

Blom-Singer®

voice restoration systems

Blom-Singer® Voice Prosthesis Placement Surgical Kit



MEDICAL PROFESSIONAL Instructions For Use

INHEALTH®
TECHNOLOGIES

R2

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Patent(s): www.inhealthpatents.com

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MEDICAL PROFESSIONAL Instructions For Use

BLOM-SINGER® VOICE PROSTHESIS PLACEMENT SURGICAL KIT

Introduction

Please refer to the diagrams located at the back of this instruction manual.

The Blom-Singer® Voice Prosthesis Placement Surgical Kit is designed to be used during surgery for primary or secondary placement of a tracheoesophageal puncture and voice prosthesis.

This Blom-Singer® medical device may be used only once with one patient. It may not be reused.

Do not use the device if it becomes contaminated; discard and replace it with an unopened product.

INDICATIONS

The Blom-Singer® Voice Prosthesis Placement Surgical Kit is indicated for use during surgery for primary or secondary puncture and dilation of the tracheoesophageal wall, selection of the proper length of voice prosthesis, and to guide the placement of the voice prosthesis.

CONTRAINDICATIONS

Tracheoesophageal puncture and therefore also the Blom-Singer® Voice Prosthesis Placement Surgical Kit is contraindicated:

- in patients whose medical status increases the risk of uncontrolled dilation of the puncture and aspiration of esophageal contents around the voice prosthesis. These patients include those with irradiation to the tracheostoma exceeding 6500 rads, uncontrolled diabetes mellitus, concurrent chemotherapy and severe malnutrition;
- in the small tracheostoma of patients in which presence of the catheter or a voice prosthesis may compromise respiration;
- in patients who cannot take care of themselves, have severe

arthritis or blindness, or are not interested in speaking.

Do not use the Blom-Singer® Voice Prosthesis Placement Surgical Kit if the patient's health status or anatomical abnormalities contraindicate performing a tracheoesophageal puncture or insertion of a voice prosthesis.

Patients with known bleeding disorders or those on anticoagulants should be assessed prior to tracheoesophageal puncture to avoid bleeding or hemorrhage complications.

HOW SUPPLIED

The Blom-Singer® Voice Prosthesis Placement Surgical Kit is provided sterile (by gamma radiation) in a tray within a pouch and ready to be introduced into the surgical field. Do not resterilize.

PRODUCT DESCRIPTION

The Blom-Singer® Voice Prosthesis Placement Surgical Kit is designed to be used during surgery for primary or secondary placement of a tracheoesophageal puncture and voice prosthesis. This set includes one of each: (1) Trocar, a 13 gauge curved needle fitted with a 9 gauge sheath (stent); (2) Catheter, a 16 Fr or 20 Fr, 33 inch catheter with taper; (3) Pharynx Protector, a tool with handle and notched cylinder.

NOTE: Blom-Singer® Voice Prosthesis Placement Surgical Kit is designed to be used with Blom-Singer® Classic™ Indwelling Voice Prosthesis - Sterile Series. Indwelling voice prosthesis and inserter stick packaged separately.

WARNINGS AND PRECAUTIONS

Use of this product is for trained physicians only.

A primary tracheoesophageal puncture procedure is only recommended with use of the included pharynx protector to provide protection of the posterior esophagus. The physician must puncture into the pharynx protector to prevent puncturing the posterior esophagus which could result in dysphagia,

bleeding, and/or spinal complications.

A secondary tracheoesophageal procedure is only recommended with use of a rigid esophagoscope to allow for adequate visualization of the tracheoesophageal wall and to provide protection of the posterior esophagus. Do not use the pharynx protector for secondary tracheoesophageal puncture. The physician must puncture the posterior esophagoscope to prevent puncturing into the esophagus which could result in dysphagia, bleeding, and/or spinal complications.

If the sheath (stent) is not kept within the puncture tract after the trocar is removed, the puncture tract may close and another puncture operation may be warranted.

