Steripack
Medical Procedure Packs and Products

FSN Ref: 2020FSN_570066S_14Aug2020 FSCA Ref: 2020FSCA_570066S_14Aug2020

Date: 14-08-2020

Urgent Field Safety Notice
Proble Bowman lacrinal 0,7 + 0,8 mm fig 00/0

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)
Proble Bowman lacrinal 0,7 + 0,8 mm fig 00/0

1. Information on Affected Devices*	
	1. Device Type(s)*
	Sterile surgical, dental and podiatry instruments
	2. Commercial name(s)
	Proble Bowman lacrinal 0,7 + 0,8 mm fig 00/0
	3. Unique Device Identifier(s) (UDI-DI)
	5608120INSTSURGICHHHEQ
	4. Primary clinical purpose of device(s)*
	Used to enter small openings in the body. **Use of a Bowman probe for determining the distance of canalicular laceration from punctum..**
	5. Affected serial or lot number range
	REF: 570066S and LOT 1908240

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2 Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*

Incident description:
The probe bends. The surface peels off.

2. Hazard giving rise to the FSCA*

Missing information on the labelling

3. Probability of problem arising

Likely to occur six times in the last 12 months
Reference: 570066S
Sales volume (2020): 650 units
Number of the Incidents (2020): 1 Incident
% incident in = 0,15%

4. Predicted risk to patient/users

Predicted risk to patients/users is classified as Rare and Moderated, but control measures are being applied in order to keep the risk.

5. Further information to help characterise the problem

In order to ensure patient safety and until further corrective actions are implemented, it is important that the end user/health professional does not bend the device.

6. Background on Issue

The probe bends. The surface peels off.

7. Other information relevant to FSCA

N/A

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 does not bend the device.

2. By when should the action be completed?	Specify where critical to patient/end user safety
This action should be performed before use. It is important that the end user/health professional does not bend the device.	None

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	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) **14-09-2020**	Yes
	5. Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None An instruction will be added on to the labelling "**Do not bend**" 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	**2020FSCA_570066S_14Aug2020**
	3. For Updated FSN, key new information as follows:	
	N/A	
	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:	
	N/A	
	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 Felix - Quality Director

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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 Felix - Quality Director