Medical Procedure Packs and Products

FSN Ref: 2020FSN_56107S5D_23Oct2020 FSCA Ref: 2020FSCA_56107S5D_23Oct2020

Date: 23-10-2020

Urgent Field Safety Notice
Swab Abdominal XR 4 ply 17 thr. 45 x 45cm 5 pcs/pouch DBL *S

For Attention of*:End User

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Urgent Field Safety Notice (FSN)
Swab Abdominal XR 4 ply 17 thr. 45 x 45cm 5 pcs/pouch DBL *S

1. Information on Affected Devices*	
	1. Device Type(s)*
	XR Abdominal Swabs
	2. Commercial name(s)
	Abdominal swab 45 x 45 cm X-ray Non-washed Without loop 4 ply 17 th Double pack, 5 pcs/pack
	3. Unique Device Identifier(s) (UDI-DI)
	5608120SWABABDOMIF1-0ZA
	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. Affected serial or lot number range
	REF:56107S5D LOT:1909315

STERIPACK S.A. Zona Industrial 1 - Lote 11 a 14 - 4560-164 Guilhufe, Penafiel - PORTUGAL - Phone: +351 255 729 090 www.sterisets.com

Steripack
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2 Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

A spider was found in between the packages.

2. Hazard giving rise to the FSCA*

N/A as the insect was not in contact with the abdominal swabs.

3. Probability of problem arising

Possible, however measures were apply in order to decrease the probability to Rare.

4. Predicted risk to patient/users

Predicted risk to patients/users is classified as improbable.

5. Further information to help characterise the problem

If any insect is seen please discard the set.

6. Background on Issue

The customers have noticed an insect in between the packaging's. This is a double pack set. Insect was not in contact with the abdominal swabs.

7. Other information relevant to FSCA

It was not possible to identify a specific root cause. A new pest control system was implemented on March 2019. This is a single incident.

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

If any insect is seen please discard the set.

2. By when should the action be completed?
This action should be performed before use.

Specify where critical to patient/end user safety
None

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)
23-11-2020

Yes

5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☒ None

	6. By when should the action be completed? **N/A**	Specify where critical to patient/end user safety
	7. Is the FSN required to be communicated to the patient /lay user?	**No**
	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?	
	N/A	

	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:	
	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:	
	6. Anticipated timescale for follow-up FSN	**N/A**
	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. * **Yes**	
	9. List of attachments/appendices:	If extensive consider providing web-link instead.
	10. Name/Signature	Nuno Félix – Quality Director Isabel Nascimento – Quality and Regulatory Affairs Manager
		

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	Transmission of this Field Safety Notice
	This notice needs to be passed on to all end users who need to be aware of this Field Safety Notice. Please maintain awareness on this notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action

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

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
Isabel Nascimento – Quality and Regulatory Affairs Manager