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**Contact Category**
☒ Initial Contact
☐ 2nd Contact
☐ 3rd Contact

62091
Kimal Distribution Center
Unit 401 Pointon Way
Droitwich Spa
WR9 0WL
GB

# URGENT VOLUNTARY MEDICAL DEVICE RECALL

# IMMEDIATE ACTION REQUIRED

## XCELA™ PICC WITH PASV™ VALVE TECHNOLOGY
## BIOFLO PICC WITH ENDEXO TECHNOLOGY
## BIOFLO PICC WITH ENDEXO AND PASV™ VALVE TECHNOLOGY

November 28, 2016

Attention: Risk Management Department

Navilyst Medical, Inc. (an AngioDynamics Company), the manufacturer of the Xcela PICC with PASV, BioFlo PICC with PASV and the BioFlo PICC, is conducting a medical device recall to the end user level based on information received from Greatbatch Medical, the manufacturer of the ViaPeel PTFE Peelable Introducer. Greatbatch Medical has determined that the products listed in their November 11, 2016 Recall Notification have the potential for the handles to detach from the sheath during use. Navilyst Medical has confirmed that the affected sheaths, Greatbatch Model Number 10890-006, have been included in packaged Xcela and BioFlo PICC Kits.

Our records indicate that your health care facility has received one or more of the Navilyst products that contain the Greatbatch Peelable Introducers subject to this Greatbatch recall.

Use of the Greatbatch Peelable Introducers that are subject to this recall may result in user dissatisfaction or prolonged procedure, or, if both handles detach, the sheath tube could migrate into the patient leading to an unplanned surgical intervention for removal. Navilyst Medical has received several complaints from users, but to date, there have been no reports of patient injuries (MDRs) as a result of this issue.

Navilyst Medical began distributing product affected by this recall on July 13, 2015.

Please refer to the Reply Verification Tracking Form, included with this Recall Notification, for the details on the affected product provided to your specific organization. (Product Descriptions, Product Numbers, Ref./Catalog Numbers, Lot/Batch Numbers, Quantity Shipped, Date Shipped, and Sales Order Number).

NOTE: The Ref./Catalog numbers and lot/batch numbers are located on the labeling.

**1. Actions to be taken:**

- IMMEDIATELY
    - Stop using the product subject to recall.
    - Immediately remove any affected (recalled) product from your inventory (whether in Inventory, Hold Cage, Unprocessed Returns or ANY other location).

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- Segregate this product in a secure location for return to AngioDynamics, Inc.
- Forward a copy of this recall notification to all sites to which you have distributed affected product.

**2. Complete and return the Reply Verification Tracking Form.**

- If affected product is located in your institution, please call AngioDynamics Customer Service at 1-800-772-6446 between 8:00 a.m. and 7:00 p.m. (Monday – Friday: Eastern Standard Time) to obtain a replacement or credit for your returned product.
- Promptly complete, sign and return the enclosed Reply Verification Tracking Form (even if you do not have any product to return); following the directions on this page and the Reply Verification Tracking Form.

  □ Email Reply Verification Tracking Form (preferred): **recall@angiodynamics.com**
  □ Fax Reply Verification Tracking Form:
  Attn: ViaPeel Recall Coordinator
  Fax number 1-800-782-1357

**3. Package and Return the Recalled Product.**

- Package any product that is being returned in an appropriate shipping box.
- Write the RMA number on the RMA/Address label (provided on the Recall Verification Tracking Form) and affix the label to the outside of the shipping box.
- Please use our FedEx Account Number (284750594) to return this package via second day delivery.
- Seal the box and return to:

  AngioDynamics, Inc.
  603 Queensbury Avenue
  Queensbury, NY 12804
  Attn: ViaPeel Recall Coordinator

We regret any inconvenience that this action may have caused and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from AngioDynamics, Inc. This medical device recall action is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Sincerely,

[redacted]

Gary Barrett
Senior Vice President, Quality and Regulatory Affairs
Tel: 1-508-658-7940 Fax: 1-800-782-1357

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CUSTOMER ACCOUNT NO: 62091
KIMAL DISTRIBUTION CENTER
UNIT 401 POINTON WAY

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☐ 3rd Contact

# Reply Verification Tracking Form

**XCELA™ PICC WITH PASV™ VALVE TECHNOLOGY**
**BIOFLO PICC ENDEXO TECHNOLOGY**
**BIOFLO PICC WITH ENDEXO AND PASV™ VALVE TECHNOLOGY**

November 28, 2016

Instructions: Complete, Sign and Return:
Attn: ViaPeel Recall Coordinator
Email: recall@angiodynamics.com
Fax: **1-800-782-1357**
Rocco Denino - Phone: 518-795-1358 or Tonya Markham - Phone: 518-795-1116
Return Products via FedEx (Account #284750594 two day delivery) to:
AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury, NY 12804
Attn: ViaPeel Recall Coordinator

Note: Only products/lots identified below are affected by this recall action.

| Product Description | Product No.: | Ref./ Catalog No.: | Batch/ Lot No. | Qty Shipped | Date Shipped | Sales Order Number | Qty to be Returned |
|---|---|---|---|---|---|---|---|
| Bio-Stable 5F DL-55CM IR-145 Kit Valved PG | H965458330 | 45-833 | 4907223 | 5 | 8/27/15 | 5026080 | |
| Bio-Stable 5F DL 55CM MST-70 Kit Valved with Nitinol Guidewire PG | H965458890 | 45-889 | 4913255 | 16 | 8/31/15 | 5026575 | |

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☐ We do NOT have any affected product

☐ We have found affected product and are returning the quantity (eaches) indicated above

**Return Authorization Number: 87VIA128 Product Return Date: _____**

☐ Affected product was redistributed to another facility to which **we have forwarded a copy** of this Recall Notification.

**Name of facility / Contact: _____**

**Address: _____**

**Telephone Number: _____ Fax Number: _____**

☐ We have not received any complaints of adverse effects associated with the use of the product.

If so, please provide details to AngioDynamics as soon as possible.

To ensure regulatory compliance, please be certain to complete this form in its entirety.

Print Contact Name: _____ Title: _____

Facility Name: _____ Department: _____

Telephone #: ____ -____ -_____ Fax #: ____ - ____ - _____ E-Mail: _____

Contact Signature: _____ Date: _____