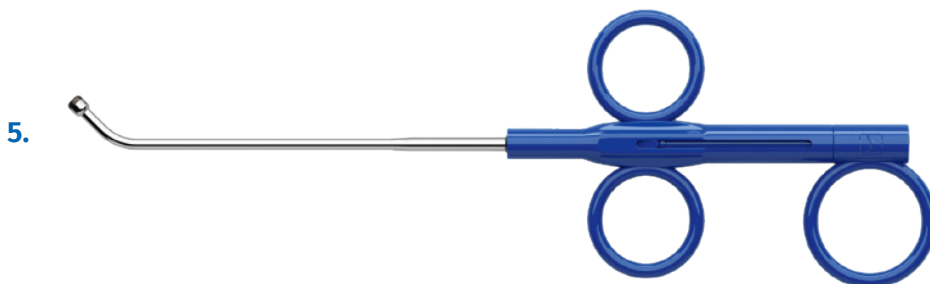


Quick Reference Guide

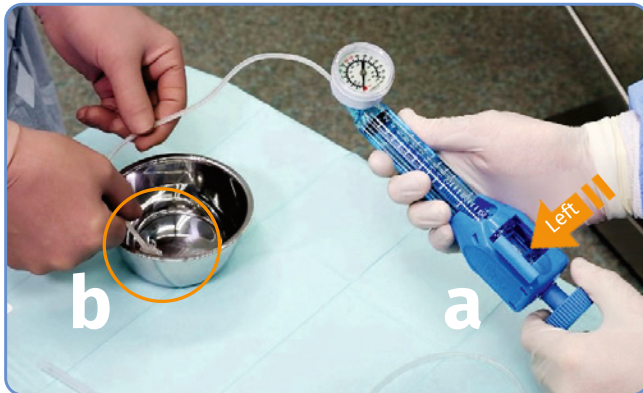
TubaVent® Balloon Dilation System

Set-up

1. Inflation device
2. Extension tube
3. Bowl filled with sterile saline solution
4. Balloon catheter TubaVent® short/short wide
5. Insertion device TubalInsert®ONE



Preparing the Inflation System



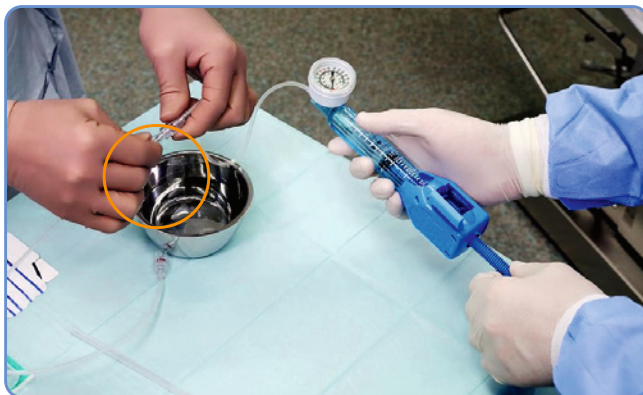
Step 1

- a) To fill pump with sterile saline solution, move the lever from the middle locked to the left unlocked position.
- b) Hold the tip of the tube into a bowl of saline solution.



Step 2

- Pull the plunger back completely to aspirate the fluid into the syringe.



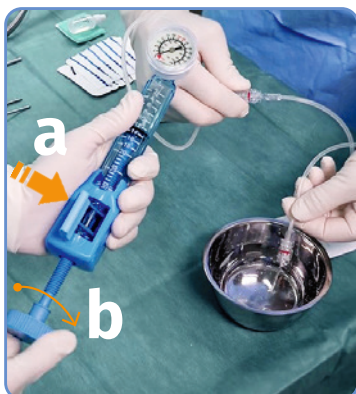
Step 3

- Connect 50 cm extension tube (optional).



Step 4

- Push the plunger of the inflation device to purge air from the system. The optimum filling quantity of the inflation device after bleeding is approx. 20-25 cc.

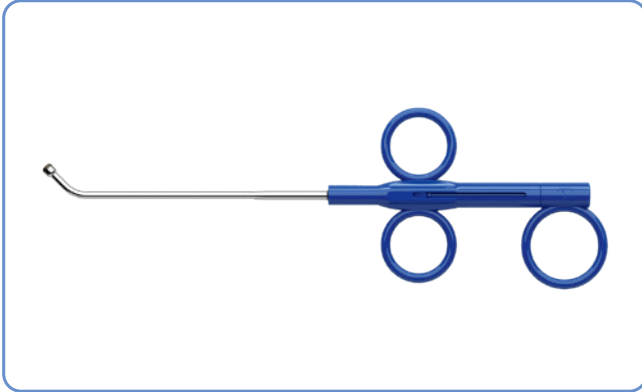


Step 5

- a) The lever should be switched back to the center position to lock the device.
- b) Turn the knob clockwise to remove remaining air.

Preparing the Catheter

The handling below illustrates in summary the product preparation and application and does not replace the Instructions For Use.



