Steripack
Medical Procedure Packs and Products

FSN Ref:2020FSN56107S5D FSCA Ref: 2020FSCA56107S5D

Date: 21-04-2020

Urgent Field Safety Notice
Swab Abdominal XR

For Attention of*:End User

Contact details of local representative (name, e-mail, telephone, address etc.)*
Aichele Medico AG, Therwilerstrasse 1 CH-4147 Aesch / BL

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Urgent Field Safety Notice (FSN)
Swab Abdominal XR

1. Information on Affected Devices*	
	1. Device Type(s)*
	Swab Abdominal XR 4 ply 17 thr. 45 x 45cm 5 pcs 
	2. Commercial name(s)
	Swab Abdominal XR
	3. Unique Device Identifier(s) (UDI-DI)
	N/A
	4. Primary clinical purpose of device(s)*
	The sterile abdominal swabs with X-ray are intended to be used in surgically invasive procedures as a mechanical barrier for compression or for absorption of exudates, keeping the wound dry.
	5. Device Model/Catalogue/part number(s)*
	N/A
	6. Software version
	N/A
	7. Affected serial or lot number range
	REF: 56107S5D and LOT 1908036
	8. Associated devices
	N/A

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2 Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

The swabs have a defective in the packaging. The swabs are non-sterile

2. Hazard giving rise to the FSCA*

N/A

3. Probability of problem arising

4. Predicted risk to patient/users

The *Severity vs Probability evaluation* is the tool used to predict the impact of each risk– *Low impact; Medium Impact; High Impact* and *Extreme Impact.* The *table* shows the contribution of each variable on risk evaluation based on a 5 x 5 matrix for the estimation of the risks:

Probability (P)	Severity (S)				
	Trivial 1	Minor 2	Moderated 3	Major 4	Severe 5
Frequent 5	L	H	H	E	E
Occasional 4	L	M	H	H	E
Possible 3	L	M	M	H	E
Improbable 2	L	M	M	H	H
Rare 1	L	L	M	M	H

In this case, the predicted risk to patient/users is *Medium impact.*
Probablily - 1
Severity - 3

5. Further information to help characterise the problem

In order to ensure patient safety, it is important that the end user/health professional verify the integrity of the package before use.

6. Background on Issue

Review of the device history records showed that there were no issues during the manufacture of the product that would contribute to this complaint condition and product was manufactured according procedure (e.g weld tests and steam sterilization). Based on the information available, no non-conformance reports were generated during production. Weld tests are being performed in all productions by manufacturer.

7. Other information relevant to FSCA

N/A

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	3. Type of Action to mitigate the risk*	
	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 it is important that the end user/health professional verify the integrity of the package before use.	
	2. By when should the action be completed? 21-04-2020	Specify where critical to patient/end user safety Due to the fragility of the device its use can cause injury
	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) 30-04-2020	Yes
	5. Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other - Provide further details of the action(s) identified. ☒ None	
	6. By when should the action be completed?21-04-2020	Specify where critical to patient/end user safety
	7. Is the FSN required to be communicated to the patient /lay user?	Yes
	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	

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	4. General Information*	
	1. FSN Type*	New
	2. For updated FSN, reference number and date of previous FSN	N/A
	3. For Updated FSN, key new information as follows:	
	In order to ensure patient safety, it is important that the end user/health professional verify the integrity of the package before use.	
	4. Further advice or information already expected in follow-up FSN? *	No
	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Please, destroy samples of the affected product	
	6. Anticipated timescale for follow-up FSN	No
	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	Steripack S.A	Only necessary if not evident on letter-head.
	Zona Industrial 1, Lote 11 a 14 4560-164 Guilhufe, Penafiel Portugal	Only necessary if not evident on letter-head.
	nfelix@sterisets.eu	Only necessary if not evident on letter-head.
	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * No	
	9. List of attachments/appendices:	If extensive consider providing web-link instead.
	10. Name/Signature	Nuno Félix – Quality Director

	Transmission of this Field Safety Notice
	N/A

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

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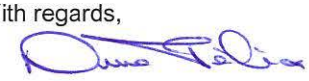
Contact manufacturer

Steripack S.A
Att.: Mr. Nuno Félix – Quality Director
Zona Industrial 1, Lote 11 a 14
4560-164 Guilhufe, Penafiel
Portugal
Tel.: +351 255 711 355
Fax: +351 255 711 357
Web site: www.sterisets.eu
E-mail: nfelix@sterisets.eu

Acknowledgment of receipt
Sterisets Medical Products requires an acknowledgment of receipt of this notice.

With regards,



Steripack S.A
Nuno Félix – Quality Director