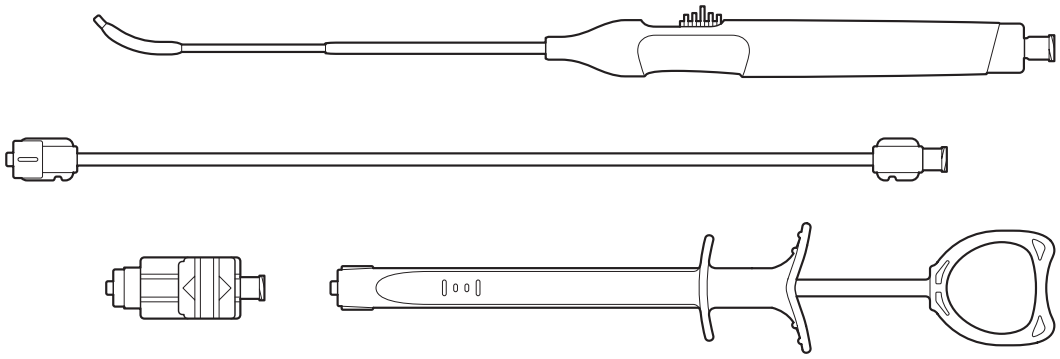
Audion™ ET dilation system

REF AET-100

Instructions For Use

℞ Only

STERILE EO



ENGLISH (EN)

ALL INSTRUCTIONS, PRECAUTIONS AND WARNINGS SHOULD BE CAREFULLY READ AND UNDERSTOOD BEFORE USE. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

Caution: **Federal (USA) law restricts this device to sale by or on the order of a physician.**

Indications For Use

To dilate the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction in patients 18 years and older using a transnasal approach.

Device Description

The Audion ET dilation system (ET is an abbreviation for Eustachian tube) is intended to dilate the Eustachian tube through use of balloon dilation and a transnasal approach. It contains a dilation device, inflation device and inflation lock. The dilation device has a 1.26 mm outer diameter (OD) curved non-malleable shaft with a balloon fixed at the distal end and a 1.91 mm atraumatic polymer ball tip. The dilation device is positioned under endoscopic visualization with the balloon fully retracted. Once the portion of the device from the ball tip to the base of the curve is seated in the Eustachian tube, the balloon is advanced and then inflated. The deployed balloon angle of the dilation device is 45˚ for optimal treatment of the Eustachian tubes. The distal leg length with balloon extended is 18.5 mm. When the balloon is inflated to 12 atm, the balloon diameter is 6 mm and the body length is 20 mm.

The inflation device is an accessory that consists of an inflation syringe and an extension line. The inflation device is designed to deliver a pressure of 12 atm and is used to inflate the balloon on the Audion device.

The inflation lock is an optional accessory that is intended to interface with the Audion dilation device, inflation syringe and extension line connections to hold or release pressure during balloon dilation.

The Audion ET dilation system is provided sterile and is for single patient use only. The dilation device, inflation device and inflation lock are sterilized using ethylene oxide.

The Audion ET dilation system has been tested to withstand multiple inflations in a surgical case.

Contents

The Audion ET dilation system includes:

- 1 dilation device
- 1 inflation device
- 1 inflation lock

Intended Users

Trained ENT physicians

Contraindications

There are not any known contraindications that directly refer to the product. The physician is responsible for deciding if the general condition of the patient allows the intended application.

Warnings

- Never advance or withdraw the Audion dilation device against any resistance. Do not use excessive force or torque to advance the dilation device when positioned in any nasopharynx space or the Eustachian tube. Such actions could lead to tissue trauma, bleeding, or device damage.
- Carefully inspect the sterile package seal and device for any signs of damage prior to use. Do not use a device with a breached sterile seal as it could be contaminated. Do not use a damaged device as it could malfunction. The Audion ET dilation system is provided sterile and intended for single patient use only. Do not resterilize and/or reuse as this may result in compromised device performance and risk improper sterilization and cross-contamination.
- Do not use the Audion dilation device in patients with known allergies to barium sulfate.
- Do not use the Audion dilation device to dilate Eustachian tubes in patients with a history of patulous Eustachian tubes.
- Do not insert the Audion dilation device beyond the tubal isthmus of the Eustachian tube, as this may increase the risk of bony fracture and injury to the internal carotid artery.

