DRENTECH WEARABLE –
PORTABLE CHEST DRAINAGE SYSTEM

INTENDED FOR USE

Drentech WearABLE is designed for the evacuation of air and fluids from the patient's thoracic cavity, in order to restore normal intrathoracic pressure gradient and facilitate a complete lung expansion, thereby restoring normal respiratory dynamics. The system is intended for in-hospital use and for the management of patient outside the hospital, as it is portable, safe, and ready to use.

Figure 1: Drentech WearABLE

PRODUCT DESCRIPTION

Drentech WearABLE is a single-use system consisting of an air-liquid separation chamber equipped with a one-way valve and two unidirectional valves for air evacuation, connected to a 300 ml collection chamber.

The device is equipped with the following features:

- Air-liquid separation chamber with a multicaliber connector on the top for direct connection or via available fittings to the thoracic drainage tube, depending on model and size.

- Mechanical anti-reflux valve at the entrance of the separation chamber to prevent potential reflux of fluid back towards the patient, Figure 2(1).

- Low pressure unidirectional valve made of silicone placed on the air-liquid separation chamber, which allows the immediate expulsion of the air coming from the chest cavity of the patient, avoiding its return. The valve is equipped with a special reservoir ("pocket") which, once filled with some drops of water, provides a qualitative indication of air leakage of the patient through bubbling, Figure 2(2).

- Supplementary silicone valve for air evacuation in the case of high flow rates, such as those resulting from the patient's coughing, or temporary unavailability of the primary valve. The supplementary valve is placed on the side of the separation chamber, Figure 2(3).

Figure 2: Drentech WearABLE valve system

- Semi-rigid collection reservoir with a capacity of approximately 300 ml, equipped with a needleless valve to allow emptying and restore the original collection capacity. For this operation a 600 ml capacity bag is included in the kit, Figure 3. The bag has a luer-lock connector, an integrated Heimlich valve and a tap to empty it. The reservoir has two loops on the sides to allow the device to be attached to the patient's waist by

means of a belt, allowing full mobility. Alternatively, two fastening straps are included to position the device on the patient's bed.

– Button to facilitate the transfer of fluid from the collection chamber to the bag, Figure 2(4). This button also functions as a valve for releasing negative pressure. When high negative pressure accumulates in the container, the valve opens to release the negative pressure.

Figure 3: Collecting bag for emptying the reservoir

– A 500 mm long rubber tube for connecting the device to the patient with a multi-gauge connector from 24 to 28 CH, Figure 4(1). The package also includes four additional connectors: a multicaliber from 15 to 22 CH, Figure 4(2), a multicaliber from 24 to 28 CH, Figure 4(3), a multicaliber from 28 to 36 CH, Figure 4(4), and a male luer-lock connector with a piece of tube, Figure 4 (5), for connecting the WearABLE to percutaneous drainage catheters.

– The elasticity of the collection chamber reservoir allows, with a simple compression, to apply a moderate and temporary negative pressure to the patient (up to -60 cmH2O). This operation can be performed to assess the patency of the drainage catheter or to facilitate drainage.

Figure 4: patient tube and fittings

CONFIGURATIONS

Code	Description	Capacity	Pcs/box
10829	Drentech WearABLE – Chest drain	300 ml	6 pcs/box

Compatible accessories	10569	WearABLE belt	20 pcs/box

Compatible devices	12005	Collection bag 600ml with luer-lock fitting	10 pcs/box

TECHNICAL DATA

Production site	**REDAX S.p.A. - Via Galileo Galilei, 18 - 46025 Poggio Rusco [Mantua, Italy]**
Materials	Air-liquid separation chamber body: ABS Air-liquid separator filter: Acrylic copolymer membrane Valves: Silicone and rubber Liquid collection reservoir: SBC Connection tube: Rubber Fittings: PP Needle-less valve: PC The disposal of the material after use must be carried out by adopting the appropriate precautions and in compliance with national and international regulations concerning

	biologically hazardous waste.
Packaging	Single sterile package: Soft blister in medical paper and neutral film. All products are placed in multiple packaging boxes.
Sterilization	Ethylene Oxide NOTE* The code 12005 (Collection bag 600ml with luer-lock fitting) and code 10569 (WearABLE belt) are Medical Device Supplied NOT-STERILE
	Single-use – Do not re-sterilize and/or reuse the product. Single-patient use.
Expiry Date	5 years
Certifications	The Redax Quality System complies with ISO 13485 standards. Redax devices are certified with the CE Mark 0123, issued by TÜV SÜD Product Service GmbH (Germany).
Classification	Class: Is – according to (UE) 2017/745 (MDR)
	Code 10829 CND: A060203 - RDM: 2685640
	Class: I – according to (UE) 2017/745 (MDR)
	Code 12005 CND: A060301 - RDM: 2713024 --- Code 10569 CND: A0699 - RDM: 2691046
Storage, Conservation and Transport	From a chemical-physical stability perspective, the product and the material from which the device is made do not undergo alterations over time. Exposure to sunlight or artificial light sources does not change the structure of the product, provided the packaging remains intact. However, it is recommended to observe the following limits: Temperature limit (Min/Max): 0°C/60°C Storage at room temperature is recommended.
Market Introduction Year	2024

REDAX S.p.A
Technical Director
Andrea Gibertoni