Earloon™ Eustachian Tube Dilation System

A PRODUCT NAME

Earloon™ Eustachian Tube Dilation System

B DESCRIPTION

The Earloon™ Eustachian Tube Dilation System consists of:
. Earloon™ Eustachian Tube Balloon Catheter(Balloon Catheter)
. Earloon™ Eustachian Tube Guide Catheter(Guide Catheter)
. Earloon™ Eustachian Tube Balloon Catheter Delivery System(Delivery System)
The Balloon Catheter is designed to be inserted and inflated in the cartilaginous portion of the Eustachian tube (ET) for treatment of ET dysfunction (Figure 1). The Balloon Catheter consists of a proximal hub(7) with inflation port, a strain relief(6), a dual lumen shaft(5) with passage to pass the guide wire lumen and passage to inflate the balloon, two radiopaque markers(4), a guide wire lumen(3), a balloon(2) at the distal end of the shaft for ET dilation, and a distal end tip(1). The device contains shaft and radiopaque markers to aid in preparing the device and positioning under fluoroscope or direct endoscopic visualization. The tip, balloon and rigid shaft are passed into the Guide Catheter, the Guide Catheter is inserted through the nose to the orifice of the Eustachian tube, and the balloon is inserted into the Eustachian tube by advancing the Balloon Catheter. The balloon is inflated by injecting sterile saline or sterile water through the inflation port of the hub.

Figure 1: Earloon™ Eustachian Tube Balloon Catheter

The Guide Catheter is designed to provide a means to access the Eustachian tube (Figure 2). The Guide Catheter consists of a proximal hub(3), blunt handle(2), a rigid shaft(1) with a central lumen, and an angled distal tip that provides a trajectory for the Balloon Catheter to pass through the guide catheter to access the Eustachian tube. The device is provided sterile and is intended for single patient use only.

Figure 2: Earloon™ Eustachian tube Guide Catheter

The Delivery System is designed for users to more easily access and manipulate the balloon catheter into the cartilaginous portion of the Eustachian tube (ET) (Figure 3). The Delivery System consists of a Balloon catheter, a Strain relief rear, push handle, body that the user holds to easily access the balloon catheter into the Eustachian tube, strain relief front a rigid shaft with a central lumen, and an angled distal tip that provides a trajectory for the Balloon Catheter to pass through the delivery system to access the Eustachian tube.

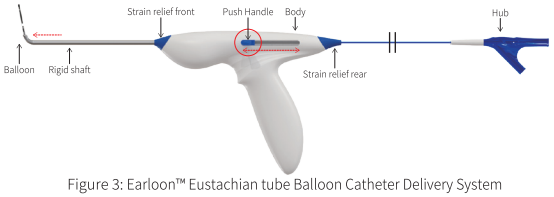


Figure 3: Earloon™ Eustachian tube Balloon Catheter Delivery System

C INDICATIONS FOR USE

The Earloon™ Eustachian Tube Dilation System is intended to dilate the Eustachian tube for treatment of persistent Eustachian tube dysfunction in adults ages 18 and older.

D CONTRAINDICATIONS

The Earloon™ Eustachian Tube Dilation System is contraindicated for use in a Eustachian tube with an ipsilateral carotid artery that is dehiscent into the ET lumen or history of ipsilateral patulous Eustachian tube.

E ⚠ WARNINGS

1. Intended for single patient use only. DO NOT REUSE.
2. Patients with a history of skull base surgery, prior ear surgery, skull fracture, or anatomic abnormalities may have elevated risk of complications and should be evaluated for eligibility before treatment.
3. DO NOT use product if the integrity of the sterile packaging has been compromi sed or if the device appears damaged.
4. DO NOT use if the device becomes damaged or touches a non-sterile object outside of the operating field.
5. Never advance or retract the device against unknown resistance, as this could cause tissue trauma or device damage.
6. Advancing the device into the Eustachian tube against resistance may cause injury.
7. DO NOT exceed the recommended maximum balloon inflation pressure of 18 atmospheres (ATM).
8. Use only liquid contrast or sterile saline for inflation. DO NOT inflate with air.
9. The EarloonTM Eustachian Tube Dilation System should be used by a physician who is well trained in manipulation and observation under endoscopic visuali zation or fluoroscopy

F ⚠ PRECAUTIONS

1. DO NOT move the balloon while it is inflated. Ensure balloon is fully deflated during insertion and withdrawal.
2. Certain nasal anatomy such as a deviated nasal septum may preclude access to the Eustachian tube/s resulting in failure to treat the target anatomy.
3. DO NOT inflate the Balloon Catheter until it has exited the Guide Catheter.
4. DO NOT bend the Guide Catheter shaft.
5. Consider using a new balloon if cross-contamination between sinuses or Eustachian tubes is a concern.

