KD Medical GmbH Hospital Products
SRN: DE-MF-000006773
FSN_CN-20250904_COMP-20250714

KD MEDICAL GMBH HOSPITAL PRODUCTS®

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Urgent Field Safety Notice FSN_CN-20250904_COMP-20250714

KD-*FINE*® *SAFETY* hypodermic needle with needle protection device

REF and LOT numbers: Refer to Table 1
Type of action: Advisory note

FSCA identifier: **CN-20250904_COMP-20250714**
FSN identifier: **FSN_CN-20250904_COMP-20250714**

Date: 13.10.2025

Addressee/Attention: Evercare Medical AB, c/o OneMed, Box 50, 40120 Gothenburg, Sweden (Distributor)
Attention: Mr Jörgen Rasmussen

Dear customer

KD Medical GmbH Hospital Products is conducting a Field Safety Corrective Action (FSCA) to provide an advisory note to the users of specific article and batch numbers of the product

KD-*FINE*® *SAFETY* hypodermic needle with needle protection device.

1. Devices affected by this FSCA:

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

Table 1 - Details on affected devices:
KD-*FINE*® *SAFETY* hypodermic needle with needle protection device

Article number (REF)	Specification	Batch number (LOT)	UDI-DI
911648B	21 G x 2" (0.80 x 50 mm)	5D41E63	Individual package: **74031881911647** Inner box à 100 pieces: **84031881911644**
		4H41E63	
		3M41563	n/a (legacy device)
		3K41563	n/a (legacy device)
		3G41563	n/a (legacy device)
911693B	22 G x 2" (0.70 x 50 mm)	4H42E63	Individual package: **74031881911692** Inner box à x100 pieces: **84031881911699**
		3G42563	n/a (legacy device)

The FSCA and advisory note is limited to the article numbers with the batch numbers (LOT) listed in Table 1. No other batch numbers (LOT) are affected.

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2. Description of the problem:

2.1 Normal situation:

In its current/past design, the safety mechanism of KD-*FINE*® *SAFETY* needles with a needle length of 50 mm consists of the major proximal locking structure (= lock on the needle hub/base and lock over the needle tube close to the needle hub (marked in red in below photo 1)) and of an additional, auxiliary distal wing plate (marked in yellow in below photo 1).

Photo 1 – top view of KD-*FINE*® *SAFETY 21G x 50 mm, REF 911648B, in its current/past design with activated safety mechanism – the needle hub and tube are locked under both the major proximal locking structure (red) and the auxiliary distal wing plate (yellow):*

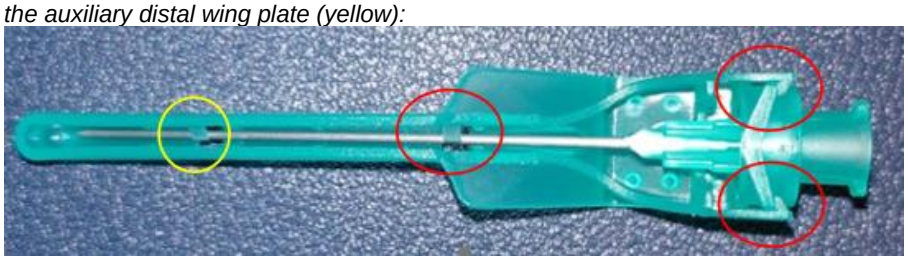
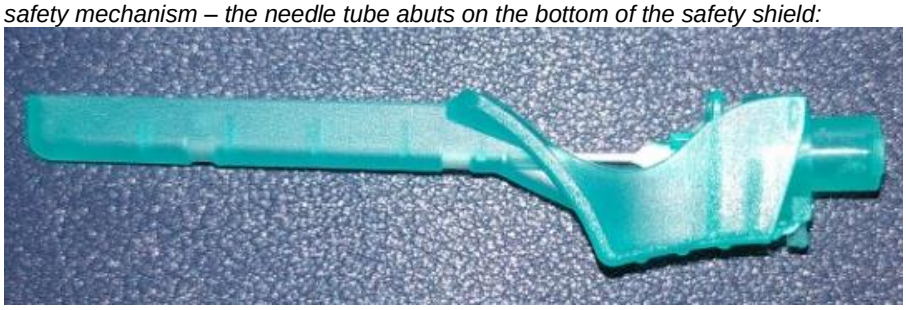


