INHEALTH
TECHNOLOGIES®

Blom-Singer® FirstFit™ Surgical Kit

INSTRUCTIONS FOR USE

Blom-Singer®
voice restoration systems

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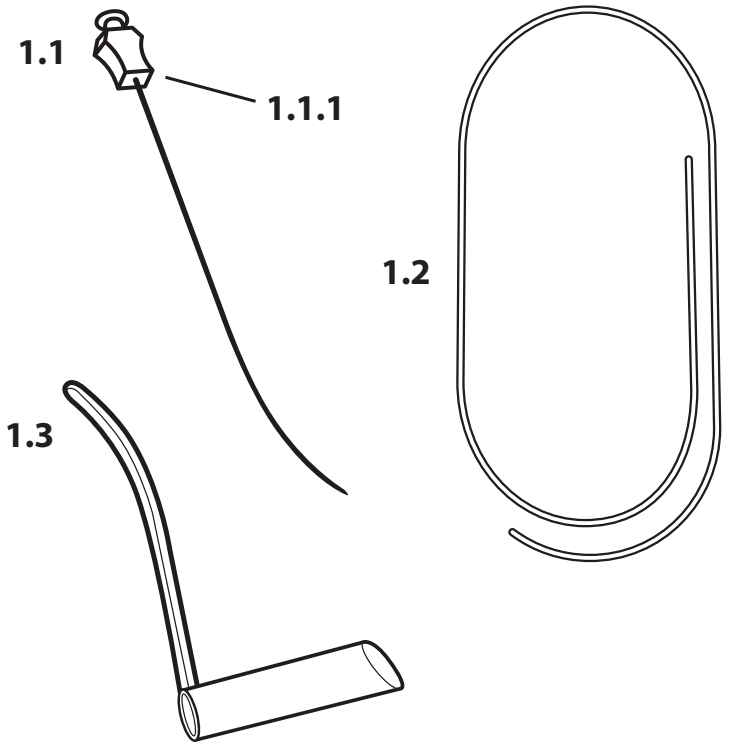
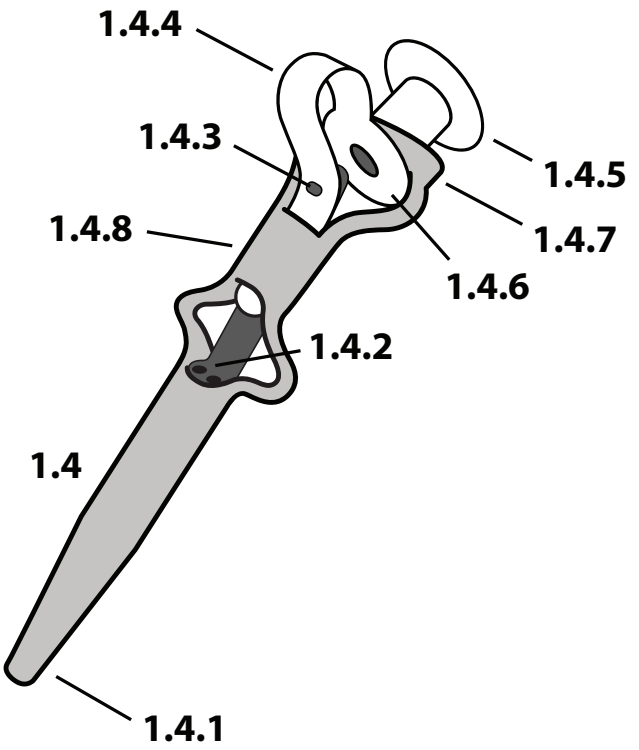
IFU: https://inhealth.com/ifu

DIAGRAMS





1.1 PUNCTURE NEEDLE
1.1.1 PUNCTURE NEEDLE HUB
1.2 GUIDEWIRE
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1.4 VOICE PROSTHESIS INSERTER BODY
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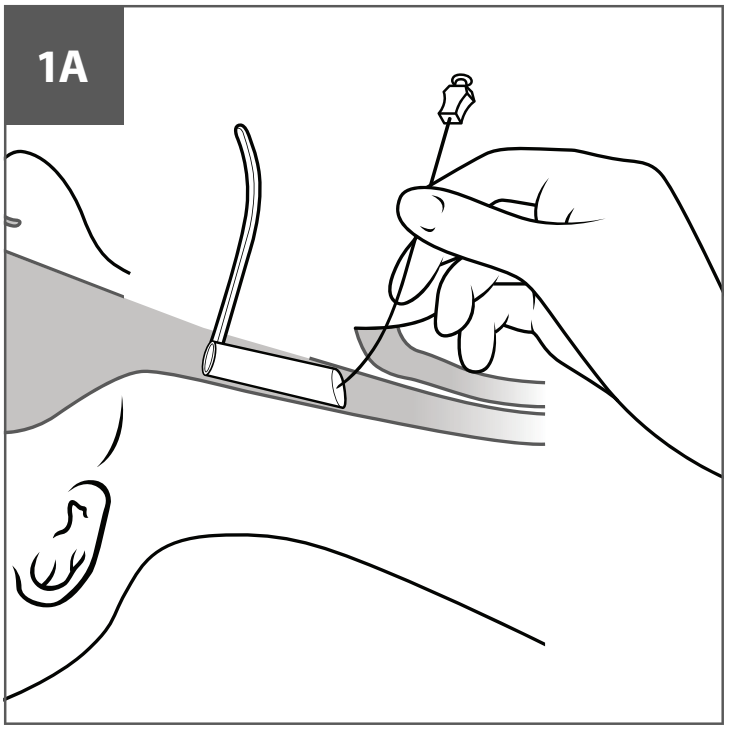
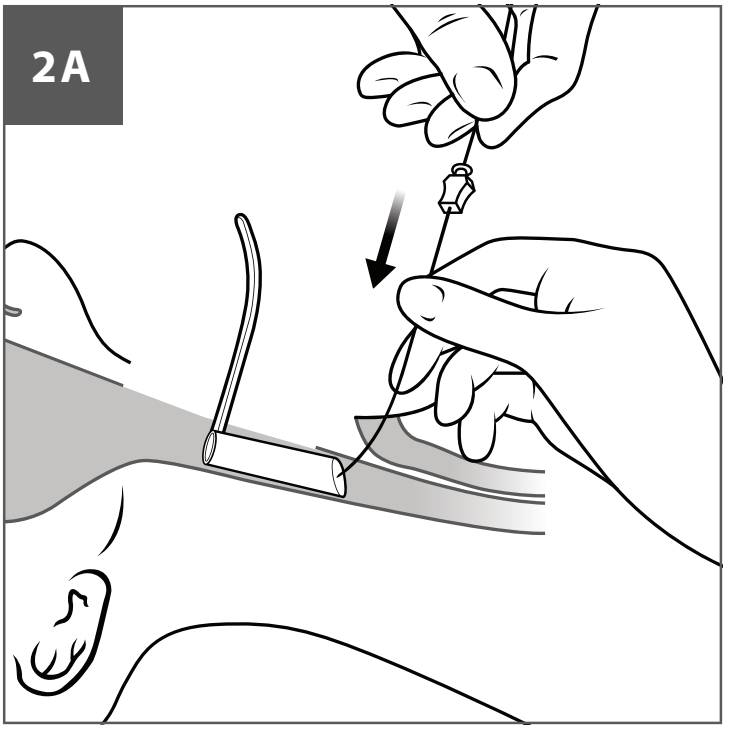
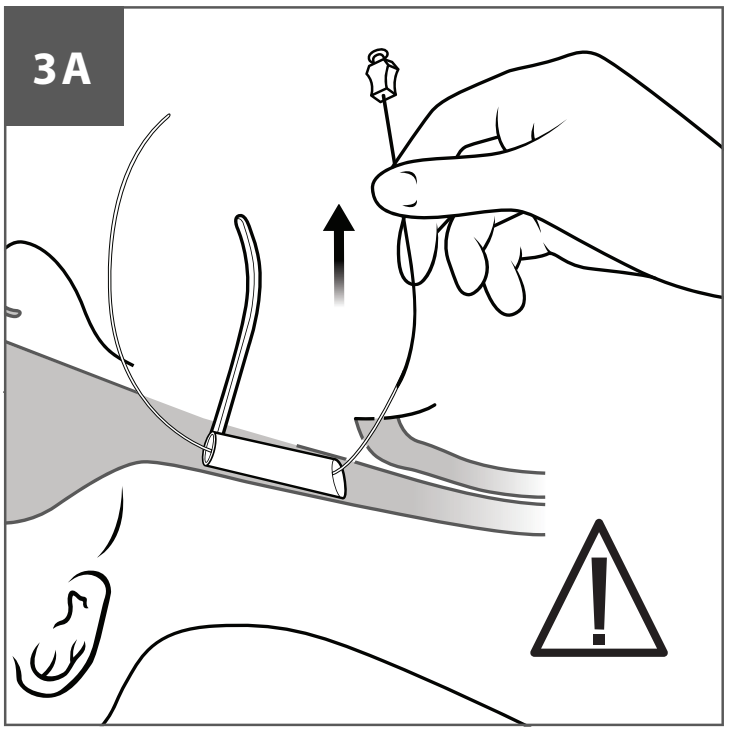
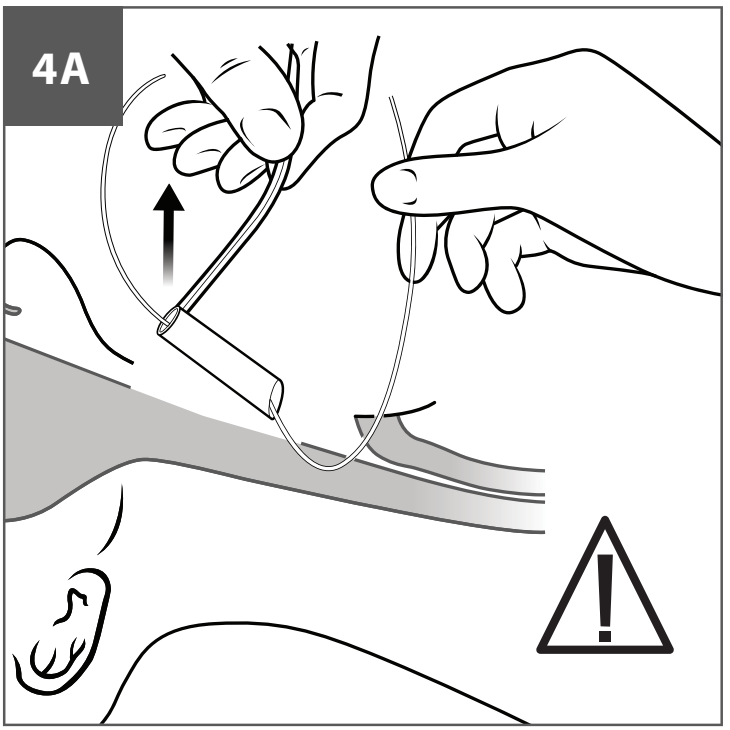
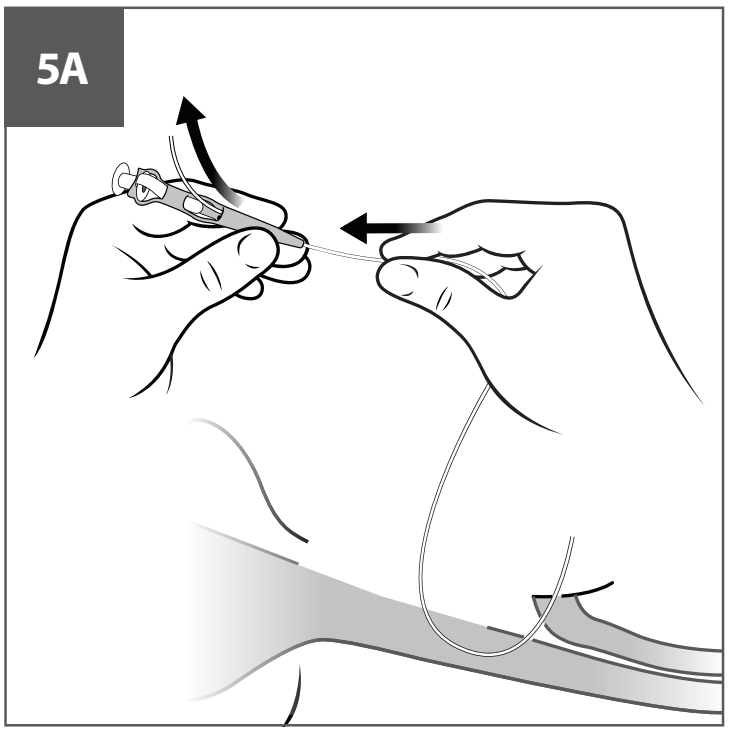
PRIMARY TRACHEOESOPHAGEAL PUNCTURE WITH VOICE PROSTHESIS PLACEMENT







