URGENT:
FIELD SAFETY NOTICE

March 30, 2016

Customer Name
Address 1
Address 2
City, Postal code

Dear Valued Customer,

Applied Medical is conducting a voluntary Field Safety Corrective Action (FSCA) of the CA090 Direct Drive® Clip Applier due to increased customer feedback indicating inconsistent clip application. Although malformed clips are typically readily apparent to the user, this failure mode may lead to unoccluded vessels. We regret this disruption in supply, yet believe that this is in the best interest of our customers. Regaining consistency with our high quality standards remains our highest priority, and our commitment to the clip applier market is unwavering. **All CA090 Direct Drive Clip Appliers with an expiration date prior to March 18, 2019 should be returned to Applied Medical.**

The model number affected is **CA090**, as well as all applicable kits containing CA090 (see **Pages 5** for a complete list of kit models). The lots affected **range from 1190181 to 1265006.**

Our records indicate that you have received units from the affected lots. For FSCA effectiveness we ask that you please complete the following actions:

- Check your inventory for recalled product.
- Complete the attached Field Safety Notice Confirmation Form **(Page 2)** to acknowledge the FSCA 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 Field Safety Notice Confirmation Form.
- Return the Field Safety Notice Confirmation Form to Applied Medical by emailing to reply-eu@appliedmedical.com.
- Return affected product and a copy of the Field Safety Notice 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. Relevant National Competent Authorities are being advised of the FSCA.

For product return questions, please contact our Customer Service department at _____ 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

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Customer and Distributor FIELD SAFETY NOTICE 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 FSCA:

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 FSCA:

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

Please note:
1. Customers who purchased directly from Applied Medical will receive 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 FIELD SAFETY NOTICE 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

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Product Return Instructions

A pick-up of the recalled CA090 Direct Drive Clip Applier(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 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: _____
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

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List of CA090 Lot Numbers Being Recalled

Our shipping records indicate YOU HAVE RECEIVED one or more of the following lots of affected Direct Drive Clip Appliers and/or kits containing product code CA090. Please complete the attached confirmation form and return any product listed below that you have in your facility with an expiration date prior to March 18, 2019.

Product Code	Product Description	Affected Lots
CA090	10mm Direct Drive Clip Applier	1190181 to 1265006
Kit Product Codes		
CK302	GK235	GK226
CK378	GK236	GK227
CK391	GK237	GK232
CK399	GK238	GK233
GK102-H	GK240	GK334
GK104-H	GK242	GK335
GK105	GK244	Any Custom kits containing CA090
GK107	GK245	
GK109-H	GK248	
GK113	GK249	
GK115	GK250	
GK128	GK251	
GK129	GK253	
GK135	GK257	
GK149	GK262	
GK201	GK264	
GK202	GK265	
GK203	GK268	
GK204	GK279	
GK205	GK280	
GK206	GK288	
GK207	GK290	
GK208	GK304	
GK209	GK306	
GK210	GK307	
GK217	GK311	
GK219	GK312	
GK220	GK316	
GK221	GK317	
GK222	GK318	
GK223	GK323	