

Date: 28th October 2013

FIELD SAFETY NOTICE (FSN)

Product	Reference code
Perfusor® Space	8713030
Battery pack	8713180

FSN identifier: CLIN/PER/28102013

Dear Customer,

As a medical device manufacturer B. Braun Medical Ltd takes patient safety and product quality very seriously.

Although there have been no reports of adverse patient incidents there is a risk when the Perfusor® Space pump is used with an aged battery that the pump may not have sufficient current to perform a syringe change, despite the battery indicator on the pump showing full charge. This is because a syringe change requires a large current which may not be available if the battery has been significantly aged. This does not affect running infusions.

The issue can only occur when the pump is not connected to the mains and presents a risk when the pump is used on battery only (for example during patient transfer) and is particularly relevant for patients on life sustaining or other critical medications.

Over time, batteries in any medical device will degrade therefore batteries should be replaced at appropriate intervals. Further details regarding battery replacement have been provided to the engineering teams responsible for maintaining Perfusor® Space pumps at your hospital.

The following actions are required:

1. For infusions of critical medications, always have an additional pump available. This is described in the Perfusor® Space Instructions for Use (section: PATIENT SAFETY).
2. If a Perfusor® Space pump used on battery only and showing full battery charge stops during syringe change and alarms, it should be removed from use. Users should then return the pumps with aged batteries (or the aged battery pack) to the Medical Engineering Department for replacement.

3. Please complete the attached reply form to confirm that you have received this FSN and have taken/will take the appropriate action described above. Return the form by fax to 0114 2259136.

4. This FSN should be passed to all those who need to be aware in your organisation including all clinical departments and users in the hospital and those who use the pumps during the transfer of patients.

A second FSN with the same subject has been issued targeting the technical staff (FSN no: TECH/PER/28102013). The MHRA has been advised of the above FSN.

If you have any questions about this FSN or require further information please contact the Quality Management team at B. Braun, Catherine Clulow (email catherine.clulow@bbraun.com, Tel: 0114 225 9155).

Yours sincerely



Karen Jackson
Medical Affairs Manager
B. Braun Medical Ltd



Andrew Pritchard
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PLEASE COMPLETE THIS FORM AND RETURN IT BY FAX TO: B. BRAUN MEDICAL LTD ON 0114 225 9136

[Hospital Name]
[Department]
[Contact Name]
[Address]

- We herewith confirm that we have received and understood the FSN (no: CLIN/PER/28102013) relating to the following:

Product	Reference code
Perfusor® Space	8713030
Battery pack	8713180

- We confirm that we have forwarded this information to the clinical departments and users in our hospitals or others as appropriate.

NAME:

POSITION:

SIGNATURE:

DATE: