

URGENT: MEDICAL DEVICE RECALL



Ikon Med PTE Ltd
203 Henderson Rd #11-03 Wing A
Singapore 159546
Attn: Alma Ditablan

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:

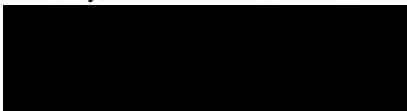
- Check your inventory for recalled product.
- Complete the attached Customer and Distributor Recall Notification Confirmation Form (Page 2) to acknowledge the recall and indicate if your facility is returning or has already used the lots listed above.
 - If no product is being returned, please indicate on the Customer and Distributor 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 the Distributor Recall Notification Confirmation Form (Page 3).
- Return the Recall Notification Confirmation Form to Applied Medical by emailing to recall60738625@appliedmedical.com or faxing to **(949) 713-8847**.
- Return affected product and a copy of the Recall Notification Confirmation Form to Applied Medical (Product Return Instructions are on **Page 4**).

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

For product return questions, please contact Karen Mitchell, Associate Manager Sales Operations, RGA Dept. at [\(949\) 713-8622](tel:9497138622) or kmitchell@appliedmedical.com.

For regulatory questions, please contact me, Lauren Contursi, at [\(949\) 713-8767](tel:9497138767) or lcontursi@appliedmedical.com.

Sincerely,



Lauren Contursi
Vice President, Regulatory Affairs
Applied Medical

2606AL0817

22872 Avenida Empresa ▲ Rancho Santa Margarita, CA 92688 ▲ Tel 949.713.8000 ▲ Fax 949.713.8200 ▲ www.appliedmedical.com
Applied Medical Removal Report Number: **2027111-031816-01R**

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Customer and Distributor Recall Notification CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND SEND TO:
Email: recall60738625@appliedmedical.com or Fax: (949) 713-8847
Applied Medical "Sold To" Account Number: 1009131
Applied Medical "Ship To" Account Number: 2006007

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 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.)

Model Number	Lot Number	Qty of Units Being Returned
CTR14	1269694	
CTR14	1275188	
CTR14	1279039	
CTR14	1283226	
CTR14	1287785	

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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Product Return Instructions

Please return the recalled CTR14 Trocar(s) to the following address:

Applied Medical
ATTN: RGA# 60738625
9401 Toledo Way
Irvine, CA 92618

Please write **RGA# 60738625** on the outside of the package.

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

Product may be returned using:

UPS Account #889737

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

Karen Mitchell
Associate Manager Sales Operations, RGA Dept.
Phone: (949) 713-8622
Email: kmitchell@appliedmedical.com

If you have any regulatory questions, please contact:

Lauren Contursi
Vice President, Regulatory Affairs
Phone: (949) 713-8767
Email: lcontursi@appliedmedical.com

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