- Due to the variability of anatomy, review appropriate radiographic imaging (e.g., a CT scan) prior to treatment. Do not use the Audion dilation device to treat patients with evidence of internal carotid artery dehiscence.
- Do not exceed the maximum recommended balloon inflation pressure of 12 atm. Over-inflation of the balloon can result in serious adverse events.
- As in any upper airway procedure or sinus surgery, do not have patient use CPAP until the physician has confirmed that the tissue is adequately healed. CPAP use prior to soft tissue healing may result in facial and/or neck swelling due to subcutaneous emphysema.
- Do not clean the Audion ET dilation system with anti-microbial agents as the compatibility of the system with these agents has not been tested.
- The Audion dilation device has been tested only with the Stryker inflation device. Do not use other inflation devices with the Audion dilation device, as doing so may result in serious patient injury.
- Do not bend the Audion dilation device shaft. No modification of this device is allowed

Precautions

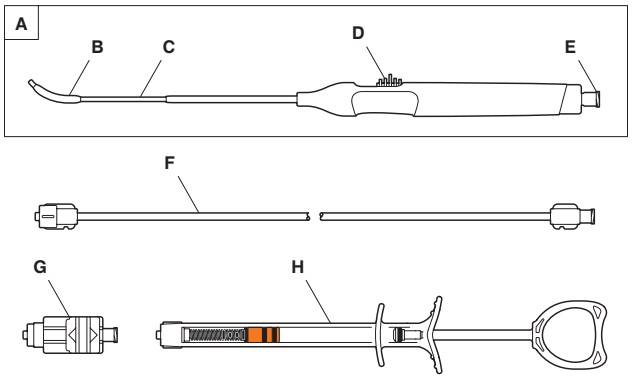
- Store the Audion ET dilation system in a dry and clean area at room temperature within its sterile package. Never use a device that is beyond its expiration date.
- Handle the Audion ET dilation system with care. Prior to use, and during the procedure, inspect the packaging, device and accessories for bends, kinks, or other damage. Discontinue the use of the Audion ET dilation system if it may have been damaged.
- Pay special attention when advancing, withdrawing, extending or retracting the Audion dilation device. If resistance is encountered, use endoscopy or direct visualization to help guide device out of the nasopharynx space and then attempt to alleviate the resistance. If the cause of resistance cannot be determined, do not use the Audion dilation device.
- Use direct endoscope visualization to ensure accurate placement of the Audion dilation device prior to balloon dilation. If balloon location cannot be verified, the balloon should not be inflated.
- Be aware that the Audion dilation device is not designed to allow for suction, irrigation, light fiber or an IGS guidewire (guidewires do not track through the dilation device). Other methods can be used to obtain confirmation of the treatment area, such as direct visualization of the Audion device with aid of an endoscope.
- Fully deflate the balloon and retract the balloon slide mechanism before withdrawing the Audion dilation device from the nasopharynx space.
- Use only sterile water or saline solution for inflation. Do not inflate with air.
- Consider using a new Audion dilation device if cross-contamination between Eustachian tubes is a concern.

Adverse Effects

Possible adverse effects include, but are not limited to, the following:

- Complications from anesthesia
- Pain
- Bleeding
- Bruising and swelling
- Tissue inflammation
- Fever and infection
- Continued or worsening symptoms
- Revision surgery
- Tinnitus
- Damage to the Eustachian tube
- Permanent hearing loss
- Carotid artery damage
- Tympanic membrane damage

Features



A	Audion dilation device
B	Balloon
C	Non-malleable shaft
D	Balloon slide mechanism
E	Inflation port
F	Extension line
G	Inflation lock (optional)
H	Inflation syringe

Supplies

The following supplies are not provided with the Audion ET dilation system and should be available and prepped prior to the use of the device:

- Appropriate endoscopes and compatible camera system
- ≥ 50 mL of sterile saline solution or sterile water
- Needles and syringes as required for injections
- Other supplies or medication as established by laboratory protocol

Optional Equipment

Refer to appropriate Instructions for Use and safety procedures when preparing and using optional equipment.