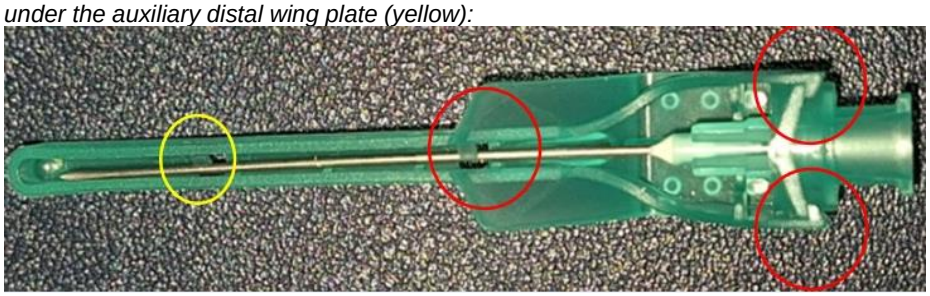
Photo 2 – side view of KD-*FINE*® *SAFETY 21G x 50 mm, REF 911648B, in its current/past design with activated safety mechanism – the needle tube abuts on the bottom of the safety shield:*



2.2 Description of the problem:

In the thin KD-*FINE*® *SAFETY* 21G x 50 mm and 22G x 50 mm (REF 911648B and 911693B), LOT numbers specified in Table 1, there is a possibility that the force required to engage the needle tube under the auxiliary distal wing plate may not be achievable:

Photo 3 - KD-*FINE*® *SAFETY 21G x 50 mm, REF 911648B in its current/past design in the situation where the needle hub and tube are locked under the major proximal locking structure (red) but the needle tube is not locked under the auxiliary distal wing plate (yellow):*



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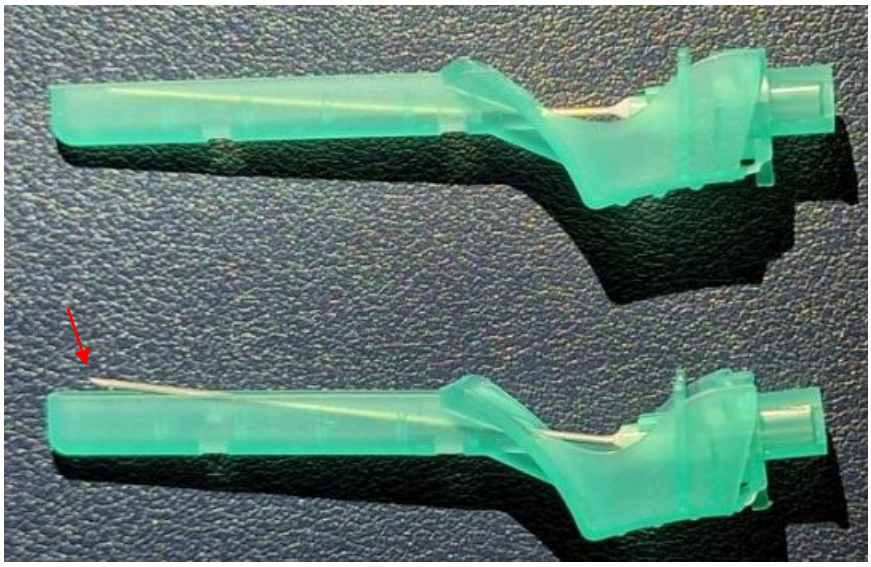
In such situation, the auxiliary distal wing plate forms an obstacle and thereby prevents the distal needle tube part from abutting on the bottom of the safety shield. Normally, the needle tip is nevertheless covered by the safety shield, however, if excessive forces are applied to the needle tube during activation of the safety mechanism, the needle might bend to such an extent that the needle tip protrudes from the safety shield:

