INHEALTH TECHNOLOGIES®

Instructions for Use

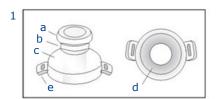
Laryngectomy Button - Silicone

This IFU is applicable for Laryngectomy Button

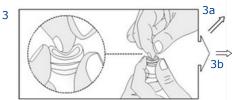
Manufactured for Freudenberg Medical, LLC 1110 Mark Avenue

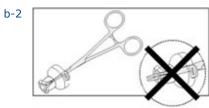
Carpinteria, CA 93013-29178 USA www.inhealth.com

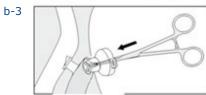
Laryngectomy button is a surgically invasive device for short term use

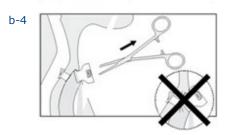












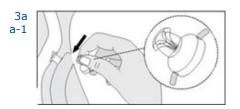


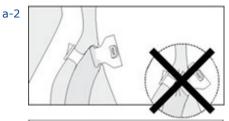


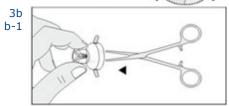


PLEASE READ THE FOLLOWING INSTRUCTIONS BEFORE USING

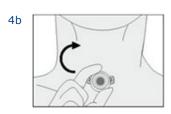


















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PRESCRIPTION INFORMATION

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 sued 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 Colla
- b) Shaft
- c) Shield (conical)
- d) HME and Accessory Holder
- e) Wings

1.4 Warnings

dislodgement of the voice prosthesis or Extra Flange

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

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 Larvngectomy 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 Fxtra 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 below.
- 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.
- If used, 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 could become dislodged and subsequently be aspirated or ingested.
- DO NOT use lubricating gels if the patent has allergies related to these substances.
- Always remove the device from the stoma before clearing. 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 of Desterilization: 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 trackpostoma.

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.

Preparing for insertion: Before first use check that you have the

correct size and that the package is not damaged or opened. Do not

1. Fold the Retention Collar with your fingers (Fig. 3) and hold it

2. Insert the Retention Collar into the stoma and release it (Fig. a-

2. Use a pair of blunt forceps or a lockable blunt hemostat from

the hemostats or forceps through the Laryngectomy Button

during insertion, the tissue of the trachea could be harmed

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

speak. This usually diminishes when the user gets used to the

device. If discomfort occurs the Laryngectomy Button should be

the Laryngectomy Button and when touching the device to

1. Hold the Laryngectomy Button in place and gently remove the

HME System component from the HME Holder (Fig. 4a).

and/or the voice prosthesis could become dislodged and

Insert the Retention Collar into the stoma (Fig. b-3).

(Fig. b-2). If the instrument tip is protruding from the button

the inside to keep it folded. CAUTION: DO NOT push the tip of

the patient has a so-called "tracheostoma lip" that is situated

1. Fold the Retention Collar with your fingers.

subsequently be aspirated or ingested.

uniformly around the tracheostoma

2.2 Operating Instructions

firmly folded.

1 and a-2).

removed

Device Removal

use otherwise.

Insertion (Fig. 3)

Alternative 3a:

Alternative 3h:

Optimal fit and performance of the Laryngectomy Button is achieved if

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).

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.

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.

Cassette with your clinician so that you can continue HME Cassette use

4.2 Ordering Information

during the night.

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 sealing pouch packaging. Each package bears an expiry date and it must not be used after the expiry date.

STORAGI

Store at dry room temperature in unopened original package. Each Laryngectomy Button bears a batch number and an expiration date and may not be used after that date.

SALES RESTRICTION

The Laryngectomy Button is supplied only to specialist surgeons or to medical technology retailers.

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



Prescription Only