URGENT:
MEDICAL DEVICE RECALL

28 December 2015

Customer Name
Address 1
Address 2
City, State Zip

Dear Valued Customer:

Applied Medical is conducting a voluntary recall of one specific lot of the CA500 Epix® Universal Clip Applier due to a potential loading mechanism nonconformance. This potential nonconformance may lead to clips not loading into the jaws, requiring the user to actuate the trigger again to load a clip per the Instructions for Use. Patient harm is unlikely if the device is used as indicated in the Instructions for Use. There have been no reported adverse events related to this nonconformance; however, to ensure our customers receive product of the highest quality, we are recalling devices in the field that may exhibit this nonconformance. Only CA500 Epix Universal Clip Appliers of lot 1231562 were found to have this potential nonconformance and should be returned to Applied Medical.

The model number affected is **CA500** and the lot affected is **1231562**.

Our records indicate that you have received ___ unit(s) from affected lot 1231562. For recall effectiveness, we ask that you please complete the following actions:

- Check your inventory for recalled product.
- Complete the attached Recall Notification Confirmation Form (Page 2) to acknowledge the recall, indicate if your facility is returning or has already used this lot.
- Return the Recall Notification Confirmation Form to Applied Medical by emailing to reply-eu@appliedmedical.com
- Return affected product and a copy of the Recall Notification Confirmation Form to Applied Medical (Product Return Instructions are on Page 3).

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

For product return questions, please contact our Customer Service department at _____ or by email at
reply-eu@appliedmedical.com

For regulatory questions, please contact me, Monique Albinus at +31 33 4798055 or by email at malbinus@appliedmedical.com or RA-QA@appliedmedical.com

Sincerely,

Monique Albinus
European Regulatory Affairs & Quality Assurance Manager
Applied Medical Europe BV

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Customer Recall Notification CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND SEND TO:

Email: reply-eu@appliedmedical.com

Applied Medical "Sold To" Account Number: XXXXX

Applied Medical "Ship To" Account Number: XXXXX

INFORMATION FOR CUSTOMER FACILITY RESPONDING TO RECALL:

Hospital Name: _____

Hospital 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.)

Quantity of units being returned from lot 1231562: _____

INFORMATION ABOUT INDIVIDUAL COMPLETING THIS FORM:

Name : _____

Title: _____

Date: _____

Telephone: _____

Fax: _____

Email: _____

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Product Return Instructions

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

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

Please include a copy of the filled out Field Safety Notice Confirmation Form (along with your returned product).

If you have questions about the Field Safety Notice Confirmation Form or how to return the product, please contact our Customer Service Department at:

Telephone number: _____
Email address: reply-eu@appliedmedical.com

If you have any regulatory questions, please contact:

Monique Albinus
European Regulatory Affairs & Quality Assurance Manager
Telephone: +31 (0) 33 4798055
Email: malbinus@appliedmedical.com **or** RA-QA@appliedmedical.com