B BRAUN

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Safety Officer Medical Devices

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

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TO WHOM IT MAY CONCERN

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.

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
Name
Title
Email
telephone

Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,