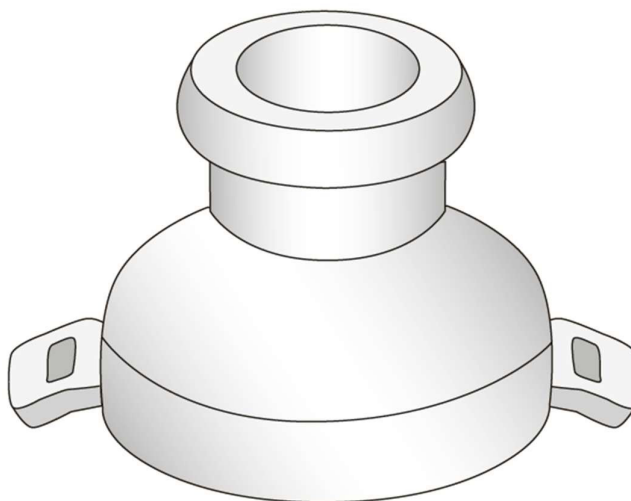


| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
|----------------|-----------|-------------------------------------|---|
| Issued: | QA | Carolina Johansson - SEHRBJNC | 2022-04-12 - 14:46 |
| Reviewed: | QA | Karolina Nilsson - KARNIL | 2022-04-12 - 15:48 |
| Approved: | DD | Diana Tieger - DIATIE | 2022-04-14 - 08:06 |
| Released: | QA | Carolina Johansson - SEHRBJNC | 2022-05-19 - 15:07 |

This document has been electronically signed by the persons above.

Provox® LaryButton™



Product description:

Provox LaryButton is delivered single packed, non-sterile, ready for use. The goal is to create a self-retaining, comfortable and airtight fit between the Provox LaryButton and the tracheostoma.

Product Information

| | | | |
|---|--|-----------------|----|
| Document ID: | PF031-01-TechInfo | Edition: | 06 |
| Manufacturer: | Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden | | |
| Classification: (EU) MDD 93/42/EEC | IIb (2.1 Rule 5) | | |
| Intended Use: | <p>The Provox LaryButton is a self-retaining holder for devices in the Provox HME System intended for vocal and pulmonary rehabilitation after total laryngectomy.</p> <p>For patients with a shrinking tracheostomas it is also used to maintain the tracheostoma for beathing.</p> <p>The Provox LaryButton is intended for single patient use.</p> | | |
| Use specifications: | <p>Intended medical indication Product for rehabilitation for patients breathing through a tracheostoma.</p> <p>Intended patient population Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient. Not intended for patients with mechanical ventilation. Not intended for patients with a low tidal volume.</p> <p>Intended usage Provox LaryButton is a single patient use device prescribed by a clinician.</p> <p>Intended part of the body/type of tissue applied to or interacted with Tracheostoma.</p> <p>Intended user profile The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.</p> <p>Intended conditions of use Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.). Outpatient clinic use. Hospital use. Frequency of use: Continuous use. Replacement rate: Max usage for 6 months. Replacement is performed by the patient, clinician or caregiver.</p> | | |
| Contraindications: | Provox LaryButton is not intended to be used by patients that are under any form of mechanical ventilation or have damaged tracheostoma tissue. | | |
| CE Mark: | Yes. Devices are CE-marked. | | |
| GMDN code: | 14093 (Tracheostoma button) | | |
| Sterilization: | Non-sterile | | |
| Raw material: | Silicone | | |
| Latex information: | Not manufactured with natural rubber latex | | |
| Biological origin: | The device is not manufactured with materials derived from human or animal source. | | |
| Handling and storage: | Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C. | | |

Product Information

| | |
|-------------------------------------|--|
| Waste handling and disposal: | Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard. |
| Hazardous components: | None |
| Expiration date: | 5 years after manufacturing. |
| Packaging: | Provox LaryButton is packed in a plastic bag of polyethylene. The product and instructions for use are packed in a cardboard box. |

Devices under Basic UDI-DI: 7331791-LTU-0-000-0000-38

| REF | Name | UDI-DI |
|------|-------------------------|----------------|
| 7671 | Provox LaryButton 12/8 | 07331791002694 |
| 7672 | Provox LaryButton 14/8 | 07331791002700 |
| 7673 | Provox LaryButton 16/8 | 07331791002717 |
| 7674 | Provox LaryButton 18/8 | 07331791002724 |
| 7685 | Provox LaryButton 12/18 | 07331791002731 |
| 7686 | Provox LaryButton 14/18 | 07331791002748 |
| 7687 | Provox LaryButton 16/18 | 07331791002755 |
| 7688 | Provox LaryButton 18/18 | 07331791002762 |

Atos Medical AB compatible products:

| Range | BASIC UDI-DI |
|-------------------------------|---------------------------|
| Provox BasePlate Adaptor | 7331791-HME-A-000-0003-F5 |
| Provox FreeHands HME Cassette | 7331791-HME-0-000-0003-XJ |
| Provox LaryClip | 7331791-LTU-A-000-0001-JT |
| Provox Micron HME | 7331791-HME-0-000-0002-XF |
| Provox ShowerAid | 7331791-ADH-A-000-0000-U8 |
| Provox Swab | 7331791-GEN-A-000-0002-EC |
| Provox TubeBrush | 7331791-GEN-A-000-0001-E9 |
| Provox TubeHolder | 7331791-GEN-A-000-0000-E6 |
| Provox XtraHME | 7331791-HME-0-000-0000-X9 |