Company Name/Logo

Rev 1: September 2018

FSN/FSCA Ref: FSCA_Simpla Profile_20190703_FSN

Urgent Field Safety Notice (FSN)
Simpla Profile
Compromised Sterility

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Simpla Profile is a sterile bedside drainage bag.
1.	2. Commercial name(s)
	Simpla Profile
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	A bedside drainage bag can be attached directly to a urisheath, intermittent catheter or indwelling catheter. Or it can be connected to a leg bag for extra drainage capacity during night.
1.	5. Device Model/Catalogue/part number(s)*
	215560-1006
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	8L03735. (Device MFR date 2018-10-01, Expiry date 2023-10-01)
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The Simpla Profile is delivered in a primary package. The welding may be broken in the corner of the primary package and if so the product is not sterile. The broken barrier may not be noticed by the end-user or Health Care Professional as it appears in the corner of the primary packaging and could be mistaken as an indicator of where to open the primary packaging.
2.	2. Hazard giving rise to the FSCA*
	An insufficient welding in the primary package compromises the sterile barrier posing a risk for the end user safety - increasing the risk of an infection e.g. a urinary tract infection.
2.	3. Probability of problem arising
	The Probability of hazardous situation occurring is assessed to be remote.
2.	4. Predicted risk to patient/users
	The anticipated risk P1=2 (probability of hazardous situation occurring) and P2=2 (probability of hazardous situation leading to harm) is therefore calculated to 4 which is within an acceptable risk level.
2.	5. Further information to help characterise the problem
	No complaints have been received from end user/users regarding this issue.
2.	6. Background on Issue
	During a quality inspection of Simpla Profile the welding of the sterile barrier was found to be insufficient – both visual- and pressure tests proved this. Approximately 30% of the tested products failed.
	7. Other information relevant to FSCA

2.	N/A

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety 1st September 2019
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No No complaints are received on the issue.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None The issue only affects Lot 8L03735	
3	6. By when should the action be completed?	All products from the affected lot should be returned by 1st September 2019 to manufacturer.
3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Not appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**Lone Zacho** **Vigilance Officer** 

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to your customers on which this action has an impact. Please collect confirmation of receipt including data of returned products from your customers in order for you to provide the information to Coloplast for reconciliation. 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.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.