

Field Information Safety Notice

Commercial Name: Rocket® IPC Drainage Bottle

Product Code: R54400, R54400-00-PP, R54410, R51400,
R51400-00-PP, R51410

Type of action: **INFORMATION**

Tuesday September 16th 2014

Rocket Medical would like to inform you that a manufacturing irregularity has occurred during the production of the **R54400, R54400-00-PP, R54410, R51400, R51400-00-PP** IPC drainage bottles.

A small number of drainage bottles have appeared to malfunction as the blue connector tube (arrowed) has not opened once the white clip has been moved.

The non-opening of the blue tube does not allow the vacuum contained in the bottle to be applied to the patient, therefore no fluid can be drained.

There is no risk to the patient with this anomaly apart from the inability to drain.

When the white clip is open the blue connector tube can be encouraged to open with gentle manipulation of the tube forwards and backwards in line with the clip.

No other Rocket Medical chest drainage units are affected by this issue.

We are actively seeking a resolution to this matter, and there is no product recall at this time.

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

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

For and on behalf of Rocket Medical plc.

Ms J.B.Irwin

QA Manager

