

Date: 09 December 2019

Address: To Theatre Manager

URGENT FIELD SAFETY NOTICE - Update

Advisory Notice

Product: Easidrape[®] Drapes (supplied sterile)
Product Code: See Table 1
Lot numbers: See Table 1

Description of Problem: Compromised integrity of primary packaging (sterile barrier).

Full-Support Healthcare Ltd have identified a potential safety issue; A small number of Easidrape[®] Drape Packs have been found to have open seals at the bottom of the primary packaging (drape pouch).

The checking of primary packaging for damage before use is indicated on the product labels, however, as a precautionary measure we have issued this Field Safety Notice to alert Customers of this issue and request affected easidrape packs are carefully checked for seal integrity before use.

Hazard giving rise to FSCA: Compromised sterile barrier due to gaps in seal of primary packaging may result in potentially serious patient risks i.e. surgical site infection.

Action to be taken by User:

Please inspect the integrity of the bottom seal of the drape packaging for all affected Easidrapes[®] before use. If open, DO NOT USE and quarantine / discard the drape appropriately to prevent use.

We advise that patients are monitored, as per normal clinical procedures, for post-procedure infection.

We apologize for the inconvenience caused by this action taken to safeguard your patients and users. Since the problem became known, appropriate measures have been introduced to prevent recurrence and additional inspection implemented.

Please note that the issue of this notice has been communicated to the appropriate Competent Authority (the MHRA).

Transmission of this Field Safety Notice:

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 impact (if appropriate).

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

Table 1.

Product Code	Lot Number (s)
50401	921190119, 946181228, 965190318, 968190407
50402	918181222
50411	965190318, 028190420, 065190622
50427	921190119, 043190512
50430	965190318
50435	917181215
50441	946181228, 920190112, 963190220, 968190407, 044190518
50615	920190112, 965190318,
50700	027190415

Contact Details:

Customer Services: Tel: 01933 672180 Email: info@fullsupportgroup.com

Manufacturer Details:

Name: Full Support Healthcare Ltd
Address: Harrowden Court, 66-80 Huxley Close, Wellingborough, Northamptonshire, NN86AB, United Kingdom.

Countries affected by this FSCA

These countries within the EEA and Switzerland and Turkey are affected by this FSCA:

GB

IE

Signed (on behalf of Full Support Healthcare Ltd):



Esther Barrows
QA/QC Manager

Date: 09 December 2019

Field Safety Notice Customer Reply Form

Field Safety Notice (FSN) information

FSN reference:	001-2019 (01)
FSN Date:	Updated 09/12/2019
Product Name:	Easidrape® Surgical Drapes
Product Code:	Easidrape® codes (Refer to FSN Table 1)
Lot No.s affected	Easidrape® lots (Refer to FSN Table 1)

Customer Details

Account No.	
Hospital / Organisation	
Address	
Department / Unit	
Shipping Address (if different to above)	
Contact Name	
Title or Function	
Telephone Number	
Email Address	

Customer Action Undertaken

<i>tick</i>	
	I confirm receipt of Field Safety Notice FSN 001-2019 (01) and that I read and understood the content.
	I confirm that our drape stock will be checked before use and any open packs will be discarded before use.
	I also agree to further distribute and communicate this important information within my facility as required.
Print Name:	
Signature:	
Date:	

Please return within 10 working days to:

Customer Services: Tel: 01933 672180 Email: info@fullsupportgroup.com

Full Support Healthcare Ltd. Harrowden Court, 66-80 Huxley Close, Wellingborough, Northamptonshire, NN86AB, United Kingdom.