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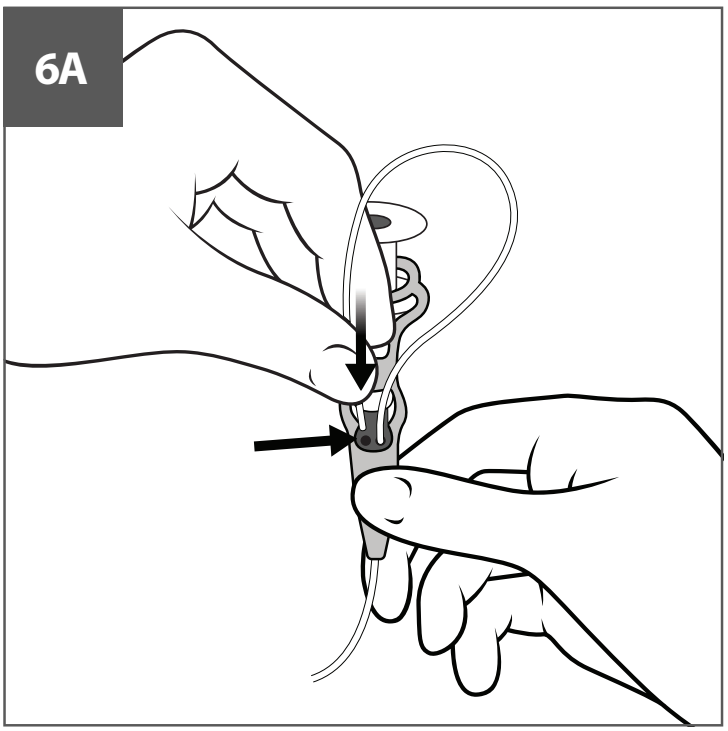
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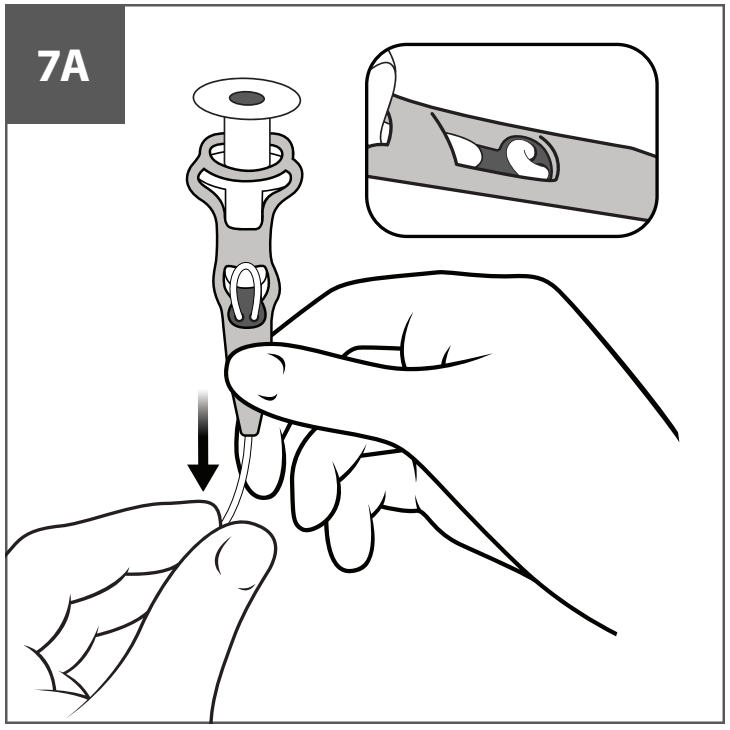
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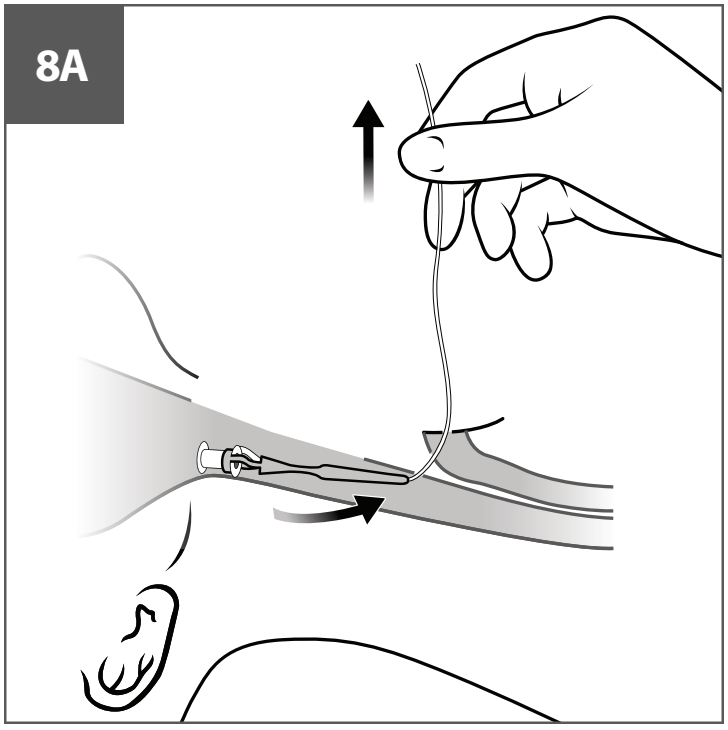
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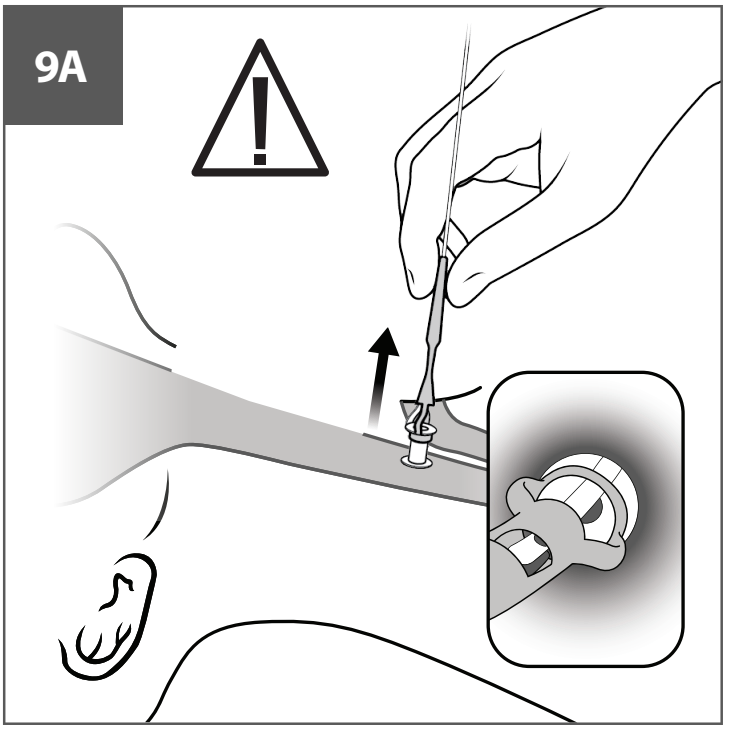
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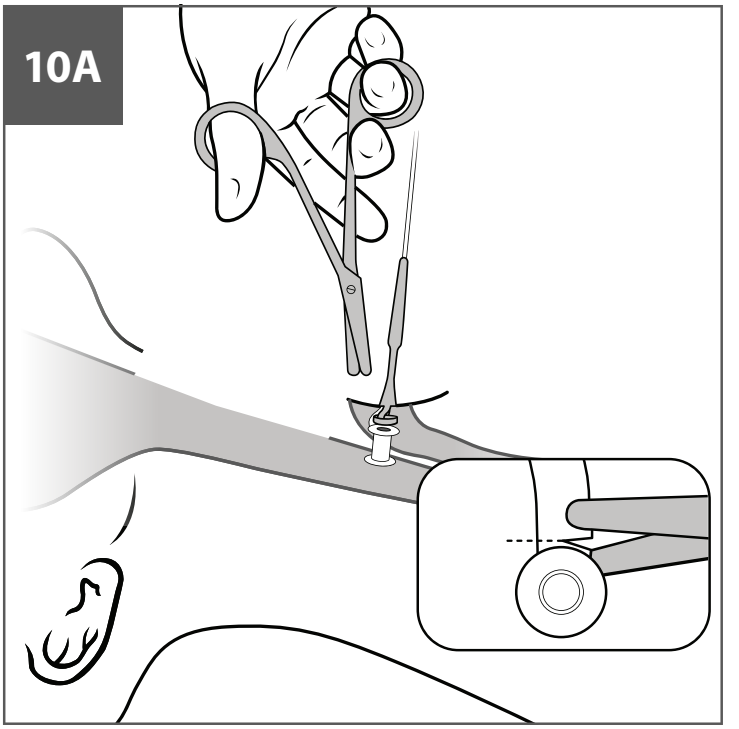
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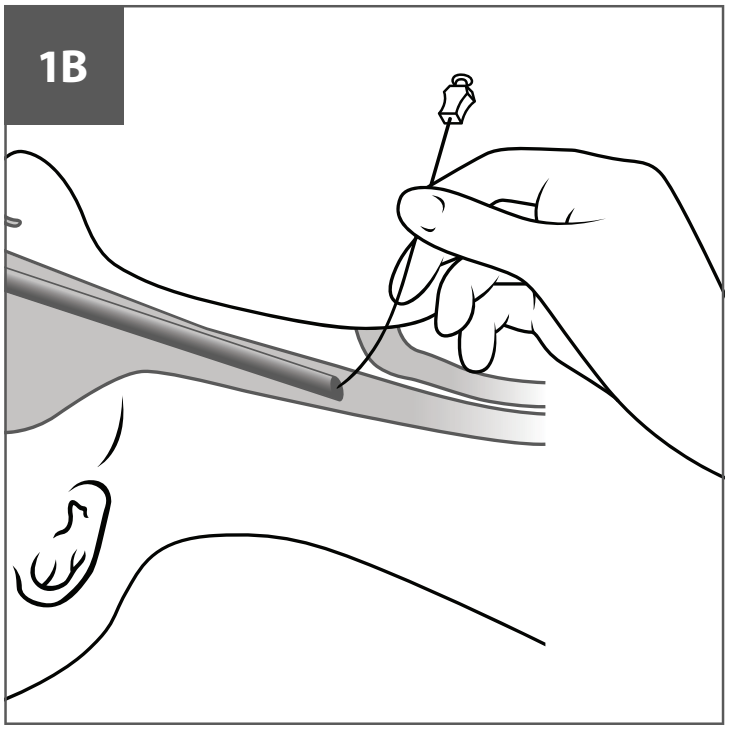
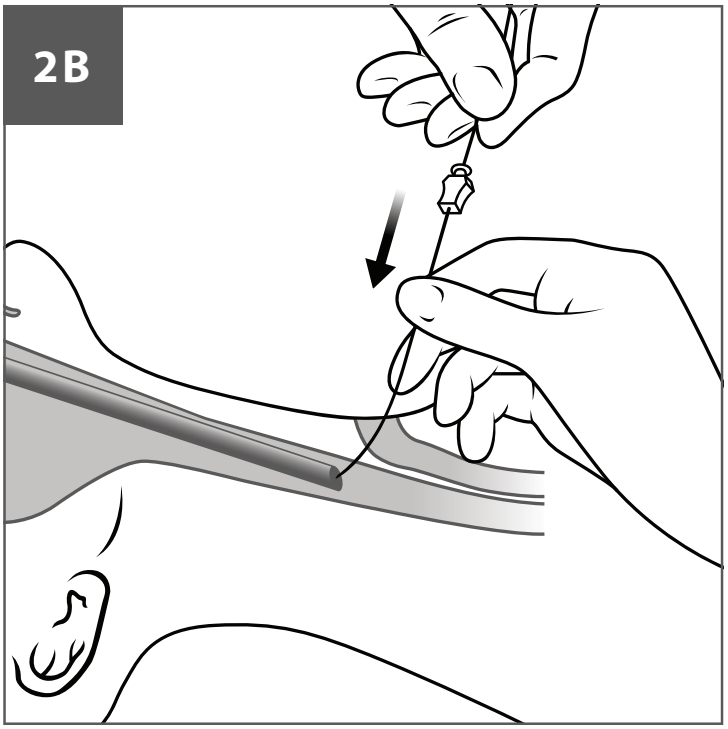
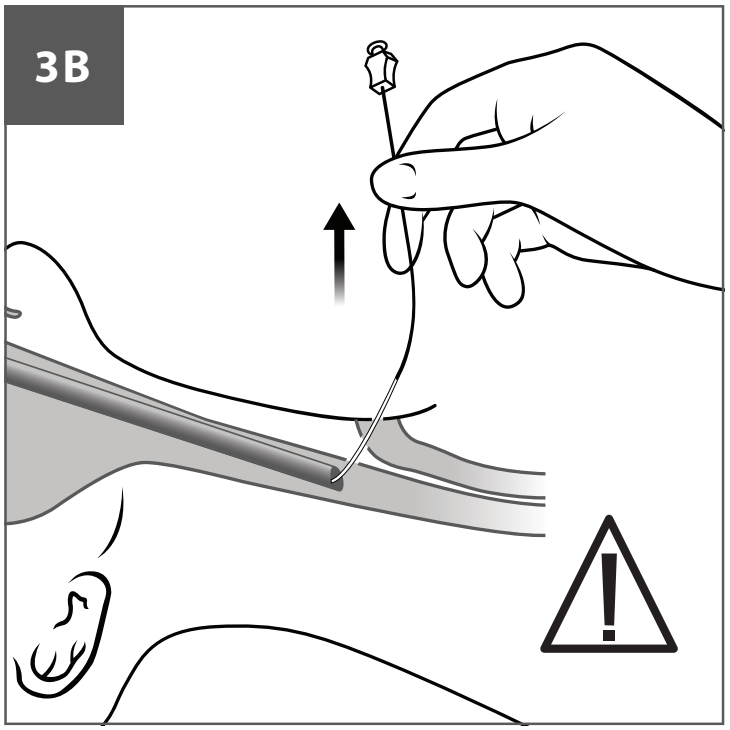
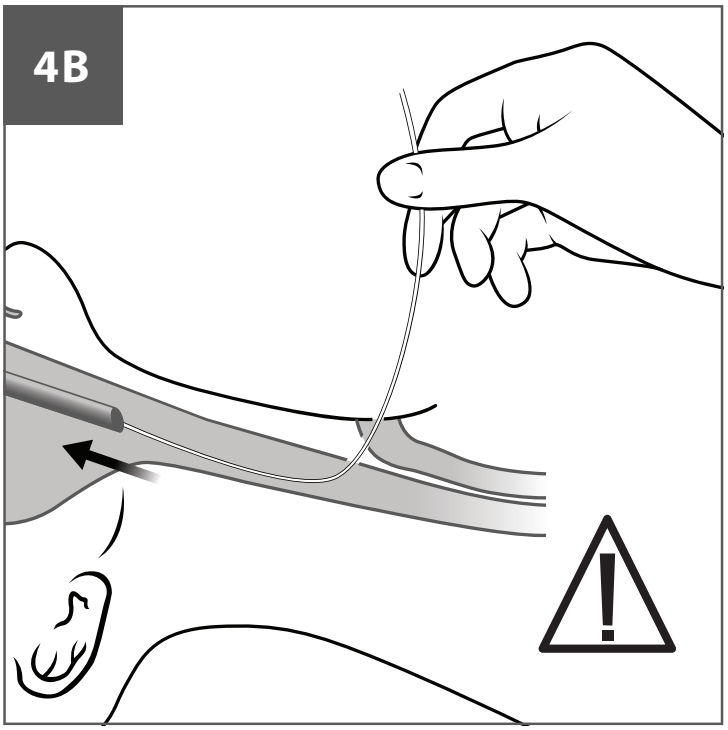
SECONDARY TRACHEOESOPHAGEAL PUNCTURE WITH VOICE PROSTHESIS PLACEMENT









