

Product Name: Rocket Chest Drainage System

ZDOCK039 Rev. 24

Language
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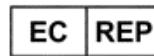
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Product Name: Rocket Chest Drainage System

Product Codes: R54500, R54509, R54517

Device Image:

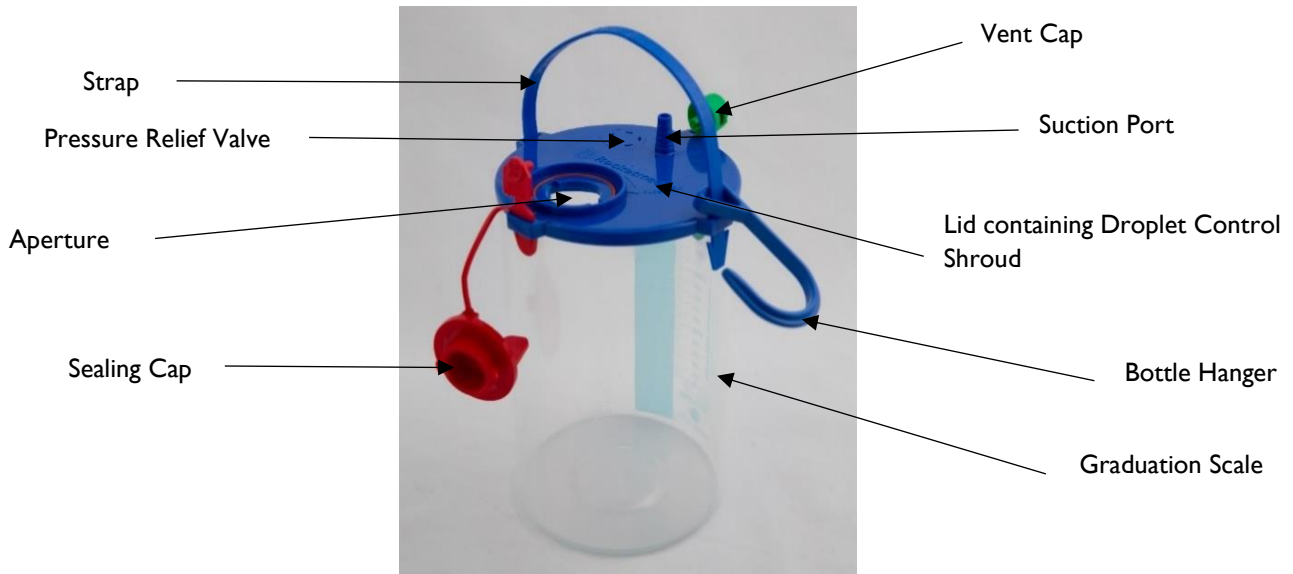


Figure 1: Chest Drainage Bottle (single) - R54500

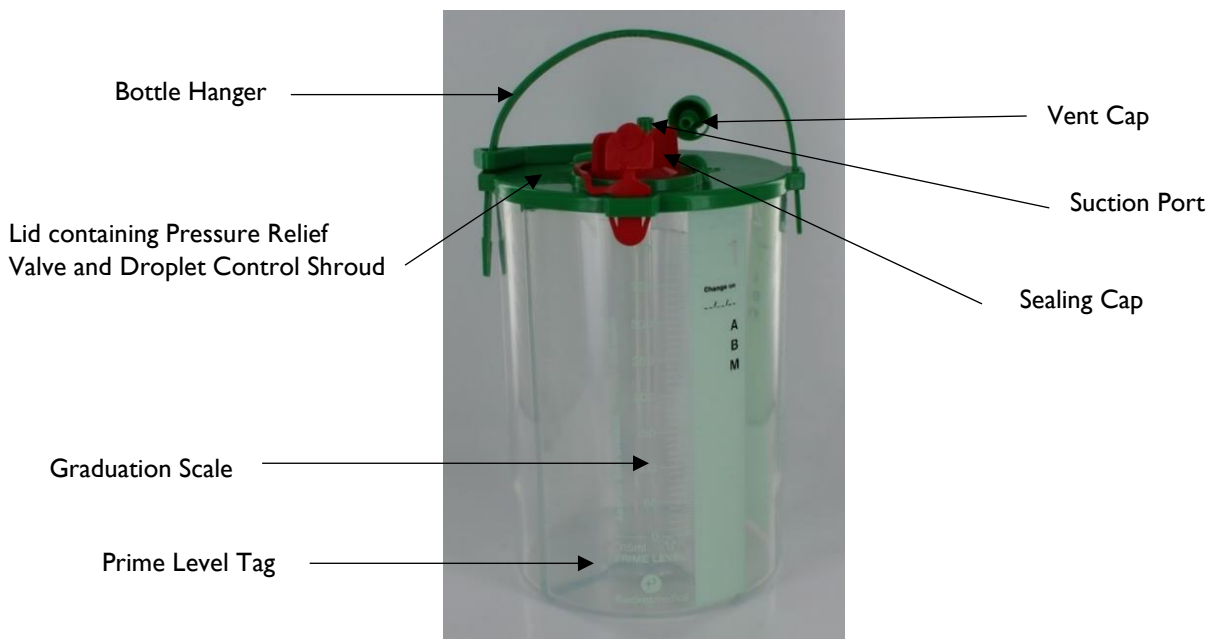


Figure 2: Chest Drainage Bottle with Droplet Control Shroud - R54509

In the event a serious incident related to this device occurs, the event should be reported to Rocket Medical at pncf@rocketmedical.com as well as to the competent health authority in the country that the user/patient resides.