Once the puncture is completed using the device and the indwelling voice prosthesis is placed, the individual should be monitored closely.

Do not use this device if the package is opened or in any way damaged. Use of a device that is not sterile may cause infection. In addition, this device is for single-use only. Should it be reused, there is a risk of infection due to microbial contamination. Do not resterilize the product. Reprocessing and/or resterilization of the device may alter its performance and device failure may occur.

If there are tears, cracks, or structural damage to the device, discontinue use.

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

COMPLICATIONS

Although rare, the following complications have been identified to occur with tracheoesophageal puncture and therefore are potential complications with the use of the Blom-Singer® Voice Prosthesis Placement Surgical Kit. They include:

- aberrant perforation of the posterior esophagus with subsequent mediastinal infection or abscess;
- peristomal infection or cellulitis, which may be prevented by appropriate use of prophylactic antibiotics;
- aspiration around the indwelling voice prosthesis positioned in the tracheoesophageal puncture.

INSTRUCTIONS FOR USE

PRIMARY TRACHEOESOPHAGEAL PUNCTURE AND VOICE PROSTHESIS PLACEMENT

The following procedural instructions are provided by Stephen B. Freeman, M.D., F.A.C.S. and Eric D. Blom, Ph.D. for primary tracheoesophageal puncture followed by simultaneous tracheoesophageal tract dilation and voice prosthesis placement.

1. Primary tracheoesophageal puncture and voice prosthesis placement is undertaken following standard wide field total laryngectomy prior to a three layer closure of the pharynx in a T or Y fashion.
2. Insert the pharynx protector deeply enough into the esophagus to ensure protection of the posterior esophageal wall at the level of the puncture (**Diagram 1**).
3. The sheath of the trocar should be completely covering all but the cutting tip of the curved needle and positioned so that the multi-color bands are closest to the tip of the curved needle.
4. Use the trocar to carefully puncture the tracheoesophageal wall at the midline 10-15mm below the mucocutaneous juncture into the lumen of the esophagus.
5. Penetration into the esophagus is carefully observed and immediately terminated when the leading edge of the white band marker on the needle sheath is observed. Simultaneously, the color association band on the sheath where it enters the puncture on the tracheal side of the tracheoesophageal wall approximates the wall thickness and appropriate length voice prosthesis to be placed. (White band 8mm, Blue band 10mm, Orange band 12mm, and Green band 14mm). (**Diagram 2**)
6. Securely grasp the needle sheath with a hemostat with sufficient force to stabilize it securely in its position of penetration into the esophagus and withdraw and discard the puncture needle.

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7. Insert a voice prosthesis of a length corresponding to the associated sheath color band observed in step 5 into the lumen of the transparent proximal end of the catheter such that its esophageal retention flange is forward folded. **(Diagram 3)** Insert the strap of the voice prosthesis through the small window and out the proximal end of the catheter. Gently pull on the strap while simultaneously deforming the flanges with your fingers until the voice prosthesis is positioned inside the catheter as shown in **(Diagram 4)**.
 8. Optionally, position the inserter stick (included with voice prosthesis) into the voice prosthesis tracheal end, and attach the strap to the inserter stick peg. **(Diagram 5)**
 9. Insert the distal (narrow) catheter tip through the sheath, past the pharynx protector and out the patient's pharyngeal defect, mating up with and carrying the sheath along with it.
 10. Firmly grasp the distal (narrow) end of the catheter and with continuous force pull the catheter through the puncture. Simultaneously guide and push the voice prosthesis with the voice prosthesis inserter stick into the puncture until the tracheal flange and strap rest exactly against the posterior wall of the trachea. The voice prosthesis will separate from the catheter. The folded esophageal retention flange will deploy securely against the anterior wall of the esophagus. **(Diagram 6.1 if no inserter stick is used; or Diagram 6.2 if inserter stick is used) Directly observe that this has occurred.**
 11. Remove and discard the pharynx protector.
 12. Detach, remove and discard the inserter stick if used.
 13. Once the esophageal retention flange has been confirmed to have deployed, carefully detach the strap on the voice prosthesis with scissors or suture into the midline peristomal skin.
 14. Closely monitor the voice prosthesis post-operatively and carefully clean as needed in situ per instructions found with

the voice prosthesis. Use of the placed voice prosthesis is strictly deferred until post-op day 12-14 at the earliest to avoid the potential of voicing related airflow causing a pharyngoesophageal fistula.