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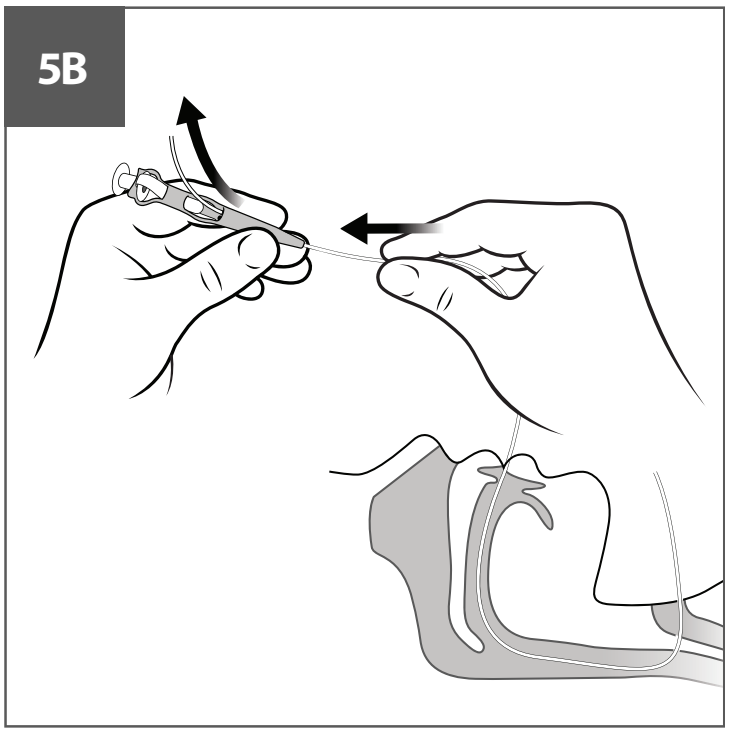

