Haiyan Kangyuan Medical Instrument Co..Ltd

Rev 2: February 2020

FSN Ref: 230625

FSCA Ref: Vk_20230627_19

Date: 2023.06.25

Field Safety Notice

Silicone Foley Catheter with Temperature Probe for single use

For Attention of*:medical care personnel

Contact details of local representative (name, e-mail, telephone, address etc.)*
Manufacturer：Haiyan Kangyuan Medical Instrument Co.,Ltd. Address：Songpodong Rd.,Shendang Town,Haiyan, Zhejiang 314311,China. Tel： 0086-0573-86725885 e-mail: 36491773@qq.com
[CH rep] OBELIS SWISS GmbH Address: Ruessenstrasse 12, 6340 Baar/ZG, Switzerland Tel:041 5441526 Fax:0415441527 E-mail:info@obelis.ch
Anandic Medical Systems AG Feuerthalen ZH | Burgdorf | Lausanne Stadtweg 24, CH-8245 Feuerthalen Helene Tuppinger Business Unit Manager Consumables Phone +41 52 646 03 47 (direct)

Haiyan Kangyuan Medical Instrument Co..Ltd

Rev 2: February 2020

FSN Ref: 230625

FSCA Ref: Vk_20230627_19

Field Safety Notice (FSN)

Silicone Foley Catheter with Temperature Probe for single use

Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Model: three cavity, four cavity specification: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr
1.	2. Commercial name(s)*
	Silicone Foley Catheter with Temperature Probe for single use
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	It can be used for clinical routine catheterization or drainage, and can be used withthe monitor to continuously monitor the bladder temperature of patients.
1.	5. Device Model/Catalogue/part number(s)*
	Model: three cavity, four cavity specification: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr
1.	6. Software version
	Do not apply
1.	7. Affected serial or lot number range
	all lot numbers currently on the market
1.	8. Associated devices
	Do not apply

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Contact of the catheter with sharp instruments such as tweezers, scissors, injection needles may damage the catheter.
2.	2. Hazard giving rise to the FSCA*
	Liquid flowed out of catheter. A detached catheter may also result in urinary retention. Placing a new catheter increases the risk of infection.
2.	3. Probability of problem arising
	very unlikely unless sharp instruments damage the catheter
2.	4. Predicted risk to patient/users
	The severity of the risk is serious, but the probability of the risk is low, and it is easyto detect. Assessed as marginal risk.
2.	5. Further information to help characterise the problem

	So far, only one case was reported to the manufacturer.
2.	6. Background on Issue
	Problem results from damage to the catheter caused by sharp instruments in contact with the catheter
2.	7. Other information relevant to FSCA
	Following warning is added to the IFU: "In clinical use, avoid contact of the catheter with sharp instruments such as tweezers, scissors, injection needles, etc."

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.

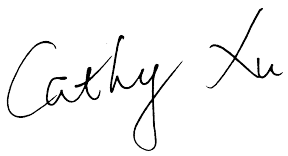
3.	2. By when should the action be completed?	31 August 2023
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required.	
3.	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

The medical staff should be reminded of the precautions during use

3.	6. By when should the action be completed?	31 August 2023
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 Choose an item.	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	/
4.	3. For Updated FSN, key new information as follows:	
	/	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	/	
4.	6. Anticipated timescale for follow-up FSN	/
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Haiyan Kangyuan Medical Instrument Co.,Ltd.
	b. Address	Songpodong Road Shendang Town,314311, Haiyan, Zhejiang China.
	c. Website address	www.zjkyyl.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Annex
4.	10. Name/Signature	Cathy Xu PRRC for Haiyan Kangyuan Medical Instrument Co.,Ltd. 

	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.

Template for a Field Safety Notice Customer Reply Form

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	230625
FSN Date*	25/06/2023
Product/ Device name*	*Silicone Foley Catheter with Temperature Probe for single use, Model: three cavity, four cavity; specification: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr*
Product Code(s)	
Batch/Serial Number (s)	ALL

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 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* Date*	Customer sign here	:

Date Returned (DD/MM/YY):	

4. Return acknowledgement to sender	
Email	Helene.Tuppinger@anandic.com
Customer Helpline	41 52 646 03 47
Postal Address	Feuerthalen ZH | Burgdorf | Lausanne Stadtweg 24, CH-8245 Feuerthalen
Web Portal	www.anandic.healthcare
Fax	/
Deadline for returning the customer reply form*	August 15,2023

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.