

Provox Life LP Kit



Product description:

Provox Laryngectomy Kits provide all-in-one packaging for immediate post-operative 24/7 pulmonary rehabilitation and the option for ready-to-use surgical placement. The kits feature Provox Heat and Moisture Exchangers (HMEs) – approved for 24-hour use.

6130

- 1x REF 7410 Provox Life LaryTube 8/36 Standard
- 1x REF 7411 Provox Life LaryTube 8/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7660 Provox TubeBrush (8mm)
- 1x REF 8308 Provox Life Shower
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6131

- 1x REF 7413 Provox Life LaryTube 9/36 Standard
- 1x REF 7414 Provox Life LaryTube 9/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7660 Provox TubeBrush (8mm)
- 1x REF 8308 Provox Life Shower
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6132

- 1x REF 7416 Provox Life LaryTube 10/36 Standard
- 1x REF 7417 Provox Life LaryTube 10/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8308 Provox Life Shower
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6133

- 1x Ref 7419 Provox Life LaryTube 12/36 Standard
- 1x REF 7420 Provox Life LaryTube 12/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8308 Provox Life Shower
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6134

- 1x REF 7410 Provox Life LaryTube 8/36 Standard
- 1x REF 7411 Provox Life LaryTube 8/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1X REF 1662 Freevent Neckband two-piece Large
- 1x REF 7660 Provox TubeBrush (8mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7438 Provox SolaTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6135

- 1x REF 7413 Provox Life LaryTube 9/36 Standard
- 1x REF 7414 Provox Life LaryTube 9/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7660 Provox TubeBrush (8mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7438 Provox SolaTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6136

- 1x REF 7416 Provox Life LaryTube 10/36 Standard
- 1X REF 7417 Provox Life LaryTube 10/55 Standard
- 1X REF 8311 Provox Life Home HME
- 1X REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7438 Provox SolaTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6137

- 1x Ref 7419 Provox Life LaryTube 12/36 Standard
- 1x REF 7420 Provox Life LaryTube 12/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7438 Provox SolaTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6138

- 1x REF 7410 Provox Life LaryTube 8/36 Standard
- 1x REF 7411 Provox Life LaryTube 8/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1X REF 1662 Freevent Neckband two-piece Large
- 1x REF 7660 Provox TubeBrush (8mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7444 Provox TruTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6139

- 1x REF 7413 Provox Life LaryTube 9/36 Standard
- 1x REF 7414 Provox Life LaryTube 9/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7660 Provox TubeBrush (8mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7444 Provox TruTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6140

- 1x REF 7416 Provox Life LaryTube 10/36 Standard
- 1x REF 7417 Provox Life LaryTube 10/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7444 Provox TruTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6141

- 1x Ref 7419 Provox Life LaryTube 12/36 Standard
- 1x REF 7420 Provox Life LaryTube 12/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7444 Provox TruTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6142

- 2x REF 7414 Provox Life LaryTube 9/55 Standard
- 2x REF 8262 Provox Life Night HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 5x REF 7660 Provox TubeBrush (8mm)
- 4x REF 7204 Provox Brush
- 1x REF 7438 Provox SolaTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6143

- 2x REF 7417 Provox Life LaryTube 10/55 Standard
- 1x REF 8311 Provox Life Home HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8262 Provox Night HME
- 1x REF 8308 Provox Life Shower
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6144

- 2x REF 7417 Provox Life LaryTube 10/55 Standard
- 2x REF 8311 Provox Life Home HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8308 Provox Life Shower
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6145

- 2x REF 7417 Provox Life LaryTube 10/55 Standard
- 2x REF 8311 Provox Life Home HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7438 Provox SolaTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6146

- 2x REF 7417 Provox Life LaryTube 10/55 Standard
- 2x REF 8311 Provox Life Home HME
- 1x REF 1662 Freevent Neckband two-piece Large
- 1x REF 7661 Provox TubeBrush (12mm)
- 1x REF 8308 Provox Life Shower
- 1x REF 7444 Provox TruTone Plus
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

6147

- 1x REF 8262 Provox Life Night HME
- 1x REF 8311 Provox Life Home HME
- 3x REF 8069 Provox Life Sensitive Experience Oval
- 1x REF 8308 Provox Life Shower
- 1x HME Change Log
- 2x Quick Guide
- 1x LCD eWriter
- 1x White Board

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Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden

Classification: (EU) 2017/745 Procedure pack listed in EUDAMED.