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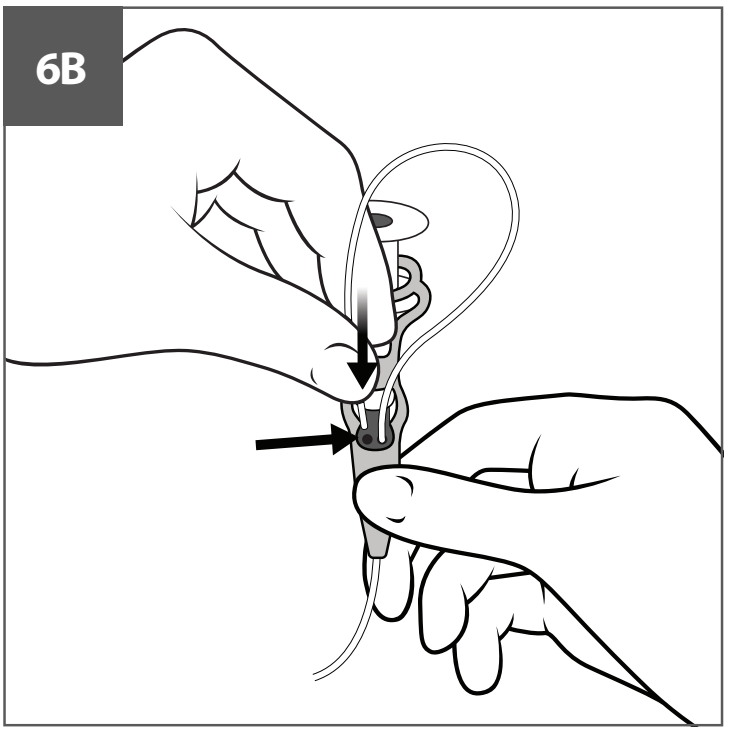

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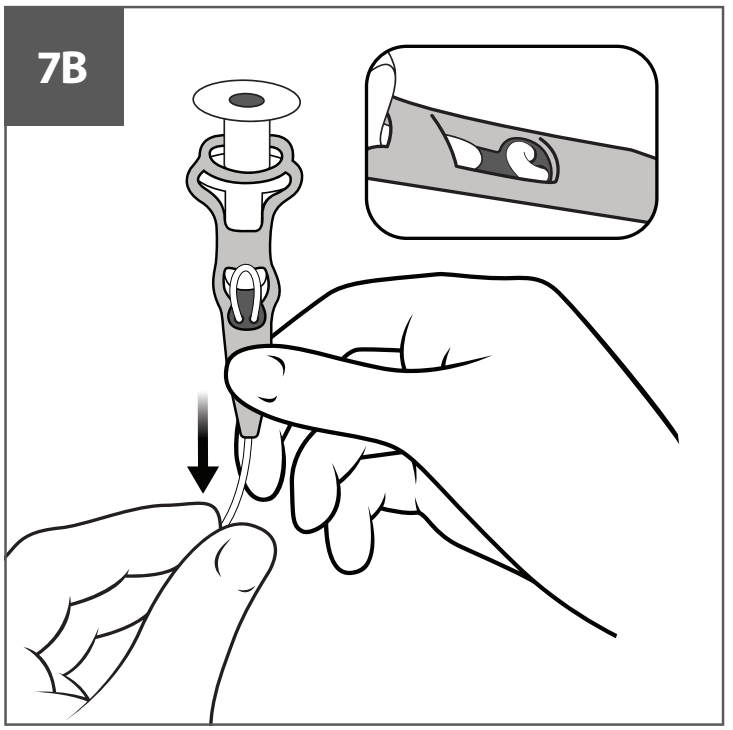

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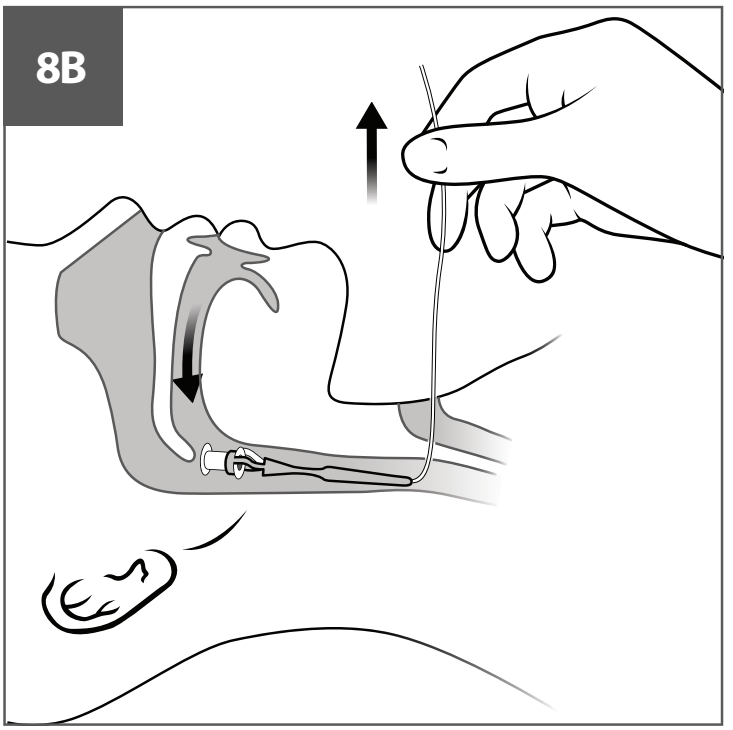

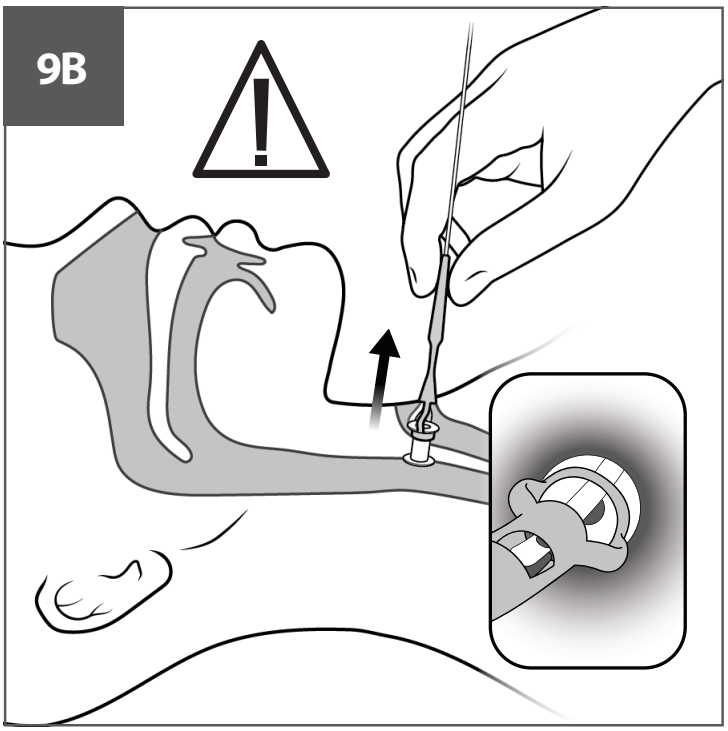
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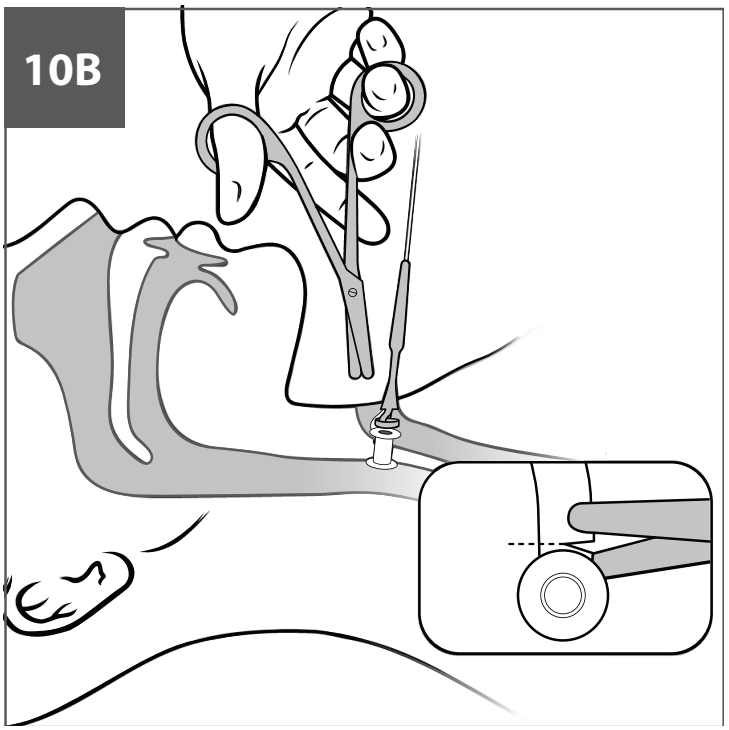
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RELEASING THE INSERTER

