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Product Information

Provox® FreeHands FlexiVoice

Provox® Life FreeHands FlexiVoice

Provox® FreeHands FlexiVoice Arch



Figure 1- Provox FreeHands FlexiVoice/Provox Life FreeHands FlexiVoice



Figure 2- Provox FreeHands FlexiVoice Arch

Product description:

The Provox FreeHands FlexiVoice/Provox Life FreeHands FlexiVoice consists of two parts assembled together, a speaking valve for single patient use and a disposable HME cassette. The speaking valve is made of plastic and the membrane is made of silicone. The HME cassette is also made of plastic and a salt treated polyurethane foam.

The speaking valve has two modes; Automatic Speaking Mode and Locked Mode. Rotating the top of the speaking valve moves the device into the automatic speaking or the locked position. Speaking can be done both by using the automatic speaking valve and by manual occlusion of the opening in the front. Manual occlusion is possible in both modes.

The Provox FreeHands FlexiVoice Arch to be used together with the Provox FreeHands FlexiVoice to keep fabric away from the opening of the device.

Product Information

Document ID:	PF058-01-TechInfo	Edition:	06
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	The Provox FreeHands FlexiVoice/ Provox Life FreeHands FlexiVoice combines pulmonary rehabilitation using a Heat and Moisture Exchanger with voice rehabilitation using an Automatic Speaking Valve or Manual Occlusion, in laryngectomized patients using a voice prosthesis.		
Use specifications:	<p>Intended medical indication: Total laryngectomy with a voice prosthesis in situ.</p> <p>Intended patient population: Male and female 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.</p> <p>Intended usage: Single patient use, prescription.</p> <p>Intended part of the body/type of tissue applied to or interacted with: The device will contact intact skin and as external communicating device the contact mode with tissue is indirect via air.</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: The HME cassette /moist/flow/Life FreeHands HME is for single use. The Speaking valve, Arch and HME Removal Aid are for single patient use. Should only be used when awake. Only intended for laryngectomized patients using a voice prosthesis. Only intended for laryngectomized patients who can tolerate using an HME. Environment including hygienic requirements: Primarily: Home use. Secondary: Hospital use. Frequency of use: Daily continuous use, not during sleep. Location: Ambient temperature -20°C to +45°C. Mobility: Only intended for use by patients with sufficient manual dexterity to handle rotation of the speaking valve, assembly/disassembly of the device and insertion/removal of the device.</p>		
Contraindications:	The product shall not be used by patients with a decreased level of consciousness, patients with reduced mobility of the arms and/or hands, or patients who are unable to remove the device themselves.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	36071		
Sterilization:	Non-sterile		
Raw material:	Speaking valve: PP, Silicone and POM. Arch: MABS		

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:	<p>Ref 7757: Provox FreeHands FlexiVoice, 1 pc/model (light, medium, strong) is packed in a plastic jar of polypropylene. Provox FreeHands HME Cassette, 30pcs (10pcs/bag) are packed in a plastic bag of polyethylene. Removal Aid, 1pc is packed in plastic bag of polyethylene. FlexiVoice Arch, 2pcs are packed in plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.</p> <p>Ref 7760: Provox FreeHands FlexiVoice (light, medium, strong) 1 pc/model is packed in a plastic jar of polypropylene. Removal Aid, 1pc is packed in plastic bag of polyethylene. FlexiVoice Arch, 2pcs are packed in plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.</p> <p>Ref 8161: Provox FreeHands FlexiVoice Light, 1pc is packed in a plastic jar of polypropylene. Removal Aid, 1pc is packed in plastic bag of polyethylene. FlexiVoice Arch, 1pc are packed in plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.</p> <p>Ref 8162: Provox FreeHands FlexiVoice Medium, 1pc is packed in a plastic jar of polypropylene. Removal Aid, 1pc is packed in plastic bag of polyethylene. FlexiVoice Arch, 1pc are packed in plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.</p> <p>Ref 8163: Provox FreeHands FlexiVoice Strong, 1pc is packed in a plastic jar of polypropylene. Removal Aid, 1pc is packed in plastic bag of polyethylene. FlexiVoice Arch, 1pc are packed in plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.</p>

Product Information

Ref 8165:

FlexiVoice Arch, 5pcs (1pc/bag) are packed in plastic bag of polyethylene.
The products and a informative insert are packed in a cardboard box.

Ref 8166:

Provox FreeHands FlexiVoice XtraStrong, 1pc is packed in a plastic jar of polypropylene.

Removal Aid, 1pc is packed in plastic bag of polyethylene.

FlexiVoice Arch, 1pc are packed in plastic bag of polyethylene.

The products and instructions for use are packed in a cardboard box.

Ref 8210:

Provox Life FreeHands HME, 20pcs (10pcs/blister) are packed in blister of PET.

Provox FreeHands FlexiVoice (light, medium, strong) 1 pc/model is packed in a plastic jar of polypropylene.

FlexiVoice Arch, 2pcs are packed in plastic bag of polyethylene.

The products and instructions for use are packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0007-XW

REF	Name	UDI-DI
7757	Provox FreeHands FlexiVoice Set Plus	07331791008276
7760	Provox FreeHands FlexiVoice Set	07331791008283
8161	Provox FreeHands FlexiVoice Light	07331791008290
8162	Provox FreeHands FlexiVoice Medium	07331791008306
8163	Provox FreeHands FlexiVoice Strong	07331791008313
8165	Provox FreeHands FlexiVoice Arch (5 pcs)	07331791010408
8166	Provox FreeHands FlexiVoice XtraStrong	07331791010668
7757-18	Provox FreeHands FlexiVoice Set Plus	07331791013508
7760-18	Provox FreeHands FlexiVoice Set	07331791013515
8161-18	Provox FreeHands FlexiVoice Light	07331791013461
8162-18	Provox FreeHands FlexiVoice Medium	07331791012365
8163-18	Provox FreeHands FlexiVoice Strong	07331791013485
8166-18	Provox FreeHands FlexiVoice XtraStrong	07331791013492
8210	Provox Life FreeHands FV Set Plus	07331791015175



Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands HME	7331791-HME-0-000-0003-XJ
Provox Life FreeHands HME	7331791-HME-0-000-0008-XZ
Removal Aid	7331791-HME-0-000-0005-XQ
Provox FreeHands Support	7331791-HME-A-000-0000-EU