URGENT:
FIELD SAFETY NOTICE

Applied Medical
A New Generation Medical Device Company

September 4th, 2017

Customer Name
Address
City, Postal Code
Attn:

Dear Valued Customer:

Applied Medical is conducting a voluntary recall of specific lots of the Kii® trocar model, CTR14 Kii 5x55mm Optical Z-Thread Dual Pack. During shipment, the trocar packaging has the potential to become punctured with small holes, which would compromise the sterile barrier. The likelihood of this situation to occur and result in patient harm is highly unlikely; 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 CTR14 trocars from the lots listed below should be returned to Applied Medical.**

Model	Description	Lots
CTR14	5x55mm Kii Optical Z-Thread Dual Pack	1269694, 1275188, 1279039, 1283226, and 1287785

Our records indicate that you have received units 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 the lots listed above.
    - If no product is being returned, please indicate on the Recall Notification Confirmation Form **(Page 2)**.
- Provide a no-charge PO number if replacements are requested.
- 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 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 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 8766 882** 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 B.V.

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Customer and Distributor 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: _____
_____

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 fill out 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.)

Lot Number	Qty of Units Being Returned
1269694	
1275188	
1279039	
1283226	
1287785	

Please note:
1. Customers who purchased directly from Applied Medical will receive a credit when product is returned. If you would like a replacement please contact our Customer Service department at **0800 8766 882**.
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:
E-mail: reply-eu@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 FSCA?	Date this facility was notified of FSCA

Applied Medical UK Ltd.
88 Wood Street - 10th-15th floor - EC2V 7RS - London
Tel: 0800 8766 882 - CustomerRelations-uk@appliedmedical.com
VAT N° GB 905 6212 47 - Companies House 6126148
Account N. 20020571 – Sort Code 406252 - IBAN GB46 FTSB 4062 5220 0205 71 - Swift FTSBGB2L

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Product Return Instructions

A pick-up of the recalled Kii® trocar models 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 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: 0800 8766 882
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