

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/52

Issued: 24 August 2006

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

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	Section
<p><b>Medical Device/Equipment:</b> Chest drain: Rocket Medical Seldinger chest drainage set, 12FG Model code - R54544-12-00</p>	▶ ①
<p><b>Problem:</b> Risk of pneumothorax due to the possible detachment of the Luer fitting and catheter during use. The manufacturer is recalling specific batches of the device. Rocket Medical recall reference - R54/3063/0606.</p>	▶ ②
<p><b>Action by:</b> General and thoracic surgeons, nurses on thoracic wards and all others involved in the use, supply and/or distribution of this device.</p>	▶ ③
<p><b>Action:</b> Ensure procedures are in place to:</p> <ul style="list-style-type: none"> <li>Identify and remove all affected stock from use.</li> <li>Contact the manufacturer to arrange collection and replacement of affected stock (see appendix).</li> </ul>	▶ ④
<p><b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> <p style="text-align: right;">Hospices</p>	▶ ⑤
<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b> None Required</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Rocket Medical Seldinger chest drainage set 12FG, model code R54544-12-00.  
NHS Logistic code – FSW214.

Chest drainage sets with this model code and the LOT number listed below are being recalled.

035210, 035813, 035826, 130804, 300404, 400818, 400850, 401918, 402222, 403008, 403312, 403313, 403705, 404204, 404557, 404807, 405103, 405492, 405823, 405964.

The recall does not affect any other product code supplied by Rocket Medical.

## 2. PROBLEM:

The MHRA and Rocket Medical received five incident reports where the Luer fitting became detached from the catheter 3-5 days after insertion of the chest drain. This failure leaves the patient at risk of a pneumothorax.

The manufacturer has identified that failure is due to the design of the joint and has rectified this issue by modifying the joint design to a compression fitting.

Rocket Medical has initiated a recall and will be replacing affected product with new product manufactured using the new style fitting. This Medical Device Alert has been issued to ensure that users are aware of this recall and to support the manufacturer's ongoing recall action.

## 3. ACTION BY:

General and thoracic surgeons, nurses on thoracic wards and all others involved in the use, supply and/or distribution of this device.

## 4. ACTION:

Ensure procedures are in place to:

- Identify and remove all affected stock from use.
- Contact the manufacturer to arrange collection and replacement of affected stock (see appendix).

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Accident & Emergency Departments
- Adult & Paediatric Intensive Care Units
- All Wards
- Anaesthetists
- Cardiothoracic Units
- Health & Safety Managers
- High Dependency Units
- Intensive Care Units
- Lead Nurse Infection Control
- Modern Matrons
- Nursing Executive Directors
- Purchasing Managers
- Respiratory Care Nurse Specialists
- Risk Managers
- Safety Officers
- Special Care Baby Units
- Supplies Managers
- Surgical Directors
- Theatre Managers
- Thoracic Physicians
- Thoracic Surgeons
- Independent Health and Social Care Providers – Private Clinics, Hospitals and Nursing Homes through RQIA

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Rocket Medical Customer Service Department  
Rocket Medical  
Wear Industrial Estate District 6  
Washington  
Tyne and Wear  
NE38 9BZ

Tel: 0191 419 6988

Fax: 0191 419 6989

Enquires to NIAIC should quote reference number MDEA(NI)2006/52 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

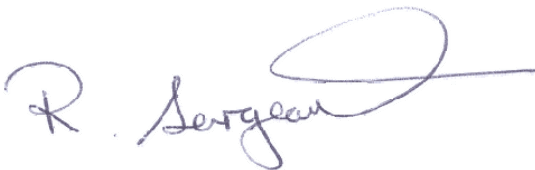
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None Required



Robert Sergeant  
NIAIC Operational Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

