



Urgent Field Safety Notice FSN_CN-20240306_COMP-20240220

KD-LINE® Extension-Connection Tubing for connection to infusion and transfusion systems

REF and LOT numbers: Refer to Table 1
Type of action: Product removal

FSCA identifier: CN-20240306_COMP-20240220
FSN identifier: FSN_CN-20240306_COMP-20240220

Date: 08.03.2024

Addressee/Attention: KD Medical Polska sp.z.o.o; 43-502 Czechowice-Dziedzice; ul. Legionów 192B / Attention: Mrs Katarzyna Kupczak

Dear customer

KD Medical GmbH Hospital Products is conducting a Field Safety Corrective Action (FSCA) to remove specific LOT numbers of **KD-LINE® Extension-Connection Tubing for connection to infusion and transfusion systems**.

Please find REF and LOT numbers of the devices affected by this FSCA in Table 1:

Table 1 - Details on affected devices:

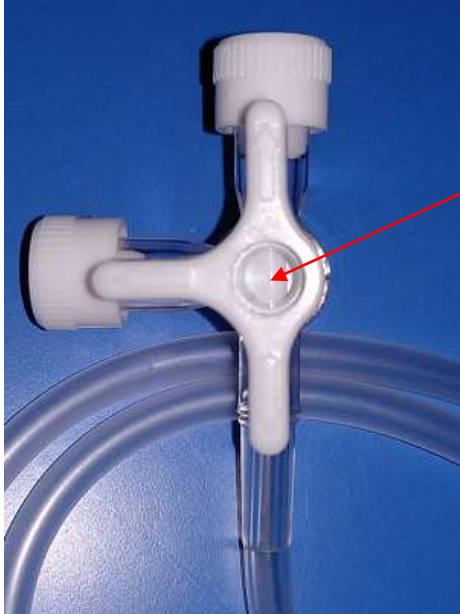
Article number (REF)	Batch number (LOT)	Product description
771303D	3D97360	7 cm tubing, with three-way stopcock
771204D	3D00360	10 cm tubing, with three-way stopcock
771327D	3D05360	25 cm tubing, with three-way stopcock
771228D	3D06360	50 cm tubing, with three-way stopcock

This product removal is limited to the article numbers with the batch numbers (LOT) listed in Table 1. No other batch numbers (LOT) are affected.

Description of the problem:

Based on customer feedback KD Medical has identified that the stopcock in KD-LINE® with batch numbers (LOT) listed in Table 1 might have a minor shrinkage depression in the cavity on the top of the stopcock handle that might lead to insufficient tightness of the stopcock with subsequent fluid leakage – see photo 1 for the potential site of leakage. The defect is normally not visible to the naked eye.

Photo 1 – potential site of fluid leakage:



Clinical risk:

The injection molding deviation might compromise the closed infusion/transfusion system which in turn might lead to liquid leakage and/or inadequate administration of fluid or medication, inability to maintain a close system, or contamination of the environment by blood or hazardous drugs.

KD Medical has received two complaints for leakage through the top of the stopcock handle, none of which reported harm.

Actions taken by KD Medical:

KD Medical has identified the root cause and is taking corrective actions to prevent reoccurrence of this issue.

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PF 060107 10051 Berlin Germany	Charlottenstrasse 65 10117 Berlin Germany
Phone	+49-30-20 39 95 91/92
Fax	+49-30-20 39 95 99
E-Mail	info@kdm-berlin.de
http	www.kdm-berlin.de

Actions to be taken by the addressee of this Field Safety Notice:

We kindly ask you to initiate the following activities immediately and with priority!

1. Please carefully review this Field Safety Notice in its entirety.
2. Distribute this Field Safety Notice to all of your customers on which this action has an impact and ask these customers
 - a. to do not use affected products listed in Table 1 anymore
 - b. it is not necessary to exchange products listed in Table 1, which are currently in use, if you did not experience leakage problems
 - c. to pass this Field Safety Notice on to any organisation where the products listed in Table 1 have been transferred, if applicable
 - d. to identify and quarantine any stocks of the products listed in Table 1 and
 - e. to send back these quarantined stocks to KD Medical Polska sp.z.o.o **by 30.04.2024**

This Field Safety Notice needs to be passed on to all those who need to be aware within your organisation and to any organisation where the products listed in Table 1 have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please send back the signed distributor reply form sent together with this Field Safety Notice to the manufacturer KD Medical GmbH Hospital Products by email **by 11.03.2024**.

Contact reference person of the manufacturer:

Dr. Andreas Pachten
KD Medical GmbH Hospital Products
Charlottenstrasse 65
10117 Berlin
GERMANY

Tel. +49 173 3827626
Fax: +49 30 20 39 95 99
E-Mail: a.pachten@kdm-berlin.de

Please accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

The undersigned confirms that this Field Safety Notice has been notified to the appropriate Regulatory Agencies.

Berlin, 08.03.2024

Signature, company's stamp
Dr. Andreas Pachten, Quality Management Representative & Deputy PRC

