

VIGMED AB
Kungsgatan 6
SE-252 21 Helsingborg
Sweden

Office +46 42-280090
info@vigmed.com
www.stick-to-safety.com

Helsingborg, September 4th, 2020
For the attention of: Distributors and Health-care professionals

Urgent Field Safety Notice Summary

Dear Customer,

Vigmed AB has voluntarily initiated a Field Safety Corrective Action (FSCA) for CLiP® Winged Automatic Safety IV catheter VW203211 batch number 94722N. 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 AN007
Product name:	CLiP® Winged Automatic Safety IV catheter
REF:	LOT:
VW203211	94722N

Description of problem

Vigmed voluntarily recalls the above listed lot number of CLiP® Winged Automatic Safety IV catheter.

Following a complaint, Vigmed AB has identified a manufacturing error affecting batch number 94722N of VW203211. The error, due to a defect component, could cause the safety mechanism not to activate properly. Corrective and preventive actions have been taken in the manufacturing to prevent similar errors. There is no risk for similar error in other batches.

Actions to be taken

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

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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:
Åsa Westrup, QA/RA Manager
Email: QA@vigmed.com
Phone: +46 703 74 92 05

Vigmed is devoted to high quality and patient safety and we apologize for the inconvenience we may have caused you and your patient. 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.



Åsa Westrup,

QA/RA Manager
Vigmed AB

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CONFIRMATION FORM 1

FSN AN007

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

Product name:	CLiP® Winged Automatic Safety IV catheter
REF:	LOT:
VW203211	94722N

We hereby confirm that we have read and understood the information in this Field Safety Notice (AN007) 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 AN007

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® Winged Automatic Safety IV catheter	
REF:	LOT:	Quantity (units) to be returned to Distributor
VW203211	94722N	

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 (AN007). 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:
(insert local distributor contact information)

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

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CONFIRMATION FORM 3

FSN AN007

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® Winged Automatic Safety IV catheter		
REF:	LOT:	Quantity (units) returned from Customers	Total quantity (units) to be returned to Vigmed AB
VW203211	94722N		

- 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)	