

Technical Info / Material Data Sheet

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Edition: 05

REF Number	7216, 7217, 7218, 7219, 7221, 7224
Product Name	Provox® 2 Voice Prosthesis
Models:	6 sizes; lengths 4.5 mm, 6 mm, 8 mm, 10 mm, 12.5 mm and 15 mm.
Classification: (MDD 93/42/EEC)	Iib (2.4 Rule 8)
CE Mark:	Yes
GMDN code:	42533 (Tracheoesophageal speech valve, indwelling)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The Provox 2 Voice Rehabilitation System is intended for use in surgical, prosthetic voice restoration after total laryngectomy. The prosthesis may be inserted by the physician at the time of the total laryngectomy (primary puncture), or at a later date (secondary puncture), or may be used to replace the present prosthesis.
Description:	The Provox 2 voice prosthesis is a hinged valve with two retention collars, made of medical grade silicon rubber. A rigid blue ring sits inside the prosthesis, adding stability and providing an even sealing surface for the valve flap. The ring can also be seen in an X-ray.
Sterilization:	EO-sterilization
Raw material:	Prosthesis: Silicone and Polyvinylidene fluoride (PVDF) Insertion system: Polypropylene (PP)
Latex information	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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:	5 years after manufacturing

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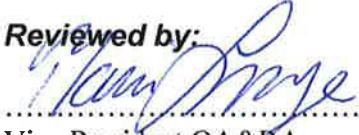
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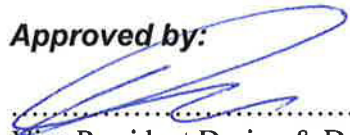
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Packaging: The Provox 2 voice prosthesis is packed together with the Insertion Tool in a blister package made of PETG film and a top film. It is then packed in a cardboard box together with a non-sterile Provox Brush and instructions for use (clinician/patient).

Reviewed by:

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Vice President QA&RA
2016-04-14
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Date

Approved by:

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Vice President Design & Development
2016-04-14
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Date

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