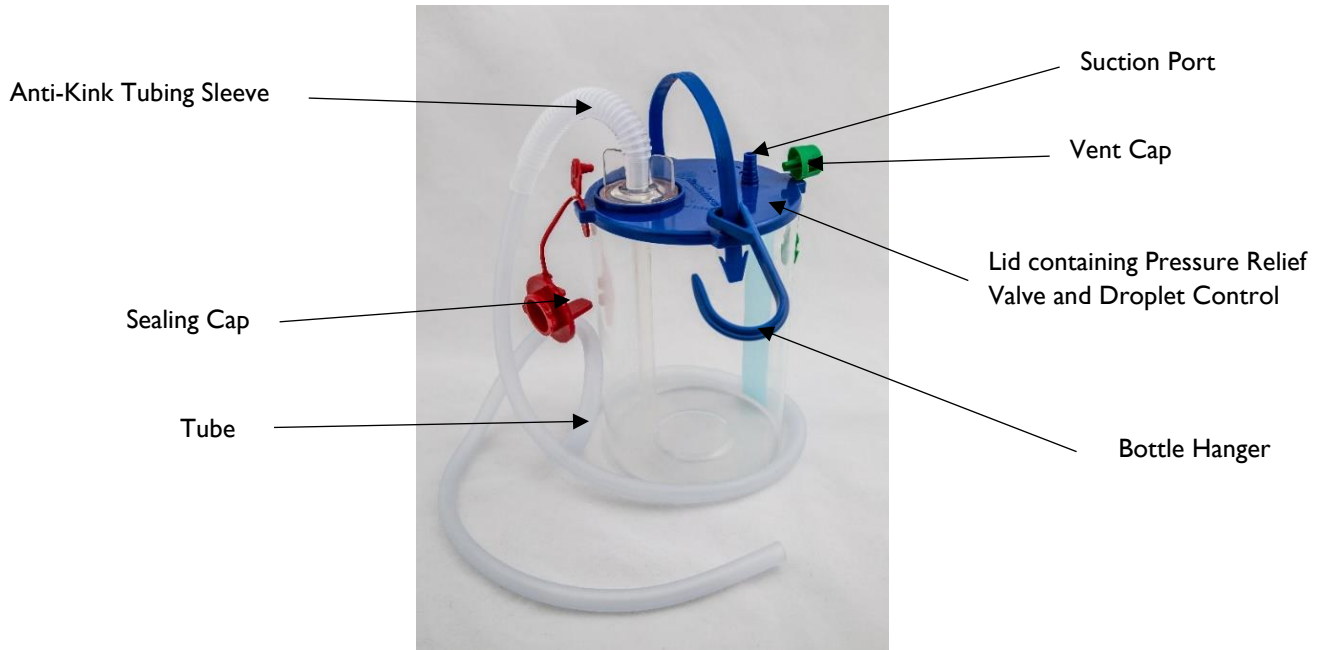


Figure 3: Single Chamber Chest Drainage Bottle with Droplet Control Shroud and Tubing Set - R54517

Intended Use: The Rocket chest drain bottles are intended to be connected to a thoracic catheter for the drainage of air and/or fluid from the pleural space and/or mediastinum. The bottles can be connected to thoracic suction or low flow/low vacuum suction.

Indications: The Rocket chest drainage bottles are indicated for pneumothorax, pleural effusion, empyema, post cardio-thoracic surgery or oesophagectomy and where patients are fitted with a thoracic catheter.

Contraindications: Not intended for any other use except as indicated above.

WARNING:	<ol style="list-style-type: none">1. Ensure that the pressure relief valve and the green venting cap is not obstructed in any way.2. Ensure that the drainage bottle is held in an upright position and below the patient's chest for maximum drainage efficiency and patient protection. If the bottle is not held correctly, its contents could siphon into the chest.3. If the Chest Drainage Bottle is damaged prior to or during use, replace it immediately with a new unit.
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Benefit Risk: Rocket Medical PLC concludes that the overall medical benefits of Rocket Chest Drainage Bottles outweigh the possible risks when used according to the intended use.

Performance Claims and Clinical Benefit: The Rocket Chest Drainage Bottles are plastic drainage containers with a measuring function that collect air and/or fluid from the pleural space and/or mediastinum. These bottles can be attached with a single catheter (single collection) or to two catheters (double collection). The bottles can be connected to thoracic suction or low flow/low vacuum suction. The degree of accuracy of the graduation scale is $\pm 7\%$.

Undesirable Side Effects: No side effects are identified.

User: The intended user is a healthcare professional proficient in managing the drainage of air and/or fluid from the pleural space and/or mediastinum, working in accordance with local and national guidelines. The intended patient demographics are patients fitted with a thoracic catheter requiring drainage of air and/or fluid from the pleural space and/or mediastinum.