Intended Use: Provox Life LP Kit is an assortment of devices and accessories, intended for rehabilitation for users breathing through a tracheostoma after a total laryngectomy.

Note: Provox Life LP Kit consists only of Atos Medical products, see information provided with the individual devices included in the kit.

Use specifications: **Intended medical indication**
Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population

Patients of any age
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.

Intended usage

Single use/Single patient multiple use, Prescription only.

Intended part of the body/type of tissue applied to or interacted with

See information provided with the individual devices included in the kit.

Intended user profile

The product is intended to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use

Environment: Home use (normal living environment without any specific environmental restrictions regarding temperature, moisture etc.).

Outpatient clinic use. Hospital use.

Frequency of use: See information provided with the individual devices included in the kit.

Replacement rate: See information provided with the individual devices included in the kit.

Operating principles

Provox Life LP Kit consists only of Atos Medical products, all of which have their own documentation in their Technical File, see Product File for operating principles of each product:

PF052 Provox TubeBrush

PF086 Provox Life HME

PF088 Provox Life Shower

PF094 Freevent Neckbands

PF101 Provox Life Adhesives

PF106 Provox Life LaryTube

PF121 Provox Electrolarynx

Contraindications: See information provided with the individual devices included in the kit.

Product Information

CE Mark:	The kit is not CE marked. Medical devices included in kit are CE marked individually.
GMDN code:	See individual Product Information.
Sterilization:	Non-sterile.
Raw material:	See individual 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. For REFs 6130 - 6146: Excursions permitted between 2°C - 42°C. For REF 6147: Excursions permitted between 2°C - 30°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. The included device with the shortest shelf life upon packing of each lot, will determine the shelf life.
Packaging:	These products are packed in a box and contain marketing materials and a mix of the following final products (configuration dependent): Provox Life LaryTube Provox Life Home HME Provox Life Night HME Provox Life Sensitive Adhesive Freevent Neckband two-piece L Provox TubeBrush Provox Life Shower Provox SolaTone Plus Provox TruTone Plus

Devices under Basic UDI-DI: 7331791-KIT-0-000-0004-HY

REF	Name	UDI-DI
6130	Provox Life LP Kit 1 - LT 8/36, 8/55	7331791015373
6131	Provox Life LP Kit 2 - LT 9/36, 9/55	7331791015380
6132	Provox Life LP Kit 3 - LT 10/36,10/55	7331791015397
6133	Provox Life LP Kit 4 - LT 12/36,12/55	7331791015403
6134	Provox Life LP Kit 5 - LT 8/36, 8/55	7331791015410
6135	Provox Life LP Kit 6 - LT 9/36, 9/55	7331791015427
6136	Provox Life LP Kit 7 - LT 10/36,10/55	7331791015434
6137	Provox Life LP Kit 8 - LT 12/36,12/55	7331791015441
6138	Provox Life LP Kit 9 - LT 8/36, 8/55	7331791015458
6139	Provox Life LP Kit 10 - LT 9/36, 9/55	7331791015465
6140	Provox Life LP Kit 11 - LT 10/36,10/55	7331791015472
6141	Provox Life LP Kit 12 - LT 12/36,12/55	7331791015489
6142	Provox Life LP Kit 13 - LT 9/55	7331791015496
6143	Provox Life LP Kit 14 - LT 10/55	7331791016165
6144	Provox Life LP Kit 15 - LT 10/55-2H	7331791016134
6145	Provox Life LP Kit 16 - LT 10/55-2HSTP	7331791016141
6146	Provox Life LP Kit 17 - LT 10/55-2HTTP	7331791016158

Devices under Basic UDI-DI: 7331791-KIT-0-000-0006-J6

REF	Name	UDI-DI
6147	Provox Life LP Kit 18 - ADH	7331791018091

Atos Medical AB compatible products:

See information provided with the individual devices included in the kit.

Document Approvals
Approved Date: 2024-11-19

Task: Approval Task Verdict: Approve	HUABOD Adrienn Bodonyi, Product Support Specialist (huabod@coloplast.com) Issuer 19-Nov-2024 11:19:10 GMT+0000
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