15. Once the patient is started on oral fluids the valve should be checked for leakage by having him or her drink while the open (tracheal) end of the voice prosthesis is carefully observed with a bright light.

SECONDARY TRACHEOESOPHAGEAL PUNCTURE AND VOICE PROSTHESIS PLACEMENT

The following procedural instructions are provided by Stephen B. Freeman, M.D., F.A.C.S., and Eric D. Blom, Ph.D. for secondary tracheoesophageal puncture followed by simultaneous tracheoesophageal tract dilation and voice prosthesis placement.

1. Confirm a tracheostoma diameter of 1.5 cm or larger. A barium swallow is also recommended to verify that pharyngoesophageal dimensions are adequate for rigid endoscopy.
2. Under anesthesia, introduce minimally a size 6mm and 25cm length, or appropriately sized, lighted rigid esophagoscope to the level of the tracheostoma (**Diagram 7**). Orient its tip to align the short aspect of the bevel adjacent to the tracheal wall 5mm between the mucocutaneous junction of the tracheostoma. Palpate or transilluminate the membranous trachea to confirm endoscope positioning.
3. The sheath of the trocar should be completely covering all but the cutting tip of the curved needle and positioned so that the multi-color bands are closest to the tip of the curved needle.
4. The puncture should be placed midline 5mm from the mucocutaneous junction of the tracheostoma. Introduce the

trocar through the posterior tracheoesophageal wall into the esophagoscope with simultaneous monitoring by the endoscopist (**Diagram 8**).

5. Penetration into the esophagus is carefully observed and immediately terminated when the leading edge of the white band marker on the needle sheath is observed. Simultaneously, the color association band on the sheath where it enters the puncture on the tracheal side of the tracheoesophageal wall approximates the wall thickness and appropriate length voice prosthesis to be placed. (White band 8mm, Blue band 10mm, Orange band 12mm, and Green band 14mm). (**Diagram 2**)
6. Use a hemostat to securely stabilize the sheath in the puncture as the needle is withdrawn.
7. Insert a voice prosthesis of a length corresponding to the associated sheath color band observed in step 5 into the lumen of the transparent proximal end of the catheter such that its esophageal retention flange is forward folded. (**Diagram 9**) Insert the strap of the voice prosthesis through the small window and out the proximal end of the catheter. Gently pull on the strap while simultaneously deforming the flanges with your fingers until the voice prosthesis is positioned inside the catheter as shown in (**Diagram 4**).
8. Position the inserter stick (included with voice prosthesis) into the voice prosthesis tracheal end, and attach the strap to the inserter stick peg (**Diagram 10**).
9. Thread the distal (narrow) end of the catheter into the sheath until it is retrieved in the proximal end of the esophagoscope.
10. Firmly grasp the distal (narrow) end of the catheter and with continuous force pull the catheter through the puncture. Simultaneously guide and push the voice prosthesis with the voice prosthesis inserter stick into the puncture until the tracheal flange and strap rest exactly against the posterior wall of the trachea. The voice prosthesis will separate from the catheter. The folded esophageal retention flange will

deploy securely against the anterior wall of the esophagus.
(Diagram 11) Directly observe that this has occurred.

11. Remove the endoscope.
12. Detach, remove, and discard the inserter stick.
13. Check the valve function for leakage by having the patient drink liquid.
14. Carefully detach the strap with scissors or suture to the midline peristomal skin.
15. Instruction in use of the voice prosthesis begins at any time in the post-operative period at discretion of the physician.

