



JOLINE GmbH & Co. KG • Neue Rothenburger Str. 50 • D-72379 Hechingen

Urgent Field Safety Notice

For Joline Acute Dialysis Catheters (list of Ref. No. in annex),
Manufacturing date 06/2012 – 02/2013

Hechingen, March 2013

Dear valued customer,

In the course of our continuous market surveillance, we became aware that occasionally there could be an increased risk of hairline cracks at the connectors of these catheters.

It was observed that during the application of the catheter crack formation sporadically occurred. Although there has been no patient endangering so far, blood loss cannot be excluded. Until now the exact cause for these observations could not be ascertained, since the defect occurs locally accumulated. Potentially, products connected to, or disinfectants used on the concerned catheters could abet the observed defects.

By means of optimized manufacturing processes and improvements of the design the mechanical and chemical resistance could be enhanced. Until these measures are completely implemented, we kindly ask our customers to waive alcoholic disinfectants, in no case connect before complete drying as already indicated in the instructions for use and avoid excessive forces when connecting as well as ensure a regular and frequent control of the connectors. Please securely clamp affected catheters with the mounted safety clamp and change the catheter.

Please pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred to.

Please maintain awareness on this notice and resulting action for an appropriate period of time to ensure effectiveness of the corrective action and return a confirmation of receipt. This notice has been notified to the appropriate Regulatory Agency.

Contact reference person:

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Joline GmbH & Co. KG

Best regards

Joline GmbH & Co. KG

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BLZ (600 501 01)
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Annex: List of Joline 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