

Field Safety Notice

Lap Gallaset Alingsås – CTP-02201
(See Appendix C for affected lot numbers and pack revisions)

FAO: Risk Managers Responsible for Vigilance and all Department Managers.

Subject: Field Safety Notice – Risk to over-threading of Connecta Stopcock

Device Type/Affected Product	Stopcock, 3 way, 10cm extension / Lap Gallaset Alingsås Procedure Pack
Type of action	Advisory FSN for understanding of Stopcock Issue
Pennine Healthcare Ref:	PHFSCA2026-6
Product code and LOT Number	See Appendix C
Clinical Purpose of the device	Pack intended for orthopaedic procedures
Manufacturer SRN	GB-MF-000004160
Basic UDI-DI	5033241PACKORTH03R
FSN Type	New

Contact details of local representative (name, e-mail, telephone, address etc.) *
Ivor Shaw Ltd. t/a Pennine Healthcare Email: recalls@penninehealthcare.co.uk & QARA@penninehealthcare.co.uk Telephone: 01332794880 Address: 300 City Gate, London Rd, Derby DE24 8WY

10th August 2026

Dear Customer,

We are writing to inform you that Ivor Shaw Ltd, trading as Pennine Healthcare, is issuing an advisory Field Safety Notice for the batches listed in Appendix C. Our records indicate that your facility has received products from these potentially affected batches.

This advisory FSN is being communicated following the receipt of a supplier FSN regarding the BD Connecta Stopcock contained within the procedure pack.

For detailed product codes and batch information, please refer to Appendix C. Should you have any questions or require further assistance, please do not hesitate to contact us.

Please follow the instructions as detailed on pages 2 & 3. There is currently no plan to initiate any further advice or information in a follow up FSN.

Description of the Product Problem:

The legal manufacturer of the Connecta Stopcock have identified an issue in how Port C of the stopcock operates during use. When using Polypropylene plastic luer lock syringes, the connection between Port C may over thread the syringe and continue to spin. The issue has not been reported to occur when Port C is connected to polycarbonate syringes or IV tubing luers.



The differing torque during connection and the resulting over-threading may cause user confusion during device use. For this reason, the legal manufacturer has issued an advisory FSN to reinforce important usage recommendations when using the BD Connecta Stopcock devices.

Hazard giving rise to the FSN:

The differing torque during connection and the resulting over-threading may cause user confusion during device use. For this reason, the legal manufacturer has issued an advisory FSN to reinforce important usage recommendations when using the BD Connecta Stopcock devices.

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.

There have been no reports of patient harm relating to the over-threading issue.

Clinical User Actions:

As 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.
- Resistance between the male luer connector and the BD Connecta Stopcock when rotating indicates the connection is fully engaged.

Actions to be taken by the Distributor:

1. Review Appendix C to identify any impacted procedure pack codes and lots and please forward this Field Safety Notice (FSN) to any affected customers.
2. Inform any impacted customers and pass the FSN along to the customers requesting the completion of Appendix B.
3. Complete and return the attached form (**Appendix A**) to confirm that you have read and understood the contents of this FSN by 21st August 2026.

Actions to be taken by the User / Hospital:

1. Review this Field Safety Notice (FSN) in its entirety and ensure all users of the affected devices in your organisation and other concerned persons are informed about this Field Safety Notice (FSN).
2. Review the information in Appendix C to determine if any procedure packs in your possession are impacted.
3. Maintain awareness of this FSN and resulting action for the appropriate period to ensure understanding of the information provided.
4. Please complete the customer response form (**Appendix B**) to confirm that you have read and understood the contents of this Field Safety Notice (FSN) and send it to your supplier of the products and email a copy to recalls@penninehealthcare.co.uk by 21st August 2026.

Transmission of this Field Safety Notice:

This notice must 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.

Please pass this notice to other organisations on which this action has an impact. Maintain awareness on this notice until all required actions have been taken within your organisation.

Report all related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Pennine Healthcare are committed to providing quality products to our customers and ensuring patient safety, and we sincerely apologise for any inconvenience this notice may cause.

The competent authority in each member state and Great Britain will be notified of this FSN.

For and On Behalf of Ivor Shaw Ltd trading as Pennine Healthcare:



Jessie Nurse
Quality and Innovation Manager

Appendix A

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN2026-6
Product/ Device name	Lap Gallaset Alingsås Procedure Pack
Product Code	Batch / Serial Number (s)

2. Distributor Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Distributors / Importers (tick all that apply)	
☐	*I confirm the receipt, the reading and understanding of the Notice.
☐	*I have informed the identified customers of this Notice.
☐	Date of Communication:
☐	*I have received confirmation of reply from all identified customers / hospitals.
☐	Neither I nor any of my customers have any affected devices in inventory
Print Name*	
Signature*	
Date *	

Return the completed form to recalls@penninehealthcare.co.uk

Mandatory fields are marked with *

Appendix B

End User (Hospital / Clinic) Reply Form

Please complete this form and return to your supplier and email a copy to Pennine Healthcare

Email: recalls@penninehealthcare.co.uk

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN2026-6
Product/ Device name*	Lap Gallaset Alingsås Procedure Pack
Product Code*	Batch / Serial Number(s)*

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action taken on behalf of Healthcare Organisation	
☐	*I confirm receipt of the Notice and that I read and understood its content.
☐	*The information and required actions have been brought to the attention of all relevant users and executed.
☐	Other Action (Define):
☐	I do not have any devices affected.
Print Name*	
Signature*	
Date*	

Return the completed form to recalls@penninehealthcare.co.uk

Mandatory fields are marked with *

Appendix C

Affected Product codes and Lot/Batch numbers

Finished Product Name	Lot/Batch Number
CTP-02201	04FXX
	19HXX
CTP-02201 Rev.2	06MXX
	17MXX
	14AXX
	03DXX
CTP-02201 Rev.3	27FXX
	03MXX
	01GXX

End of List