

URGENT FIELD SAFETY NOTICE

Commercial Name: Rocket® NRFit™ Spinal Manometer
Product Code: R55990-ISO-6
LOT: 477977
Type of action: RECALL
Date of Notice: Wednesday, 28th March 2018

Rocket Medical would like to inform you that a manufacturing irregularity has occurred during the production of the **Rocket® NRFit™ Spinal Manometer LOT: 477977**

An internal audit has identified that there is a possibility that some items from this lot may contain a component which prevents correct connection to a NRFit or luer spinal needle.

Although the likelihood of this failure reaching the market is small, Rocket Medical are taking the precautionary measure of recalling this specific LOT.

The failure can be identified as indicated in these image which show a correct moulding on the left and a faulty, INCORRECT moulding on the right.

The faulty component can be seen as having a missing central male connector. In this condition, the spinal manometer cannot be correctly attached to a spinal needle and CSF samples and pressure measurements obtained.

As a precautionary measure and to ensure patient safety, all stock of **R55990-ISO-6 Rocket® NRFit™ Spinal Manometer LOT: 477977** should be returned and replaced with stock from a different LOT.

No other Rocket Medical devices are affected by this issue.

Please pass this notice to those who need to be aware of it, specifically Hospital Supplies Departments, Emergency Departments, Medical, Neurological and Neurosurgical wards.

To arrange to replace your stock with alternative product please contact:

Rocket Medical Customer Services Department on telephone number **0191 419 6988**, stating quantities, along with a contact person and pick up address.

For further information please contact our QA Manager:
Jackie Irwin on 0191 419 6956 or jackie@rocketmedical.com.

