Rev 2: February 2020

FSN Ref: VIG-18-2024-FN07 FSCA Ref: VIG-18-2024-FC08

Date: 2023:12:31

Field Safety Notice
Amecath Short Term Haemodialysis Catheter Kit

For Attention of*:ELYSE HOLDING B.V.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Name: Emile Suerink, Address: ManagerDirinco BV I Lauwersmeer 9C I 5347 JR I Oss, T +31(0)881 501 116, Email: emile.suerink@dirinco.com

Rev 2: February 2020

FSN Ref: VIG-18-2024-FN07 FSCA Ref: VIG-18-2024-FC08

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

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	AMECATH Short Term Haemodialysis Catheter is a soft radiopaque biocompatible polyurethane sterile catheter. The catheters are placed centrally or through femoral vein. Intended Use: Sterile single use device indicated for use in attaining short term access for Haemodialysis or aphaeresis. Supplied Sterile
1.	2. Commercial name(s)*
	AMECATH Short Term Haemodialysis Catheter
1.	3. Unique Device Identifier(s) (UDI-DI)
	6221139DIA-SHT-2aXT
1.	4. Primary clinical purpose of device(s)*
	indicated for use in attaining short term access for Haemodialysis or aphaeresis. Supplied Sterile
1.	5. Device Model/Catalogue/part number(s)*
	SDLC-1415-KPC & all SDLC range distributed in 2023 and 2024
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	Batch: 510515, Manufacturing date: 03/02/2023 Expiration Date: 31/01/2026
1.	8. Associated devices
	NA

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Unfortunately we have received a new complaint about the same issue of the suture-wing on an SDLC catheter dislodging from the catheter, resulting in the catheter (partially) existing the blood vessel.
2.	2. Hazard giving rise to the FSCA*
	Catheter inexplicably removed from patient after insertion. It appears the suture wing slipped over its hub sometime after insertion
2.	3. Probability of problem arising
	This case was encountered with our customer in Netherlands and was handled .
2.	4. Predicted risk to patient/users
	Evaluated as Critical and it may cause a harm on the patient. Evaluated as critical, as the mobility of the fixation wing (which is crucial to fix the catheter in place) may lead to catheter slippage out of the vessel, which may cause bleeding and put patient's health at risk.
2.	5. Further information to help characterise the problem
	NA
2.	6. Background on Issue
	Manufacturer became aware when the distributor notified us by mail Root cause of the problem is missing the inspection step on the assembly step of the rotating wing over the hub. The containment action is to create FSNs to be circulated to users who received the defect batch, and they will be instructed to use "Unifix Catheter Tube Fixation Adhesive"

	for catheter fixation instead of rotating wing suturing. In addition, to prevent the incident recurrence, a step will be added in visual inspection process to ensure the proper assembly of the rotating wing over the hub and to ensure that the rotating wing is placed after the stopper. In addition, a process step was edited by changing the mold used to manufacturer these catheters. Then, a recall of defective lots was suggested by the Dutch HA, consequently the manufacturer followed by applying a voluntary recall on the whole SDLC range supplied during the year 2023 and 2024 till date.
2.	7. Other information relevant to FSCA
	"Unifix Catheter Tube Fixation Adhesive" is already included in all supplied kits

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

SDLC range that was supplied during the year 2023 and 2024 till date will be collected by the Distributor

3.	2. By when should the action be completed?	Within 45 days from the date of circulation of this FSN

3. 3. Particular considerations for: Choose an item.

Is follow-up of patients or review of patients' previous results recommended?
Choose an item.

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

a recall of defective lots was suggested by the Dutch HA, consequently the manufacturer followed by applying a voluntary recall on the whole SDLC range supplied during the year 2023 and 2024 till date.

3.	6. By when should the action be completed?	Within 45 working days. Action is not critical to patient/user safety
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	Provide reference and date of previous FSN if relevant.
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	Eg patient management, device modifications etc.	
4.	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Ameco Medical Industries
	b. Address	Industrial area B4 Plot 119 east, 10th of Ramadan city - Egypt
	c. Website address	www.amecathgroup.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	NA
4.	10. Name/Signature	

	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.