G ADVERSE EVENTS

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

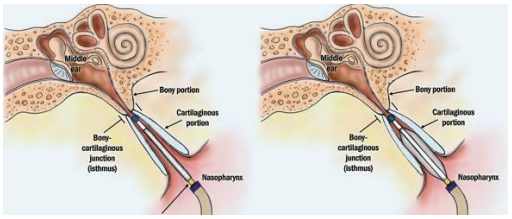
- Complication from anesthesia
- Damage to the lamina papyracea
- Damage of the orbital wall or other structures of the eye
- Cerebrospinal fluid leak
- Loss of vision or diplopia (double vision)
- Pain
- Bleeding
- Cavernous sinus syndrome
- Damage to the lacrimal sac affecting tearing
- Pneumocephalus
- Bruising and swelling
- Tissue inflammation
- Fever and infection
- Continued or worsening symptoms
- Revision surgery
- Tinnitus
- Damage to the Eustachian tube
- Patulous Eustachian tube
- Permanent hearing loss
- Carotid artery damage
- Tympanic membrane damage
- preauricular emphysema
- Blood-tinged
- Rhinorrhoea
- Epistaxis
- Subcutaneous emphysema
- Nasal discharge

H INSTRUCTIONS FOR USE

Use endoscopy for visualization during balloon access and dilation.
1. Preparation and inspection
   a. The following supplies are not provided with the EarloonTM Eustachian Tube Dilation System and should be available and prepped prior to use of the device.
      - Appropriate endoscopes and compatible camera system
      - **The inflation fluid is used sterile saline solution, sterile fluoroscopic constrast solution, or sterile water.**
      - Needles and syringes as required for injections
      - If the use of a sterile guidewire is desired, the recommended guidewire should be sterile and ≤0.035 inches in diameter with a minimum length of 50 cm.
   b. Before opening 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.
   c. Flush the Guide Catheter by injecting sterile saline or sterile water through the proximal hub.
   d. Wipe the surface of the catheter with a sterile saline or sterile water-soaked gauze pad.
   e. Infill the inflation fluid **10ml** in inflation device and check volume in window of it.
2. Integrating the Eustachian Tube Balloon Catheter, Inflation Device and Eustachian Tube Guide Catheter
   a. Connect the tubing of the inflation device to the inflation port on the Balloon Catheter
   b. Insert the Balloon Catheter tip into the proximal hub end of the Guide Catheter and advance the Balloon Catheter until the tip is visible.
3. Accessing the Eustachian tube

3.1 <GEBC-XX-XXX-XXX / GECS-XX-XXX-XXX> Model
   a. Hold the Guide Catheter by the proximal hub and, under endoscopic visualization, gently insert the guide catheter through the nose on the side to be treated, positioning the tip near the orifice of the Eustachian tube.
   b. Rotate the Guide Catheter so that the tip angle is aligned with the trajectory of the Eustachian tube.
   c. Once in position, stabilize the Guide Catheter. Place a finger from the same hand on the shaft of the balloon catheter, and using a motion similar to depressing a syringe, gently advance the Balloon Catheter through the Guide Catheter and into the Eustachian tube.
   d. The Balloon Catheter should advance smoothly into the E ustachian tube until the proximal balloon marker exits the Guide Catheter or until resistance to advancem ent is felt and the marker is visible distal to the bend at the tip of the Guide Catheter (this resistance indicates that the balloon catheter bulb tip has reached the narrow isthmus of the Eustachian tube).
   Note: If resistance is encountered during initial advancement of the Balloon Catheter and the proximal balloon marker has not passed the bend at the tip of the Guide Catheter, DO NOT continue to advance the balloon catheter. Retract the Balloon Catheter back into the Guide Catheter, rotate and reposition the tip of the guide and gently re-advance the balloon catheter according to instructions 3c-3d.
   e. If the proximal balloon marker is within the guide tip, withdraw the Guide Catheter slightly while holding the Balloon Catheter in position until the marker is visible distal to the Guide Catheter tip. When in correct position, the marker should be visible distal to the Guide Catheter tip, but should not be within the Eustachian tube. See Figure 4A.
   Note: Do not inflate the balloon if the proximal balloon marker is not visible distal to the Guide Catheter tip.

