WORLD'S LARGEST CONDOM MAKER

karex

Date: XXXX
Reference Number: FSN – KISB 04/2024

Urgent Field Safety Notice
Medline Endocavity Probe Cover (ICE33230L & ICE28295L)

For Attention of*: **[Company/ Organization Name]**

Contact details of local representative (name, e-mail, telephone, address, etc)*
[Contact detail name] [Address] Tel: +[Telephone Numbers] Email: [email address]

Urgent Field Safety Notice
Medline Endocavity Probe Cover (ICE33230L & ICE28295L)
Risk Address by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Sterile Natural Rubber Latex Protective Transducer Covers
1.	2. Commercial Name(s)
	Medline Endocavity Probe Cover
1.	3. Unique Device Identifier(s) (UDI – DI)
	19556564097591
1.	4. Primary Clinical Purpose of Device(s)
	For barrier protection during invasive medical examination and diagnosis using a transducer probe.
1.	5. Device Model/ Catalogue/ Part Number(s)*
	KX07 / ICE33230L & ICE28295L
1.	6. Software Version
	N/A
1.	7. Affected Serial or Lot Number Range

Catalogue No	Lot No	Expiry Date	Quantity (pcs)
ICE33230L	22SP003	2027-08-31	10,000
	23SP010	2028-04-30	10,000
	23SP011	2028-09-30	10,000
ICE28295L	22SP004	2027-08-31	10,000

1.	8. Associated Devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the Product Problem*
	Incorrect symbol related to product made with Natural Rubber Latex printed on primary packaging. Symbol printed convey the information product is not made with Natural Rubber Latex.
2.	2. Hazard Giving Rise to the FSCA*
	This may lead to serious incident related to allergic reaction due to the exposure of Type I Latex Allergy person on Natural Rubber Latex.
2.	3. Probability of Problem Arising
	Low
2.	4. Predicted Risk to Patient/ Users
	Immediate health consequence with symptoms range from skin irritation to respiratory symptoms to life-threatening anaphylaxis

2.	5. Further Information to Help Characterise the Problem
	N/A
2.	6. Background on Issue
	Incorrect symbol related to product made with Natural Rubber Latex printed on primary packaging. Symbol printed convey the information product is not made with Natural Rubber Latex. The non-compliant symbol is only on the primary packaging, while the secondary packaging which contains 100pc of the covers are with correct symbol of Natural Rubber Latex.
2.	7. Other Information Relevant to FSCA
	N/A

	3. Type of Action to Mitigate the Risk*	
3.	1. Action to be Taken by User*	
	☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On – site Device Modification/ Inspection ☐ Follow Patient Management Recommendation ☐ Take Note of Amendment/ Reinforcement of Instruction for Use (IFU) ☐ Other ☐ None:	
3.	2. By When Should the Action be Completed?	**2 months from date of FSN issuance**
3.	3. Probability of Problem Arising: **Rare** Is Follow – Up of Patients or Review of Patients' Previous Results Recommended? **Not Required**	
3.	4. Is Customer Reply Required?* **N/A** (if yes, form attached specifying deadline for return)	Concession acknowledgement by
3.	5. Further Information to Help Characterise the Problem ☐ Product Removal ☐ On – Site Device Modification/ Inspection ☐ Software Upgrade ☐ IFU or Labelling Change ☐ Other: ☒ None	
3.	6. By When Should the Action Completed?	**N/A**
3.	7. Is the FSN Required to be Communicated to the Patient/ Lay User?	**Not required**
	8. If Yes, has Manufacturer Provided Additional Information Suitable for the Patient/ Lay User in a Patient/ Lay User or Non – Professional User Information Letter/ Sheet?	
	N/A	

4. General Information

4.	1. FSN Type*	**Advisory Notice**
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? *	**N/A**
4.	5. If Follow–up FSN is 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 the local representative refer to page 1 of this FSN)	
	a. Company Name	**N/A**
	b. Address	**N/A**
	c. Website Address	**N/A**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to the customer. **TBA**	
4.	9. List of attachments/ appendices:	**N/A**
4.	10. Name/ Signature	**Khairunnisa Warsito/ Group RA Manager**

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.