Photo 4 – side view of KD-*FINE*® *SAFETY 21G x 50 mm, REF 911648B in its current/past design in the situation where the needle hub and tube are locked under the major proximal locking structure but the needle tube is not locked under the auxiliary distal wing plate. The auxiliary distal wing plate forms an obstacle and thereby prevents the distal needle tube part from abutting on the bottom of the safety shield. Normally, the needle tip is nevertheless covered by the safety shield (device at the top), however, if excessive forces are applied to the needle tube during activation of the safety mechanism, the needle might bend to such an extent that the needle tip protrudes from the safety shield (device at the bottom, red arrow):*



3. Clinical risk:

There is a risk of a needlestick injury in case the needle tip protrudes from the safety shield if the product is not handled in accordance with the instructions for use.
Any needlestick injury bears the risk of exposure to and infection with bloodborne pathogens such as HBV, HCV and HIV, requiring postexposure prophylaxis and related aftercare.

KD Medical has received two complaints about a needlestick injury with KD-*FINE*® *SAFETY*, REF 911648B (1 x LOT 3G41563, 1 x LOT 4H41E63), none of which reported cross infection.

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4. Actions taken by KD Medical:

KD Medical has identified the root cause and is taking corrective actions as follows:

a) Issuance of Field Safety Notice/advisory note: The product can be used for its intended purpose. With this Field Safety Notice and advisory note we want to raise the user's awareness to strictly follow the instructions provided in the instructions for use to avoid the risk of a needlestick injury (see details in section 5).

b) Design adjustment for future deliveries: The design of the safety shield has been slightly adjusted by removing the distal wing plate to avoid the problem described in section 2. With this slight design adjustment, the needle is safely engaged under the major proximal locking structure and abuts on the bottom of the safety shield throughout its entire length.

Photo 5 – side view of KD-*FINE® SAFETY 21G x 50 mm, REF 911648B with removed distal wing plate and activated safety mechanism: The needle is engaged under the major proximal locking structure and abuts on the bottom of the safety shield throughout its entire length.*

The mode of operation/functionality and the two possible modes of activation of the safety mechanism (either by using the thumb or by pressing the safety shield against a hard surface) as well as the overall appearance of the safety shield remain unchanged.

As all KD-*FINE® SAFETY* needles with a length of 50 mm share the same mold design for the safety shield, this slight design adjustment will be applicable for all 50-mm-needles, i.e. for the following five specifications of KD-*FINE® SAFETY*:

Article no/REF	Size	
911518B	18 G x 2"	1.20 x 50 mm
911563B	19 G x 2"	1.10 x 50 mm
911594B	20 G x 2"	0.90 x 50 mm
911648B	21 G x 2"	0.80 x 50 mm
911693B	22 G x 2"	0.70 x 50 mm

Any future LOT of above-mentioned REF of KD-*FINE® SAFETY* will be manufactured using the adjusted injection mold.

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5. Actions to be taken by the addressee of this Field Safety Notice (distributor Evercare Medical AB):

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 those who need to be aware within your organisation.

