

Product Name: Rocket Ambulatory Chest Drainage Bag

ZDOCK158 Rev. 22

Language
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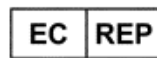


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Rocket Ambulatory Chest Drainage Bag INSTRUCTIONS FOR USE

Product Name: Rocket Ambulatory Chest Drainage Bag

Product Code: R54564

Device Image:

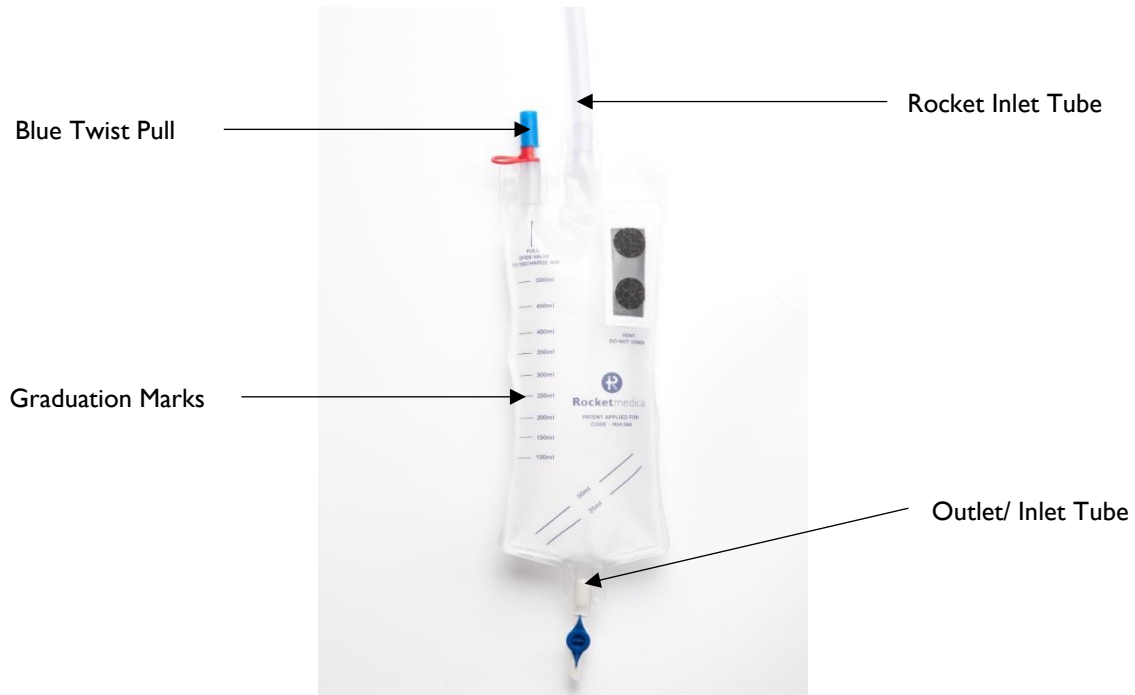


Image 1. Rocket Chest Ambulatory Bag – R54564

Intended Use: The Rocket Ambulatory Bag is intended for the drainage of air from the pleural space in ambulatory patients including for home care.

Indications: The Rocket Ambulatory Bag is indicated for patients with pneumothorax, pleural effusion & empyema being treated by a chest cannulisation where suction is not required, where patient mobility is established or desirable and who have a minimal air leak and/or drainage volume.

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

WARNING:

CONTINUOUS USE SHOULD NOT EXCEED 28 DAYS

- Do not disconnect the bag without clamping the chest catheter. Failure to clamp the catheter would entrain air into the pleural space.
- Ensure the chest drainage catheters are not blocked. Blocked or partially blocked chest drainage catheters can result in complications such as tension pneumothorax.

Benefit Risk: Rocket Medical PLC concludes that the overall medical benefits of Rocket Ambulatory Chest Drainage Bag outweigh the possible risks when used according to the intended use.

Performance Claims and Clinical Benefit: The Ambulatory Chest Drainage Bag is a drainage container with a measuring function that collects air from the pleural space in ambulatory patients including for home care. It can drain up to 500ml of fluid, and the graduations of the scale are accurate to +/- 10%.

Undesirable Side Effects: No undesirable side effects have been identified.

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.

User: The Ambulatory Chest Drainage Bag is intended to be connected to a thoracic catheter by a healthcare professional proficient in managing the drainage of air and/or fluid from the pleural space and/or mediastinum. The intended patient demographics are patients requiring drainage of air from the pleural space in ambulatory patients including for home care.




















Patient Population: The intended patient demographics are patients requiring drainage of air from the pleural space in ambulatory patients including for home care.

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.

Sterile: the device is 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.

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:

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.

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

PREPARE:

- CAUTION:**
1. The drainage bag **MUST** be primed to ensure the internal one-way valve is working correctly before use
 2. Failure to prime the valve prior to use or occlusion of the vent area may prevent the bag from functioning correctly, and prevent air from venting.
 3. Only qualified personnel who are familiar with chest drain care should administer the drainage bag.
 4. Fluid continuously in contact with the vent material may cause the material to saturate and leak fluid.

USE:

1. To prime, use the 60ml syringe supplied, extended to a minimum of 50ml. Pass air through the drainage tube by inserting the syringe nozzle into the drainage tube and compressing the syringe. Air will pass through the flutter valve. This makes sure the valve has not been compromised whilst it has been in storage.
2. If required, fit the fir-tree barb connector provided, to the drainage tubing on the ambulatory bag so that it can connect to a plain ended chest catheter. (If the patient has a Luer lock Seldinger type drain in situ this will not be required.)
3. If the patient has a chest drain already in situ and **IF IN ACCORDANCE WITH LOCAL POLICY** use two clamps to double clamp the chest catheter.
4. Attach the drain by pushing the fir-tree barb connector into the chest catheter, or the plain end of the tube onto the tapered Seldinger drain connector.
5. Ensure the white moisture absorbing material is placed towards the patient so that the venting discs are facing outwards.
DO NOT LAY DOWN SO FLUID CAN COVER THE VENT, THIS WILL PREVENT THE DRAIN FROM VENTING AIR.
6. Remove **BOTH** the clamps. The drain is now in use.
7. If the patient has a brisk air leak, open the blue valve at the top of the bag using a quarter twist and pulling motion. Place the red clip underneath the blue valve cap to prevent the valve being shut accidentally and to indicate the valve is open.
8. Remember if the blue valve at the top of the bag is open, if the patient is draining fluid this may drain out of the valve.
9. Fit and adjust the belt by undoing the Velcro tag and threading through the belt loops on the valve protector. Then place, so that the bag sits comfortably on the patient's side. The belt size can be adjusted using the Velcro. Alternatively, the belt can be utilised as a shoulder strap.
10. To empty the bag use the valve at the bottom of the bag, remember to close the valve after use.
11. If during the use of the bag it becomes necessary to reconnect the patient to an underwater seal drain, apply two clamps to the chest catheter and disconnect the ambulatory bag from the catheter. Refit the drainage device with a fir-tree barb connector fitted. Remove the clamps; check the drainage device is working.
12. If the bag needs replacing with another ambulatory chest drain, apply two clamps to the chest catheter and follow steps **1** to **8** as above.
13. If the patient is draining large amounts of fluid, the drain may, **IN ACCORDANCE WITH LOCAL POLICY**, be connected to a larger fluid collection bag via the overnight bag connection.

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.

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