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Date: 30 November, 2021

Urgent Field Safety Notice
CLiP® Ported Automatic safety IV catheter
CLiP® Winged Automatic safety IV catheter

For Attention of*:Greiner Bio-One Ltd., Greiner Bio-One GmbH, Greiner Bio-One VACUETTE Schweiz GmbH, Greiner Bio-One B.V., Greiner Bio-One España S.A.U., Vygon Ireland Ltd, Danyel Biotech Ltd, CODAN France Sarl, CODAN DEHA ApS, Pamark Oy

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	CLiP® Ported and CLiP® Winged respectively is an automatic safety intravenous (IV) 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 needlestick injuries.   CLiP® Ported CLiP® Winged
1.	2. Commercial name(s)
	CLiP® Ported Automatic safety IV catheter and CLiP® Winged Automatic safety IV 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 (up to 30 days). The use of this product is restricted to qualified healthcare professionals. Indication for use: Infusion of I.V. solutions including blood and fluid of similar viscosity, Intermittent intravenous drug administration, Sample blood, The products withstand use with power injectors rated for a maximum pressure of 21 bar (305 psi)
1.	5. Device Model/Catalogue/part number(s)*
	VP183211, VP184511, VP203211, VW184511, VW203211
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot number 12551N, 12552N, 12611N, 12612N, 12631N, 12632N, 12641N, 12642N, 12311N and 11361N.
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	Severe deformation in the primary packaging. The blister part of the packing is deformed and the sterile barrier is no longer intact.
2.	2. Hazard giving rise to the FSCA*
	Risk that an unsterile product is used in clinical situation
2.	3. Probability of problem arising
	It is deemed as a low probability that product with deformed packaging will be used in clinical situation as the deformation and defect is easily detected. However, if the packaging deformation is not detected (or ignored), it can be a risk that an unsterile product is used on patients. Symbol for "do not use if package is damaged" is attached on the primary packaging.
	4. Predicted risk to patient/users

2.	Unsterile product inserted to patient's vascular system
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The products received from the initial complaint shows severe deformation in the primary packaging and the sterile barrier is no longer intact.
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 Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately put the devices in quarantine and return to the products 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 and then returned to manufacture, 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 Remove product from market and destroy.	
3	6. By when should the action be completed?	Immediately put the devices in quarantine and return to the products 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?	
	N/A N/A	

	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, will be with this FSCA and FSN.	
4.	9. List of attachments/appendices:	1) FSN-Summary included Annexes 1-4
4.	10. Name/Signature	**Elisabeth Andersson** 

	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.