Instructions for Use

System Preparation

1. Prepare the inflation device. Note the three referenced inflation syringe plunger positions (Figures 2, 3, and 4).
   1.1. Remove the inflation syringe, extension line and inflation lock from its sterile package.
   1.2. If desired, attach the optional inflation lock to the tip of the inflation syringe (Figure 1).

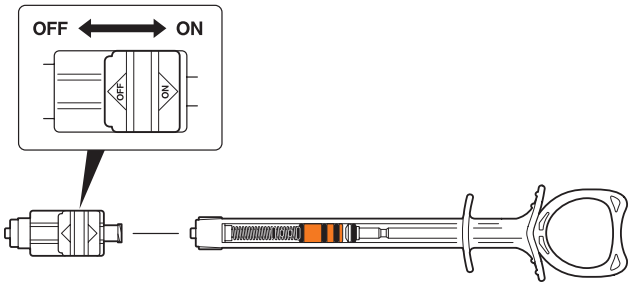


Figure 1 – Inflation lock attachment and positions

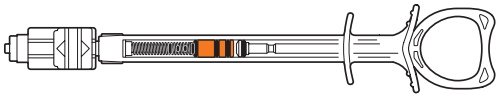


Figure 2 – Plunger all the way in

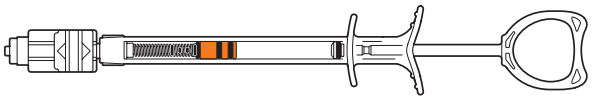


Figure 3 – First click position

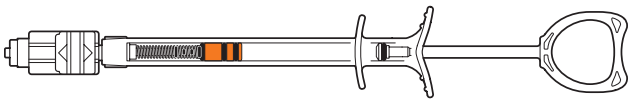
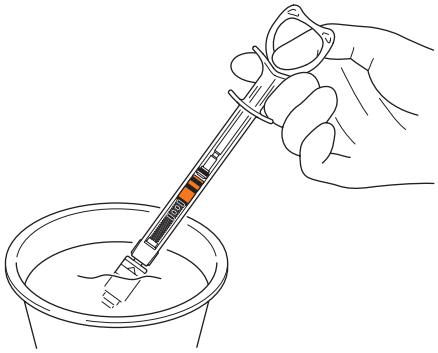


Figure 4 – Second click position (all the way out)

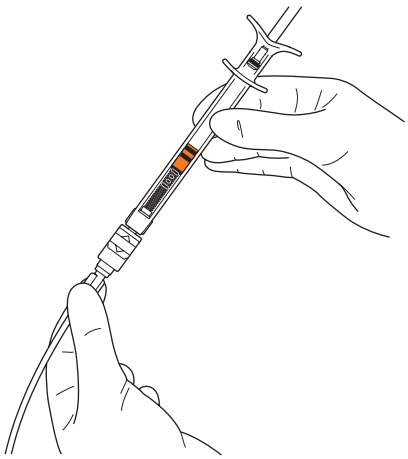
1.3. Begin with the inflation syringe plunger all the way in (Figure 2) and the inflation lock in the ON position (Figure 1).

