DRAFT

BEROMED GMBH HOSPITAL PRODUCTS®

Postal Address	Office
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Urgent Field Safety Notice FSN_CN-20260703_COMP-B20260305

*BERO*SET® Disposable infusion set

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

FSCA identifier: **CN-20260703_COMP-B20260305**

FSN identifier: **FSN_CN-20260703_COMP-B20260305**

Date: yyyy-mm-dd

Addressee/Attention:

A. **Distributors**
B. **Health care professionals**

Dear distributor, dear health care professional

Beromed GmbH Hospital Products, SRN: DE-MF-000007458, is conducting a Field Safety Corrective Action (FSCA) to remove *BERO*SET® Disposable infusion set, REF B700719, LOT 5F811369 in Portugal.

1. Devices affected by this FSCA:

Please find the details on the devices affected by this FSCA in Table 1:

Table 1 - Details on affected devices:

***BERO*SET® Disposable infusion set**

Article number (REF)	Batch number (LOT)	Product description
B700719	5F811369	For gravity-fed infusion, DEHP-free, small chamber, middle size flow regulator, 15 µm particle filter, 150 cm tubing, Luer lock

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2. Description of the problem:

Beromed has established that there was a one-off failure of production equipment during the manufacture of *BERO*SET® LOT 5F811369 resulting in a potential bonding defect between the drip chamber and the tubing in up to eight devices.
The bonding defect can lead to a separation of the tubing from the drip chamber in the unused product, during preparation of the infusion set or during the running infusion.

Photo 1 – site of separation of the tubing from the drip chamber (red arrow):

The problem can be limited to this single production incident and this specific batch.

3. Clinical risk:

Separation of the tubing from the drip chamber compromises the closed infusion system which in turn might lead to liquid leakage, blood loss and/or inadequate administration of fluid or medication, ingress of air or microorganisms or contamination of the environment by blood or hazardous drugs.

Beromed has received reports of five instances where the tube detached from the drip chamber from one hospital in Portugal. No serious consequences were reported as a result of these incidents.

4. Actions taken by Beromed:

Beromed has identified the root cause and is taking corrective actions to prevent reoccurrence of this issue:

- A maintenance inspection of the automatic assembly machine was made together with the machine manufacturer with particular focus on the gluing equipment.
- The machine inspection plan was strengthened.
- The sampling plan for product testing was enhanced in order to refine the detectability of any such errors.

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Further information:

In the manufacturing process of *BERO*SET® disposable infusion set REF B700719 there are two validated production line procedures: a) using the fully automatic assembly machine (used for LOT 5F811369) or b) manual assembly production line.
Starting from October 2025, all batches of *BERO*SET® disposable infusion set REF B700719 have been produced on the manual assembly production line (first LOT: 5L771369, MAN DATE: 2025-10-01) so that the error leading to the problem reported is inherently excluded for all batches manufactured as of October 2025.

5. Actions to be taken by the addressees of this Field Safety Notice:

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

A – Distributor:

1. Please carefully review this Field Safety Notice in its entirety.
2. Please forward this Field Safety Notice to all those who need to be aware within your organisation.
3. Distribute this Field Safety Notice to any organisation in Portugal where the products listed in Table 1 have been transferred and ask these organisations
    a. to do not use affected products listed in Table 1 anymore, if applicable.
    b. to pass this Field Safety Notice on to any organisation where the product listed in Table 1 has been transferred, if applicable.
    c. to identify and quarantine any stocks of the product listed in Table 1 and
    d. to inform you of their stock situation by 24.07.2026.
4. Please organize with your identified customers the return of any identified stocks to your warehouse. We will then organize the destruction of the collected goods.
5. Please confirm receipt by completing and signing the **distributor reply form** sent together with this Field Safety Notice and send it to the manufacturer Beromed GmbH Hospital Products by email **by 24.07.2026** (see contact details under section 6.).

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

B – Health care professional:

1. Please carefully review this Field Safety Notice in its entirety.
2. Please forward this Field Safety Notice to all those who need to be aware within your organisation.
3. Please do not use affected products listed in Table 1 anymore.
4. Please identify and quarantine any stocks of the product listed in Table 1.
5. Please return all identified products to your direct supplier.
6. Please confirm receipt by completing and signing the **customer reply form** sent together with this Field Safety Notice and send it to the manufacturer Beromed GmbH Hospital Products by email **by 24.07.2026** (see contact details under section 6.).