ORDERING INFORMATION

USA

InHealth Technologies products may be ordered directly from InHealth Technologies. TELEPHONE: Toll-Free (800)477-5969 or (805)684-9337, Monday — Friday, 9:30 am — 7:00 pm, Eastern Standard Time. FAX: Toll-Free (888)371-1530 or (805)684-8594. EMAIL: order@inhealth.com ORDER ON-LINE: www.inhealth.com POST: InHealth Technologies, 1110 Mark Avenue, Carpinteria, CA 93013-2918, USA, Attention: Customer Service.

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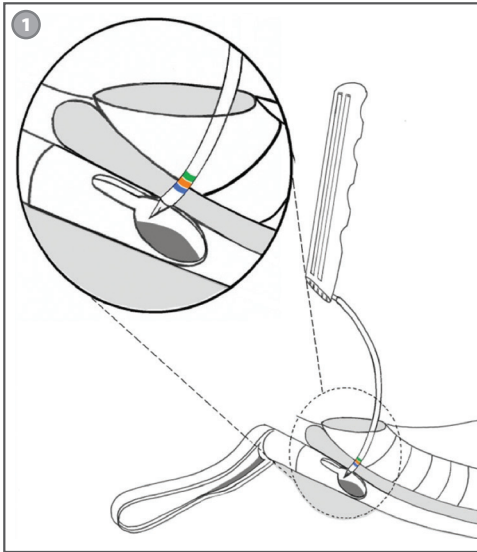
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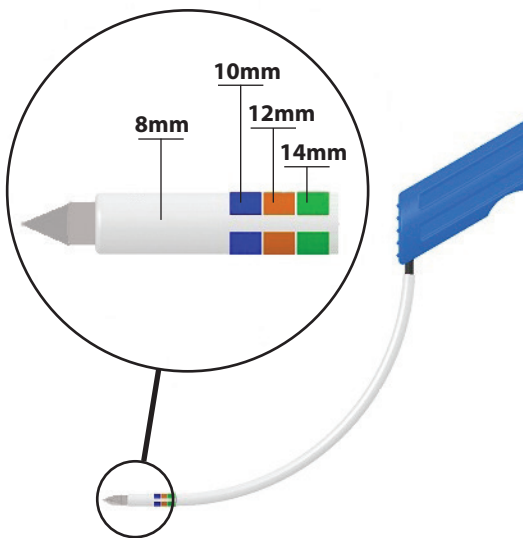
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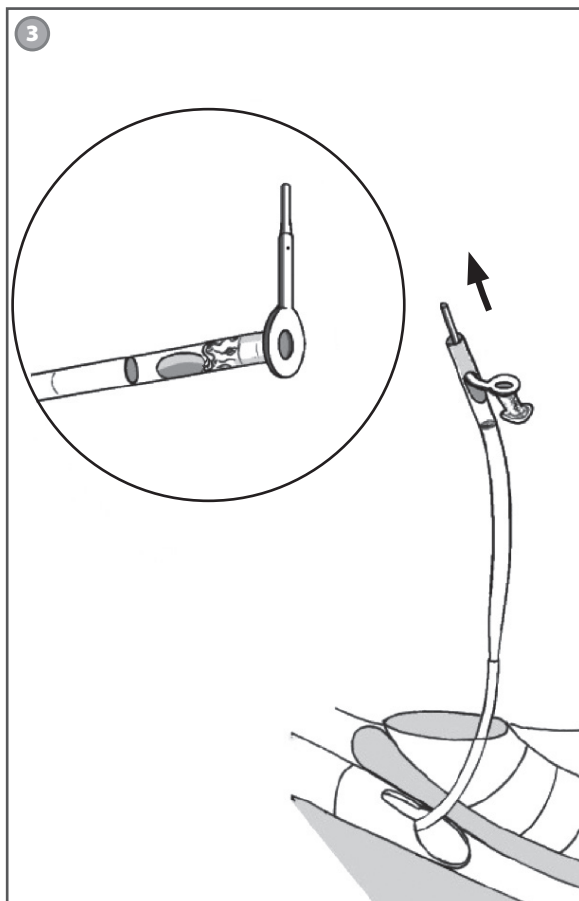
DIAGRAMS