3. Distribute this Field Safety Notice to any organisation where the products listed in Table 1 have been transferred or will be transferred and ask these organisations

    a. to distribute this Field Safety Notice to all those who need to be aware within their organisation.

    b. to pass this Field Safety Notice on to any organisation where the products listed in Table 1 have been transferred or will be transferred, if applicable.

    c. if applicable, to ensure that **all (potential) users of KD-*FINE*® *SAFETY* hypodermic needle with needle protection device as specified in Table 1** within their organisation **are informed of the problem described in section 2, of the clinical risk described in section 3 and of the following precautions:**

    The product can be used for its intended purpose. To avoid the risk of a needlestick injury, please strictly follow the instructions provided in the instructions for use, namely the following points:
    - *Visually confirm that the needle is fully engaged under the lock after activation of the safety mechanism.*
    - *Immediately dispose of the device into an approved sharps container if the activation failed.*
    - *Handle the product with care to avoid needlestick injuries.*
    - *Keep the hands behind the needle at any time during use and disposal.*
    - *Dispose of the product after single use following federal and local regulations for sharps disposal by using an appropriate container for sharp medical waste.*

    The instructions for use are provided with each inner box of KD-*FINE*® *SAFETY* and are also available online:
    eIFU KD-FINE SAFETY

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

    e. to acknowledge receipt, reading and understanding of this Field Safety Notice to Evercare Medical AB **by 15.11.2025.** For this purpose we will provide you with a corresponding customer reply form. These organisations = your customers will communicate directly with you and not directly with KD Medical.

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 31.10.2025.**

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6. Contact reference person of the manufacturer:

Karolin Koch
KD Medical GmbH Hospital Products
Charlottenstrasse 65
10117 Berlin
GERMANY

Tel. +49 157 36 62 43 14
Fax: +49 30 20 39 95 99
E-Mail: k.koch@kdm-berlin.de

Please accept our apologies for any inconveniences caused and thank you in advance for your cooperation.

The undersigned confirms that this Field Safety Notice has been notified to the relevant competent authorities.

Berlin, 13.10.2025

Signature, company's stamp
Karolin Koch, PRRC Reporting obligations/vigilance

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN_CN-20250904_COMP-20250714
FSN Date	13.10.2025
Product/ Device name	KD-*FINE*® *SAFETY* hypodermic needle with needle protection device
Product Code(s) (REF)	911648B 911693B
Batch/Serial Number (s) (LOT)	5D41E63 4H41E63 3M41563 3K41563 3G41563 4H42E63 3G42563

2. Customer Details	
Name of the organisation	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Confirmation

We acknowledge receipt, reading and understanding of the above-mentioned Field Safety Notice (FSN) and confirm the implementation of the following actions:

1. We have distributed the FSN to all those who need to be aware within our organisation.

   ☐ confirmed

2. We have distributed the FSN to any organisation where the products listed in Table 1 have been transferred and will distribute the FSN to any organisation where the products listed in Table 1 will be transferred.

   ☐ confirmed
   ☐ not applicable (no transfer of KD-*FINE*® *SAFETY* specified in Table 1 of the FSN to any other organisation)

3. We have informed all (potential) users of KD-*FINE*® *SAFETY* specified in Table 1 of the FSN within our organisation of the problem described in section 2 of the FSN, of the clinical risk described in section 3 of the FSN and have informed them of the following precautions:

   The product can be used for its intended purpose. To avoid the risk of a needlestick injury, please strictly follow the instructions provided in the instructions for use, namely the following points:
   - *Visually confirm that the needle is fully engaged under the lock after activation of the safety mechanism.*
   - *Immediately dispose of the device into an approved sharps container if the activation failed.*
   - *Handle the product with care to avoid needlestick injuries.*
   - *Keep the hands behind the needle at any time during use and disposal.*
   - *Dispose of the product after single use following federal and local regulations for sharps disposal by using an appropriate container for sharp medical waste.*

   ☐ confirmed
   ☐ not applicable (no (potential) users of KD-*FINE*® *SAFETY* specified in Table 1 of the FSN within our organisation)

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

Print Name	
Signature	
Date	

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence needed to monitor the progress of the corrective actions.

Please send back the signed customer reply form to Evercare Medical AB by email **by 15.11.2025.**

Contact reference person of the distributor:

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Box 50, 40120 Gothenburg
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E-Mail: Jorgen.Rasmussen@evercare-medical.com

Thank you!