

Provox Coming Home



Product description:

Provox Coming Home is an assortment of products and information for newly laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care at home. Content in the Coming Home package:

8224DE, 8224CA

- 10 pcs Provox FlexiDerm Oval
- 5 pcs Provox OptiDerm Oval
- 3 pcs Provox StabiliBase
- 7 pcs Provox Luna Adhesive
- 10 pcs Provox Luna HME
- 20 pcs Provox XtraFlow HME
- 1 pc Provox Micron *
- 6 pcs Skin Barrier
- 6 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox ShowerAid
- 1 pc Provox Luna ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

*8224DE does not include Micron

8224ES, 8224EM

- 10 pcs Provox FlexiDerm Oval
- 15 pcs Provox OptiDerm Oval
- 3 pcs Provox StabiliBase
- 20 pcs Provox XtraMoist HME
- 20 pcs Provox XtraFlow HME
- 1 pc Provox Micron
- 6 pcs Skin Barrier
- 6 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

8224PL

- 14 pcs Provox FlexiDerm Oval
- 15 pcs Provox OptiDerm Oval
- 3 pcs Provox StabiliBase
- 20 pcs Provox XtraFlow HME
- 20 pcs Provox XtraMoist HME
- 1 pc Provox Micron
- 6 pcs Skin Barrier
- 6 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

8224FR

- 7 pcs Provox FlexiDerm Oval
- 10 pcs Provox OptiDerm Oval
- 3 pcs Provox FlexiDerm Round
- 5 pcs Provox OptiDerm Round
- 3 pcs Provox StabiliBase
- 20 pcs Provox XtraMoist HME
- 20 pcs Provox XtraFlow HME
- 1 pc Provox Micron
- 6 pcs Skin Barrier
- 6 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

8224JP

- 9 pcs Provox FlexiDerm Oval
- 15 pcs Provox OptiDerm Oval
- 20 pcs Provox XtraMoist HME
- 20 pcs Provox XtraFlow HME
- 1 pc Provox Micron
- 9 pcs Skin Barrier
- 9 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

8224PT

- 20 pcs Provox XtraFlow HME
- 1 pc Provox Micron
- 1 pc Provox ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

Provox Life Coming Home



Product description:

Provox Life Coming Home is an assortment of products and information for newly laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care at home.

Content in the Life Coming Home package:

8224DK, 8224FI, 8224NL, 8224SE, 8224IT, 8224DERW, 8224FRRW, 8224ENRW, 8224NO, 8224HU

- 10 pcs Provox Life Standard Adhesive Oval
- 10 pcs Provox Life Sensitive Adhesive Oval
- 10 pcs Provox Life Night Adhesive
- 3 pcs Provox Life Stability Adhesive
- 10 pcs Provox Life Go HME
- 10 pcs Provox Life Home HME
- 10 pcs Provox Life Night HME
- 2 pcs Provox Life Protect HME
- 10 pcs Skin Barrier
- 10 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox Life Shower
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

8224JP23

- 5 pcs Provox Life Standard Adhesive Oval
- 10 pcs Provox Life Sensitive Adhesive Oval
- 5 pcs Provox Life Night Adhesive
- 3 pcs Provox Life Stability Adhesive
- 10 pcs Provox Life Go HME
- 20 pcs Provox Life Home HME
- 20 pcs Provox Life Night HME
- 2 pcs Provox Life Protect HME
- 10 pcs Skin Barrier
- 10 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox Life Shower
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

Provox Life Coming Home USA



8224US21

- 5 pc Provox Life Go HME
- 5 pc Provox Life Home HME
- 5 pc Provox Life Night HME
- 2 pc Provox Life Protect HME
- 1 pc Provox Cleaning towel

Document ID:	PF075-01-TechInfo	Edition:	3.0
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (1.1 rule 1)		
Intended Use:	Provox Coming Home/Provox Life Coming Home is an assortment of products and information for newly laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care at home.		
Use specifications:	<p>Intended medical indication Product for rehabilitation for patients breathing through a tracheostoma.</p> <p>Intended patient population Patients 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. Not intended for patients with a low tidal volume.</p> <p>Intended usage Single patient multiple use (bag). See documentation in the Technical File of each product included for Intended usage.</p> <p>Intended part of the body/type of tissue applied to or interacted with The included devices will contact intact skin and mucosal membrane.</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 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 rate: See documentation in the Technical File of each product included for replacement rates. Replacement is performed by the patient, clinician or caregiver.</p>		
Contraindications:	See Instructions for use of each product included for contraindications.		
CE Mark:	Yes. Coming Home and included products are CE-marked in their own right.		
GMDN code:	58705 (Tracheostoma protective filter)		
Sterilization:	Non-sterile		
Raw material:	The main fabric used in the bag is a polyester that fulfills the REACH regulations. Materials in included devices are not accounted for here.		

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:	Temperature limit: 2-30 °C for 8224SE, 8224DK, 8224NO, 8224FI, 8224DE, 8224NL, 8224CA, 8224HU, 8224IT, 8224FR, 8224DERW, 8224FRRW, 8224ENRW, 8224JP23. Temperature limit: 2-42 °C for 8224PL,8224US21, 8224PT, 8224JP, 8224ES, 8224EM.
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:	The included device with the shortest shelf life upon packing of each lot, will determine the shelf life.
Packaging:	Provox Coming Home/Provox Life Coming is a textile bag and each bag is surrounded with a cardboard sleeve holding the label and symbols.

Devices under Basic UDI-DI: 7331791-KIT-0-000-0000-HL

REF	Name	UDI-DI
8224CA	Provox Coming Home Canada	7331791009594
8224FR	Provox Coming Home France	7331791009549
8224EM	Provox Coming Home Generic	7331791011108
8224DE	Provox Coming Home Germany	7331791009310
8224JP	Provox Coming Home Japan	7331791009471
8224PL	Provox Coming Home Poland	7331791011443
8224PT	Provox Coming Home Portugal	7331791009563
8224ES	Provox Coming Home Spain	7331791009556
8224DK	Provox Life Coming Home Denmark	7331791009440
8224NL	Provox Life Coming Home Dutch	7331791009327
8224ENRW	Provox Life Coming Home English	7331791015809
8224FI	Provox Life Coming Home Finland	7331791009464
8224FRRW	Provox Life Coming Home French	7331791015786
8224DERW	Provox Life Coming Home German	7331791015793
8224HU	Provox Life Coming Home Hungary	7331791016035
8224IT	Provox Life Coming Home Italian	7331791009570
8224NO	Provox Life Coming Home Norway	7331791009457
8224SE	Provox Life Coming Home Sweden	7331791009433
8224US21	Provox Life Coming Home USA	7331791015564
8224JP23	Provox Life Coming Home Japan	7331791016417

Atos Medical AB compatible products:

N/A

Previous generations of Provox Coming Home & Provox Life Coming Home:

None

Similar devices on the market:

See product file of each individual device included in the kit.

Document Approvals
Approved Date: 2024-07-31

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Task: Final Approval Verdict: Approve	NINROG Nina Rogelius, Regulatory Affairs Professional (nina.rogelius-atosmedical@coloplast.com) Regulatory 31-Jul-2024 09:46:05 GMT+0000