Urgent Field Safety Notice

Address of customer
& name of contact person

Sales Division
Lohmann & Rauscher GmbH & Co.KG
Westerwaldstr. 4 · D-56579 Rengsdorf
Tel.: XXXX/ Fax: XXXX
Email: xxxx.xxxx@de.LRmed.com

10.06.2026

Urgent Field Safety Notice
regarding BD Connecta™ Stopcock in L&R Kitpacks

Dear customers,

Please find enclosed a copy of the cover letter from **BD Switzerland Sàrl** regarding the above-mentioned safety information. We have been informed by the manufacturer, **BD Switzerland Sàrl,** that a problem has arisen with the operation of the C-port (Port C) on the BD Connecta™ Stopcock during use. This issue means that some clinical users perceive the connection at Port C to be unstable.
*(Please refer to **Appendix 1** for further details)*

These stopcocks were included in L&R Kitpacks that you received between 15 April 2024 and 28 May 2026. Please observe the attached precautions with immediate effect. The products can continue to be used. No risk to patients is anticipated. A return shipment is not required.
*(Information on the affected REF numbers can be found in **Appendix 2**.)*

In the interests of patient safety, we ask that you strictly adhere to the additional warnings set out in this safety information and ensure within your organisation that all users and other relevant parties are made aware of this safety information.

If you have supplied the products to third parties, please forward a copy of this information to them. Please confirm receipt of the safety information on the enclosed confirmation form and return it to us **by 30 June 2026 at the latest**.

This is merely a safety notice, not a product recall. The items listed may continue to be used at your own discretion.

Should you have any questions, please do not hesitate to contact us.

With best regards,

Lohmann & Rauscher GmbH & Co KG

i.V. / on behalf of	i.V. / on behalf of
XXXYYY Sales department	XXXYYY Regional Vigilance Officer

Appendices:
1) Safety information by BD
2) Confirmation form

21 MAY 2026

NEW

URGENT: FIELD SAFETY NOTICE – MDS-26-06018

BD Connecta™ Stopcocks

REF: Table 1

Type of Action: Advisory

Attention: Clinical Personnel, Risk Managers, Purchasing Managers

This letter contains important information which requires your immediate attention.

Dear Customer,

BD is issuing an advisory Field Safety Notice for BD Connecta™ Stopcocks. According to our distribution records your organisation may have received the impacted product in Table 1.

Manufacturer's (SRN): CH-MF-000026539

Catalogue Number	Product Name	UDI - DI
394501	Stopcock with BD Q-Syte™ Luer access split septum – White	038290LCPRQBMIB9
394600	Stopcock – White	038290DXQVBQHQJJ
394601	Stopcock – White with colored pegs	038290DXQVBQHQJJ
394602	Stopcock – Blue	038290DXQVBQHQJJ
394605	Stopcock – Red	038290DXQVBQHQJJ
394926	Stopcock with Extension Tube – 30 cm	038290JSEISQNUEM
394936	Stopcock with Extension Tube and Injection Valve – 30 cm	038290DOVABTMT9P
394945	Stopcock with Extension Tube and Injection Valve – 16 cm	038290DOVABTMT9P
394951	Stopcock with Extension Tube – 54 cm	038290JSEISQNUEM
394961	Stopcock with Extension Tube – 105 cm	038290JSEISQNUEM
394971	Stopcock with Extension Tube and Injection Valve – 105 cm	038290DOVABTMT9P
394982	Stopcock with Extension Tube – 21 cm (low volume)	038290JSEISQNUEM
394983	Stopcock with Extension Tube – 35 cm (low volume)	038290JSEISQNUEM
394995	Stopcock with Extension Tube – 16 cm (White)	038290JSEISQNUEM
394997	Stopcock with Extension Tube – 16 cm (Blue)	038290JSEISQNUEM

Table 1: Impacted product

Appendix 1: Safety information by BD

21 MAY 2026

This advisory is limited to the catalogue numbers listed in Table 1.

Device Type

The BD Connecta™ Stopcock is a stopcock with two ports and a rotating lever to control fluid direction through the device. Refer to image below.

