Medical Procedure Packs and Products

FSN Ref:2020FSN10617020_12Aug2020 FSCA Ref: 2020FSCA10617020_12Aug2020

Date: 12-08-2020

Urgent Field Safety Notice
Eye surgery set

For Attention of*:End User

Contact details of local representative (name, e-mail, telephone, address etc.)*
H. Dam Kaergaard, Gammel Kongevej 601850 Frederiksberg Denmark

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Urgent Field Safety Notice (FSN)
Eye surgery set

1. Information on Affected Devices*	
	1. Device Type(s)*
	Eye surgery set
	2. Commercial name(s)
	Eye surgery set
	3. Unique Device Identifier(s) (UDI-DI)
	5608120SETSSURGICEEE-0X4
	4. Primary clinical purpose of device(s)*
	The trays and bowls are intended to be used in the preparation of the cleaning or disinfection solution and/or to contain the used dressing products after the treatment
	5. Affected serial or lot number range
	REF: 10617020 and LOT 2004104
	6. Associated devices
	Ref: 217014 - Bowl PP 120 ml 84 x 30 x 71 mm transp. w. graduation

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2 Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

Incident description:
When the water comes in bowl 120 ml, which is in the eyset 10617020 the customers have noticed membrane (oil) in the bowl. The head doctor has forbidden, to use the bowl because of danger what comes in the eye, during operation.

2. Hazard giving rise to the FSCA*

Dirty - oil

3. Probability of problem arising

Likely to occur six times in the last 12 months
Reference: 10617020
Sales volume (2020): 1800 units
Number of the Incidents (2020): 1 Incident
% incident in = 0,055%

4. Predicted risk to patient/users

Predicted risk to patients/users is classified as possible and minor, but control measures are being applied in order to mitigate this risk to improbable.

5. Further information to help characterise the problem

Based on the information available, we will inform our supplier of the encountered problem and correctives actions will be implemented.

6. Background on Issue

The customers have noticed membrane (oil) in the bowl.

7. Other information relevant to FSCA

In order to ensure patient safety and until further corrective actions are implemented, it is important that the end user/health professional verify the integrity of the bowl before use. If an oil membrane is observed, please discard the bowl.

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

In order to ensure patient safety and until further corrective actions are implemented, it is important that the end user/health professional verify the integrity of the bowl before use. If an oil membrane is observed, please discard the bowl.

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	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 **In order to ensure patient safety and until further corrective actions are implemented, it is important that the end user/health professional verify the integrity of the bowl before use. If an oil membrane is observed, please discard the bowl.**	
	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) **12-09-2020**	Yes
	5. Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None **A formal supplier complaint will be raised to ensure that our products corresponds with the highest standards of quality and to avoid similar situations.**	
	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?	**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?	
	N/A	

	4. General Information*	
	1. FSN Type*	**New**
	2. For updated FSN, reference number and date of previous FSN	**2020FSN10617020_12Aug2020**
	3. For Updated FSN, key new information as follows:	
	Please refer to section 7	
	4. Further advice or information already expected in follow-up FSN? *	**Yes**
	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Improvements should be performed by Supplier.	
	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**	

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	9. List of attachments/appendices:	If extensive consider providing web-link instead.
	10. Name/Signature	Nuno Felix - Quality Director 

	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.

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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 Felix - Quality Director