Primary Tracheoesophageal Puncture and Voice Prosthesis Placement

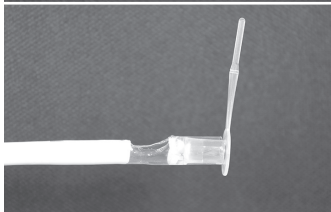
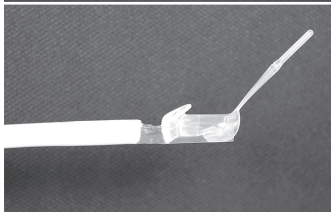
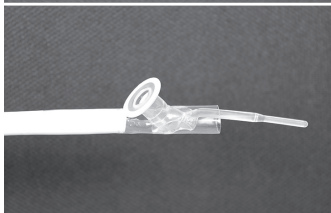
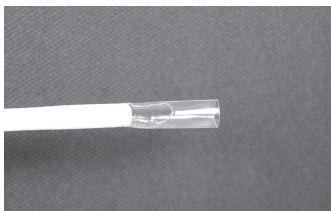


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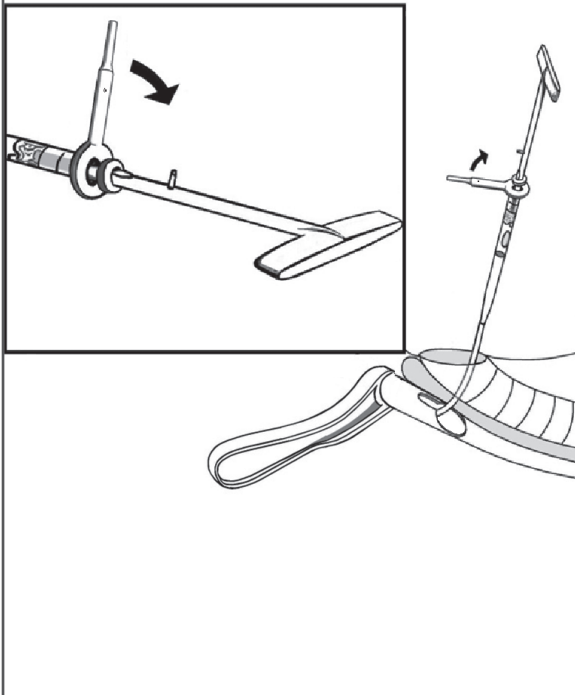




