Fannin UK Ltd
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14th September 2018

URGENT – FIELD SAFETY NOTICE

Subject: Voluntary Medical Device Field Safety Corrective Action / Recall

Relevant information:
▪ Brand Name: Espiner Medical Tissue Retrieval System
▪ Manufacturers Reference: 2018/009/013/601/022

Dear Partner,

Fannin UK Ltd has issued this Field Safety Notice to inform you of a voluntary recall action proposed for the RoboSac (EMP112-WG-6), see batch details in the table below:

Product Code	Barcode/UDI	Lot/Batch	Expiry Date
EMP112-WG-6	(01)05060358120701(17)190331(10)A1796	A1796	03/2019
	(01)05060358120701(17)190331(10)A1822	A1822	03/2019
	(01)05060358120701(17)190331(10)A1823	A1832	03/2019
	(01)05060358120701(17)190431(10)A1886	A1886	04/2019
	(01)05060358120701(17)190731(10)A2154	A2154	07/2019
	(01)05060358120701(17)200731(10)A2978	A2978	07/2020
	(01)05060358120701(17)200731(10)A2980	A2980	07/2020
	(01)05060358120701(17)200731(10)A2997	A2997	07/2020
	(01)05060358120701(17)200831(10)A3017	A3017	08/2020
	(01)05060358120701(17)201231(10)A3348	A3348	12/2020
	(01)05060358120701(17)210431(10)A3364	A3364	04/2021
	(01)05060358120701(17)210831(10)1254	1254	08/2021
	(01)05060358120701(17)220231(10)1667	1667	02/2022
	(01)05060358120701(17)220631(10)2051	2051	06/2022
	(01)05060358120701(17)220831(10)2193	2193	08/2022
	(01)05060358120701(17)230131(10)2480	2480	01/2023
	(01)05060358120701(17)230531(10)2845	2845	05/2023

Description of Issue:

Fannin UK Ltd is conducting a voluntary recall for the product code EMP112-WG-6. This is due to the identification of an issue when loading the bag into the Espiner Cannula. The Springrod arms that hold the mouth of the bag open, have been reported to break prior to surgical use.

The batches affected by this issue have been listed in the table above. As a result, these batches should be immediately removed and as required, replaced with alternative product. Please note that we have no records of Adverse Events related to this issue.

Potential Hazard:

The potential hazard of not removing the above batches, is that if the arms were to fail during use within a patient, this may cause a serious deterioration in the patients state of health.

Any adverse events reported following the use of a product batch listed in this recall notification letter should be documented and communicated to Fannin UK Ltd.

Actions & Timeframe for this Voluntary FSCA/Recall:

1. It is the responsibility of the distributor to communicate this recall notification letter to their customers (this includes: hospital/healthcare facilities/end-users). These product batches should not be used and segregated, if necessary, by the hospital/healthcare facility

2. Please communicate this notification throughout your facility, segregate these product batches and cease disposition.

3. Please complete the acknowledgement form (Appendix A) with stock disposition of all relevant product batches listed in the table above and return it to Fannin UK Ltd. Immediate response required.

4. Organise the return of the affected products and the stock will be replaced by Fannin UK Ltd (if required).

Method of Stock Removal:

Please return all stock to Fannin UK Ltd, Unit D, Yeo Bank 3, Kenn Road, Clevedon, BS21 6TH. For any queries regarding this recall, please contact the QA department using the email address detailed in 'Additional Information' below.

Additional Information:

This voluntary medical device field safety notice was reported to all relevant competent authorities and the related notified body, as required under the applicable regulations for medical devices.

An RMA returns number will be issued to you, prior to the return of affected stock.

Please keep Fannin UK Ltd informed of any adverse events associated with these products by emailing: espiner.quality@fannin.eu

Please be aware that the names of user facilities notified will be provided to the competent authorities as part of our reporting process.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field action.

Sincerely

Elizabeth Wall
Quality Technician

Kirstie Eydes MSc
Regulatory Affairs & Quality Manager

ESPINER

Fannin
Caring for Life since 1829

APPENDIX A

Field Safety Corrective Action - Acknowledgement & Feedback Form

Please return completed form immediately to:

Email: espiner.quality@fannin.eu or **Fax:** +44 (0) 1275 878354

Company Name: _____ **Date:** ___/___/___

Email address: _____

Address: _____

I acknowledge receipt of this Field Safety Notification (2018/009/013/601/022) and confirm that *(Please tick all that apply):*

☐ We do not have any affected devices in our inventory

☐ We have affected devices in our inventory and have clearly segregated this product for return to Fannin UK Ltd

☐ We have further distributed devices to the following organization(s):

Facility name: _____

Facility Address: _____

***Please print product details clearly**

Batch No.	Quantity to be Returned (No. Boxes)

By signing below, I acknowledge that the required actions have been considered in accordance with this RECALL Notice.

Printed Name: _____ **Signature:** _____