Figure 1 BD Connecta™ Stopcock device

Primary clinical purpose of devices

BD Connecta™ Stopcocks are used to administer fluids or medication through one or two different ports via an IV cannula or extension tube. The ports can be used to sample blood or for hemodynamic monitoring. When used with IV lipid nutritional products, the stopcock device can be used for up to 24 hours. BD Connecta™ Stopcock with a BD Q-Syte™ needle-free connector is used to administer fluids or medications through one or two different ports via an IV cannula or extension tube. Both ports can be used to sample blood and the port without the attached BD Q-Syte™ connector can be used for hemodynamic monitoring. When used with IV lipid nutritional products, the stopcock device can be used for up to 24 hours. The BD Q-Syte™ needle-free connector is activated by inserting a male luer into the septum which creates a barrier against microorganisms.

Description of the product problem

Through customer feedback, BD has identified an observed issue in how Port C of the BD Connecta™ Stopcock (Figure 2) operates during use. Reports received by BD indicate that when using polypropylene plastic luer lock syringes, the connection at Port C may over thread the syringe and continue to spin. This behaviour has led some clinical users to perceive the connection as unstable.

Appendix 1: Safety information by BD

21 MAY 2026

BD testing demonstrated a secure connection and did not identify any leakage under clinically relevant simulated conditions related to this issue. Also, BD testing confirmed the issue does not occur when Port C is connected to polycarbonate syringes or IV tubing luers.
When tested with polypropylene syringes, Port C showed a lower amount of torque was required to override the syringe threading and cause apparent over-threading of the connection. This observation is consistent with feedback received from users.

Figure 2. BD Connecta™ Stopcock device

This differing torque during connection and the resulting over-threading may cause user confusion during device use. For this reason, BD is issuing this communication to reinforce important usage recommendations when using BD Connecta™ Stopcock devices.

Clinical risk

Although BD testing has demonstrated that a secure connection can be achieved at Port C even in instances of continued rotation (over-threading), the differing torque and tactile resistance required for Port C compared to other ports may lead users to conclude that additional corrective steps are necessary and apply unnecessary manipulation, repositioning, or force to the connection. Under such circumstances, connection integrity could be adversely affected, which may result in interruption or delay of therapy and, in some cases, leakage at the connection site. Such outcomes could lead to under delivery of fluids or medications.

Appendix 1: Safety information by BD

21 MAY 2026

BD complaint investigations did not confirm any of the events reported for the over-threading issue to have led to patient harm.

There is no requirement for customers to return any BD Connecta™ Stopcocks to BD. These products can continue to be used in accordance with the guidance in this safety notice.

Clinical User Actions

Per current Instructions for Use:

- Ensure all connections are secure before use and verify that injection ports are closed before and after each use.
- When using the product, avoid over-threading. Excessive threading may damage the integrity of the product.
- Use of excessive force during connection can over stress stopcock ports, particularly when lubricious infusates, such as fat emulsions, are present.

Note: Resistance between the male luer connector and the BD Connecta™ Stopcock when rotating indicates the connection is fully engaged and secure.

BD Actions:

BD has investigated the root cause and is taking corrective actions to prevent recurrence of this issue.

BD has launched a project to enhance the design of Port C of the BD Connecta™ Stopcock.

To date, BD does not plan to initiate any further advice or information in a follow-up FSN

Customer Actions:

- Review the information in **Table 1** to determine if **BD Connecta™ Stopcock** in your possession are impacted.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 19th June 2026.**
- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)
- Please transfer this notice to other organisations on which this action has an impact. (As appropriate)
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Appendix 2: Confirmation form

Urgent Field Safety Notice

regarding BD Connecta™ Stopcocks in L&R Kitpacks

(please return via Fax to +49 2634 - 99 xxxx / via mail to xxxxx, until 30 June 2026)

Sender:

Lohmann & Rauscher GmbH & Co. KG
Westerwaldstr.4
56579 Rengsdorf, Germany

Addressee:

Address of customer
+ name of contact person + customer number

& all users who use the mentioned products

We hereby confirm that

- ✓ we have taken note of this customer information and BD's safety notice and will take the necessary precautions when continuing to use the product.
- ✓ we will ensure within our organisation that all users of the above-mentioned products and any other persons who need to be informed are made aware of this customer information.
- ✓ we will forward a copy of this information to all third parties to whom we have supplied the products.

Important:
The stopcock can continue to be used in accordance with the instructions for use. Therefore, no credit note will be issued and no replacement will be supplied.

Date / Signature: _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and email: _____

Appendix 2: Confirmation form

The following Kitpacks contain the affected BD Connecta™ Stopcocks:

REF	Product	LOT(s)
xx	xx	xxx

(adjust to respective customer order)