

Adult Esophageal Balloon Catheter Set

R_x Only



Device Description:

The set contains an 86-cm closed-end catheter with a balloon of 9.5 cm length. The catheter has depth markings to aid in positioning the balloon in the lower third of the thoracic cavity. See Figure 1.

A stylet with a "Y" connector is provided to allow pressure readings during placement to aid in positioning.

A pressure extension tube with male/female luer and a 3-way stopcock is provided for connection to pressure measurement instruments.

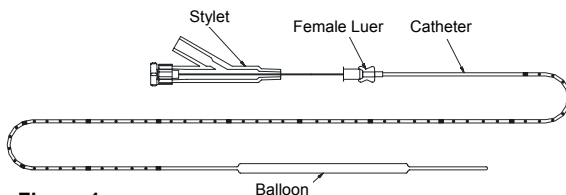


Figure 1

Intended Use/ Indications:

The balloon catheter is inserted by nasal intubation into the esophagus for monitoring and measuring intrathoracic pressure changes related to respiration. It is intended for use in pulmonary function studies, sleep apnea diagnostic studies and for patients on mechanical ventilation.

Contraindications:

Use of the esophageal catheter is contraindicated in patients with diseases such as esophageal ulcerations, tumors, diverticulitis, bleeding varices or in patients with sinusitis, epistaxis or recent nasopharyngeal surgery.

Precautions:

The stylet and "Y" connector are bonded into a single unit and should be removed from the catheter before taking final pressure measurements (Pressure measurements for placement can be done with the stylet in place).

Warnings:

If the catheter meets obstruction, **DO NOT FORCE THE CATHETER**. Remove it and insert it through the other naris.

Avoid placement of the catheter in the trachea to avoid risk of airway obstruction or trauma to the respiratory system.

Particular care should be taken if the patient has an endotracheal tube in place, as devices of this nature tend to direct the catheter into the trachea.

Do not insert the stylet while the catheter is in the patient as there is a chance that the stylet could exit through a catheter shaft balloon hole, puncture the balloon and cause injury.

Adverse Events:

None known.

How Supplied:

Sterile for single use

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Do not reuse



Patient Counseling Information:

Have the patient be NPO for 4 hours prior to catheter insertion.

The patient should be instructed to wait for numbness to vanish before eating.

Instructions for Use:

Patient/Catheter Preparation

- Step 1:** Have available for use an emesis basin, tissues, a protective drape, topical anesthetic, water-soluble lubricant and a 1 to 5 cc glass syringe.
- Step 2:** Select a naris with the best airflow for catheter insertion.
- Step 3:** If necessary apply a suitable topical anesthetic (e.g. 2-4% Lidocaine[®] Spray) to the patient's nasal passage and throat.
- Step 4:** Remove the sterile radiopaque catheter with the stylet from its protective package.
- Step 5:** Remove the yellow protective sleeve from the catheter and discard.
- Step 6:** Apply water-soluble lubricant to the distal tip of the catheter.
- Step 7:** With the patient's head in a neutral position or flexed slightly forward, slowly insert the catheter through the naris and hypopharynx using a gentle advancing motion.
- Step 8:** Avoid placement of the catheter in the trachea. Tracheal placement can be identified by patient choking or airway obstruction causing an increase in airway resistance and pressure.

Adult Esophageal Balloon Catheter Set (continued)

- Step 9:** To estimate depth in which to place catheter calculate the product of the patient's height x 0.288.
- Step 10:** Advance the catheter to the calculated depth mark. (If the catheter meets obstruction, **DO NOT FORCE THE CATHETER.** Remove it and insert it through the other naris). At this depth, the balloon will be entering the thoracic cavity.
- Step 11:** Attach the extension tubing to the "Y" connector of the stylet, a syringe and an isolated physiologic transducer to the 3-way stopcock. See Figure 2.

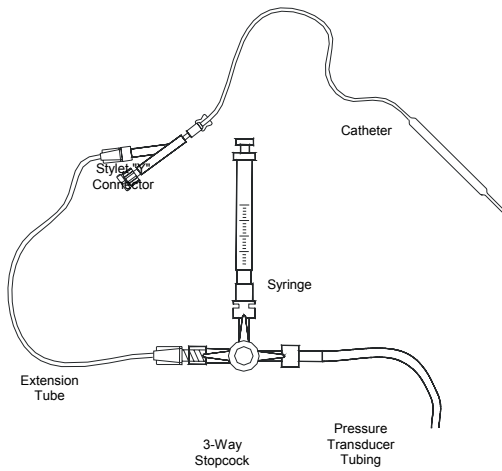


Figure 2

Catheter Placement

- Step 12:** Turn the 3-way stopcock open to the syringe and extension tube. Evacuate all the air from the balloon by pulling back on the syringe plunger and then allowing the plunger to return to a non-vacuum position. Use of a glass syringe avoids creating a vacuum in the balloon catheter.
- Step 13:** Turn the 3-way stopcock off to the extension tube, remove the syringe and fill the syringe with 1cc of air.
- Step 14:** Attach the syringe to the 3-way stopcock, open the 3-way stopcock from the syringe to the extension tube. Introduce 1 cc of air into the balloon. The balloon will now be semi inflated. An incorrect amount of air in the balloon will adversely affect pressure wave performance (see Trouble Shooting Guide below).
- Step 15:** After 1 ml of air is injected, turn the stopcock off to the syringe, and open from the extension tube to the transducer to read pressure from the catheter.

If no or a damped pressure signal is seen, the catheter may need to be advanced further into the thoracic cavity or may be kinked on itself and needs to be withdrawn.

In the absence of diaphragmatic paralysis, the pressure recorded should be negative on inspiration. A positive inspiratory pressure recording may indicate gastric placement and the catheter should be pulled back.

Pressures taken through the "Y" connector are for balloon placement only. The stylet, luer cap and "Y" connector are bonded into a single unit and must be removed from the catheter before taking pressure measurements for clinical purposes.

- Step 16:** Once the catheter has been positioned properly, disconnect the extension tube from the stylet "Y" connector and remove the stylet assembly from the catheter. Excessive curvature of the catheter may cause the stylet to bind in the catheter making removal difficult. **If the stylet binds in the catheter during removal, instruct the patient to raise their head to straighten the catheter.**

Pressure Data Acquisition

- Step 17:** After removing the stylet assembly, reattach the extension tube to the luer of the catheter and repeat steps 12 through 15.
- Step 18:** Radiographic placement of the balloon is recommended to verify proper balloon placement.
- Step 19:** When the catheter is properly positioned it can be secured with tape to prevent extubation or movement.
- Step 20:** Take pressure measurements.
- Step 21:** Upon completion of the pressure measurements, deflate the catheter prior to removal.

TROUBLE SHOOTING GUIDE	
Problem	Cause
Pressure waveform flat on top	Not enough air in balloon
Pressure waveform flat on bottom	Too much air in balloon
Pressure waveform all positive	Too much air in balloon. Balloon may be in stomach. Transducer not zeroed to atmosphere. Patient position may need adjustment.
Pressure waveform is dampened	Too much air in balloon. Air/fluid interface in pressure line. Do not use fluid.
Pressure waveform is flat with CPAP	Added pressure from CPAP requires additional air in balloon - 1 cc more for a CPAP of 5-6 cm H ₂ O
European Authorized Representative: Leisegang Feinmechanik GmbH • Leibnizstraße 82 • 56105, Berlin, Germany	CPAP of 5-6 cm H ₂ O