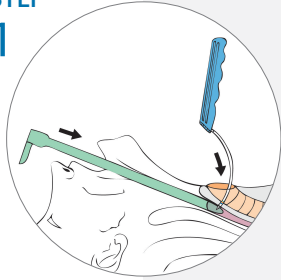


SECONDARY TRACHEOESOPHAGEAL PUNCTURE AND VOICE PROSTHESIS PLACEMENT

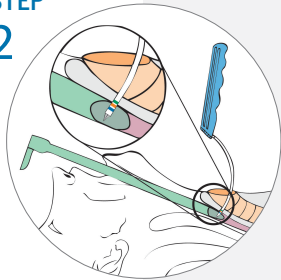
STEP 1



STEP 1 : PUNCTURE

- Under anesthesia, introduce appropriately sized, lighted rigid esophagoscope to level of tracheostoma
- Orient tip of esophagoscope to observe tracheal wall 5mm below mucocutaneous junction of tracheostoma
- Use trocar to carefully puncture tracheoesophageal wall at midline 5mm from mucocutaneous juncture into lumen of esophagus with simultaneous monitoring by endoscopist

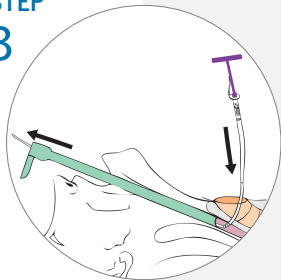
STEP 2



STEP 2 : SIZE

- Observe colored band on sheath where it enters puncture on tracheal side
- Simultaneously observe trocar penetration and terminate when leading edge of white band marker on needle sheath is observed
- Color band approximates party wall thickness and size of voice prosthesis to use; White band 8mm, Blue band 10mm, Orange band 12mm, Green band 14mm

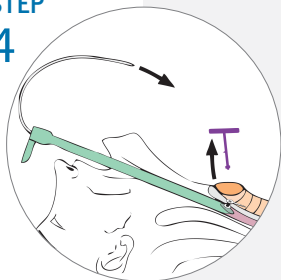
STEP 3



STEP 3 : LOAD & INSERT

- Securely grasp needle sheath with hemostat to hold in place, remove and discard trocar needle
- Insert strap of prosthesis into clear plastic carrier of dilating catheter as shown in page 4
- Position inserter stick into voice prosthesis and attach strap to inserter stick peg
- Insert narrow end of catheter tip through sheath until it is retrieved in esophagoscope

STEP 4



STEP 4 : DILATE & DEPLOY

- Firmly grasp distal (narrow) end of catheter and with continuous force, pull catheter through puncture and out mouth
- Simultaneously guide and push voice prosthesis folded within clear plastic carrier into puncture until tracheal flange and strap rest exactly against posterior wall of trachea
- While firmly holding tracheal flange against tracheal wall, a final pull of catheter will separate prosthesis from clear plastic carrier and esophageal retention flange will deploy
- Visually confirm esophageal flange has deployed

*Abbreviated from IFU instructions from Stephen B. Freeman, M.D., F.A.C.S. and Eric D. Blom, PhD.

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Overview of Placement Instructions for the Blom-Singer® VOICE PROSTHESIS PLACEMENT SURGICAL KIT (Sterile)

Designed by Eric D. Blom Ph.D.



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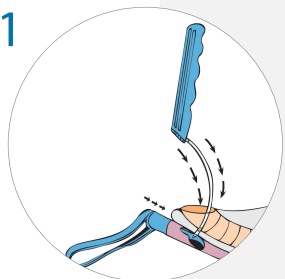
For Complete Instructions See IFU

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PRIMARY TRACHEOESOPHAGEAL PUNCTURE AND VOICE PROSTHESIS PLACEMENT

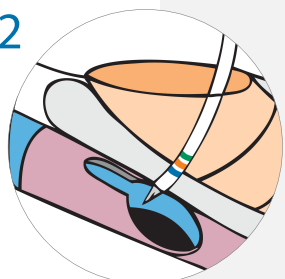
STEP 1



STEP 1 : PUNCTURE

- Insert pharynx protector to ensure protection of posterior esophageal wall at level of puncture
- Position sheath of trocar so that only cutting tip of trocar is exposed
- Use trocar to carefully puncture tracheoesophageal wall at midline, 10-15mm below mucocutaneous junction into lumen of esophagus

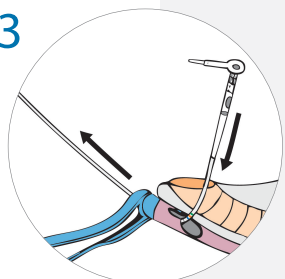
STEP 2



STEP 2 : SIZE

- Observe colored band on sheath where it enters puncture on tracheal side
- Simultaneously observe trocar penetration and immediately terminate when leading edge of white band marker is observed
- Color band approximates party wall thickness and size of voice prosthesis to use; White band 8mm, Blue band 10mm, Orange band 12mm, Green band 14mm

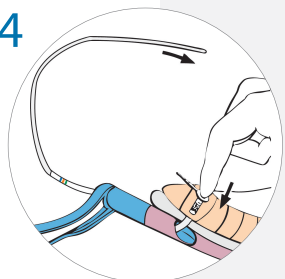
STEP 3



STEP 3 : LOAD & INSERT

- Securely grasp needle sheath with hemostat to hold it in place and remove and discard trocar needle
- Insert strap of prosthesis into clear plastic carrier of dilating catheter as shown in page 4
- Insert distal (narrow) catheter tip through sheath, past pharynx protector and out pharyngeal defect; Catheter will mate up and carry sheath along with it

STEP 4



STEP 4 : DILATE & DEPLOY

- Firmly grasp distal (narrow) end of catheter and with continuous force pull catheter through puncture
- Simultaneously guide and push voice prosthesis folded within clear plastic carrier into puncture until tracheal flange and strap rest exactly against posterior wall of trachea
- While firmly holding tracheal flange against tracheal wall, final pull of catheter will separate prosthesis from clear plastic carrier and esophageal retention flange will deploy
- Visually confirm esophageal flange has deployed

*Abbreviated from IFU instructions from Stephen B. Freeman, M.D., F.A.C.S. and Eric D. Blom, PhD.

HOW TO LOAD THE VOICE PROSTHESIS INTO THE CATHETER

STEP 1

Identify window at proximal transparent end of dilating catheter.



STEP 2

Insert strap of sterile Blom-Singer® Classic™ Indwelling Voice Prosthesis into window and out proximal end of catheter.



STEP 3

Pull strap of voice prosthesis into opening to fold flanges into opening.

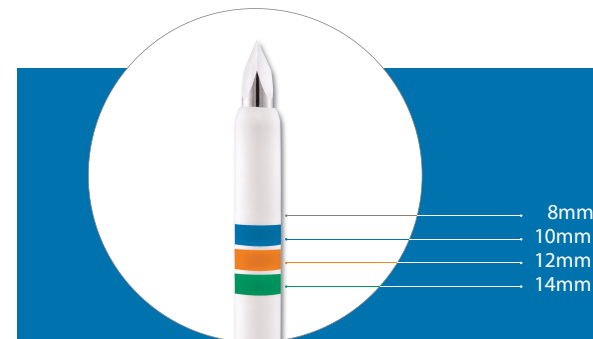


STEP 4

Continue to pull gently on strap until it is fully exposed and esophageal flange is extended.

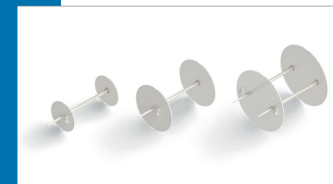


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