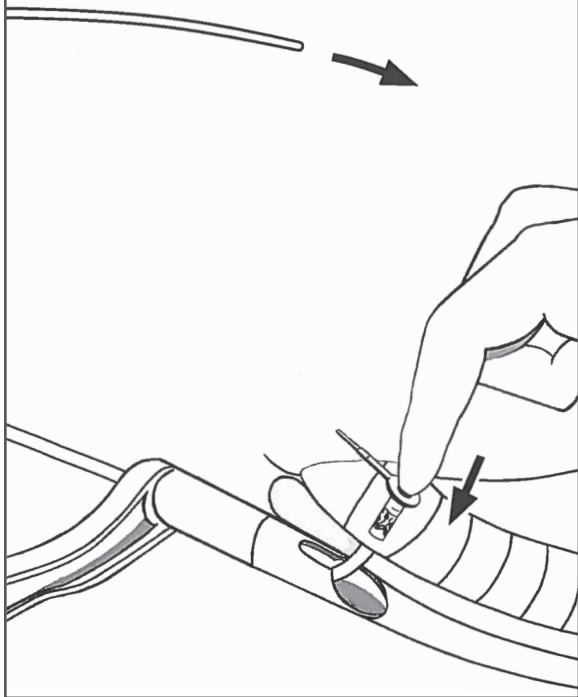
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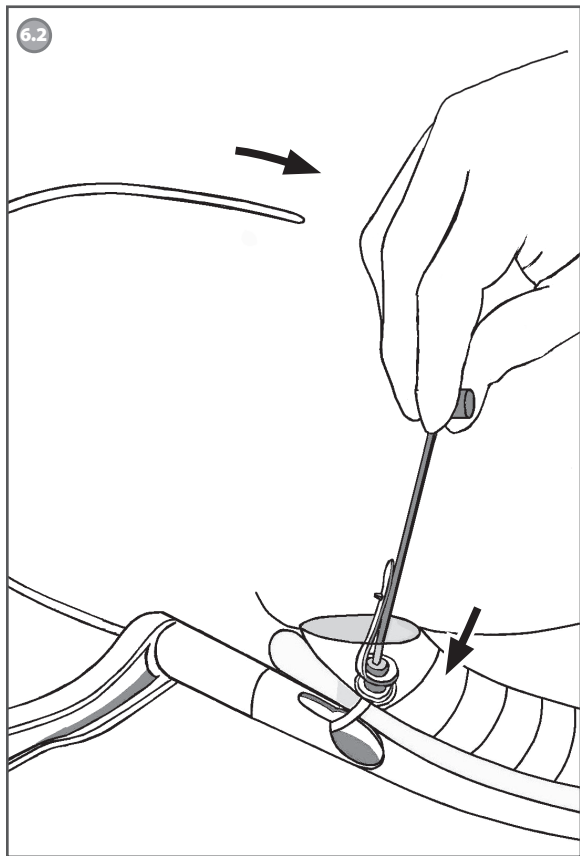


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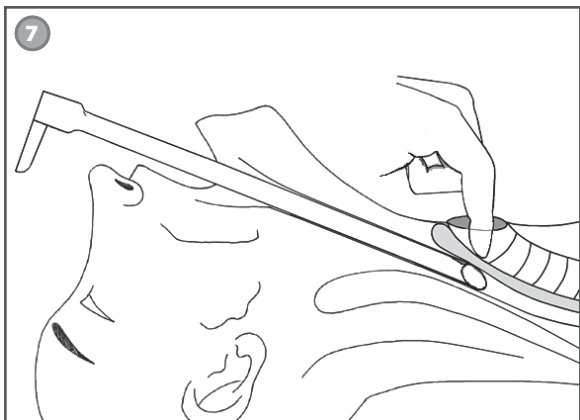


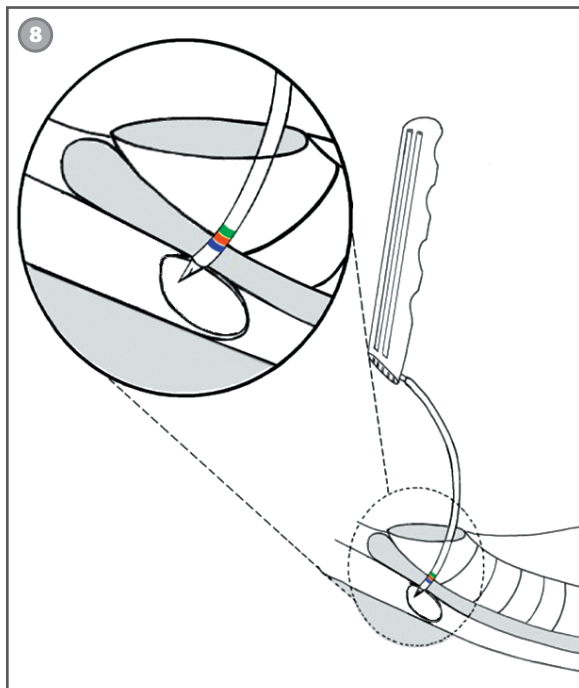
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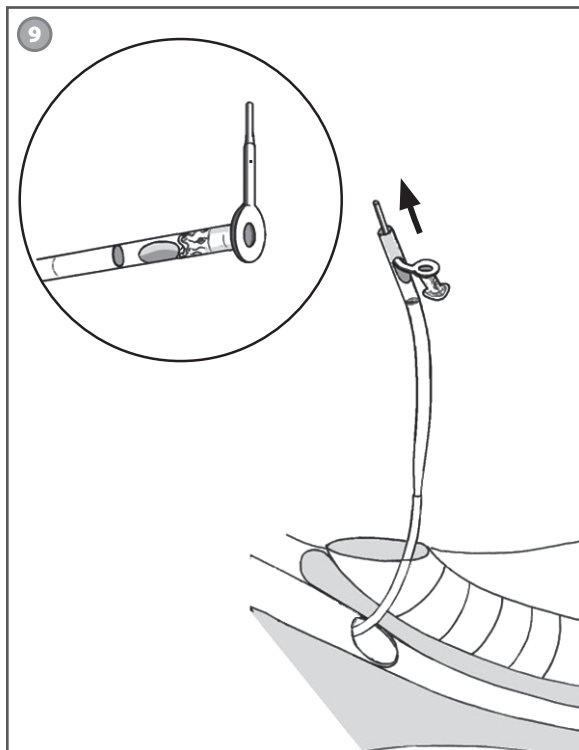