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

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6. Contact reference person of the manufacturer:

Mrs Karolin Koch
Beromed GmbH Hospital Products
Kronenstrasse 19
10117 Berlin
GERMANY

Tel. +49 157 36624314
Email: jb@beromed.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 relevant competent authorities.

Berlin, yyyy-mm-dd

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

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Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN_CN-20260703_COMP-B20260305
FSN Date	Yyyy-mm-dd
Product/ Device name	*BERO*SET® disposable infusion set
Product Code (REF)	B700719
Batch/Serial Number (LOT)	5F811369

2. Distributor details	
Company Name	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Distributor actions (Tick and complete all that apply)			
I confirm receipt of the Field Safety Notice and that I read and understood its content.	☐ confirmed		
I performed all actions requested by the FSN.	☐ confirmed		
A. Distributor's stocks:			
☐	I have **identified and quarantined** affected devices **in stock**- enter number of identified devices in stock and date completed.	Qty (pieces):	Date completed (yyyy-mm-dd):
☐	No affected devices are available for return/ destruction	Distributor to comment, if applicable	

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☐	I have **destroyed** affected devices – enter number destroyed and date completed.	Qty (pieces):	Date completed (yyyy-mm-dd):
B. Downstream supply chain:			
☐	I have **identified customers** that received or may have received this device.	Distributor to comment, if applicable	
☐	I have attached a list of customers identified.	Distributor to comment, if applicable	
☐	I have informed the identified customers of the Field Safety Notice.	Distributor to comment, if applicable	
☐	I have received a confirmation of receipt of the Field Safety Notice from all identified customers.	Distributor to comment, if applicable	
☐	There are stocks of the affected devices in customers' stocks – enter name of customer(s) and quantity in pieces.	Enter name of customer(s) with affected devices in stock and quantity in pieces.	
☐	Other Action (Define):	Distributor to comment, if applicable	
☐	Neither I nor any of my customers has any affected devices in inventory.	-	
Print Name			
Signature			
Date			

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4. Return acknowledgement to Sender	
Email	jb@beromed.de
Postal Address	Beromed GmbH Hospital Products, Charlottenstrasse 65, 10117 Berlin, GERMANY Attention: Mrs Karolin Koch
Deadline for returning the Distributor reply form*	**2026-07-24**

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 we need to monitor the progress of the corrective actions.

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN_CN-20260703_COMP-B20260305
FSN Date	Yyyy-mm-dd
Product/ Device name	*BERO*SET® disposable infusion set
Product Code (REF)	B700719
Batch/Serial Number (LOT)	5F811369

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

3. Customer action undertaken on behalf of Healthcare Organisation (Tick and complete all that apply)			
I confirm receipt of the Field Safety Notice and that I read and understood its content.		☐ confirmed	
I performed all actions requested by the FSN.		☐ confirmed	
The information and required actions have been brought to the attention of all relevant users and executed.		☐ confirmed	
☐	I have **identified and quarantined** affected devices **in stock**- enter number of identified devices in stock and date completed.	Qty (pieces):	Date completed (yyyy-mm-dd):
☐	I have **returned** affected devices to my direct supplier - enter number of devices returned and date completed.	Qty (pieces):	Date completed (yyyy-mm-dd):

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☐	I have **destroyed** affected devices – enter number destroyed and date completed.	Qty (pieces):	Date completed (yyyy-mm-dd):
☐	No affected devices are available for return/ destruction	Customer to comment, if applicable	
☐	Other Action (Define):	Customer to comment, if applicable	
☐	I do not have any affected devices.	-	
Print Name			
Signature			
Date			

4. Return acknowledgement to manufacturer	
Email	jb@beromed.de
Postal Address	Beromed GmbH Hospital Products, Kronenstrasse 19, 10117 Berlin, GERMANY; Attention: Mrs Karolin Koch
Deadline for returning the customer reply form	**2026-07-24**

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 we need to monitor the progress of the corrective actions.