3.2 <GECD-XX-XXX-XXX/GEDS-XX-XXX-XXX/ GEDS-XX-XXX-XXXS > Model
   a. Hold the balloon catheter delivery system, under endoscopic visualization, gently insert the rigid shaft of delivery system through the nose on the side to be treated, positioning the tip near the orifice of the Eustachian tube.
   b. Rotate the rigid shaft of delivery system so that the tip angle is aligned with the trajectory of the Eustachian tube.
   c. Once in position, stabilize the rigid shaft of the delivery system. Place a finger from the same hand on the Push handle of the delivery system, and using a motion similar to depressing a syringe, gently advance the Balloon Catheter through rigid shaft and into the Eustachian tube.
   d. The Balloon Catheter should advance smoothly into the Eustachian tube until the proximal balloon marker exits the rigid shaft or until resistance to advancement is felt and the marker is visible distal to the bend at the tip of the rigid shaft (this resistance indicates that the balloon catheter end tip has reached the narrow isthmus of the Eustachian tube).
   Note: If resistance is encountered during initial advancement of the Balloon Catheter and the proximal balloon marker has not passed the bend at the tip of the rigid shaft of delivery system, DO NOT continue to advance the balloon catheter. Retract the Balloon Catheter back into the rigid shaft, rotate and reposition the tip of the rigid shaft and gently re-advance the balloon catheter according to instructions 3c-3d.
   e. If the proximal balloon marker is within the guide tip, withdraw the rigid shaft slightly while holding the Balloon Catheter in position until the marker is visible distal to the rigid shaft tip. When in correct position, the marker should be visible distal to the rigid shaft tip, but should not be within the Eustachian tube. See Figure 4A.
   Note: Do not inflate the balloon if the proximal balloon marker is not visible distal to the rigid shaft tip.



4. Inflate the balloon
   a. Inflate the balloon per the inflation device instructions for use.
   b. As the balloon is inflating, monitor the diameter, shape, and position of the balloon under endoscopic visualization. Stabilize the handle of the Guide Catheter to minimize slippage of the balloon out of the Eustachian tube into the nasal canal.
   c. Inflate the balloon to the desired pressure. DO NOT exceed the maximum pressure of the balloon (18 atm).
   Note: The recommended total hold time for inflation is two minutes. Users should assess patient tolerability for this hold time when performing the procedure under local anesthesia.
5. Deflate and remove the balloon
   a. Once desired inflation is achieved, deflate the balloon per the inflation device instructions for use.
   b. Additional inflation may be performed if desired, followed by balloon deflation.
   c. After the balloon is fully deflated, retract the Balloon Catheter into the Guide Catheter or rigid shaft, and remove the entire system from the patient.
6. If dilating the patient's other Eustachian tube
   a. After removal of the devices from the patient, the devices may be used again in the same patient on the other Eustachian tube by repeating steps 3-5. DO NOT use the device on a different patient.
7. Discard device after use
   a. After use, the Balloon Catheter and Guide Catheter may be a potential biohazard. Handle and dispose of in accordance with accepted facility procedures.

I STORAGE AND MANAGEMENT METHOD

a. Since this product is a disposable product, clearly state "once-use" and "no reuse" and discard immediately after use.
b. Store at cool, dry, and dark room temperature (1 to 30°C).

J SYMBOLS

REF	Catalogue number	LOT	Batch code
	Do not re-use		Caution
	Do not use if package is damaged	1°C 30°C	Temperature limit
STERILE EO	Sterilized using ethylene oxide		Keep away from sunlight
	Use by date		Date of manufacture
	Consult instructions for use		Manufacturer
EC REP	Authorized representative		Do not resterilize
	Keep dry		

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