Rev 1: September 2018
FSN Ref: AN007, QR1271 FSCA Ref: Report QR1272

Date: 3 Sep 2020

Urgent Field Safety Notice
CLiP® Winged Automatic safety I.V. catheter

For Attention of*: CODAN DEHA ApS, Greiner Bio-One GmbH, Codan France Sarl and Pamark Oy

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

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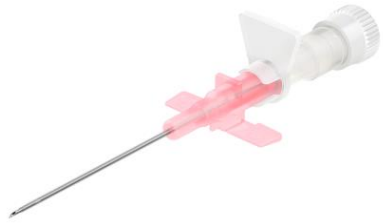
Urgent Field Safety Notice (FSN)
CLiP® Winged Automatic safety I.V. catheter

Safety mechanism not functioning in some devices in one specific lot. This could lead to accidental needle stick injury.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	CLiP® Winged is an automatic safety intravenous (I.V.) catheter (sterile, for single use). The product has a built in safety mechanism that encapsulates the tip of the used needle when extracted from the catheter. This prevents accidental needle stick injuries. 
1.	2. Commercial name(s)
	CLiP® Winged Automatic safety I.V. catheter
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	Intravenous/Intravascular access for short term peripheral cannulation. Indication for use eg. Infusion of I.V. solutions including blood and fluid of similar viscosity and Intermittent intravenous drug administration
1.	5. Device Model/Catalogue/part number(s)*
	VW203211
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot number 94722N
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Safety mechanism not functioning in some devices in one specific lot.
2.	2. Hazard giving rise to the FSCA*
	Contaminated sharps exposed: Accidental needle stick injury of medical healthcare professional with contaminated blood from patient.
2.	3. Probability of problem arising
	Minor part of lot 94722N has a manufacturing error that could cause the safety mechanism not to active properly and thereby leave the needle tip unprotected when extracted from the catheter. Approximately 2 %.
2.	4. Predicted risk to patient/users
	NSI with contaminated blood, Blood borne infection
2.	5. Further information to help characterise the problem

	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	Complaint (REK2020-013) from France regarding unprotected needle
2.	7. Other information relevant to FSCA
	N/A

	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 N/A	
3.	2. By when should the action be completed?	Immediately put the devices in quarantine and return to the producer as soon as possible.
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No If all devices are put in quarantine there is no risk for the patient.	
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 CLiP Winged 20Gx32mm, VW203211 lot number 94722N	
3	6. By when should the action be completed?	Immediately put the devices in quarantine and return to the producer as soon as possible.
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? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Will be followed up in documents attached to this FSN regarding return of product.	
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	**Vigmed AB**
	b. Address	**Kungsgatan 6, SE-252 21 Helsingborg**
	c. Website address	**www.stick-to-safety.com/**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes, this FSN, and FSCA	
4.	9. List of attachments/appendices:	1) Summary FSN; 2) Confirmation form 1 (received FSN distributor); 3) Confirmation form 2 (received FSN heath care facility); 4) Confirmation form 3 (return material from heath care facility);
4.	10. Name/Signature	**Åsa Westrup, QA/RA Manager Vigmed AB** 

	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.