

INHEALTH TECHNOLOGIES®

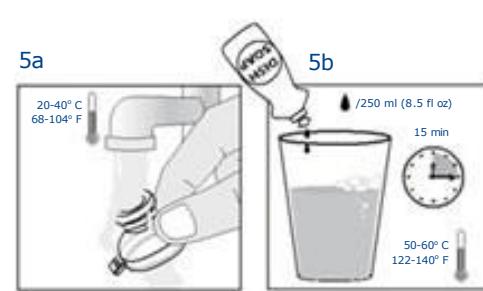
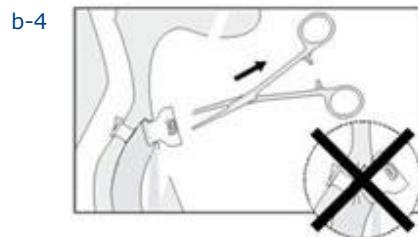
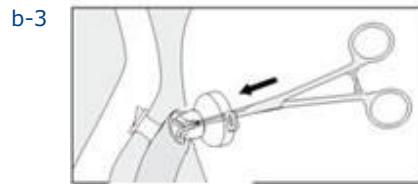
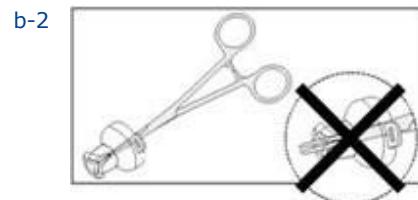
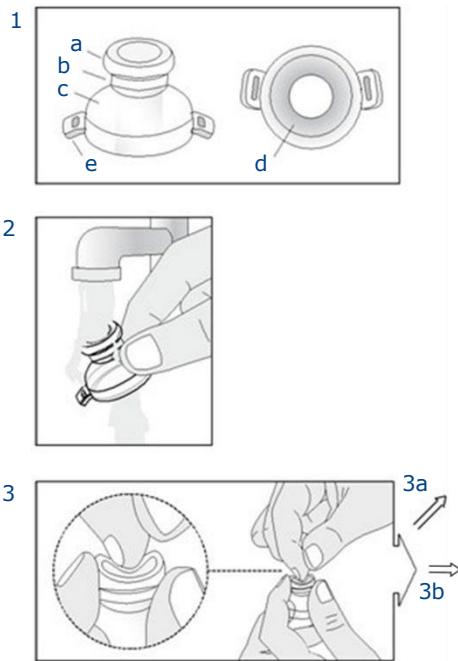
Instructions for Use

Laryngectomy Button – Silicone

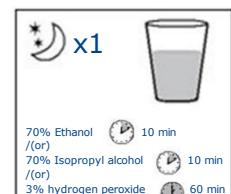
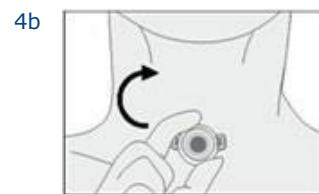
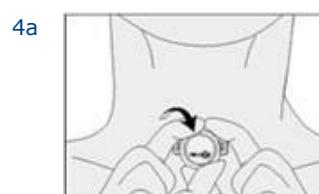
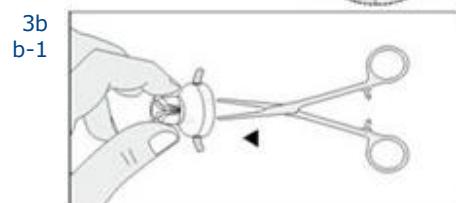
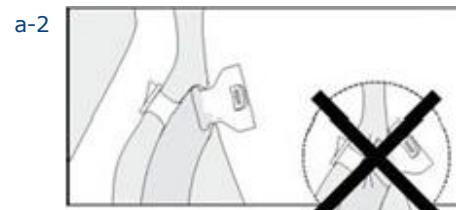
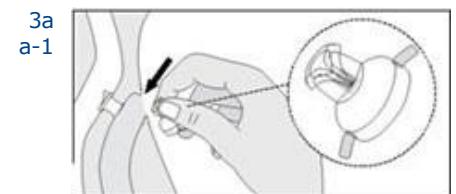
This IFU is applicable for Laryngectomy Button

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Laryngectomy button is a surgically
invasive device for short term use



**PLEASE READ THE FOLLOWING
INSTRUCTIONS BEFORE USING**



PRESCRIPTION INFORMATION

The Instructions for Use, which accompanies this product, may be revised from time to time and must therefore be reviewed prior to each procedure in which the product is used.