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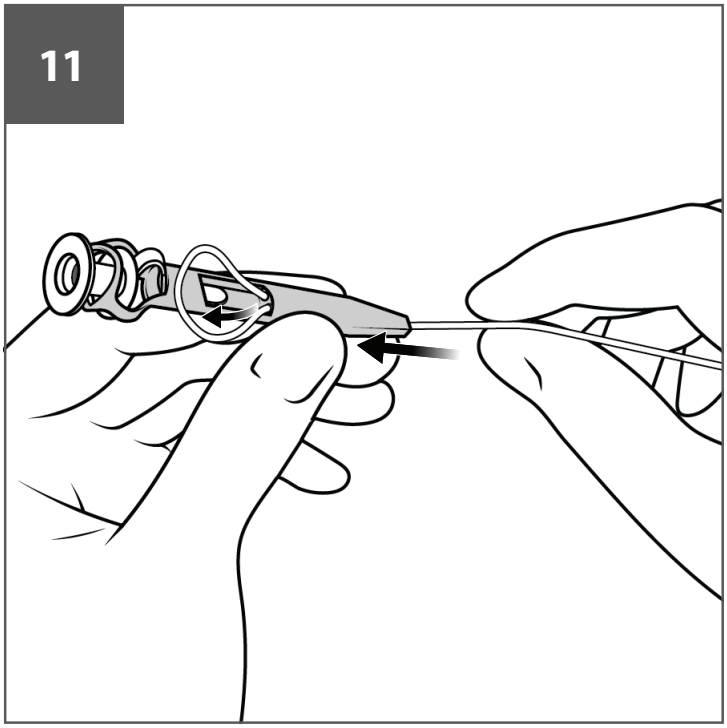

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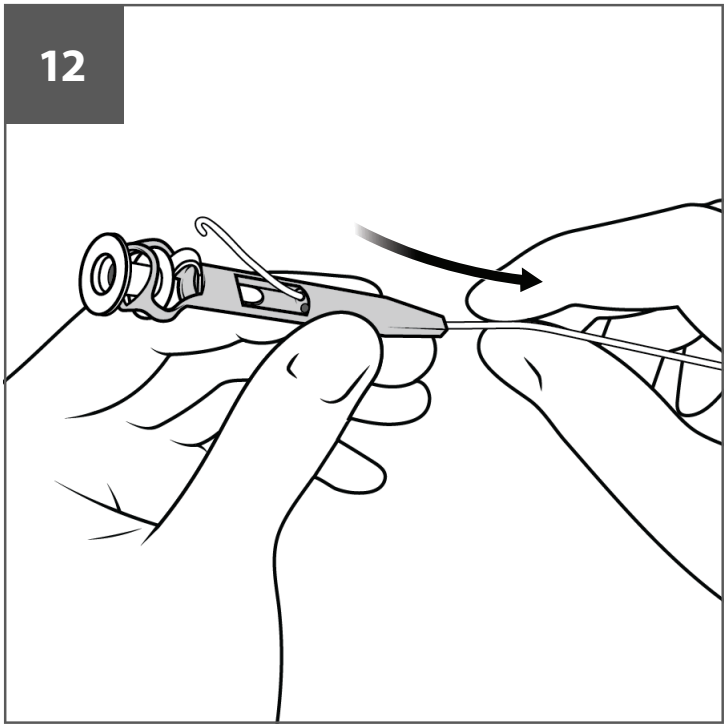

RELOADING THE VOICE PROSTHESIS

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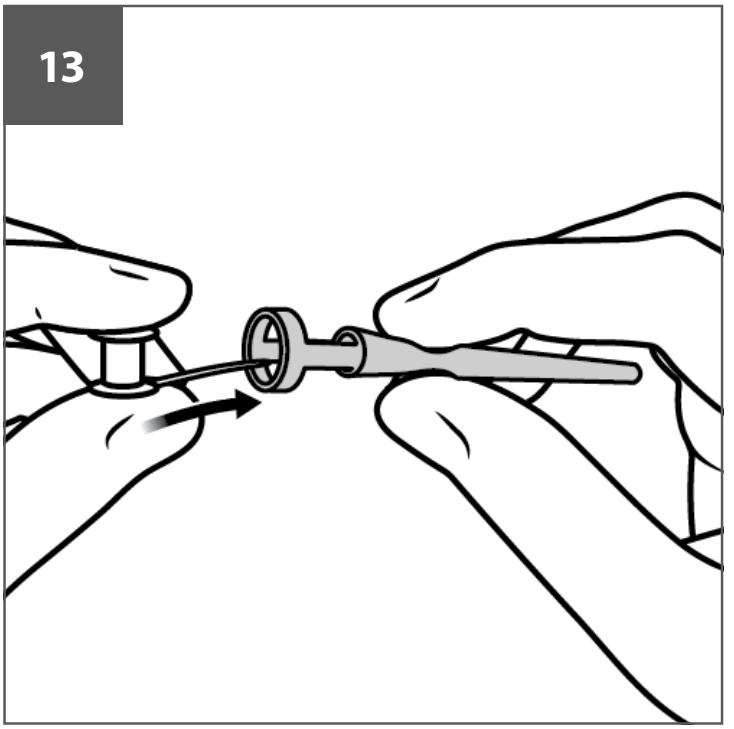

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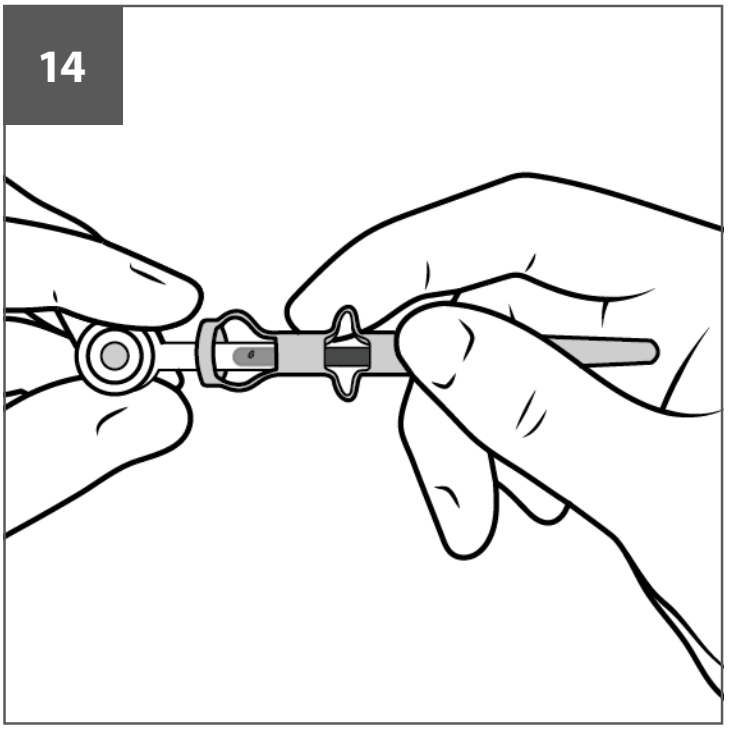

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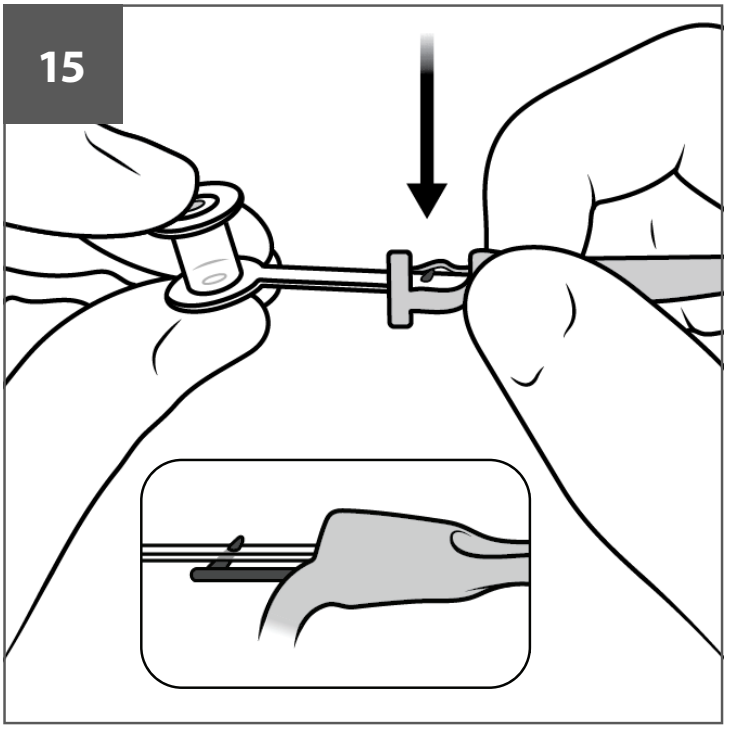

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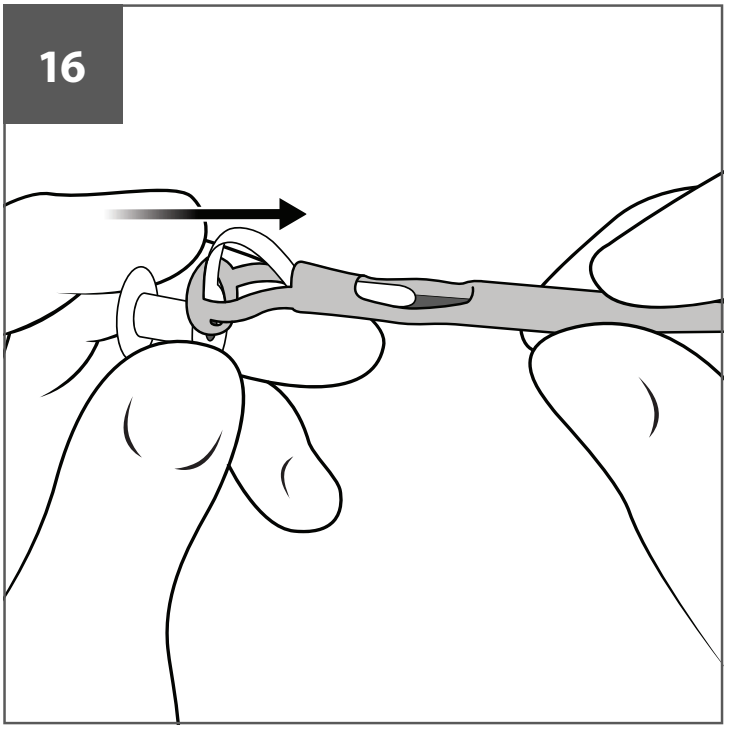

