URGENT:
MEDICAL DEVICE RECALL

Customer Name
Contact name
Street Name, house number
Postal code, City
Country

Affected Product: Stealth® Spring Clips

February XX, 2020

Dear Valued Customer,

Applied Medical is conducting a voluntary recall of three (3) lots of the Stealth Spring Clips due to a potential defect that can result in inadequate vessel occlusion (see **Table 1** below for affected lots). Please note that not all devices in these lots are affected by this potential device defect. This nonconformance presents minimal risk to the patient and/or user safety as the issue is detected upon initial vessel application. Out of an abundance of caution for patient safety and a commitment to provide only the highest quality products, Applied Medical has decided to recall all potentially affected units. We regret this inconvenience and assure you that maintaining high quality standards continues to be our highest priority. **All Stealth Spring Clips from the lots listed below should be returned to Applied Medical.**

Model	Description	Lots
A1601	6MM L/L STEALTH CLIP 1/2 F 10/BX	1359929
A1602	6MM L/L STEALTH CLIP 1/4 F 10/BX	1360356
A1603	6MM L/L STEALTH CLIP 3/4 F 10/BX	1357103

Our records indicate that you have received units from one or more of the affected lots. For recall effectiveness, we ask that you please complete the following actions:

- Check your inventory for the recalled product.
- Complete the attached Customer Recall Notification Confirmation Form (**Page 2**) to acknowledge the Recall. Please then indicate if your facility is returning or has already used devices from this lot. **Please note that you must return the form even if you have no devices in inventory.**
- If you are a distributor, please notify any facilities to which you distributed the affected product. Please also complete **Page 3** of the Recall Notification Confirmation Form.
- Return the Recall Notification Confirmation Form to Applied Medical by emailing it to: Reply-Europe@appliedmedical.com.
- Return affected product and a copy of the Recall Notification Confirmation Form to Applied Medical (Product Return Instructions are on **Page 4**).

Applied Medical will ensure that the appropriate Regulatory Agencies have been notified

We apologise for any inconvenience this action may cause. Your immediate attention is appreciated.

For product return questions, please contact our Customer Service Department at 0800 0200 144 or by email at Reply-Europe@appliedmedical.com

For regulatory questions, please contact the Regulatory Department at +31 (0) 33422 90 40 (option 4) or by email at: RA-QA@appliedmedical.com

Sincerely,

Dolf Bouma
Director Quality & Regulatory Affairs
Applied Medical Europe B.V.

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Customer and Distributor Recall Notification CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND SEND TO:

Email: Reply-Europe@appliedmedical.com

The form must be returned even if you have zero devices in inventory.

Applied Medical "Sold To" Account Number: XXXXX

Applied Medical "Ship To" Account Number: XXXXX

If you have transferred devices to another facility, please send them a copy of this recall letter. If possible, list the facility information, including contact information. Also, please add a note if you received the devices from another facility.

INFORMATION FOR CUSTOMER FACILITY RESPONDING TO RECALL:

Hospital Name: _____

Hospital Address: _____

If products were supplied to you by a distributor other than Applied Medical, please also provide:

Distributor's Name: _____

INFORMATION FOR DISTRIBUTOR FACILITY RESPONDING TO RECALL:

If you are a distribution facility, please provide the below information and complete **Page 3**:

Distributor Name: _____

Distributor Address: _____

RETURNING PRODUCT INFORMATION:

If no products are being returned, please check here: ☐

(If no products are returning, it is assumed that all products were previously used and/or are no longer available.)

Model Number	Lot Number	Qty of Units Being Returned
A1601	1359929	
A1602	1360356	
A1603	1357103	

Please note:

1. Customers who purchased directly from Applied Medical will receive credit when product is returned.
2. Customers who received recalled product from a distributor other than Applied Medical may request credit through their original distributor by returning the recalled product to that distributor.

INFORMATION ABOUT INDIVIDUAL COMPLETING THIS FORM:

Name: _____ **Date:** _____

Title: _____ **Telephone:** _____

Email: _____ **Fax:** _____

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Distributor Recall Notification CONFIRMATION FORM

IF YOU ARE A DISTRIBUTOR, PLEASE ALSO COMPLETE THIS FORM AND SEND TO:

Email: Reply-Europe@appliedmedical.com

(If you are not a distributor, please disregard this form.)

Information about Distributor's Units Sent to Other Distribution Centers and/or Other Customers:

Lot Number	Name and location of Distribution Centers or Other Customers who received recalled product	Number of units distributed	Has this facility been notified of the recall?	Date this facility was notified of recall

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Product Return Instructions

A pick-up of the recalled unit(s) will be arranged by our Customer Service team after receiving the Field Safety Notice Confirmation form.

Please write the RGA number on the outside of the package, which will be given to you by our Customer Service Department.

Please include a copy of the completed Recall Notification Confirmation Form(s) with your returned product.

If you have questions about the Recall Notification Confirmation Form or how to return the product, please contact Customer Service:
Phone number: 0800 0200 144
Email: Reply-Europe@appliedmedical.com

If you have any regulatory questions, please contact Regulatory Affairs:
Phone number: 033 422 9040 – option 4
E-mail: RA-QA@appliedmedical.com