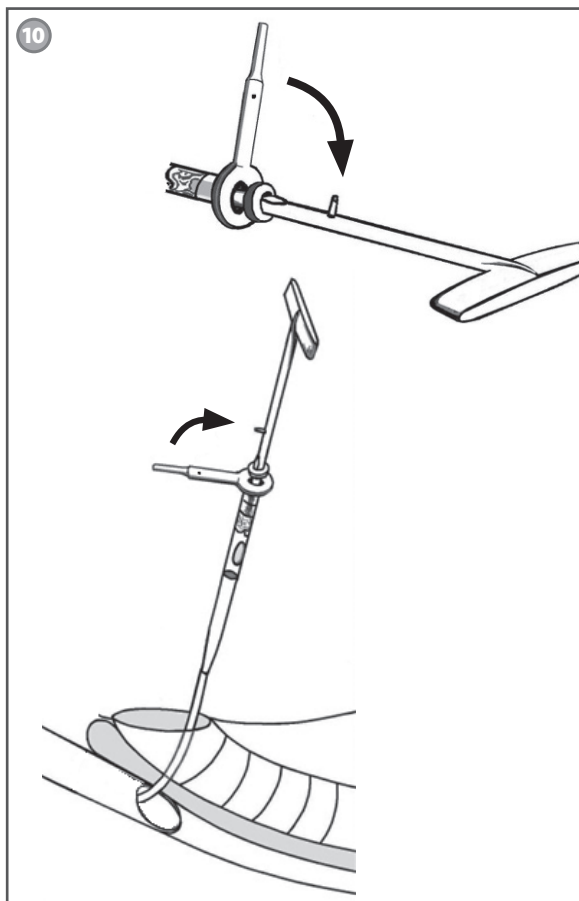


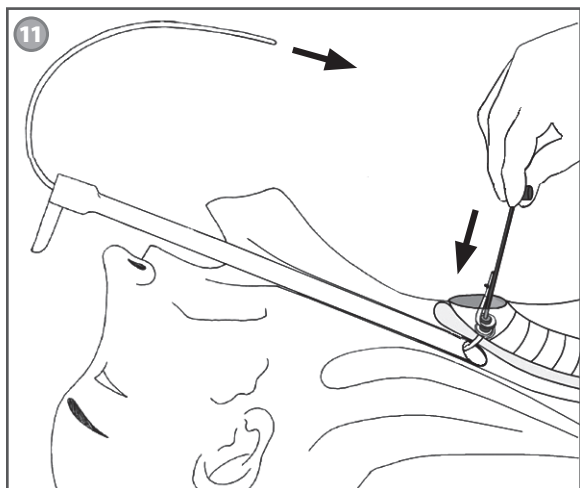
Secondary Tracheoesophageal Puncture and Voice Prosthesis Placement











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