URGENT
MEDICAL DEVICE RECALL

NOVEMBER XX, 2019

Customer Name
Address 1
City, State Zip
Attn:

Dear Valued Customer:

Applied Medical is conducting a voluntary Class II recall on specific lots of its Python® Catheters, BARD Latex-free Arterial Embolectomy Catheters, and Over-the-Wire *latis*® Graft Cleaning Catheters. This recall is due to reported issues of tip separation during usage of these devices; therefore, using these devices may expose patients to unintended dislodgement of the tip from the body of the device. Applied has not received any reports of impairment or permanent injury related to tip separation; 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.

The model numbers affected include: A4EXX, A4GW6 and CE0XXXDR. A complete list of the affected model and lot numbers are located on **Page 2**.

Our records indicate that you have received units from one or more of the affected lots. For recall effectiveness, we ask that you please complete the following actions:

- Check your inventory for the recalled product.
- Complete the attached Recall Notification Confirmation Form **(Page 3)** to acknowledge the recall and indicate if your facility is returning or has already used product from the lot listed above.
    - If no product is being returned, please indicate on the Recall Notification Confirmation Form **(Page 3)**.
- If you are a distributor, please notify any facilities to which you distributed the affected product. Please also complete **Page 4** of the Recall Notification Confirmation Form.
- Return the Recall Notification Confirmation Form to Applied Medical by emailing it to: **Reply-Europe@appliedmedical.com** .
- Return affected product and a copy of the Recall Notification Confirmation Form to Applied Medical (Product Return Instructions are on **Page 5**).

Applied Medical will ensure that the appropriate Regulatory Agencies have been notified

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 _____ or by email at Reply-Europe@appliedmedical.com

For regulatory questions, please contact the Regulatory Department at +31 (0) 33422 90 40 (option 4) or by email at: RA-QA@appliedmedical.com

Sincerely,

Dolf Bouma
Director Quality and Regulatory Affairs
Applied Medical Europe BV

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List of Models and Lot Numbers Being Recalled

Our shipping records indicate YOU HAVE RECEIVED one or more of the following lots of affected Vascular Catheters. Please complete the attached confirmation form and return any product listed below that you have in your facility.

Model Numbers	Lot Numbers
A4E01, PYTHON 5MM-40CM	1259463, 1268371, 1274343, 1281314, 1288397, 1291497, 1302766, 1305919, 1312958, 1317578, 1319209, 1324383, 1326383, 1333050, 1338309, 1339544
A4E02, PYTHON 5MM-80CM	1257416, 1268372, 1281315, 1283401, 1293028, 1294897, 1303013, 1305920, 1317579, 1319807, 1324384, 1331435, 1332003, 1338732, 1339490
A4E03, PYTHON 9MM-40CM	1256874, 1263093, 1269005, 1276315, 1281787, 1287079, 1298430, 1303017, 1308139, 1319211, 1330447, 1331896, 1333407, 1337644, 1341362
A4E04, PYTHON 9MM-80CM	1255539, 1262756, 1269004, 1276316, 1281786, 1288847, 1293169, 1299257, 1303808, 1312595, 1319212, 1321387, 1325381, 1331884, 1332592, 1337686, 1339491
A4E05, PYTHON 11MM-40CM	1263092, 1268170, 1273184, 1278603, 1283650, 1288347, 1292823, 1296020, 1299013, 1305922, 1310451, 1318835, 1320036, 1323535, 1325777, 1330446, 1331328, 1337641, 1339492
A4E06, PYTHON 11MM-80CM	1261855, 1268451, 1276317, 1284924, 1290454, 1298079, 1305921, 1310623, 1320183, 1323280, 1330449, 1332579, 1337652, 1339493
A4E08, PYTHON 13MM-80CM	1252636, 1259464, 1263484, 1265630, 1266989, 1267854, 1268688, 1276314, 1281784, 1283399, 1287076, 1290936, 1294898, 1303211, 1306288, 1308127, 1312957, 1315919, 1317577, 1319637, 1320236, 1324382, 1332433, 1335657, 1339494
A4E09, PYTHON 14MM-80CM	1260019, 1273374, 1281783, 1283770, 1295466, 1299012, 1305368, 1317203, 1317876, 1319210, 1324390, 1330448, 1332593, 1337653, 1339495
A4GW6, LATIS DUAL LUMEN, 9MM-60CM	1267676, 1272322, 1284680, 1295323, 1306127, 1312586, 1330450, 1334826, 1338738, 1339555
CE0340DR, BARD CATHETER	1276248, 1283930, 1284935, 1286527, 1295731, 1317372, 1326198
CE0380DR, BARD CATHETER	1253338, 1260036, 1263505, 1268151, 1276218, 1283938, 1289018, 1299712, 1301797, 1308727, 1312145, 1314562, 1324334, 1335171
CE0440DR, BARD CATHETER	1286829
CE0480DR, BARD CATHETER	1263515, 1268153, 1276227, 1283943, 1284950, 1289021, 1293173, 1299711, 1301798, 1308737, 1312147, 1312986, 1318084, 1325785
CE0540DR, BARD CATHETER	1284054, 1284951, 1328361
CE0580DR, BARD CATHETER	1255414, 1263517, 1276230, 1283948, 1286831, 1289126, 1295732, 1301799, 1308735, 1317737, 1318091, 1325790, 1335172
CE0680DR, BARD CATHETER	1250869, 1260041, 1268157, 1276234, 1283950, 1284954, 1289024, 1295730, 1303736, 1308740, 1314577, 1318092, 1324358

Applied Medical Distribution Europe B.V. Irish Branch
5th floor, Beaux Lane House, Mercer Street Lower, Dublin 2
Tel. 1800 948 859 CustomerRelations-ie@appliedmedical.com
VAT N° IE 2974611LH • Company Registration Number 32127003
IBAN NL98 ABNA 0528 6975 87 • Swift ABNANL2A

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Customer and Distributor Recall Notification CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND SEND TO:
Email: Reply-Europe@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 complete 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

Please note:
1. Customers who purchased directly from Applied Medical will receive 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: Reply-Europe@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 recall?	Date this facility was notified of recall

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Product Return Instructions

A pick-up of the recalled unit(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 completed Recall Notification Confirmation Form(s) with your returned product.

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

Customer Service Department
Phone: .....
Email: Reply-Europe@appliedmedical.com

If you have any regulatory questions, please contact:

Regulatory Department
Phone: +31 (0) 33422 90 40 – option 4
Email: RA-QA@appliedmedical.com

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