Patient Population: The intended patient demographics are patients fitted with a thoracic catheter requiring drainage of air and/or fluid from the pleural space and/or mediastinum.

For Single Use Only: The device may not have structural integrity to support reuse, resulting in harm to the patient and/or user. Re-use may result in harm to patients and users from cross-contamination and infection.

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Sterile: The devices are supplied sterile by Ethylene Oxide (EO). Do not re-sterilise; it may not be possible to achieve the required sterility assurance level upon re-sterilisation of a used device. Re-sterilisation may also compromise the structural integrity of the device, leading to device failure.




















MRI Safety: MRI compatibility has not been verified. The device is made solely of plastic components.

General Information:

The Rocket Chest Drain Bottles can be used along with Rocket Chest Drain Tubing Sets (R54502 / R54533 / R54537 / R54539 / R60558 / R60594) for the drainage of air and fluid from thoracic catheter(s).

The Rocket Chest Drain Bottles can also be used along with the Rocket Chest Drain Filter & Coupling Gasket (R54500-RFE) to reduce the risk of bacterial and viral contamination from the air released from the bottles.

Symbols and safety signs used on the device and labelling:

Symbol or Safety Sign	Meaning	Symbol or Safety Sign	Meaning
	Manufacturer		Keep away from sunlight
	Caution: Federal law restricts this device to sale by or on the order of a physician.		Keep dry
	Date of manufacture		Do not re-use
	Use-by date		Consult the instructions for use
	Batch code		Caution
	Catalogue number		Does not contain natural rubber latex
	Sterilized using ethylene oxide		Non-pyrogenic
	Do not re-sterilise		Medical device
	Distributor		Do not use if package is damaged and consult instructions for use
	Single sterile barrier system		

Operating Instructions:

CHECK: do not use if the packaging is open or damaged or the device is damaged.