## Appendix to MDEA(NI)2006/52

Dear Sir / Madam,

### Rocket® Seldinger Chest Drainage Set – Recall

Ref: R54/3063/0606

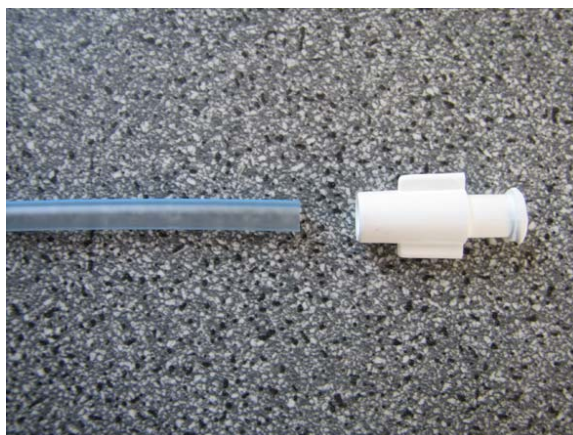
Product codes implicated: **R54544-12-00 Rocket® Seldinger Chest Drainage Set, 12FG.**  
Batches included in this recall are:

LOT	LOT	LOT	LOT
035210	300404	403008	404557
035813	400818	403312	404807
035826	400850	403313	405103
035826	401918	403705	405492
130804	402222	404204	405823
			405964

Rocket® Seldinger Chest Drainage Sets bearing the product code: (REF) R54.544-12-00 and above noted LOT numbers have been found to have a risk of failure during use, resulting in disconnection at the joint between the white luer fitting and the catheter tube.

Five reported incidents have occurred in two centres covering the above LOT numbers.

The reported incidents indicate that joint failure had occurred 3-5 days after insertion of the chest drain.



Luer fitting subject to recall

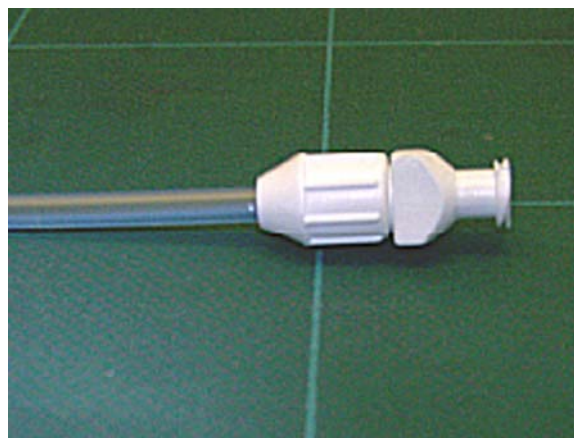
## Appendix to MDEA(NI)2006/52

The problem has now been rectified by a change in the manufacture of this luer joint and the use of a 'compression fitting' which is an established design for use in drains and other catheter systems.

Product manufactured with **LOT** numbers other than those indicated above are **not** implicated in this recall.

Specifically, this recall does not affect the 18FG version of the device, product code R54544-18-00 as this version uses a different method of assembly.

To prevent any further incidents Rocket Medical plc. are withdrawing stock from their client hospitals, all of Rocket® Seldinger Chest Drainage Sets bearing the above noted **LOT** numbers, which will be replaced with new product manufactured using the new style fittings.



New style, replacement fitting

Please pass this letter onto those who need to be aware of it, specifically Hospital Supplies Departments, Thoracic and Medical Wards.

We kindly request you to co-operate with this recall and pass onto us details of any transfers to other organisations that you may have made. In order to facilitate rapid recall, please check current stocks and isolate any devices bearing the above product **REF** and **LOT** numbers, then contact Rocket Medical Customer Services Department on telephone number 0191 4196988, stating the product **REF**, **LOT** and quantities, along with a contact person and pick up address.

We will arrange delivery of the replacement units and collection of the old tube sets. Our sales representatives will be calling to assist in the above matter.

The Medicines and Healthcare products Regulatory Agency (MHRA) have been informed about this recall.

For and on behalf of Rocket Medical plc.

Ms J.B.Irwin  
QA Manager