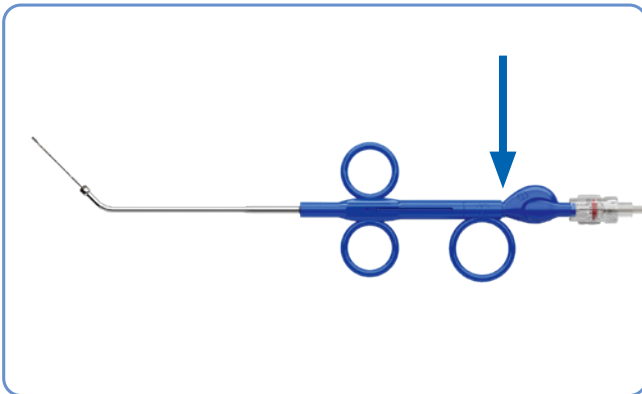
Step 1

Do not change the preset position of the guide rail on the inserter device.



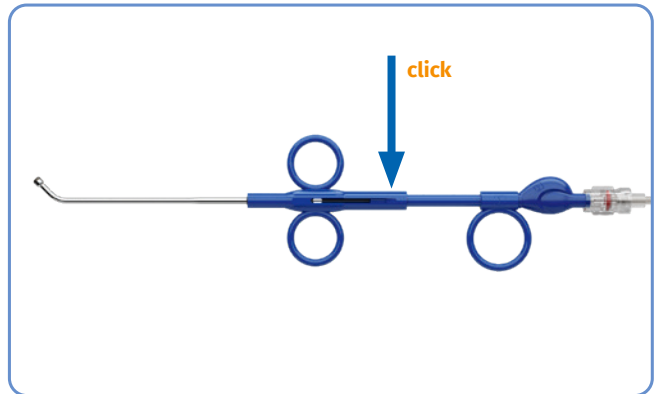
Step 2

Connect the tubing of the inflation device to the Luer-Lock of catheter.



Step 3

Insert the catheter into the inserter and advance it until the connector of the catheter is seated proximally tightly in the inserter.



Step 4

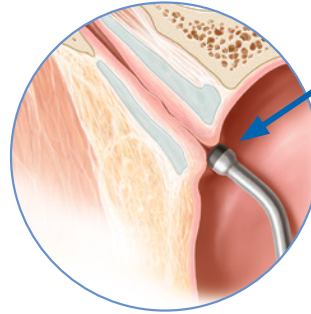
Pull back the guide rail until the locking mechanism engages.

Accessing the Eustachian Tube



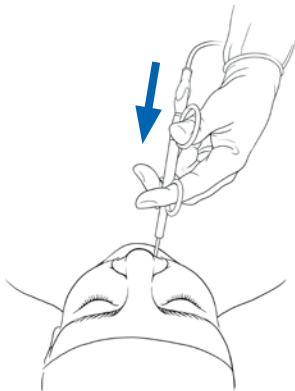
Step 1

Under endoscopic visualization, gently insert the insertion device through the nose on the side to be treated until the tip of the inserter is positioned proximal to the Eustachian tube orifice. The locking mechanism is released by applying light pressure on the thumb ring. The catheter remains in the insertion device.



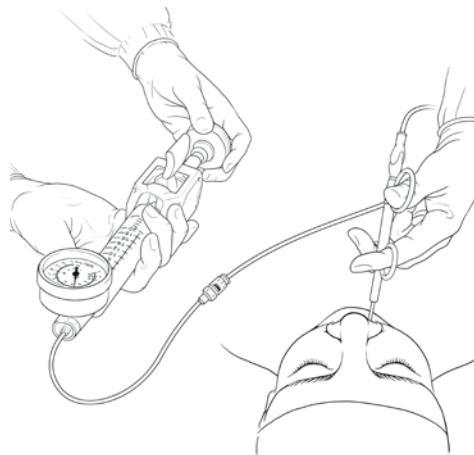
Step 2

Place the insertion device against the lateral epipharyngeal wall in front of the pharyngeal tubal ostium, so that the black marking on the olive tip of the inserter is visible. Rotate the insertion device so that the tip angle is aligned with the trajectory of the Eustachian tube.



Step 3

After placement of the inserter, the catheter is inserted into the Eustachian tube by sliding the thumb ring forward.



Step 4

The balloon is inflated with sterile saline solution up to a pressure of 10 bar (~9.87 atm) for **2 minutes**. Deflate the balloon completely according to IFU. Carefully remove the entire system from the patient under endoscopic control. If you would like to use the catheter again in the same patient on the other Eustachian tube, retract the balloon into the insertion device.

Compatibility: The components of the TubaVent® Balloon Dilation System are compatible with each other. They are intended to be used with the whole system and not with other devices from a different company.

Important Safety Information: TubaVent® Balloon Dilation System should only be used by experienced medical professionals (e.g., a qualified otolaryngologist/ENT physician) trained on the product. Prior to use, it is important to read the Instructions For Use and to understand the contraindications, warnings, and precautions associated with these devices.

RxOnly – Caution: U.S. federal law restricts this device to sale by or on the order of a physician

Distribution USA



BRYAN MEDICAL
A SPIGGLE & THEIS GROUP COMPANY

6100 Wooster Pike · Cincinnati · Ohio 45227
Phone: +1 513-272-1600 · sales@bryanmedical.net
www.bryanmedical.net



SPIGGLE & THEIS
Medizintechnik

Burghof 14 · 51491 Overath · Germany
Phone: +49 2206 90 81 - 0
Fax: +49 2206 90 81 - 13
info@spiggle-theis.com
www.spiggle-theis.com