are achieved, deflate the Balloon. Refer to the IFU of the inflation device for instructions regarding Balloon deflation.

WARNING: Fully deflate the balloon prior to removal from anatomy.

22. If physician wishes to irrigate the sinus cavity after dilation, remove the device after fully deflating the balloon.

NOTE: Irrigation/suction are not possible with VenSure™ Nav

23. Remove the inflation device by turning the connection to the device COUNTERCLOCKWISE.

24. 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.

25. 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.

26. 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.

27. Dispose of the entire device (balloon, inflation device, and bending tool) according to Federal, state, and local regulations, and appropriate environmental health safety guidelines.