URGENT:
MEDICAL DEVICE RECALL

October 28, 2013

Dear Valued Customer:

Applied Medical is conducting a voluntary recall of the Inzii® 12/15mm retrieval system. During shipment, the retrieval system packaging has the potential to become punctured with small holes, which could 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 has decided to recall all potentially affected units.

The model number affected is **CD004**. The complete list of affected lot numbers is located on **Page 5**.

Our records indicate that you have received 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 Recall Notification Confirmation Form **(Page 2)** to acknowledge the recall and indicate if your facility is returning or has already used any of these products.
- 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 confirmation form(s) to Applied Medical by emailing to **reply-eu@appliedmedical.com** or faxing to +31 33 4229049.
- Return affected product and a copy of the confirmation form(s) 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 our Customer Service Department at +31 33 7517776 or by e-mail at **reply-eu@appliedmedical.com** .

For regulatory questions, please contact me, Monique Albinus, at +31 (0) 33 4798055 or by e-mail at malbinus@appliedmedical.com.

Sincerely,

Monique Albinus
European Regulatory Affairs & QA Manager
Applied Medical

Applied Medical Removal Report Number: **2027111-10/10/2013-003R**

Applied Medical Distribution Europe BV - Wiekenweg 21 - 3815 KL -Amersfoort -The Netherlands
T: +31 33 7517776, F: +31 33 4229049 E : international-eu@appliedmedical.com
Skype: AppliedMedicalEurope
BTW N°: NL818557163B01 - KvK N°: 32127003
IBAN: NL37 ABNA 0400 8198 99 - Swift: ABNANL2A

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Customer and Distributor Recall Notification CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND SEND TO:
E-mail: reply-eu@appliedmedical.com or Fax: +31 33 4229049

Applied Medical "Sold To" Account Number:
Applied Medical "Ship To" Account Number:

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 4:

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

If you have unit(s) to return, you will receive a credit note upon receipt of the product.
Please select "New Order" if you would like to receive new unit(s): New order ☐
In the case of a new order this will be invoiced at the current price.
Indicate your PO# here in case of a new order _____

Please note: Customers who received recalled product from a distributor other than Applied Medical may either:
1. Request replacement product through Applied Medical by returning recalled product directly to Applied; OR,
2. 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:** _____

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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 or Fax: +31 33 4229049

(If you are not a distributor, please disregard this form.)

Information about Distributor's Units Sent to Other Distribution Centers and/or Other Customers:

Model Number	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

Please include additional pages as necessary.

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Product Return Instructions

A pick-up of the recalled Inzii 12/15mm retrieval systems units will be arranged by our Customer Service team after receiving the Recall Notification 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 Recall Notification Confirmation Form(s) along with your returned product.

If you have questions about the Recall Notification Confirmation Forms or how to return the product, please contact our **Customer Service Department** at:

Telephone number: +31 33 7517776

Email: reply-eu@appliedmedical.com

If you have any regulatory questions, please contact:

Monique Albinus
European Regulatory Affairs & QA Manager
Phone: +31 (0) 33 4798055
Email: malbinus@appliedmedical.com

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List of Model and Lot Numbers Being Recalled

Our shipping records indicate YOU HAVE RECEIVED one or more of the following lots of affected Inzii 12/15mm retrieval systems. Please complete the attached confirmation form and return any product listed below that you have in your facility.

MODEL NUMBERS	LOT NUMBERS
CD004- Inzii 12/15mm Retrieval System	1161268, 1161269, 1164934, 1168358, 1168361, 1169317, 1169318, 1170694, 1170700, 1170701, 1171214, 1172482, 1172664, 1174287, 1174793, 1174857, 1175123, 1175280, 1175472, 1176555, 1177023, 1177871, 1179069, 1179392, 1179460, 1179775, 1179890, 1180291, 1180411, 1180576, 1181647, 1181648, 1181649, 1181939, 1182760, 1182934, 1183225, 1183823, 1183957, 1184273, 1184728, 1184915, 1184916, 1187779, 1188817, 1189117, 1189957, 1190294, 1190358, 1191208, 1192057, 1192969, 1193196, 1193661, 1194010, 1194666, 1194807, 1195518, 1195727, 1195997, 1197182, 1197404, 1197832, 1198055, 1198968, 1199899, 1200658, 1200828, 1200829, 1200830, 1201739, 1201740, 1201741, 1203154, 1204054

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