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Provox® FreeHands Support™



Product description:

The Provox FreeHands Support system consists of two parts; Provox FreeHands Support and Provox FreeHands Support Adhesive.

The reusable Provox FreeHands Support is available in three different variants; 'Flat', 'Medium' and 'Deep'. The three variants, as well as the possibility to adjust the metal ring and plastic parts, enable personal fit. Provox FreeHands Support Adhesive is a single-use adhesive that is attached to the skin, beneath the Provox Adhesive.

Product Information

Document ID:	PF078-01-TechInfo	Edition:	05
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class 1, Rule 1		
Intended Use:	Provox FreeHands Support provides support to the Provox adhesive when using a Provox hands-free speaking valve after total laryngectomy. The device is a single patient use device with a single use adhesive.		
Use specifications:	<p><i>Intended medical indication:</i> Product for rehabilitation for patients breathing through a tracheostoma after a total laryngectomy.</p> <p><i>Intended patient population:</i> Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient.</p> <p><i>Intended usage:</i> The FreeHands Support is a reusable single patient device whereas the FreeHands Support Adhesive is a (disposable) single use device. The product is intended to be available to patients over-the-counter. Should only be used when awake (i.e., not during sleep). Intended for laryngectomized patients using Provox hands free speaking valves. The product should only be used by patients with sufficient manual dexterity to handle attachment/removal of the device.</p> <p><i>Intended part of the body/type of tissue applied to or interacted with:</i> The device will contact intact skin.</p> <p><i>Intended user profile:</i> Patient (Nurse, physician or other caregiver only for fitting and instructions).</p> <p><i>Intended conditions of use:</i> Environment of use: (Primarily) Home use, secondary hospital use. Frequency of use: Daily use, not during sleep. Location: Ambient temperature -20°C to +45°C Mobility: The product should only be used by patients with sufficient manual dexterity to handle attachment/removal of the device."</p>		
Contraindications:	Do not use Provox FreeHands Support on breached skin. Provox FreeHands Support is NOT intended to be in place during MRI examination (Magnetic Resonance Imaging), or during the period of Radiation Therapy treatment.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	62155 (Tracheostomy base plate, reusable)		
Sterilization:	Non-sterile		
Raw material:	Provox FreeHands Support consists of a ring of stainless steel and a plastic part (Polycarbonate, PC).		

Product Information

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.
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:	Provox FreeHands Support is packed in a cardboard box together with instructions for use.

Product Information

Devices under Basic UDI-DI: 7331791-HME-A-000-0000-EU

REF	Name	UDI-DI
8020	Provox FreeHands Support Starter Set	07331791009266
8021	Provox FreeHands Support Flat	07331791009273
8022	Provox FreeHands Support Medium	07331791009280
8023	Provox FreeHands Support Deep	07331791009297

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands Support Adhesive	7331791-HME-A-000-0004-F8
Provox FreeHands FlexiVoice	7331791-HME-0-000-0007-XW