1.4. Submerge tip in sterile saline or sterile water solution.

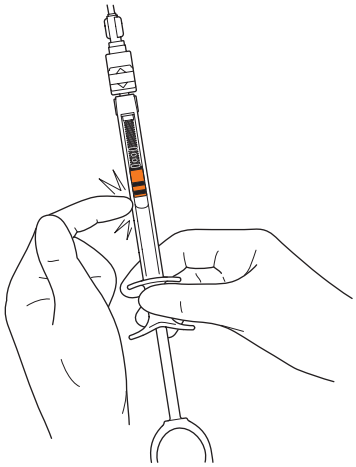


1.5. Fill inflation syringe by slowly drawing plunger back to second click position (all the way out) (Figure 4).

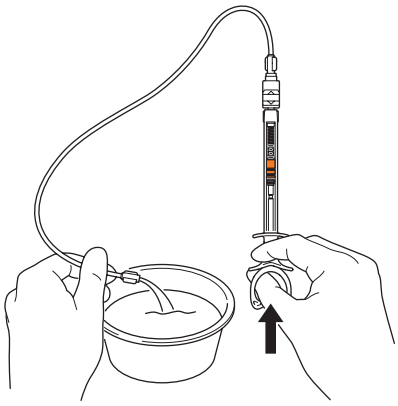
1.6. Attach the extension line to the inflation lock which is attached to the primed inflation syringe.



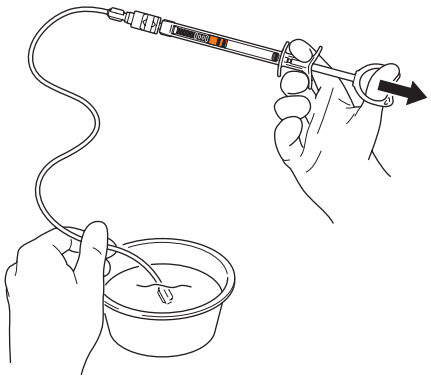
1.7. Point the syringe tip towards the ceiling. Tap the inflation syringe until a large bubble is visible beneath the orange piston.



1.8. While still pointing the syringe tip towards the ceiling, push the plunger all the way in (Figure 2), to purge all air and fluid from the syringe.



1.9. Submerge the free end of the extension line in sterile saline solution. Slowly draw plunger back to the first click position (Figure 3) to fill the syringe.



2. Prepare Audion ET dilation system.
   2.1. Remove the Audion device from its sterile package.
   2.2. Remove the balloon protector.
   2.3. Connect the free end of the prepped extension line to the Audion balloon inflation port.

NOTE: Inspect the syringe barrel to ensure there is minimal air in the system. If excessive air remains in the system, repeat prepping process.

3. Perform a test inflation of the system by depressing the plunger rod until the distal black seal on the orange piston is aligned with the distal black mark of the inflation syringe (figure 5). If the seal and black mark do not align, disconnect the inflation syringe with inflation lock from the extension line and repeat the prepping process.
4. Pull the plunger rod back to the second click position (Figure 4) to apply a vacuum to the balloon. Ensure there is no air introduced into the Audion ET dilation system during the deflation of the balloon. If a leak is detected disconnect all connection points and try set-up again. If the source cannot be identified and corrected, do not use the dilation device, extension line, inflation lock and inflation syringe. Use a new Audion ET dilation system to complete the procedure.

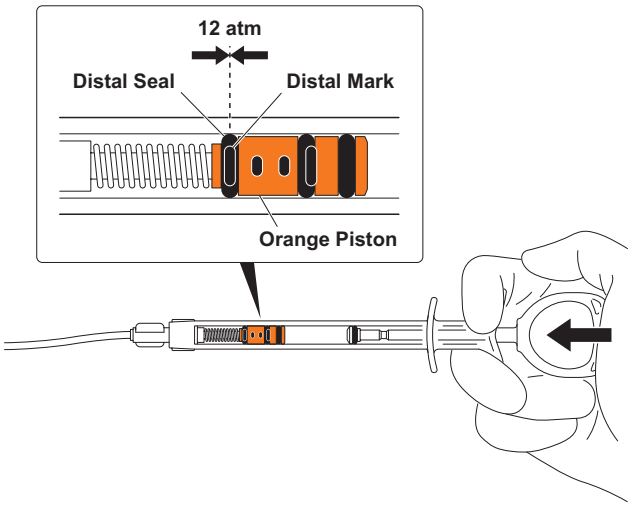


Figure 5 – Alignment between Distal Seal and Distal Mark corresponds to 12 atm

Patient Preparation

1. Patient preparation should be consistent with standard practice.
2. Anesthesia should be administered appropriately to allow patient tolerance.