1. DESCRIPTIVE INFORMATION

1.1 Intended Use

The Laryngectomy Button is a self-retaining holder for devices in the HME System intended for vocal and pulmonary rehabilitation after total laryngectomy. For patients with a shrinking tracheostoma, it is also used to maintain the tracheostoma for breathing.

The Laryngectomy Button is intended for single patient use. Laryngectomy Button can be used on all patient populations (including Pediatric). Responsibility of proper selection of Laryngectomy Button as per patient need, rests with the surgeon.

1.2 Contraindications

Laryngectomy Button is not intended to be used by patients that:

- are under any form of mechanical ventilation.
- have damaged tracheostoma tissue.

1.3 Description of the Device

The Laryngectomy Button is a self-retaining tracheostoma button made of medical grade silicone rubber. The purpose of the device is to create a comfortable and airtight fit between the Laryngectomy Button and the tracheostoma and to provide attachment for devices from the HME System. The device is delivered single packed, sterile and ready to use.

The different parts of the Laryngectomy Button are (Fig. 1):

- a) Retention Collar
- b) Shaft
- c) Shield (conical)
- d) HME and Accessory Holder
- e) Wings

1.4 Warnings

- Always use a Laryngectomy Button of an appropriate size. If the Laryngectomy Button is too wide or too long, it may cause tissue damage or irritation. If it is too long, it may also cause dislodgement of the voice prosthesis or Extra Flange.

Furthermore, insertion or removal of the HME Cassette, as well as pressing on the HME Cassette to speak, may exert pressure on the voice prosthesis if the Laryngectomy Button is too long.

- **DO NOT** cut off the wings or otherwise mechanically modify the Laryngectomy Button since it will change the outer diameter and/or the mechanical stability of the product. This may result in the Laryngectomy Button being pushed into the trachea, which may obstruct breathing. A modified Laryngectomy Button may also cause irritation and/or bleeding.
- **DO NOT** fenestrate the Laryngectomy Button as the fenestration might cause dislodgement of the voice prosthesis or Extra Flange.
- **DO NOT** reuse the Laryngectomy Button between patients. The devices are intended for single patient use only. Reuse between patients may cause cross contamination.
- Always insert and remove the Laryngectomy Button according to the instruction provided.
- **DO NOT** use force and do not fold the part of the Laryngectomy Button that holds the HME Cassette during insertion. If the product is pushed too far into the trachea it may obstruct breathing and the use of force during insertion may cause bleeding.
- **DO NOT** push the tip of the hemostats or forceps (if used) through the Laryngectomy Button (Fig. b-2). If the instrument tip is protruding from the button during insertion, the tissue of the trachea could be harmed and/or the voice prosthesis could become dislodged and subsequently be aspirated or ingested.
- **DO NOT** use lubricating gels if the patient has allergies related to these substances.
- Always remove the device from the stoma before cleaning. **DO NOT** at any time attempt to clean the device while inside the stoma since this could cause tissue damage and dislodgment of the prosthesis.
- Make sure that the patient has been trained in the use of the device and has demonstrated the ability to understand and consistently follow the Instructions for Use without clinician supervision.
- **DO NOT** re-sterilize. If the device is re-sterilized, it may cause harm or infection to the patient due to re-sterilization of the device.

- **Risk when using a product that is no longer sterile:** It may be exposed to contamination which can cause infection to patient.