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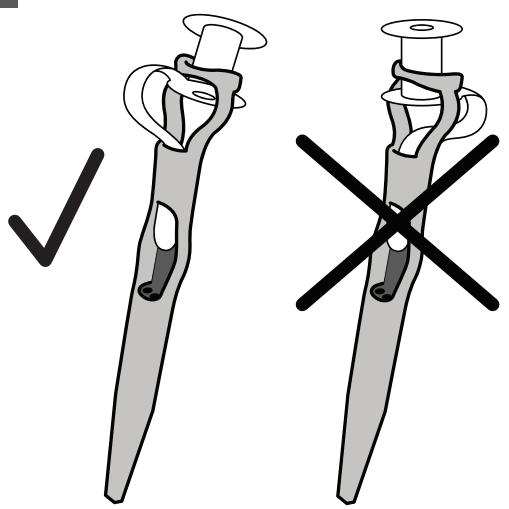

ENGLISH

BLOM-SINGER FIRSTFIT SURGICAL KIT

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

DESCRIPTION

The Blom-Singer® FirstFit™ Surgical Kit is designed for primary or secondary tracheoesophageal puncture (TEP) with retrograde voice prosthesis insertion. This set includes: one (1) 13-gauge curved cored puncture needle (Diagram 1.1); one (1) 36-inch guidewire with rounded tips (Diagram 1.2); one (1) pharynx protector tool with handle and notched cylinder (Diagram 1.3); one (1) voice prosthesis inserter pre-loaded with a Blom-Singer Indwelling Voice Prosthesis (Diagram 1.4) of the diameter and length specified on the package label. The voice prosthesis is made of medical-grade silicone and consists of a one-way silicone flap valve, an esophageal flange, a body that holds the valve assembly, a tracheal flange, and a safety strap. The device and its components are provided sterile (by ethylene oxide) in a sealed tray, ready to be introduced into the surgical field.

Tracheoesophageal puncture diameter selection is typically based on surgeon's practice and preference. Tracheoesophageal puncture and subsequently voice prosthesis length can vary by an individual patient's anatomy and should be considered when selecting which surgical kit to use.

INDICATIONS

The Blom-Singer® FirstFit™ Surgical Kit is indicated for use during surgical creation of primary or secondary tracheoesophageal puncture, dilation of the tracheoesophageal wall, and to guide the placement of the voice prosthesis for tracheoesophageal voice restoration following total laryngectomy. The FFSK contains a sterile single-use Blom-Singer® Indwelling Voice Prosthesis device intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is performed by the patient while it remains in situ.

CONTRAINDICATIONS

Tracheoesophageal puncture and therefore the device is contraindicated:

- in patients whose medical status or anatomical abnormalities increase the risk of uncontrolled dilation of the puncture and aspiration of esophageal contents around the voice prosthesis, including those with significant irradiation to the tracheostoma, uncontrolled diabetes mellitus, concurrent chemotherapy, bleeding disorders, and severe malnutrition;
- in a small tracheostoma where presence of a voice prosthesis may compromise respiration;
- in patients who have severe arthritis or blindness, are not able to care for a voice prosthesis, or are not interested in speaking with a voice prosthesis.
- For secondary puncture procedures: in patients who cannot safely undergo rigid esophagoscopy due to trismus, upper esophageal stricture or stenosis, or any other identifiable reason.

WARNINGS AND PRECAUTIONS

Use of this product is for trained physicians only.

This device and its components are for single patient use only. It may not be reused due to risk for infection. Use of a device that is not sterile may cause infection. Do not resterilize the product. Reprocessing and/or resterilization of the device may alter its performance and device failure may occur. Do not use the device if the package is opened or in any way damaged, is expired or becomes contaminated; discard and replace it with an unopened product. If there are tears, cracks, or structural damage to any components of the kit, discontinue use.

A primary TEP procedure with this device is recommended only with use of the included pharynx protector to guard 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 TEP procedure is recommended only 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 attempt to use the pharynx protector for secondary TEP. The physician must puncture into the esophagoscope to prevent puncturing directly into the esophagus, which could result in dysphagia, bleeding, and/or spinal complications.

In either primary or secondary TEP procedures, the guidewire must be placed and kept in the puncture tract before the needle is removed. If the guidewire is not kept within the puncture tract after the needle is removed, the puncture tract may be lost and another puncture procedure may be warranted. Once the puncture is completed using the device and the indwelling voice prosthesis is placed, the individual should be monitored for any complications.

This device and its components are indicated for retrograde voice prosthesis placement only. Anterograde placement would result in improper voice prosthesis function.

Use of a surgical kit that includes a smaller diameter voice prosthesis may result in complete pull-through of the prosthesis during the insertion portion of procedure. The procedure can be restarted so long as there is no observable tissue damage.

Conversely, while use of a kit with a larger diameter voice prosthesis may reduce the likelihood of complete pull-through of the prosthesis, the additional dilation force may result in tissue damage. Ensure tissue is supported during dilation to mitigate this risk. In cases with inadequate tissue, e.g. due to excessive scar tissue or radiation fibrosis, proceed with caution and abandon the procedure if dilation of the tracheoesophageal puncture requires too much force. If the procedure needs to be abandoned after the puncture has been created, consider placement of red rubber catheter to maintain puncture as desired versus allowing puncture to close with consideration of re-puncture at later date as appropriate.

Failure to follow specific insertion and placement instructions may result in unsuccessful puncture or possible damage to tissue, which may require an additional TEP procedure or other medical

interventions.

Voice Prosthesis

The clinician is to instruct patients on the use and care of the voice prosthesis as appropriate. Please refer to Instructions for Use for Indwelling Voice Prosthesis and Voice Prosthesis Cleaning system for further information.

Changes in the anatomy or medical status of the patient may lead to improper fitting and/or function of the voice prosthesis. Dislodgement or extrusion of the voice prosthesis from the TEP may occur and result in ingestion, aspiration (inhalation) or tissue damage. A foreign body such as a voice prosthesis in the airway may cause complications such as acute respiratory distress and/or respiratory arrest. Prosthesis size/length selection can vary by individual patient's anatomy and should be considered when selecting which surgical kit to use. If the voice prosthesis is improperly sized, it may cause tissue necrosis (tissue death) and/or device dislodgement.

The attached safety strap on an indwelling voice prosthesis should only be removed after the esophageal flange has been verified to have deployed in the esophagus. Never attempt to insert or reinsert an indwelling voice prosthesis that has the safety strap removed or unsecured from the safety peg.

Voice Prosthesis Leakage

When the flap valve of the voice prosthesis fails to close completely, fluid may pass through the device from the esophagus to the trachea, which may cause coughing or aspiration. Use of a smaller diameter voice prosthesis than the tracheoesophageal puncture size may result in peripheral leakage (leakage around the device). Recurrent leakage of the voice prosthesis should be evaluated by a clinician as leakage could cause aspiration pneumonia. Selection of a different device size, model/option may be indicated. Gentle handling and pressure should always be used when cleaning the voice prosthesis to avoid device damage or dislodgement.

Voice Production

To prevent post-operative complications, the patient should not begin speaking with the voice prosthesis until the clinician has indicated that it is safe to do so. The lumen of the voice prosthesis must be kept clear of blockage for it to function properly to allow the patient to voice.

In some users, the inability to relax the muscles of the throat may account for an inability to speak fluently and with minimal effort. This problem requires professional assessment.

Patients requiring post-operative radiation may have transient interruption of voice in the third or fourth week of treatment. The device can remain in place as determined by the clinician.

Voice Prosthesis Dislodgement

Care must be exercised during device insertion, removal, or use of cleaning devices to avoid injury to the TEP or accidental displacement of the device, which could result in aspiration of the device into the trachea. Should aspiration occur, the patient should attempt to cough the device out of the trachea. Further medical attention is necessary if coughing the device out is unsuccessful. Further medical attention is needed to address prosthesis aspiration because if further attention is not given to the aspiration there is potential for serious injury to the patient. If the voice prosthesis is dislodged from the TEP post-operatively, a Blom-Singer Puncture Dilator or suitable device of the appropriate diameter should be immediately placed in the puncture to keep it from closing and leaking fluids. A replacement device should be inserted within 24 hours. Foreign objects should not be inserted into the voice prosthesis. Inserting objects other than the Blom-Singer cleaning devices may cause dislodgment and subsequent aspiration or ingestion of the voice prosthesis or its components.

Voice Prosthesis Replacement

The indwelling voice prosthesis is not intended to be inserted or removed by the patient. The indwelling voice prosthesis is not a permanent device and requires replacement periodically. The device may be left in place in the TEP until it has persistent leakage or is not providing adequate voice for speech, requires resizing, or as otherwise indicated by the clinician. Removal of the indwelling voice prosthesis should only be done by grasping the tracheal flange of the device securely with a locking hemostat. Please refer to the Instructions for Use manual packaged with the selected replacement device for further information.

Voice Prosthesis Cleaning And Care

The following information should be made clear to the patient regarding the routine care and cleaning of the indwelling voice prosthesis. The purpose of cleaning the prosthesis is to remove blockage of its lumen that impairs the patient's ability to voice while the voice prosthesis is in the patient's TEP. Cleaning should be done by using the Blom-Singer Cleaning Brush and the Blom-Singer Flushing Device. Please refer to the Voice Prosthesis Cleaning System instructions for use for complete instructions on how to use the cleaning devices.

CAUTION: Use only the Blom-Singer cleaning devices. Do not insert objects other than the Blom-Singer cleaning devices into the voice prosthesis as this may cause damage or dislodgement of the voice prosthesis or its components. Cleaning of the indwelling voice prosthesis should only be done in front of a mirror with a bright light focused directly on the stoma so that the open end of the voice prosthesis is clearly visible. Only use a lint free cloth or tissue to dry the device. Use of non-lint free materials may leave debris, which can be aspirated into the airway. Do not use solvents or petroleum-based products for cleaning or lubricating the device. These materials may damage the silicone or cause the device to not work properly.

