smiths medical
bringing technology to life

Smiths Medical International Ltd.
St Crispin Way, Haslingden, Rossendale
Lancashire, BB4 4PW. UK
T: +44 (0)1706 233800
F: +44 (0)1706 218834
www.smiths-medical.com

Our Ref: CAR - 172

Date: 26th February 2008

IMPORTANT PRODUCT INFORMATION

PRODUCT:
Smiths Medical Logical, NovaTrans, and Transtar Invasive Pressure Monitoring Kits with Trigger Flush Device, Product Codes DPSXXXXXX / MX95XXXX / MX96XXXX / MXXXX / SXXXXXXX

DETAILS OF AFFECTED DEVICES:
All product codes above manufactured between October 2007 and February 2008

TYPE OF ACTION:
Field Safety Corrective Action

ATTENTION:
Risk/ Safety Managers, Distributors, Clinicians and other Customers

Dear Customer,

Smiths Medical International has received reports that some pressure monitoring kits allow flow rates which exceed the 3ml/ hour nominal flow rate specification. In the affected devices, the flow rate can be between the nominal flow rate, of 3ml/ hour, and the flush rate. This increased flow rate allows for more fluid than intended to be delivered to the patient and the higher flow rate can cause a positive offset in the pressure measurement indicated on the patient monitor leading to an inaccurate pressure reading.

Smiths Medical International recommends that you take action(s) as detailed in the attached "Field Safety Corrective Action Notice".

If after reading the Field Safety Corrective Action Notice you still have questions or queries relating to this matter please do not hesitate to contact: -

UK Customer Services – Tel: 01923 241411
International Customer Services – Tel: +44 (0)1303 260551
Quality Assurance Department- +44 (0)1706 233831

Yours Sincerely

Omar Khan

QA Manager
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Urgent Field Safety Notice

Affected Devices: Smiths Medical Logical, NovaTrans, and Transtar Invasive Pressure Monitoring Kits with Trigger Flush Device, Product Codes DPSxxxxxx / MX95xxxx / MX96xxxx / MXxxx / SXxxxxxx

Type of Action: Field Safety Corrective Action

Manufacturers Reference: CAR-172

Date: 21st February 2008

Details on affected devices: All product codes above manufactured between October 2007 and February 2008

Complete and Fax promptly to: Omar Khan, Quality Manager , Smiths Medical International Ltd.

Fax No.: +44 1706 211878

SECTION 1 -:

Distributor Name: _____

Printed Name: _____

Country: _____

Tel No.: _____ Ext: _____ Fax No.: _____ E-mail: _____

Tick one of the Boxes:

We **have not received any products covered by the Field Safety Notice** ☐

We **have passed a copy of this notice on to all customers in receipt of items manufactured during the affected period** ☐

SECTION 2 - ANSWER ALL ITEMS BELOW AND SIGN.

Has Regulatory Authority been notified? ☐ YES ☐ NO

If yes, please indicate name of regulatory authority:

IF no please indicate why notification hasn't occurred

Questions should be directed to Omar Khan at +44 1706 211878 (e-mail omar.khan@smiths-medical.com)

Submitted By .... Date:...../...../.....
(Name). Signature:

For Smiths Medical Use Only
Customer Account No.