URGENT:
MEDICAL DEVICE RECALL

Customer Name
Hospital Name
Street Address
City, State, Zip Code

Affected Product: Epix® *latis*® Graspers

XX March 2020

Dear Valued Customer,

Applied Medical is conducting a voluntary recall of specific lot numbers of the Epix *latis* Grasper due to the potential for tissue to catch on a slightly protruding rivet on the distal end of the device, which may lead to tissue damage. Please note that not all devices in these lots are affected by this potential device defect. Applied has not received any reports of impairment or permanent injury related to tissue catching; however, 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 affected lots (see table) for models C4130 and C4140 of the Epix *latis* Graspers should be returned to Applied Medical.

Model/REF	Description	Lots
C4130	Epix *latis* Grasper 5mm x 35cm	1364578, 1366453, 1371249, 1373050, 1373248, 1373249, 1373255, 1373260, 1373261, 1373262, 1373263, 1377363, 1377364
C4140	Epix *latis* Grasper 5mm x 45cm	1366454, 1371261, 1371262, 1373051, 1373256, 1376369

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 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 the Distributor Recall Notification Confirmation Form (**Page 3**).
- Return the Customer Recall Notification Confirmation Form to Applied Medical by email at Reply-Europe@appliedmedical.com.
- Return affected product and a copy of the Customer Recall Notification Confirmation Form to Applied Medical. Product Return Instructions are on **Page 4**.

NOTE: If you are a distributor, please notify any facilities to which you distributed the affected product.

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 Customer Service at 0800 0347 333 or by email at Reply-Europe@appliedmedical.com.
- For regulatory questions, please contact Regulatory Affairs at +31 (0) 33422 90 40 (Option 4) or by email at RA-QA@appliedmedical.com.

Sincerely,

xxx
Applied Medical Europe B.V.

Applied Medical Europe B.V.
Wiekenweg 21, 3815 KL Amersfoort, The Netherlands
Tel: 0800 0200 144 Email: CustomerRelations-NL@appliedmedical.com
BTW Nº NL818557163B01 KvK Nº 32127003

URGENT:
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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

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

Collection of the recalled C4130 and C4140 Epix *latis* Graspers will be arranged by our Customer Service team after receipt of the Customer Recall Notification Confirmation Form.

Please write the provided RGA Number on the outside of the package.

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

If you have questions about the Customer Recall Notification Confirmation Form or how to return product, please contact the Customer Services team at:

Telephone: 0800 0347 333
Email: Reply-Europe@appliedmedical.com

If you have any regulatory questions, please contact:

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

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