COMPLICATIONS

Although rare, the following complications may occur:

- 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
- Accidental aspiration of the voice prosthesis into the airway, which may require removal by a physician; puncture dilation resulting in leakage of fluids around the voice prosthesis; inflammatory reaction around the puncture site and formation of granulation tissue; dislodgment of the voice prosthesis and

subsequent closure of the TEP; intractable (uncontrollable) leakage around the voice prosthesis, requiring surgical revision or closure of the puncture; dysphagia (difficulty swallowing); microbial growth deposits causing voice prosthesis leakage or valve incompetence; accidental ingestion of the voice prosthesis into the esophagus.

- Although rare, the following complications have been identified to occur with silicone voice prostheses of the Blom-Singer type. They include: stoma (opening through neck into trachea or wind pipe) contamination or sepsis, which may require removal of the voice prosthesis and/or appropriate antibiotics; accidental aspiration of the voice prosthesis into the airway, which may require removal by a physician; occasional extrusion of the prosthesis, requiring replacement after dilation of the TEP and additional supervision of the stoma care regimen; puncture dilation resulting in leakage of fluids around the voice prosthesis; inflammatory reaction around the puncture site and formation of granulation tissue; dislodgment of the voice prosthesis and subsequent closure of the TEP; intractable (uncontrollable) leakage around the voice prosthesis, requiring surgical revision or closure of the puncture; dysphagia (difficulty swallowing); tearing or other damage to the voice prosthesis from improper use; microbial growth deposits causing voice prosthesis leakage or valve incompetence; accidental ingestion of the voice prosthesis into the esophagus, difficulty speaking.
- In some users, the inability to relax the muscles of the throat may account for an inability to speak fluently and with minimal effort. This problem requires professional assessment. Patients requiring post-operative radiation may have transient interruption of voice in the third or fourth week of treatment. The device can remain in place as determined by the clinician.

INSTRUCTIONS FOR USE

The clinician must carefully determine the device size and model to address the clinical needs of the individual patient.

PRIMARY TRACHEOESOPHAGEAL PUNCTURE WITH VOICE PROSTHESIS PLACEMENT

Primary tracheoesophageal puncture and voice prosthesis placement is undertaken following total laryngectomy.

1. Insert the pharynx protector deep enough into the esophagus to ensure protection of the posterior esophageal wall at the level of the puncture. Palpate the tissue on the tracheal side to confirm proper placement of pharynx protector.
2. Remove and discard the blue needle protector from the tip of the puncture needle.
3. Use the puncture needle to carefully create the TEP in the tracheoesophageal wall at the midline 5-10mm below the mucocutaneous juncture into the lumen of the esophagus.
4. Penetration into the esophagus is carefully performed and immediately terminated when the leading edge of the puncture needle is observed (Diagram 1A).
5. While holding the puncture needle in place, pass one end of the guidewire through the puncture needle hub until it exits the pharynx protector (Diagram 2A).
6. Withdraw the puncture needle while maintaining grasp on the esophageal end of the guidewire to ensure the guidewire does not pass completely through the TEP (Diagram 3A).
7. Remove pharynx protector (Diagram 4A).
8. While maintaining grasp on the tracheal end of the guidewire to secure it in the TEP, pass the esophageal end of the guidewire into the nose of the voice prosthesis inserter until it exits one of the holes of the device (Diagram 5A).
9. To lock the guidewire in place on the voice prosthesis inserter, push the guidewire tip back into the device via the adjacent open hole (Diagram 6A) and pull the guidewire from the nose of the inserter until flush to create a looped lock (Diagram 7A).
10. Firmly grasp the tracheal end of the guidewire and with continuous force pull the guidewire back through the puncture until the tip of the voice prosthesis inserter is observed on the tracheal side of the TEP (Diagram 8A). Manually support TE wall to reduce dilation force.
11. Adjust grip to the portion of the guidewire closest to the voice prosthesis inserter body and manually support TE wall to reduce dilation force.
12. Slowly but firmly pull the nose of the voice prosthesis inserter through the TEP until the tracheal flange is visualized in its entirety and deployed against the posterior tracheal wall. The inserter device should release from the prosthesis EXCEPT for at its safety strap (Diagram 9A). **CAUTION:** Additional instrumentation may be introduced to aid in dilation if needed. A cadaver study resulted in 3 out of 37 cadavers needing additional instrumentation for dilation to complete the placement of the voice prosthesis. Proceed with great care and abort the procedure if dilation of the TE puncture requires too much force. Use of excessive pull force may result in complete pull-through of the voice prosthesis. Care should be exercised during this step. Should complete pull-through occur, please refer to the "Releasing/Reloading the Inserter" section.
13. Visually confirm appropriate seating of the esophageal and tracheal flanges against the tracheoesophageal wall. Once confirmed, the voice prosthesis can be released from the device by cutting the safety strap (Diagram 10A). If leaving the safety strap is desired, it can be carefully released from the inserter by lifting the safety strap from the peg of the inserter.

POST-PRIMARY PROCEDURE INSTRUCTIONS

Closely monitor the voice prosthesis post-operatively and carefully clean as needed using only Blom-Singer cleaning devices (sold separately). Use of the placed voice prosthesis for speaking is strictly deferred until deemed appropriate by treating physician to avoid the potential of voicing related airflow causing a pharyngoesophageal fistula.

Once any oral intake is initiated, the voice prosthesis can be checked for leakage by having the patient drink while the clinician observes the device with a bright light.

SECONDARY TRACHEOESOPHAGEAL PUNCTURE WITH VOICE PROSTHESIS PLACEMENT

Prior to consideration of a secondary TEP, confirm a tracheostoma diameter of 1.5 cm or larger. A barium swallow may also be

indicated to verify that pharyngoesophageal dimensions are adequate for rigid endoscopy. Insufflation testing (kit sold separately) can be completed to assess for tracheoesophageal speech candidacy.

NOTE: The pharynx protector is not used during secondary TEP procedures. A lighted rigid esophagoscope should be used to ensure protection of the posterior esophageal wall at the level of the puncture.

1. Under anesthesia, introduce a lighted rigid esophagoscope (at minimum: a size 6 mm diameter and 25 cm length) to the level of the tracheostoma. 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 and/or transilluminate the membranous trachea to confirm endoscope positioning.
2. Remove and discard the blue needle protector from the tip of the puncture needle.
3. Use the puncture needle to carefully create the TEP in the tracheoesophageal wall at the midline 5-10mm below the mucocutaneous juncture into the lumen of the esophagus.
4. Penetration into the esophagus is carefully performed and immediately terminated when the leading edge of the puncture needle is observed (Diagram 1B).
5. While holding the puncture needle in place, pass one end of the guidewire through the puncture needle hub until it exits the needle tip into the esophagoscope and out of the mouth (Diagram 2B).
6. Withdraw the puncture needle while maintaining grasp on the esophageal end of the guidewire to ensure the guidewire does not pass completely through the TEP (Diagram 3B).
7. Withdraw the esophagoscope while maintaining grasp on the tracheal end of the guidewire to ensure the guidewire does not pass completely through the TEP (Diagram 4B).
8. While maintaining grasp on the tracheal end of the guidewire to secure it in the TEP, pass the esophageal end of the guidewire into the nose of the voice prosthesis inserter until it exits one of the holes in the body of the device (Diagram 5B).
9. To lock the guidewire in place on the voice prosthesis inserter, push the guidewire tip back into the device via the adjacent open hole (Diagram 6B) and pull the guidewire from the nose of the inserter until flush to create a looped lock (Diagram 7B).
10. Firmly grasp the tracheal end of the guidewire and with continuous force pull the guidewire back through the puncture until the tip of the voice prosthesis inserter is observed on the tracheal side of the TEP (Diagram 8B). Manually support TE wall to reduce dilation force.
11. Adjust grip to portion of guidewire closest to voice prosthesis inserter body and manually support TE wall to reduce dilation force.
12. Slowly but firmly pull the nose of the voice prosthesis inserter through the TEP until the tracheal flange is visualized in its entirety and deployed against the posterior tracheal wall. The inserter device should release from the prosthesis EXCEPT for at its safety strap (Diagram 9B). **CAUTION:** Additional instrumentation may be introduced to aid in dilation if needed. A cadaver study resulted in 3 out of 37 cadavers needing additional instrumentation for dilation to complete the placement of the voice prosthesis. Proceed with great care and abort the procedure if dilation of the TE puncture requires too much force. Use of excessive pull force may result in complete pull-through of the voice prosthesis. Care should be exercised during this step. Should complete pull-through occur, please refer to the "Releasing/Reloading the Inserter" section.
13. Visually confirm appropriate seating of the esophageal and tracheal flanges against the tracheoesophageal wall (reinsertion of esophagoscope may be needed). Once confirmed, the voice prosthesis can be released from the device by cutting the safety strap (Diagram 10B). If leaving the safety strap is desired, it can be carefully released from the inserter by lifting the safety strap from the inserter peg.

POST-SECONDARY PROCEDURE INSTRUCTIONS

Closely monitor the voice prosthesis post-operatively and carefully clean as needed in situ using only Blom-Singer cleaning devices (sold separately). Use of the placed voice prosthesis for speaking is strictly deferred until deemed appropriate by treating physician.

If oral intake is initiated, the voice prosthesis should be checked for leakage by having the patient drink while the clinician observes the device with a bright light.

RELEASING/RELOADING THE INSERTER

In the event of complete pull-through of the voice prosthesis, the inserter can be released and reloaded onto the guidewire and the procedure can be restarted. The tissue should be assessed to confirm restarting is appropriate, then the TEP tract and guidewire should be secured following the steps below. Do not proceed if any tissue damage is observed.

1. Pass the available end of the guidewire through the TEP tract into the esophagus. If during a secondary procedure, reintroduce the esophagoscope as needed.
2. Firmly hold the voice prosthesis inserter while pushing the guidewire toward the voice prosthesis to release the guidewire from the looped lock (Diagram 11 and 12).
3. Remove the inserter from the guidewire. It can now be re-locked on the other end of the guidewire as per steps 8 and 9 in above instructions.

