URGENT:
MEDICAL DEVICE RECALL

December XX, 2018

Customer Name
Address 1
City, State Zip
Attn:

Dear Valued Customer:

Applied Medical is conducting a voluntary recall on specific lot numbers of the **Epix® Electrosurgical Probe with Smoke Evacuation, Angled L-Hook Tip**. This voluntary recall is being conducted due to the possibility that the insulation near the device tip may unintentionally shift. 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 CW002 Epix Electrosurgical Probes with Smoke Evacuation, Angled L-Hook Tip purchased from the lots listed below should be returned to Applied Medical.**

Model	Description	Affected Lots
CW002	5mm x 42cm Epix Electrosurgical Probe with Smoke Evacuation, Angled L-Hook Tip	1336418, 1340206

Our records indicate that you have received units or kits from the affected lots. 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 and indicate if your facility is returning or has already used units or kits from the lots listed above.
    - If no product is being returned, please indicate that on the Recall Notification Confirmation Form **(Page 2)**.
- Provide a no-charge P.O number if replacement units or kits are requested.
- If you are a distributor, please notify any facilities to which you distributed units or kits from the affected lots. Please also complete **Page 3** of the Recall Notification Confirmation Form.
- Return the completed 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 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-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

Manager Quality & Regulatory Affairs
Applied Medical Europe B.V.

Applied Medical Europe B.V.
Wiekenweg 21, 3815 KL Amersfoort, The Netherlands
Tel. +31 (0)33 422 90 40 CustomerRelations-nl@appliedmedical.com
BTW N° NL815780382B01• KvK N° 32115550
IBAN NL37 ABNA 0400 8198 99 • Swift ABNANL2A
Applied Medical Removal Report Number: **2027111-12/06/18-001R**

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PLEASE COMPLETE THIS FORM AND SEND TO:

Email:Reply-Europe@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: _____

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	Quantity of Units Being Returned
CW002	1336418	
CW002	1340206	

Please select credit or replacement: **Credit** ☐ **Replacement** ☐

If requesting replacement product, please include the No-Charge P.O.# _____

Please note:

1. Customers who purchased directly from Applied Medical will receive replacement product or a 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: _____ Title: _____

Date: _____ Telephone: _____ Fax: _____

Email: _____

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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

Applied Medical Europe B.V.
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Product Return Instructions

A pick-up of the recalled CW002 unit(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 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 Department
Phone: .....
Email: Reply-Europe@appliedmedical.com

If you have any regulatory questions, please contact:

Regulatory Department
Phone: +31 (0) 33422 90 40 – option 4
Email: RA-QA@appliedmedical.com