FSN Ref: FSN 20-10-001 FSCA Ref: FSCA 20-10-001

Incident Number: 2020/009/023/401/006

Date: 29-Oct-2020

Urgent Field Safety Notice
Device Commercial Name

For Attention of*:Blackrock Clinic, Letterkenny Hospital, Mater Public Hospital, Tullamore Hospital, St Vincent's University, Galway Clinic, Citadelle Chateau Rouge, Cellule Pharmacie, Onze Lieve Vrouwziekenenhais , Universitetetssykehuset, Akershus Universitetetssykehus, UZ Leuven

Contact details of local representative (name, e-mail, telephone, address etc.)*
GS Medical, Suite 6, Block 5.1 Woodford Court, Woodford Business Park, Dublin 9, Ireland

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Sterile X-ray detectable
1.	2. Commercial name(s)
	Robotic Sponge
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	X-ray detectable gauze balls intended to be used inside the body, or surgical incision to control bleeding, absorb fluid
1.	5. Device Model/Catalogue/part number(s)*
	20062
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	LOT: 180019-1
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	None
2.	2. Hazard giving rise to the FSCA*
	Hazard: Risk to patient. There is a remote residual risk of x-ray detectable thread being pulled, detached from the device if not used correctly. User/healthcare professional is asked to adhere to the issued IFU attached to this FSN to ensure safe and correct use of the device.
2.	3. Probability of problem arising
	Probability is between 10 X-5 and 10 X -6 (between 1/10,000 and 1/100,000)
2.	4. Predicted risk to patient/users
	contamination / foreign object/ particulates released into body of patient during operation. May result in irritation inside the body, and/or result in further surgery necessary to remove the object.
2.	5. Further information to help characterise the problem
	There have been no other reported issues with this device or LOT number.
2.	6. Background on Issue
	Issue was reported by a Hospital to MHRA and to GS Medical Healthcare on the 23rd September.
	7. Other information relevant to FSCA

2.	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

	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 Provide further details of the action(s) identified.
3.	2. By when should the action be completed? — Immediately
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Residual risk is remote, is non-life threatening and will not cause serious harm
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) — Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.
3	6. By when should the action be completed? — 29/Oct/2020
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? Choose an item. Choose an item.

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item.
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Kingstar Industries
	b. Address	No. 5 Xiaoxiangxi Road, Jinyinhu, Dongxihu District, 430040Wuhan City, Hubei Province, Peoples Republic of China
	c. Website address	www.kingstarmedical.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	See attached IFU.
4.	10. Name/Signature	Carolyn Boughton Quality and Regulatory Manager

	Transmission of this Field Safety Notice
5	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.

Customer Response Card

Ref: Field Safety Notice

I the user and receiver of this Field Safety Notice, confirm that I have received the notice and I have attached the IFU for the Robotic Sponge 20062 to the devices in stock. I have also completed the transmission of this FSN and accompanying IFU as instructed in section 5.

Product Name:
Product Reference:
Lot Numbers:
Type of Action:

Hospital Name:	
Hospital Address:	
Contact Name:	
Department:	
Telephone Number:	
Email Address:	

I have read and understood the contents of this Field Safety Notice and can confirm all Collection Pads within my area of responsibility have been recalled for replacement.

Signature: _____

Date: _____