Protek Medical Products, Inc.

Rev 1: September 2018

FSN Ref: CAN 0003 FSCA Ref: N/A

Date: 22 February 2019

Urgent Field Safety Notice

Sterile PullUp Small Form Fitted Probe Cover Kit (Ref # 2016)

For Attention of*:- Healthcare professionals / end users of the Sterile PullUp Form-Fitted Probe Cover kit, Ref. #2016

Contact details of local representative (name, e-mail, telephone, address etc.)*

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Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Sterile single use probe cover kit, kit containing one soft non-latex probe cover, two clips and sterile transmission gel
1.	2. Commercial name(s)
	Sterile PullUp Small Form Fitted Probe Cover Kit,
1.	3. Unique Device Identifier(s) (UDI-DI)
	00841912105588
1.	4. Primary clinical purpose of device(s)*
	Sterile probe cover is used over probes for minimizing cross contamination between non-sterile probe and the patient (invasive device or surgically invasive device). Probe cover is designed to fit small diameter probes used for diagnostic imaging.
1.	5. Device Model/Catalogue/part number(s)*
	Reference # 2016
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot # 73730
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The cover broke during use in a laparoscopic procedure with trocar. However, this probe cover is not intended to be used in laparoscopic procedure with trocar.
2.	2. Hazard giving rise to the FSCA*
	When probe cover is used in laparoscopic procedures with trocar, the trocar could damage the probe cover, resulting in the non-sterile probe becoming exposed and could result in patient infection. This probe cover is not intended to be used in laparoscopic procedures with trocars.
2.	3. Probability of problem arising
	If the probe cover is used in laparoscopic with trocar procedures, it is most probable that the probe cover is damaged by the trocar.
2.	4. Predicted risk to patient/users
	From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect).
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
	6. Background on Issue

2.	Protek Medical Product, Inc. (manufacturer) has been informed by Bicommerciale (Protek's distributor in Italy) that a hospital in Italy (….) experienced breakage of the probe cover toward the tip of the probe when using the cover in a laparoscopic procedure with trocar. When the event was noticed by the healthcare professional, the patient was preventively administered antibiotics to overcome possible infection.
2.	7. Other information relevant to FSCA
	After finding out the type of procedure being performed using the probe cover, Protek instructed Biocommericale to stop distributing this type of probe cover to be used for laparoscopic procedures with trocar.

	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 End users to be informed to not use the Probe cover kit (Ref. # 2016) in laparoscopic procedures using trocars – this probe cover is not intended to be used in this kind of procedures. There is a high probability that the probe cover could be damaged by the trocar, which might result in a patient infection.	
3.	2. By when should the action be completed?	Within a week after receiving the FSN.
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**4. 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	5. By when should the action be completed?	N/A
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

3	7. 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	
	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? *	No
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	**Protek Medical Products, Inc.**
	b. Address	**4125 Westcor Court, Coralville, IA 52246, USA**
	c. Website address	**www.protekmedical.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * No	
4.	9. List of attachments/appendices:	**N/A**
4.	10. Name/Signature	**……** ……..

	Transmission of this Field Safety Notice
	Sterile single use Probe Cover kit, Reference # 2016, is not intended to be used in laparoscopic procedures with trocars. Stop using this cover when using trocars in laparoscopic procedures! This notice is addressed to Biocommerciale S.R.L. (distributor in Italy), who is requested to transfer it to the end users/hospitals which purchased this product. This FSN is also communicated to the Italian Ministry of Health, Emergo Europe (EU Authorized Representative), and the Dutch Health and Youth Care Inspectorate.

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.