1.5 Precautions

- **DO NOT** use a dirty or contaminated Laryngectomy Button. Clean and disinfect the device according to the cleaning and disinfection instructions below.
- **DO NOT** use toothed or sharp instruments at any time during insertion since they could damage the Laryngectomy Button and cause tissue damage.
- **DO NOT** use a damaged device since this might cause aspiration of small parts or cause formation of granulation tissue.
- Only use water-soluble lubricants. Oil-based lubricants (e.g., Vaseline) may weaken, damage or destroy the product and should not be used at any time.
- Carefully monitor the tracheostoma tissue during radiation therapy and stop using the device if the stoma gets irritated or starts to bleed.
- Patients with bleeding disorders or patients on anti-coagulants should not use the device if it causes bleeding that reoccurs.
- Stop using the device if granulation tissue forms in the tracheostoma.

2. INSTRUCTIONS FOR USE

2.1 Preparation

Choosing correct size

Diameter: To achieve an airtight fit and good retention the diameter of the Retention Collar of the Laryngectomy Button should exceed the diameter of the tracheostoma entrance. This is especially important for hands-free speech.

Measure the size of the tracheostoma (largest diameter) with a ruler and fit the Laryngectomy Button accordingly. In irregularly shaped tracheostomas, it may be difficult to achieve an airtight fit.

Selection of a too small diameter will lead to a too loose fit; the device may fall out or air may escape when speaking.

Selection of a too wide Laryngectomy Button may irritate or damage the tracheostoma.

Length: In most cases, the shorter size where the Retention Collar of the Laryngectomy Button fits right behind the edge of the tracheostoma will provide a correct fit. However, if the device is too short it may fall out of the tracheostoma.

CAUTION: During fitting always make sure that the Laryngectomy Button does not reach the tracheal flange of the voice prosthesis. Optimal fit and performance of the Laryngectomy Button is achieved if the patient has a so-called "tracheostoma lip" that is situated uniformly around the tracheostoma.

Preparing for insertion: Before first use, check that you have the correct size and that the package is not damaged or opened. Do not use otherwise.

2.2 Operating Instructions

Insertion (Fig. 3)

Alternative 3a:

1. Fold the Retention Collar with your fingers (Fig. 3) and hold it firmly folded.
2. Insert the Retention Collar into the stoma and release it (Fig. a-1 and a-2).

Alternative 3b:

1. Fold the Retention Collar with your fingers.
2. Use a pair of blunt forceps or a lockable blunt hemostat from the inside to keep it folded.
- CAUTION:** DO NOT push the tip of the hemostats or forceps through the Laryngectomy Button (Fig. b-2). If the instrument tip is protruding from the button during insertion, the tissue of the trachea could be harmed and/or the voice prosthesis could become dislodged and subsequently be aspirated or ingested.
3. Insert the Retention Collar into the stoma (Fig. b-3).
4. Release the forceps to unfold the button (Fig. b-4). Check the correct fit by slightly pulling and/or rotating the button. Gently insert the HME System component into the HME Holder.
- NOTE:** Some patients might experience more coughing after inserting the Laryngectomy Button and when touching the device to speak. This usually diminishes when the user gets used to the device. If discomfort occurs the Laryngectomy Button should be removed.

Device Removal

1. Hold the Laryngectomy Button in place and gently remove the HME System component from the HME Holder (Fig. 4a).

2. Grasp the Laryngectomy Button and gently turn it (about half a turn) to allow the Retention Collar to collapse there by reducing its width (Fig. 4b).

3. Remove the device by gently tilting it out of the stoma (Fig. 4c). Alternatively, the device can be removed by pushing with a finger on the shaft from one direction and tilt the device out.

NOTE: The insertion or removal procedures may occasionally cause some slight bleeding, irritation or coughing. Inform your clinician if the bleeding persists.

2.3 Cleaning and Disinfection

CAUTION: Always remove the device from the stoma before cleaning. **DO NOT** at any time attempt to clean the device while inside the stoma since this could cause injury. Clean the Laryngectomy Button after each use, or at least daily with the Tube Brush (Fig. 5a-5f).

DO NOT use any water other than drinking water to clean and rinse the device.

