URGENT:

MEDICAL DEVICE RECALL

April 5, 2016

Ikon Medical PTE Ltd
203 Henderson Rd, #11-03 Wing A
Singapore 159546
Singapore

Dear Valued Customer:

Applied Medical is conducting a voluntary recall 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 to 7** 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 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 Recall Notification Confirmation Form to Applied Medical by emailing to recall60698158@appliedmedical.com or faxing to (949) 713-8921.
- 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, Sales Operations Supervisor, RGA Dept. at (949) 713-8622 or by email at kmitchell@appliedmedical.com.

For regulatory questions, please contact me, Lauren Contursi, at (949) 713-8767 or by email at lcontursi@appliedmedical.com.

Sincerely,

[redacted]

Lauren Contursi
Director, Regulatory Affairs
Applied Medical

Applied Medical Removal Report Number: **2027111-031816-01R**

22872 Avenida Empresa ▲ Rancho Santa Margarita, CA 92688 ▲ Tel 949.713.8000 ▲ Fax 949.713.8200 ▲ www.appliedmedical.com

URGENT:

MEDICAL DEVICE RECALL

Customer and Distributor
Recall Notification
CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND SEND TO:
Email: recall60698158@appliedmedical.com or Fax: (949) 713-8921

Applied Medical "Sold To" Account Number: 1009131

Applied Medical "Ship To" Account Number: 1009131

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

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 Recall Notification
CONFIRMATION FORM

IF YOU ARE A DISTRIBUTOR, PLEASE ALSO COMPLETE THIS FORM AND SEND TO:
E-mail: recall60698158@appliedmedical.com or Fax: 949-713- 8921

(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

Please return the recalled Direct Drive Clip Applier(s) to the following address:

Applied Medical
ATTN: RGA# 60698158
9401 Toledo Way
Irvine, CA 92618

Please write **RGA# 60698158** 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
Sales Operations Supervisor, RGA Dept.
Phone: (949) 713-8622
Email: kmitchell@appliedmedical.com

If you have any regulatory questions, please contact:

Lauren Contursi
Director, Regulatory Affairs
Phone: (949) 713-8767
Email: lcontursi@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	GK221	GK290
CK378	GK222	GK304
CK391	GK223	GK306
CK399	GK226	GK307
GK102-H	GK227	GK311
GK104-H	GK232	GK312
GK105	GK233	GK316
GK107	GK235	GK317
GK109-H	GK236	GK318
GK113	GK237	GK323
GK115	GK238	GK334
GK128	GK240	GK335
GK129	GK242	K0312
GK135	GK244	K0456
GK149	GK245	K0477
GK201	GK248	K0491
GK202	GK249	K0509
GK203	GK250	K0522
GK204	GK251	K0588
GK205	GK253	K0592
GK206	GK257	K0640
GK207	GK262	K0646
GK208	GK264	K0651
GK209	GK265	K0687
GK210	GK268	K0693
GK217	GK279	K0694
GK219	GK280	K0713
GK220	GK288	K0722

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K0724	K2357	K2569
K0748	K2363	K2574
K0750	K2367	K2587
K0762	K2368	K2590
K0779	K2369	K2591
K0780	K2370	K2592
K0896	K2371	K2607
K0901	K2372	K2613
K0903	K2383	K2619
K2113	K2387	K2634
K2114	K2394	K2640
K2136	K2399	K2654
K2150	K2401	K2656
K2154	K2402	K2664
K2155	K2403	K2673
K2179	K2405	K2680
K2184	K2406	K2687
K2191	K2408	K2691
K2200	K2421	K2703
K2202	K2423	K2704
K2203	K2424	K2705
K2207	K2426	K2706
K2209	K2427	K2707
K2212	K2431	K2710
K2214	K2437	K2711
K2253	K2438	K2713
K2255	K2439	K2716
K2265	K2449	K2731
K2269	K2476	K2732
K2282	K2477	K2733
K2285	K2478	K2735
K2290	K2482	K2737
K2308	K2484	K2738
K2329	K2485	K2741
K2330	K2492	K2751
K2332	K2495	K2756
K2334	K2502	K2760
K2345	K2503	K2762
K2348	K2552	K2765
K2355	K2568	K2773

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K2781
K2782
K2790
K2794
K2795
K2804
K2805
K2806
K2815
K2818
K2819
K2820
K2823
K2825
K2831
K2842
K2856
K2858
K2872
K2879
K2883

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