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Product Information

Provox® LaryClip™



Product description:

The Provax LaryClip consists of a square adhesive base and a hook-and-loop clip that allows for optimal fit to the wings of the Provax LaryButton and LaryTube. When the adhesive Base is attached to the skin at both sides of the stoma and is eventually removed due to loss of its stickiness, the Clip part can be removed and re-attached as needed.

Product Information

Document ID:	PF061-01-TechInfo	Edition:	08
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (1.1, Rule 1)		
Intended Use:	The Provox LaryClip is used for extra support for LaryButton and LaryTube. The product consists of two parts, one that is attached to the patients' skin on each side of the stoma and the other part is attached to the LaryButton or the LaryTube. The two parts are then connected by Velcro.		
Use specifications:	Intended medical indication: Product for rehabilitation for patients breathing through a tracheostoma. Intended patient population: Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient. Intended usage: Single use, Over-the-counter Intended part of the body/type of tissue applied to or interacted with: The device will contact intact skin (neck). 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. 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 is performed by the patient, clinician or caregiver.		
Contraindications:	There are no known contraindications.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	35752 (Tracheostomy tube neck holder, reusable)		
Sterilization:	Non-sterile		
Raw material:	LaryClip Base: Polyethylene (PE), Acrylic Adhesive, velcro LaryClip: Knitted fabric, Polyamide (PA)		
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:	3 years after manufacturing.
Packaging:	One package consists of 8 pcs of LaryClip and 40 pcs of LaryClip Base. They are packed together with instruction for use in a cardboard box.

Devices under Basic UDI-DI: 7331791-LTU-A-000-0001-JT

REF	Name	UDI-DI
7669	Provox LaryClip	07331791002687

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox LaryButton Sizer Kit	7331791-LTU-0-000-0001-3B
Provox Vega Plug 17	7331791-VPS-A-000-0004-RU
Provox Vega Plug 20	7331791-VPS-A-000-0004-RU
Provox Vega Plug 22.5	7331791-VPS-A-000-0004-RU