VIGMED AB
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Sweden

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www.stick-to-safety.com

Helsingborg, November 30th, 2021
For the attention of: Distributors and Health-care professionals

Urgent Field Safety Notice Summary

Dear Customer,

Vigmed AB has voluntary initiated a Field Safety Corrective Action (FSCA) for CLiP® Ported Automatic Safety IV catheter VP183211 batch number 12551N and 12552N, VP184511 batch number 12611N and 12612N, and VP203211 batch number 12631N, 12632N, 12641N and 12642N, and for CLiP® Winged Automatic Safety IV catheter VW184511 batch number 12311N and VW203211 batch number 11361N.

This document is a summary of official FSN doc. Ref. Ares (2018) 5836250 - 15/11/2018. See attachment 1 for complete FSN in English.

The required corrective action is to return below product to manufacturer.

Vigmed Reference:	FSN AN010
Product name:	CLiP® Ported Automatic Safety IV catheter
REF:	**LOT:**
VP183211	12551N
VP183211	12552N
VP184511	12611N
VP184511	12612N
VP203211	12631N
VP203211	12632N
VP203211	12641N
VP203211	12642N

Vigmed Reference:	FSN AN010
Product name:	CLiP® Winged Automatic Safety IV catheter
REF:	**LOT:**
VW184511	12311N
VW203211	11361N

Description of problem
Vigmed voluntarily recalls the above listed lot numbers of CLiP® Ported Automatic Safety IV catheter and CLiP® Winged Automatic Safety IV catheter.

Following a complaint, Vigmed has identified products that show severe deformation in the primary packaging and the sterile barrier is no longer intact. The root cause analysis indicates that it is most likely shortcomings in the logistics chain that has caused the deformation as products have been kept in unsuitable environment during transshipment.

The deformation in the packaging is clearly visible, however if not detected there is a risk that an unsterile product is used on patients. In addition, the symbol for "do not use if package is

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damaged" is clearly indicated on the primary packaging. The performed investigation cannot limit the extent of deformed products to specific boxes on the pallets. Therefore, all products in the table shall be withdrawn and returned to the manufacturer.

Actions to be taken

1. **Distributor:**
   Within 10 working days Ensure that all Customers that have received products subject to the recall, receive this information and complete Confirmation Form 1 and return the form to Vigmed.

2. **Health-care provider:**
   Within 1 month, return products subject to the recall together with Confirmation Form 2 to the Distributor.

3. **Distributor:**
   Within 3 months, complete Confirmation Form 3 and return the form to Vigmed in order to obtain a Return Goods Authorization number (RGA). Once a RGA is received, return the goods clearly labelled with the RGA number to Vigmed.

Forward this Field Safety Notice
Please forward this notice to any person in or outside your organization that might be affected of the information. Keep awareness of the information until the requested actions are completed.

Contact information
If you have any question, please do not hesitate to contact your Distributor or Vigmed directly.

Contact details Vigmed:
Elisabeth Andersson, Director Commercial Operations
Email: QA@vigmed.com
Phone: +46 42 28 00 90

Vigmed is devoted to high quality and patient safety and we apologize for the inconvenience we may have caused you. We are very grateful for your cooperation to resolve this issue promptly.

The undersigned confirms that the appropriate regulatory agency will be notified consistent with applicable regulations.

Elisabeth Andersson
Director Commercial Operations, Vigmed AB

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CONFIRMATION FORM 1

FSN AN010

Please complete and return to **Vigmed** within 10 working days from receipt.

Product name:	CLiP® Ported Automatic Safety IV catheter
REF:	**LOT:**
VP183211	12551N
VP183211	12552N
VP184511	12611N
VP184511	12612N
VP203211	12631N
VP203211	12632N
VP203211	12641N
VP203211	12642N

Product name:	CLiP® Winged Automatic Safety IV catheter
REF:	**LOT:**
VW184511	12311N
VW203211	11361N

We hereby confirm that we have read and understood the information in this Field Safety Notice (AN010) regarding above listed products. All our Customers and other persons or organization that need this information have been notified promptly.

Kindly send the completed form by e-mail to: **QA@vigmed.com**

Distributor	
Date	
Name	
Title	
Signature	
Contact information (e-mail, fax or phone)	

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CONFIRMATION FORM 2

FSN AN010

Please complete and return to **Distributor** within 1 month from receipt.

☐ We confirm that we have products subject to the recall in stock, as listed below:

Product name:	CLiP® Ported Automatic Safety IV catheter	
REF:	**LOT:**	**Quantity (units) to be returned to Distributor**
VP183211	12551N	
VP183211	12552N	
VP184511	12611N	
VP184511	12612N	
VP203211	12631N	
VP203211	12632N	
VP203211	12641N	
VP203211	12642N	

Product name:	CLiP® Winged Automatic Safety IV catheter	
REF:	**LOT:**	**Quantity (units) to be returned to Distributor**
VW184511	12311N	
VW203211	11361N	

☐ We confirm that we do not have any of above products subject to the recall in stock.

We hereby confirm that we have read and understood the information in this Field Safety Notice (AN010). We ensure that anyone concerned in or outside of our organization will be notified promptly. Further, we ensure that the listed products have been contained and will be returned to the Distributor.

Kindly send the completed form by e-mail or fax to:

Customer	
Date	
Name	
Title	
Signature	
Contact information (e-mail, fax or phone)	

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CONFIRMATION FORM 3

FSN AN010

Please complete and return to **Vigmed** promptly and latest within 3 months from receipt.

☐ We confirm that we have products subject to the recall in stock or to be returned from Customers to our stock, as listed below:

Product name:	CLiP® Ported Automatic Safety IV catheter		
REF:	**LOT:**	**Quantity (units) returned from Customers**	**Total quantity (units) to be returned to Vigmed**
VP183211	12551N		
VP183211	12552N		
VP184511	12611N		
VP184511	12612N		
VP203211	12631N		
VP203211	12632N		
VP203211	12641N		
VP203211	12642N		

Product name:	CLiP® Winged Automatic Safety IV catheter		
REF:	**LOT:**	**Quantity (units) returned from Customers**	**Total quantity (units) to be returned to Vigmed**
VW184511	12311N		
VW203211	11361N		

☐ We confirm that we do not have any of above products subject to the recall in stock or to be returned from Customers to our stock.

We hereby confirm that the information provided is correct and that the required actions are completed to our best knowledge.

Kindly send the completed form by e-mail: **QA@vigmed.com**

Customer	
Date	
Name	
Title	
Signature	
Contact information (e-mail, fax or phone)	