INSTRUCTIONS FOR SET UP:

- I. Take one sterile bottle

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2. Inspect outer bags - if ruptured do not use
3. Peel apart pouch and remove bottle.
4. Remove red sealing cap by rotating anti-clockwise from "CLOSE" to "OPEN" position.
5. Fill bottle with fluid to prime level noted on label.
6. Open tubing package and attach tubing set to bottle by inserting straw and cap into the aperture and twisting clockwise until clicked shut. Take care not to touch the straw.
7. Once underwater seal has been established, place bottle on the floor and connect drainage catheter to a tubing connector.
8. If required, insert bottle into Rocket Chest Drainage Bottle Stand

USE:

IF SUCTION IS USED:

1. Attach suction pump tubing to the suction port.
2. Switch on suction pump and regulate to the required negative pressure.

IF SUCTION IS NOT USED:

1. The **GREEN** cap marked **V** (for vent) is a venting cap, which allows the free flow of air from the bottle. **IT DOES NOT SEAL THE BOTTLE.**
2. Please ensure the **GREEN** vent cap is inserted into the suction port on the top of the bottle, as this acts as a dust cover.
3. **DO NOT** place the red cap over this port during drainage, as this is a sealing plug for disposal.

TO CHANGE THE BOTTLE:

1. Obtain a replacement bottle and remove from packaging, having first checked for sterile integrity.
2. Remove red sealing cap .
3. Fill bottle with fluid to prime level noted on label.
4. In line with hospital policy clamp shut the tubing set in use.
Turn the bayonet closure cap on the tubing set anti-clockwise from the "CLOSE" position to "OPEN" position, and remove, taking care to shake off excess fluid in straw before removing from bottle.
5. Insert tubing set into replacement bottle and twist in a clockwise direction from "OPEN" position to "CLOSE" position
6. Replace bottle in stand, if required.
7. Unclamp tubing set.
8. Transfer suction pump tube to the replacement bottle, if suction is used.

Disposal of Full Bottle and Tubing Set

1. Remove tubing set for disposal in the usual manner by turning the clear plastic bayonet closure cap anti-clockwise from "CLOSE" position to "OPEN" position.
2. If suction has been applied, remove the suction pump tubing, tear/pull the **RED** seal cap located on the bottle lid and marked **SEAL**, from its tether.
3. **PUSH THE RED SEALING CAP FIRMLY WITH A TWISTING ACTION** into the suction port on the lid of the bottle to seal.
4. Remove the RED BAYONET cap from its bracket on the side of the lid and replace in hole vacated by the tubing set.
5. Seal cap in place by rotating the cap clockwise from "OPEN" to "CLOSE".
6. Should the red bayonet cap be mislaid, do not remove tubing set, but cut through the tubing and place the end of the tubing over the suction port on the lid of the bottle to create a seal.
7. **Place the adhesive label over the pressure relief valve**
8. Bottle is now ready for disposal.



In the event a serious incident related to this device occurs, the event should be reported to Rocket Medical at pncf@rocketmedical.com as well as to the competent health authority in the country that the user/patient resides.

Disposal: This device, its accessories and the consumables used with it, should be handled and disposed of in accordance with policy of the healthcare setting and with regard to all applicable regulations, including but without limitation to, those pertaining to human health and safety and care of the environment. Failure to do so may increase the risks of infection or other microbial hazards. Take care when handling sharps, to avoid needlestick injuries. Ensure sharps are disposed of in sharps containers.

In the event a serious incident related to this device occurs, the event should be reported to Rocket Medical at pncf@rocketmedical.com as well as to the competent health authority in the country that the user/patient resides.