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Product Information

Provox® FreeHands Support™ Adhesive



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:	PF078-02-TechInfo	Edition:	05
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, 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.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	62175 (Stomal appliance skin-adherent patch, non-sterile)		
Sterilization:	Non-sterile		
Raw material:	Provox FreeHands Support Adhesive consists of a plastic plate (Polycarbonate, PC) and an adhesive tape (Acrylate and Polyester film).		
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 Adhesive is packed in a blister package made of PET film and with a re-sealable top film (PP). It is then packed in a cardboard box.		

Product Information

Devices under Basic UDI-DI: 7331791-HME-A-000-0004-F8

REF	Name	UDI-DI
8024	Provox FreeHands Support Adhesive (15pc)	07331791009303

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands Support	7331791-HME-A-000-0000-EU