

B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices

34209 Melsungen
Germany

Your reference:

Our reference: RECALL 2016-09-15 LS/STK

Contact:

Fon: 05661 71-2769

Fax: 05661 75-2769

Email: Ludwig.schuetz@bbraun.com

Internet: <http://www.bbraun.de>

Date: September 15, 2016

Attn: [REDACTED]

Urgent FIELD SAFETY NOTICE – SPINOCATH

To whom it may concern,

We, the B. Braun Melsungen AG have decided to recall the following products in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

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

Reason for the Recall

In the course of internal quality checks we discovered that the above listed SPINOCATH articles may have holes in 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 to the above described observation has been reported to the B. Braun Melsungen AG.

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.

Your Purchase Orders: [REDACTED]

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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 facilities .
- Confirm the receipt of this information.

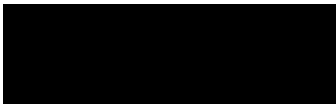
If more information is needed, please contact

Local contact 1
Loo Bee Keong
General Manager, Sales
bee_keong.loo@bbraun.com
96680547

Local contact 2
Teng Hui Min
Senior Regulatory Affairs Executive
hui_min.teng@bbraun.com
62130941

Kindly accept our apologies for any inconveniences.

Yours sincerely,



Loo Bee Keong
General Manager, Sales



Teng Hui Min
Senior Regulatory Affairs Executive

B.Braun Singapore Pte Ltd
600 North Bridge Road
#15-05 Parkview Square
Singapore 188778

Receipt of notice: _____
(Name & designation)

Date: _____

Quantity to be returned: _____