CAUTION: Be careful not to burn your finger in the warm cleaning water. Disinfect the Laryngectomy Button at least once a day (Fig. 5e) with one of the following methods:

- Ethanol 70% for 10 minutes
- Isopropyl alcohol 70% for 10 minutes
- Hydrogen peroxide 3% for 60 minutes

CAUTION: **DO NOT** use the device until it is completely dry. Inhalation of disinfectant fumes can cause severe coughing and irritation of the airways. If the Laryngectomy Button looks dirty or has air dried in an area with a risk of contamination the device should be both cleaned and disinfected before use. A risk of contamination could exist if the device has been dropped on the floor or if it has been in contact with a pet, someone with a respiratory infection, or any other gross contamination. During hospitalization it is important to both clean and disinfect the Laryngectomy Button after use, but also before use since there is an increased risk of infection and contamination. In a hospital it is better to use sterile water for cleaning and rinsing, rather than drinking water.

CAUTION: **DO NOT** clean or disinfect by any other method than described above as this might cause product damage and patient injury.

2.4 DEVICE LIFETIME

The Laryngectomy Button shall be replaced depending upon medical condition of patient and doctor's recommendation.

2.5 Disposal

The product shall not be disposed and reused in general method as it may contain infection or microbial hazards contaminated with potentially infectious substances of human origin. Therefore, shall be disposed as per applicable local regulations.

CAUTION: Use only original components. Other accessories may cause product damage and/or malfunction. Some of the devices that can be kept in place by the Laryngectomy Button are:

- HME Cassettes (Heat and Moisture Exchangers).
- Free Hands HME, for speaking without manual stoma occlusion.
- Shower Aid that can help to prevent water from entering the Laryngectomy Button during showering.

If needed, a Tube Holder or Laryngectomy Clips can be used for additional support to prevent the Laryngectomy Button from falling out of the stoma.

3. TROUBLESHOOTING INFORMATION

Bleeding of the stoma

Stop using the device. After the tracheostoma is healed try gradually increasing the duration of using the device. If even short periods of use cause bleeding or if the bleeding persists after removing the device, stop using it and consult your clinician.

Rapid shrinking of the stoma

If you are wearing the Laryngectomy Button because of a rapidly shrinking tracheostoma, discuss with your clinician the possibility of having two devices (of the same size). This would allow you to remove the Laryngectomy Button from your stoma and replace it immediately with a clean one. Cleaning of the removed device can then be done afterwards.

Stoma enlarges during use

If your tracheostoma enlarges after using the device for some hours, ask your clinician if it is possible for you to use two devices (one smaller and one larger diameter). This allows you to use the larger size when the tracheostoma has enlarged, and the smaller size to allow the tracheostoma to shrink. It may be necessary to discontinue use of the button during the night, so that the tracheostoma can shrink. In that case, discuss alternative options to attach the HME Cassette with your clinician so that you can continue HME Cassette use during the night.

4. ADDITIONAL INFORMATION

4.1 Compatibility with MRI Examination

MR-Safe: This device does not contain any metallic elements and has no potential for interaction with the MRI field.

4.2 Ordering Information

See end of this Instructions for Use.

4.3 User Assistance Information

For additional help or information please see back cover of this Instructions for Use for contact information.

PACKAGING

- a) Primary packaging: The Laryngectomy Button is packed into Tyvek Pouch
- b) Secondary packaging
- c) Instructions for Use

STERILIZATION

The contents of unopened or undamaged package are sterile.

This Laryngectomy Button is sterilized by ETO sterilization process in protective sealed pouch packaging. Each package bears an expiry date and it must not be used after that date.

STORAGE

Store at room temperature in unopened original package. After cleaning and disinfection, store in a clean and dry container at room temperature.

Each Laryngectomy Button bears a batch number and an expiration date and may not be used after that date.

	Do not reuse
	Use by
	Consult Instructions for Use
	Date of Manufacture
	Caution
	Sterilized using ethylene oxide
	Single sterile barrier system
	Keep dry
	Do not re-sterilize
	Keep away from sunlight
	Temperature limitation
	Lot number
	Catalogue number
	Do not use if package is damaged
	Medical Device
	Single patient multiple use
	UDI symbol
	RX ONLY
	Prescription Only

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