B BRAUN

B. Braun Medical Ltd.
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Dublin 12
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http://www.bbraun.com

Date
September 16, 2016

Urgent FIELD SAFETY NOTICE – Spinocath Recall

Article Number	Article Name	Batch
4517717	SPINOCATH G24/G29	All
4517725	SPINOCATH G22/G27	All

Dear Sir/Madam,

B. Braun Melsungen AG has decided to recall the above listed products in the context of a FIELD SAFETY CORRECTIVE ACTION from the market.

Reason for the Recall
In the course of internal quality checks it was discovered that the above listed SPINOCATH articles may have holes in the PVC film of the sterile barrier system.

In spite of the potentially impaired sterile barrier system no harm or any other adverse patient outcome associated with the above described observation has been reported to B. Braun.

Actions to be taken by the USER
Our records show that your hospital has received potentially affected SPINOCATH products as specified in the table above.

We kindly ask you to initiate the following activities immediately and with priority:

- Identify, quarantine and return affected devices.
- Do not use affected devices anymore.
- Patients with affected devices in place should be monitored carefully. If clinically uneventful, an exchange of the device is not indicated.
- Inform the responsible personnel in the affected departments/facilities.
- Complete and sign the enclosed 'Recall Confirmation Form' and fax this back to us (fax no. 01-7091889) to confirm that you have received this notice and advise the quantity of affected product to be returned.

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*Please return the completed form by **Thursday 22nd September 2016**, or sooner if possible.*

A member of B. Braun Medical will then be in touch with you to organise collection of any quarantined units. Please enclose the Recall Confirmation Form with this collection.

Credit will be provided for any affected product returned.

If more information is needed, please contact:

Robert Egan
Business Unit Manager
Medical Technologies Division
Telephone: 086 2606917
Email: rob.egan@bbraun.com

We appreciate your immediate attention and apologise for any inconvenience caused.

Yours sincerely,

Robert Egan
Business Unit Manager
Medical Technologies Division

Roberta Egan
Regulatory Affairs Manager

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September 16, 2016

RECALL CONFIRMATION FORM

Spinocath

Please complete this form, even if you do not have any of the concerned product and fax this form back to Fax No. 01-7091889

1. **We acknowledge receipt of the recall-notification from B. Braun Medical.**
2. **Please mark accordingly:**
   - ☐ We do not have any of the affected product in stock.
   - ☐ We will return the following products:

Article Number	Device Name	Batch Number	Quantity to be Returned
4517717	SPINOCATH G24/G29		
4517725	SPINOCATH G22/G27		

Hospital:	
Address:	
Contact Name:	
Contact Phone Number:	
Contact e-mail address:	
Date and signature	