Advanced Medical Solutions Limited
Western Wood Way,
Langage Science Park,
Plymouth,
Devon,
PL7 5BG,
United Kingdom
Tel: +44 (0) 1752 209955 **Fax:** +44 (0) 1752 209956
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

Field Safety Notice
01-31-2022-001-FSCA

Date issued: 08th February 2022

Affected products:

Product name: LiquiBandFIX8® Open Hernia Mesh Fixation Device
Product code: FX002
UDI-DI: 05036912001229

Lot Number	Expiration Date	Lot Number	Expiration Date
P00221182	03 2022	P00221983	08 2022
P00221313	04 2022	P00225605	11 2022
P00221396	05 2022	P00225801	02 2022
P00221600	06 2022	P00226740	01 2023
P00221756	06 2022		

Dear valued customer

Advanced Medical solutions Limited ("AMS") has initiated a voluntary recall for the LiquiBandFIX8® Open Hernia Mesh Fixation Device ("Product"). This affects all Product in the field within shelf life, affected lots are detailed in the table above.

Product Issue

AMS has become aware of a mechanical device defect in the Product during an internal testing of device. The defect causes uncontrolled leakage of glue from the distal tip of the device.

Potential Risk

In the worst case there is risk of adhesive being applied to unintended areas in the field of application which may lead to potential injury/irritation to structures, adhesion formation, or additional foreign body material.

Required actions regarding the use of the Product
Our records indicate that you have received stock of the Product and you are therefore affected by this action.

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We kindly request that you read this Field Safety Notice ("FSN") carefully and complete the following actions:

Distributor

1. Immediately check your internal inventory and quarantine all Product pending safe destruction.
2. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached 'Appendix 1 – Distributor Reply Form' and return it to AMS either by post or by email to the addresses stated on the form.
3. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached 'Appendix 3 - Certificate of Destruction' form and return it to AMS either by post or by email to the addresses stated on the form.
4. Please immediately distribute this FSN to all affected end customers alongside the attached 'Appendix 2. Field Safety Notice: Healthcare Organisation Reply Form' and 'Appendix 3 - Certificate of Destruction'. Please advise them to execute the actions and collect the forms from your customers.
5. Please contact AMS customer services for replacement/ credit for any affected Product.
   Email: Customer.Support@admedsol.com
   Contact Number: 01606 545617
6. Please ensure that all those who need to be aware of this notice within your organisation receive a copy of this notice.

End User/Healthcare Facility

1. Immediately check your internal inventory and quarantine all Product pending safe destruction.
2. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached 'Appendix 2. Field Safety Notice: Healthcare Organisation Reply Form' and return it to AMS either by post or by email to the addresses stated on the form.
3. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached 'Appendix 3 - Certificate of Destruction' form and return it to AMS either by post or by email to the addresses stated on the form.
4. Please contact AMS customer services for replacement/ credit for any affected Product.
   Email: Customer.Support@admedsol.com
   Contact Number: 01606 545617
5. Please ensure that all those who need to be aware of this notice within your organisation receive a copy of this notice.

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Contacts

We sincerely apologise for any inconvenience caused by this FSN, patient safety and compliance is very important to us and we assure you that we are working diligently to resolve this issue in a timely manner.

In the meantime, please do contact your local sales representative or customer service at Customer.Support@admedsol.com if you have any further questions regarding this FSN.

The undersigned confirms this FSN will be notified to the appropriate Regulatory Agencies.

Appendix 1. Field Safety Notice: Distributor/Customer Reply Form
Appendix 2. Field Safety Notice: Healthcare Organisation Reply Form
Appendix 3. Certificate of Destruction

Yours faithfully,

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Rose Guang
Group QA/RA Director
For and on behalf of Advanced Medical Solutions Limited

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Appendix 1. Field Safety Notice: Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	01-31-2022-001-FSCA
FSN Date	08th February 2022
Device name	LiquiBandFIX8® Open Hernia Mesh Fixation Device
Product Code(s)	FX002
LOT Number (s)	See FSN

2. Return acknowledgement to Sender	
Email	Regulatory.Plymouth@admedsol.com
Distributor Helpline	01606 545617
Postal Address	Regulatory Department Advanced Medical Solutions Limited. Premier Park, 33 Road one, Winsford Industrial Estate, Winsford, Cheshire. CW7 3RT
Deadline for returning the Distributor reply form	This form is to be returned no later than 14 days after receipt of this FSN.

3. Distributor Details	
Company Name	
Company Address	
Contact Name	
Title or Function	
Telephone number	
Email	

4. Distributors (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the FSN	Distributor to complete or enter N/A
☐	I have checked my Product stock and quarantined inventory	Quantity: Date Quarantined: Distributor to enter quantity and date
☐	I have identified customers that received or may have received this Product	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have destroyed affected Product – enter number destroyed and date complete	Please provide a Certificate of Destruction as attached in Appendix 3:

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☐	Neither I nor any of my customers has any affected Product in inventory	
	Print Name:	Distributor Print Name Here
	Signature:	Distributor Sign Here
	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 we need to monitor the progress of the corrective actions.

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Appendix 2. Field Safety Notice: Healthcare Organisation Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	01-31-2022-001-FSCA
FSN Date	08th February 2022
Device name	LiquiBandFIX8® Open Hernia Mesh Fixation Device
Product Code(s)	FX002
LOT Number (s)	See FSN

2. Return acknowledgement to Sender **Distributor will need to put their contact details in here for their customers to respond to them directly.**	
Email	
Helpline	
Postal Address	
Deadline for returning the Healthcare Organisation reply form	This form is to be returned no later than 14 days after receipt of this FSN.

3. Healthcare Organisation Details	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email*	

4. Healthcare Organisation (Tick all that apply)		
	I confirm the receipt, the reading and understanding of the FSN	Healthcare Organisation to complete or enter N/A
	I have checked my Product stock and quarantined inventory	Quantity: Date Quarantined: Healthcare Organisation to enter quantity and date
	I have destroyed affected Product – enter number destroyed and date complete	Please provide a Certificate of Destruction as attached in Appendix 3:

Print Name:	Healthcare Organisation Print Name Here

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Signature:	Healthcare Organisation Sign Here
Date :	

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Appendix 3 - CERTIFICATE OF DESTRUCTION

In respect of LiquiBandFIX8® Open Hernia Mesh Fixation Device (REF FX002) subject of FSCA [01-31-2022-001-FSCA], and in regard to the provided FSN ; I hereby confirm that I have destroyed the following items and quantities as instructed:

Device Name	REF	LOT Number	Qty (each)

Name: _____

Institution/Company Name: _____

Signature: _____

Date: _____

This form is to be returned **no later than 14 days after receipt of this FSN** to Regulatory.Plymouth@admedsol.com.