

Product Name: R54500-RFE Chest Drain Filter & Coupling Gasket

ZDOCK327 Rev. 04

Language
en

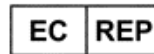
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Chest Drain Filter & Coupling Gasket INSTRUCTIONS FOR USE


Product Name: Chest Drain Filter & Coupling Gasket

Product Code: R54500-RFE

Device Image:



Device Contents: Check you have the full contents of the kit prior to use.

DEVICE REF	DEVICE NAME	QTY	LEGAL MANUFACTURER DETAILS 
ZMOLD699	Red Coupling	1	ROCKET MEDICAL PLC Sedling Road, Washington, NE38 9BZ, UK www.rocketmedical.com
ZFILT014	Clear-Guard 3 Breathing Filter	1	Intersurgical Ltd, Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK CE1639

Intended Use: The Chest Drainage Bottle Filter is intended to reduce the risk of bacterial and viral contamination from the air released from a Rocket chest drain bottle.

Indications: The Chest Drainage Bottle Filter is indicated for patients suspected or confirmed to have an airborne viral or bacterial infection.

Contraindications: The Chest Drainage Bottle Filter is contraindicated for connection to any other device than the Rocket Medical chest drainage bottles (R54500, R54509 or R54517) since a secure connection would not be achieved and filtration would not occur.

WARNING: BOTH the red coupling and filter should be changed every 24 hours.

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: Reduces the risk of bacterial and viral contamination from the air released from the Rocket chest drain bottles.

Undesirable Side Effects: No side effects are identified.

Description of the device: The filter can be connected to the exhaust vent located on the top of the chest drainage bottle (54500/R54509/R54517). This filter is an electrostatic breathing filter that reduces the risk of bacterial and viral contamination from the air released from the Rocket chest drain bottles.

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.

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.

Environment: Clinical environment where a chest drainage bottle (R54500/R54509/R54517) is being used.





















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.

For Single Use Only: the device may not have the 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.

Non-Sterile: the device is supplied non-sterile. They are not intended to be sterilised prior to use. Do not sterilise as doing so may 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
	Authorized representative in the European Community/European Union		Keep dry
	Caution: Federal law restricts this device to sale by or on the order of a physician.		Do not re-use
	Date of manufacture		Consult the instructions for use
	Use-by date		Caution
	Batch code		Does not contain natural rubber latex
	Catalogue number		Importer
	Non-sterile		Medical device
	Distributor		Single sterile barrier system with protective packaging outside
	Single sterile barrier system		Do not use if package is damaged and consult instructions for use

Operating Instructions:

CHECK: do not use if the device is damaged. Ensure you have the full contents of the kit prior to use

USE:

Warning: **BOTH the red coupling and filter should be changed every 24 hours.**

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.

Procedure:

1. Place the red coupling gasket on the exhaust port of the R54500/R54567 Family of Chest Drain Bottles.
2. Orientate the filter so the correct aperture will fit and tightly grip the R54500-RFE.
3. Place the filter onto the coupling gasket, and push to secure the fit.
4. If the chest drain bottle is changed, replace the Chest Drain Filter & Coupling Gasket.
5. Replace the filter and red coupling gasket every 24 hours as per Intersurgical instructions.

Disposal: This device should be handled and disposed of in accordance with the policy of the healthcare setting and with regard to all applicable regulations, including but without limitation to, those pertaining to human health & safety and care of the environment.

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.