System Operation

1. Locate the Eustachian tube orifice using the following confirmation method:
   - Direct Visualization: Locate the treatment area using the Audion dilation device with or without a standard sinus ostium seeker, and with the aid of an endoscope. Observe the location of the treatment area relative to the anatomical landmarks through the endoscope.
2. Position the Audion dilation device tip within the cartilaginous portion of the Eustachian tube.
3. Once the curved tip is fully seated in the Eustachian tube, use the balloon slide mechanism to extend the balloon deeper into the Eustachian tube stopping when the blue to gray transition is at the opening of the Eustachian tube. This is approximately 10 mm of extension. Do not force the balloon.
4. Balloon dilation of the treatment site:
   4.1. Slowly depress the inflation syringe plunger rod to inflate the balloon. The pressure should be increased slowly (3-5 seconds) until the orange piston bottoms out (distal black seal of the piston reaches the distal black mark on the Inflation Syringe – see Figure 5). If these do not align, deflate the balloon and remove the Audion dilation device and perform a test inflation (as described in steps 3 and 4 of the System Preparation section). Alignment of the distal mark and distal seal will ensure that 12 atm of pressure is reached.
   4.2. Inflate the balloon until the desired result is achieved or until it reaches 12 atm. Observe that the balloon is inflated endoscopically.
   4.3. Hold in the plunger rod or slide the inflation lock switch to the OFF position to hold pressure in the balloon for approximately 2 minutes.
   4.4. Deflate the balloon by sliding the inflation lock switch to the ON position and retracting the inflation syringe plunger rod to the second click position. Observe the results endoscopically.

4.5. Perform additional inflations if needed until desired result is achieved.

NOTE: Do not use air or any gaseous medium to inflate the balloon.

5. Remove device from treatment site:

5.1. When the Eustachian tube has been adequately dilated, after the balloon is fully deflated, retract the balloon using the balloon slide mechanism and remove the Audion dilation device from the treatment site.

6. Repeat the same procedure to treat the contralateral Eustachian tube if desired.

6.1. If desired, you may re-wrap the deflated balloon using the balloon protector or fingers prior to re-inserting the Audion device.

Device Disposal

1. After completing the entire procedure, dispose of the Audion ET dilation system and all waste products in accordance with federal, state or local regulations and procedures for disposal of biomedical waste. Biomedical waste should be considered infectious and requires special management/treatment.

Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to Stryker by calling Customer Service at (866) 620-7615. If dialing outside the United States, precede the number with your country's exit code and the US country code (+1). EU Member States should also notify the competent authority of the Member State in which the incident occurred.

Limited Warranty

Refer to *Entellus Medical, Inc. Standard Terms and Conditions.*

Symbols

This table defines symbols located on the product labels and/or in the instructions for use:

SYMBOL	DEFINITION
	Medical device (ISO 15223-1, 5.7.7)
	Consult instructions for use (ISO 15223-1, 5.4.3)
	Do not use if package is damaged (ISO 15223-1, 5.2.8)
	Do not re-use (ISO 15223-1, 5.4.2)
	Use-by date (ISO 15223-1, 5.1.4)
	Catalogue number (ISO 15223-1, 5.1.6)
	Quantity per box
	Batch code (ISO 15223-1, 5.1.5)
	*Caution:* Federal (USA) law restricts this device to sale by or on the order of a physician.
	Manufacturer (ISO 15223-1, 5.1.1)
	Sterilized using ethylene oxide (ISO 15223-1, 5.2.3)
	Single sterile barrier system with protective packaging inside (ISO 15223-1, 5.2.13)

This table defines symbols located on the devices:

SYMBOL	DEFINITION
	OFF position
	ON position

Trademarks and Patents:

Stryker and Audion are trademarks or registered trademarks of Stryker Incorporated in the U.S and other countries.

Consult a list of patents covering this product at https://ent.stryker.com/patents.

Entellus Medical Inc.
3600 Holly Lane North, Suite 40
Plymouth, MN 55447 USA
+ 1 866-620-7615
www.ent.stryker.com

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