Company Name/Logo
Sunmedix Co., Ltd.

FSCA Ref: MDD23.246

Date: 2023.11.14

Field Safety Notice
ACOS - Sterile Single-Use Skin Stapler

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Stapleline Medizintechnik GmbH Bessemer Str. 3044793 Bochum Deutschland Tel.: +49 234 936 487 10 Fax: +49 234 936 487 12

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Field Safety Notice (FSN)
ACOS - Sterile Single-Use Skin Stapler
Contamination / Malfunction

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Sterile Single-Use Skin Stapler
1.	2. Commercial name(s)*
	Acos
1.	3. Unique Device Identifier(s) (UDI-DI)
	(01)18809240391072
1.	4. Primary clinical purpose of device(s)*
	This Skin Stapler is a sterile and ergonomic disposable instrument, with which wounds can be closed quickly and effortless. In surgery, this skin stapler is used for a variety of skin closures.
1.	5. Device Model/Catalogue/part number(s)*
	Acos 35W
1.	6. Affected serial or lot number range
	Lot# 2313100

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Sunmedix received complaints about contaminations in the sterile packages and malfunctions with the device. Really tiny dust(lint) and tiny dot were found in the tray(resulting from high temperatures during injection molding from vendor factory). The dust(lint) and dot are really tiny so we couldn't find dust by naked eyes so we had to use to find dust(lint) and tiny dot by magnifying glasses. And the stapler damage(that causes malfunction) was happened from courier service in Germany.
	2. Hazard giving rise to the FSCA*
	Investigation have done and there is no possibility of non-sterilization. And Microfiber and dot can't be harm on the skin and injured body. Because it is not protein like hair or animal hair. Dot cannot be fallen from stapler. Regarding stapler malfunction(Jamming), we've checked the photo that was took in German courier service. The boxes were broken and wet too much when those were sent to distributor in Germany. We can realize that there was big and strong shock on the box and also the boxes was wet due to the rain. So the box strength was really weakened due to water and goods couldn't be protected by box. That caused malfunction(Janmming).
2.	3. Probability of problem arising
	Sunmedix investigated defective samples to identify the probability. And the defective problem can be happened (include malfunction) as 0.25%. 0.25% is internal shipment standard of Sunmedix. The defective issues is overrated.
2.	4. Background on Issue
	The LOT# delivered was produced together with another order for another Japanese customer. There is no received claim from the Japanese customer. It is suspected that the malfunction resulted from transport damage. The dust came into the tray during the cleanroom production process and was also sterilized together.

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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	
3.	2. By when should the action be completed?	2023-12-31
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Sunmedix analyzed samples of the samples and we found no quality problem.	
3.	5. By when should the action be completed?	2023-12-31
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

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4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Sunmedix Co. Ltd.
	b. Address	5&9&11, Buma-ro 164 beon-gil, Jinjeop-eup, Namyangju-si KOR-12000 Gyeonggi-do
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	Reply form
4.	6. Name/Signature	[redacted]

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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.

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	MDD23.246
FSN Date*	2023-11-14
Product/ Device name*	Acos/ Sterile Single-Use Skin Stapler
Product Code(s)	Acos 35W
Batch/Serial Number (s)	Lot# 2313100

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
☐	Other Action (Define):			

☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Pre-filled by manufacturer/sender/requester

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.