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B. Braun Melsungen AG
Division Hospital Care

TO WHOM IT MAY CONCERN

Your reference	Our reference	Tel. +49/56 61/71-	Fax +49/56 61/71-	Date
	RECALL 2015-10-12 LS/STK			October 13, 2015

Urgent FIELD SAFETY NOTICE – Spiral Line, ProSet

To whom it may concern,

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

Article Number	Article Name	Batch
4092937	SPIRAL LINE 150 CM	15G03F00B1
		15F19F00B1
		15D08F00B1
		15C16F00B1
		15A29F00B1
		15A07F00B1
		14N17F00B1
		14N12F00B1
		14M07F00B1
		4I303400B1
		4I173400B1
		4I123400B1
		4H073400B1
4092945	SPIRAL LINE 300 CM	15G04F00B1
		15F26F00B1
		15F15F00B1
		15D13F00B1
		15C11F00B1
		15A28F00B1
		15A23F00B1
		14N08F00B1
		14M19F00B1
		4K103400B1
		4K093400B1

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		4I263400B1
		4I233400B1
		4I123400B1
		4H073400B1
		4G243400B1
		4G223400B1
4092953	PROSET SPIRAL LINE 500 CM	15G03F00B1
		15F23F00B1
		15F15F00B1
		15C23F00B1
		15C11F00B1
		15A28F00B1
		14N08F00B1
		14M19F00B1
		4K213400B1
		4I123400B1
		4H073400B1
4092961	PROSET SPIRAL LINE 700 CM	15G03F00B1
		15D13F00B1
		15A19F00B1
		14N11F00B1
		14M19F00B1
		14L30F00B1
		4H073400B1
		4G303400B1
4092970	PROSET SPIRAL LINE 850 CM	15A30F00B1
		14N15F00B1
		4K143400B1
		4H073400B1
4093070	PROSET CONNECTION-TUBING PUR 700CM	14N18F00B1
4187886	PROSET DISCOFIX C MANIFOLD SET (1X=5PCS)	15D02F00B1
4188105	PROSET MANIFOLD SET WITH STERIFIX FILTER	15F24F00B1
		15B10F00B1
		14M05F00B1
		4I243400B1

Reason for the Recall

In the course of our post market surveillance activities we observed several times that an LLI-cone was disconnected from a thin PUR tube. During investigation it turned our that the UV-glue between the thin PUR tube (1x1.9 mm) and the LLI cone was not fully cured in all instances. Due to the specific type

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of affected connection and a shift of production the described failure can be limited to the above mentioned product/batch combinations.
Up to now, no harm or any other adverse patient outcome which could be associated to the above described observation has been reported to the B.Braun Melsungen AG.
As the mislabeling, however, bears a serious risk of patient harm, we have decided to recall the affected batches from the market.

Actions to be taken by the USER
Our records show that your hospital has received the potentially affected 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.
- 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,