Surgikare

Rev 2: February 2020

FSN Ref: 2024080801

Field Safety Notice (FSN)
Bipolar Forceps
Surgikare

Date: 2024-12-18

For Attention of*: Danish Medicine Agency

Contact details of local representative (name, e-mail, telephone, address etc.)*
Address:Obelis S.ABd. General Wahis, 53 1030 Brussels, Belgium **Tel:+3227325954** **Fax+3227326003** **EMail:sales@obelis.net**

Manufacture:
Address: Surgikare Toorabad Daska Road Sialkot-51310 Pakistan. Tele:+92 52 3552711 Fax +92 52 3555128 Email:info@surgikare.com

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Bipolar forceps
1.	2. Commercial name(s)*
	Bipolar forceps
1.	3. Unique Device Identifier(s) (UDI-DI)
	050563825SUBIF210QB
1.	4. Primary clinical purpose of device(s)*
	See attached IFU
1.	5. Device Model/Catalogue/part number(s)*
	SKG-20-586
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	Lot#S3345
1.	8. Associated devices
	No

	2. Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*

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	During the unpacking of a sterile loose pack, two stiff metal wires/fibers suddenly appeared which originated from the black wire of the monopolar diathermy burner, lying on the sterile drape that had been placed over the patient. We changed the burner and kept the two metal wires for further documentation, as it is too uncertain to use these new burners moving forward. If the patient had an open access, it could have had serious consequences, as the wires could have ended up in the abdomen.
2.	2. Hazard giving rise to the FSCA*
	In the investigation ,we found that one small piece of wire has stuck with folded cable of device and not identified during QC inspection which was dropped down during unfolding the cable of device by the user.
2.	3. Probability of problem arising
	, it could had serious consequences if the patient had open access.
2.	4. Predicted risk to patient/users
	loose wire can be drop in open access.
2.	5. Further information to help characterise the problem
	No
2.	6. Background on Issue
	During the unpacking of a sterile loose pack, two stiff metal wires/fibers suddenly appeared which originated from the black wire of the monopolar diathermy burner, lying on the sterile drape that had been placed over the patient. We changed the burner and kept the two metal wires for further documentation, as it is too uncertain to use these new burners moving forward. If the patient had had an open access, it could have had serious consequences, as the wires could have ended up in the abdomen.
2.	7. Other information relevant to FSCA
	Manufacturer has re-called all the device from the customer and current stock of effected device has re-inspected for reported incident.

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 Devices has returned to the manufacturer.	
3.	2. By when should the action be completed?	Action has completed, All the devices has re-called back and manufacture has received in its facility.

3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No No patient involve in the incident and no need of follow up of the patient.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer*** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Devices have removed from the customer	
3.	6. By when should the action be completed?	Devices have recalled back from the customer. Action completed
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	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 Not appended to this FSN	

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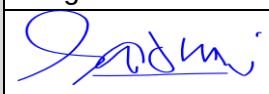
4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	3. For Updated FSN, key new information as follows:	
	No update New information	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	No follow up	
4.	6. Anticipated timescale for follow-up FSN	No Follow up
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Surgikare
	b. Address	Toorabad Daska Road Sialkot Pakistan
	c. Website address	www.surgokare.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	FSCA
4.	10. Name/Signature	Sabir Ghumman QA Manager Surgikare
		

	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.