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Hechingen, 10.05.2013

Field Safety Corrective Action: Recall of medical products

BfArM-case number: 970/13
Concerned products: **Joline Short term/Acut-Dialysis-Catheter (Catalog Nr. in Annex), Production date period 06/2012 – 02/2013**

Problem description:

During the usage of the Joline Acute Dialysis catheters of the production period from **06/2012 – 02/2013** sporadically hairline cracks occurred in the connectors of the catheters. This may occur more frequently if highly alcoholic disinfectants are used.

The reason for the hairline cracks was identified and eliminated.

Advisory Notice for the operator or customer:

- Stop the sale of affected products of the specified manufacturing period.
- Take any necessary action to address all your customers and ask them to stop the use of the products affected by this recall.
- Check your stock and put all affected products under quarantine.
- If you have delivered products affected by this recall, to your customers, please make sure to inform them about the recall and arrange that they initiate their recall routine.
- Please assure that this information is forwarded to all qualified personnel to which affected products were delivered.
- Fill in the table of the return record (attached) and send it to your responsible distributor.
- Your responsible distributor will get in touch with you to organize all necessary steps for the return of the affected products.



Risk for the patient:

There was no endangerment to patients when connector cracks occurred so far. But it can't be excluded that there might be blood loss.

There is no additional aftercare for patients necessary.

We apologize for all inconvenience caused by this recall and want to thank you in advance for your help and understanding.

A handwritten signature in blue ink, appearing to read "ERIK RIEKENBERG", with a large, stylized flourish extending to the right.

Erik Riekenberg
Director QS

Contact person:

Erik Riekenberg, Director QS

qa@joline.net

Telephone: 07471-9881-177, 07471-9881-0

The signatory confirms that this FSCA has been reported to the corresponding competent authority (BfArM).



Please fill in this form even if you did not get any of the affected products and send it either to your responsible distributor or to Joline GmbH & Co. KG; e-mail: ga@joline.de; FAX: +49 (0) 7471 9881 111

Customer / distributor Form

Urgent Recall of Medical products

1. We confirm the receipt of this recall concerning following products:
 - **Short Term / Acute Dialysis Catheters (see Annex) production period 06/2012 – 02/2013**
2. We confirm, that all departments in which affected products could be found, were checked.
3. We confirm that other departments in case they received these products have been informed about this recall.
4. We have read this notification and did understand that products of this range and production period should not be used and need to be quarantined.

PLEASE SELECT ONE OF THE FOLLOWING STATEMENTS, SIGN THE FORM AND SEND IT TO YOUR RESPONSIBLE DISTRIBUTOR OR TO Joline GmbH & Co. KG; e-mail: ga@joline.de ; FAX: +49 (0) 7471 9881 111

- We don't sell the affected products.
- We have affected products on stock. We confirm that we entered all affected lots and amounts of identified products in the attached list (amount on stock and amount already used).



Catalog number	Lot number	Manufacturing date	Expiration date	Total amount received	Total amount on stock	Total amount used

Date:

Signature:

Name in printed letters:

Customer:

Address:

E-Mail:

Telephone:



Annex: List of Joline Short term / Acute Dialysis Catheters

SL08P125	KTL12P125R	PKEF11P150
SL08PH125C	KTL12P150R	PKEF11P150R
SL08PH150C	KDL08P100R	PKEF11P200
DL11P150C	KHF13PH150	PKEF11P250
DL11P150D	KHF13PH175	PKHF13PH150
DL11P200C	KHF13PH200	PKHF13PH150R
DL11P200D	KHF13PH225	PKHF13PH200
DL11P200CD	KHF13PH250	PKHF13PH250
KSL08P150	KEF11P200C	PKTL12P150
KSL08P175	KDL06P075C	KTHF13P200
KSL08P200	KDL11PH125	KTHF13P250
KSL08P200C	KDL11PH150	PKTHF13P150
KSL08PH150C	KDL11PH150C	PKTHF13P200
KDL11P125	KDL11PH150R	KDL06P100 21
KDL11P150	KDL11PH175C	PKTHF13P150R
KDL11P150C	KDL11PH175R	PKTHF13P200R
KDL11P175	KDL11PH200	KEF11P175 21
KDL11P175C	KDL11PH200C	PKDL11P200
KDL11P200	KDL11PH200R	PKDL11P150
KDL11P200C	KDL11PH250	PKDL11P150R
KDL11P250	DL11PH125CD	PKTL12P150C
KTL12P125	KEF11PH150R	PKEF11P175R
KTL12P150	KDL11PH125R	PKHF13PH175R
KTL12P150C	KHF13PH150R	KDL11P175C 21
KTL12P175	KHF13PH200R	KTL12P150C 21
KTL12P175C	KHF13PH250R	KTHF13P150C 21
KTL12P200	KHF13PH150C	KTL12P250 21
KTL12P200C	KHF13PH200C	KDL08P150 21
KDL11P150R	KHF13PH250C	PKTHF13P150C
KDL11P200R	KEF11P200 21	KDL06P075R 21
KDL11P175R	KTL12P200 21	KHF13PH150C 21
KEF11P150	KTL12P175 21	PKTHF13P175
KEF11P200	KEF11P150 21	PKEF11P175
KEF11P150R	KDL11P200 21	KDL06P075 21
KEF11P175R	KHF13PH175 21	PKDL06P075R
KEF11P200R	KDL11P150 21	KDL08P100R 21
KEF11P300R	KDL11P150C 21	KDL06P075C 21
KDL11P250R	KDL11P175 21	KDL11P250R 21
KEF11P300	KEF11P250 21	KHF13PH225R 21
KEF11P250	KDL08P100 21	KTHF13P150R
KDL06P075	KDL11PH100R	KTHF13P175 21
KDL06P100	KEFS250 N	KHF13PH175C
KDL06P125	KEFS300 N	KDL08P125 21
KDL06P150	KEFS350 N	KDL08P150
KDL08P100	KEF11P150C 21	KEF11P175C
KDL08P125	KEF11P175C 21	DL11P150CD
KDL08P100C		