RELOADING THE VOICE PROSTHESIS

Only a fully intact, undamaged voice prosthesis (including the safety strap) may be re-loaded onto the inserter. Do not attempt to reload a voice prosthesis after the safety strap has been cut/removed. To re-load the voice prosthesis onto the inserter:

1. Slide the central sleeve of the inserter towards the nose of the device to reveal the safety peg.
2. Pass the tip of the voice prosthesis safety strap through the blue ring on the inserter (Diagram 13) and advance it into the central sleeve of the inserter (Diagram 14).
3. Press the safety strap onto the safety peg, then release the

central sleeve so that it covers the pegged portion of the inserter (Diagram 15).

4. Advance the strap through the inserter ring and gently fold the edges of the tracheal flange of the voice prosthesis to guide it through the inserter ring into place (Diagram 16 and 17). Do not apply pressure near the valved esophageal side of the prosthesis when reloading.

Once the voice prosthesis is re-loaded and the inserter is re-attached to the guidewire for voice prosthesis insertion, refer back to step 10 in either the Primary or Secondary TEP instructions above and resume the given procedure and post-procedure instructions.

SPECIAL STORAGE AND/OR HANDLING CONDITIONS

There are no special storage and/or handling conditions for this device.

DISPOSAL INSTRUCTIONS

CAUTION: Exercise care when handling the Blom-Singer FirstFit™ Surgical Kit, as it contains sharp instruments. The device is not biodegradable and can be considered contaminated when used. Carefully dispose of this device per local guidelines (including for contaminated devices/sharps).

PRODUCT COMPLAINTS/EU SERIOUS INCIDENTS

If you are dissatisfied with the device or have any questions, please contact **productcomplaints@inhealth.com**

Telephone: +1-800-477-5969

Fax: +1-888-371-1530

Any serious incident that has occurred in relation to the device should be reported to Freudenberg Medical, LLC as noted above and the competent authority of the EU Member State in which the user and/or patient is established.

INTERNATIONAL CUSTOMERS

InHealth Technologies products are available worldwide through authorized InHealth Technologies distributors. For assistance or additional product information please contact your distributor.

SYMBOLS GLOSSARY

符号汇总表 / 記号の用語集 / Fjalorthi i simboleve / مَسرد الرموز / Речник на символите / Pojmovnik simbola / Rejstřík symbolů / Symbolliste / Verklaring van symbolen / Sümbolite sõnastik / Symbolisanasto / Glossaire des symboles / Symbolglossar / Γλωσσάρι συμβόλων / מילון הסמלים / Jelmagyarázat / Orðalisti yfir tákn / Glossario dei simboli / 기호표 / Simbolu glosārijs / Simbolių žodynėlis / Symbolforklaring / Słowniczek symboli / Glossário de símbolos / Glosar de simboluri / Глоссарий символов / Tumač simbola / Slovník symbolov / Glosario de símbolos / Symbolordlista / Sembol Sözlüğü

SYMBOL

符号 / 記号 / Simboli / الرمز / Символ / Simbol / Symbol / Symbol / Symbool / Sümbol / Symboli / Symbole / Symbol / Σύμβολο / Tákn / Szimbólum / סמל / Simbolo / 기호 / Simbols / Simbolis / Symbol / Symbol / Símbolo / Simbol / Символ / Simbol / Symbol / Símbolo / Symbol / Sembo

MEANING OF SYMBOL

符号的含义 / 記号の意味 / Kuptimi i simbolit / معنى الرمز / Диаметър / Značenje simbola / Význam symbolu / Symbolets betydning / Betekenis van het symbool / Sümboli tähendus / Symbolin merkitys / Signification du symbole / Symbolbedeutung / Σημασία του συμβόλου / משמעות הסמל / Szimbólum jelentése / Merking tákns / Significato del simbolo / 기호의 의미 / Simbola nozīme / Simbolio reikšmė / Betydning av symbol / Znaczenie symbolu / Significado do símbolo / Semnificația simbolului / Значение символа / Značenje simbola / Význam symbolu / Significado del símbolo / Betydelse av symbol / Sembolün Anlamı

SYMBOLS GLOSSARY

SYMBOL	MEANING OF SYMBOL
MD	Medical device / 医疗器械 / 医療機器 / Pajisje mjekësore / جهاز طبي / Медицинско изделие / Medicinski uređaj / Zdravotnický prostředek / Medicinsk udstyr / Medisch hulpmiddel / Meditsiiniseade / Lääkintälaite / Dispositif médical / Medizinprodukt / Ιατροτεχνολογικό προϊόν / התקן רפואי / Orvostechnikai eszköz / Lækningatæki / Dispositivo medico / 의료 기기 / Medicīniska ierīce / Medicinos įtaisas / Medisinsk enhet / Wyrób medyczny / Dispositivo médico / Dispozitiv medical / Медицинское изделие / Medicinski uređaj / Zdravotnícka pomôcka / Dispositivo médico / Medicinsk enhet / Tıbbi cihaz
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician / 注意：美国联邦法律规定本器械仅限医生销售或按医嘱销售 / 注意：連邦（米国）法によると、この装置の販売は医師によるもの、またはその医師の指示によるものに限定しています / Kujdes: Sipas ligjit federal (SHBA), kjo pajisje mund të shitet vetëm nga mjeku ose me urdhër të tij / تنبيه: يحظر القانون الفيدرالي (بالولايات المتحدة الأمريكية) بيع هذا الجهاز إلا بإذن من طبيب أو بناءً على طلبه / Внимание: Федералното законодателство (на САЩ) ограничава продажбата на това изделие да се извършва само от или по заявка на лекар / Oprez: savezni zakon (SAD) ograničava prodaju ovoga uređaja samo na liječnike ili po nalogu liječnika / Upozornění: Podle federálního zákona (USA) smí být toto zařízení prodáváno pouze lékařem nebo na lékařský předpis / Forsigtig: Ifølge amerikansk (USA) lovgivning må denne anordning kun sælges af eller efter ordinering af en læge / Let op: volgens de Amerikaanse federale wetgeving mag dit hulpmiddel uitsluitend door of in opdracht van een arts worden aangeschaft / Ettevaatust: föderaalseaduse kohaselt võivad seda seadet müüa arstid või nende tellimusel / Huomio: Liittovaltion (USA) laki rajoittaa tämän laitteen myytäväksi ainoastaan lääkärin toimesta tai lääkärin määräyksellä / Attention : selon la loi fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur ordonnance / Achtung: In den USA darf dieses Produkt laut Gesetz nur durch einen Arzt oder auf dessen Anordnung verkauft werden / Προσοχή: Η ομοσπονδιακή νομοθεσία των Η.Π.Α. επιτρέπει την πώληση της συσκευής αυτής μόνον από ιατρό ή κατόπιν συνταγογράφησης από ιατρό / זהירות: החוק הפדרלי (ארה"ב) מאפשר מכירה של התקן זה על-ידי רופא בלבד או בהוראת רופא בלבד / Figyelem: az Amerikai Egyesült Államok szövetségi törvényei értelmében az eszköz csak orvos által vagy annak rendelvényére értékesíthető / Varúð: Alríkislög (Bandaríkin) takmarka sölu þessa búnaðar við lækna eða samkvæmt fyrirmælum læknis / Attenzione: la legge federale degli Stati Uniti limita la vendita del presente dispositivo ai medici o su prescrizione medica / 주의: 미국 연방법은 이 기기를 의사만 판매하거나 또는 의사의 지시하에서만 판매하도록 제한하고 있습니다 / Uzmanību! Saskaņā ar federālajiem (ASV) tiesību aktiem šo ierīci drīkst pārdot tikai ārsts vai ar ārsta norīkojumu / Dėmesio. Pagal Federalinį (JAV) įstatymą šį įtaisą galima parduoti tik gydytojui arba jo nurodymu / Forsiktig: I henhold til føderal lovgivning (USA) skal dette utstyret kun selges av eller etter ordre fra lege / Przestroga: prawo federalne (USA) ogranicza obrót tym wyrobem do sprzedaży lekarzom lub na ich zamówienie / Cuidado: a lei federal dos EUA só permite a venda deste dispositivo sob prescrição médica / Atenție: În conformitate cu legislația federală (din SUA), vânzarea acestui dispozitiv nu poate fi efectuată decât de către sau la recomandarea unui medic / Предупреждение. Федеральное законодательство (США) разрешает продажу этого устройства только врачам или по предписанию врача / Oprez: Savezni (SAD) zakon ograničava ovaj uređaj na prodaju od strane ili po nalogu lekara / Upozornenie: Federálny zákon (USA) obmedzuje predaj tohto zariadenia na lekára alebo na jeho predpis / Precaución: Las leyes federales de EE. UU. restringen la venta de este dispositivo a médicos o bajo prescripción médica / Var försiktig: Enligt federal lag (USA) får denna utrustning endast säljas av läkare eller på läkares ordination / Dikkat: Federal (ABD) yasalar bu cihazı yalnızca hekim tarafından veya hekim talimatıyla satılacak şekilde kısıtlar

SYMBOLS GLOSSARY

SYMBOL	STANDARD No.	SYMBOL TITLE & REF No.	MEANING OF SYMBOL
	EN ISO 15223-1:2016	Manufacturer; 5.1.1	Indicates the medical device manufacturer, as defined in EU Directives or Regulations
	EN ISO 15223-1:2016	Catalogue number; 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be indentified
	EN ISO 15223-1:2016	Batch code; 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be indentified
	EN ISO 15223-1:2016	Use-by date; 5.1.4	Indicates the date after which the medical device is not to be used
	EN ISO 15223-1:2016	Caution; 5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	EN ISO 15223-1:2016	Do not use if package is damaged; 5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened
	EN ISO 15223-1:2016	Do not re-use; 5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	EN ISO 15223-1:2016	Do not resterilize; 5.2.6	Indicates a medical device that is not to be resterilized
	EN ISO 15223-1:2016	Consult electronic instructions for use; 5.4.3	Indicates the need for the user to consult the electronic instructions for use
	EN ISO 15223-1:2016	Sterilized using ethylene oxide; 5.2.3	Indicates a medical device that has been sterilized using ethylene oxide gas

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