Navilyst Medical

26 Forest Street
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Contact Category
☐ Initial Contact
☒ 2nd Contact
☐ 3rd Contact

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Somnotec (S) Pte Ltd
Kaki Bukit Rd 2
#04-07 Eunos Warehouse Complex 417835
SG

URGENT VOLUNTARY MEDICAL DEVICE RECALL

IMMEDIATE ACTION REQUIRED

XCELA™ PICC WITH PASV™ VALVE TECHNOLOGY/KITS
BIOFLO PICC WITH ENDEXO AND PASV™ VALVE TECHNOLOGY/KITS

February 2, 2015

Attention: Risk Management Department:

Navilyst Medical, Inc. (an AngioDynamics Company), the manufacturer of Xcela™ PICC w/PASV and the BioFlo PICC w/ Endexo and PASV is conducting a medical device recall on specific lots of power injectable PICC catheters. Navilyst Medical is recalling PICC catheters that contain valve(s) manufactured prior to October 9, 2013. Valves manufactured after this date incorporate a manufacturing specification change that reduces the incidence of hemolysis during blood sampling through the PICC catheter. Use of the PICC catheters that are subject to this recall may have an increased incidence of hemolyzed blood samples which may require additional peripheral access or replacement of the PICC catheter.

Our records indicate that your health care facility has received one or more of the products subject to this recall. 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 both the lid sealed tray/pouch label and box label. No other products/lots are affected.

To date, no patient injuries have been reported to Navilyst Medical as a result of this issue. This recall will need to be carried out to the end user level.

1. **Actions to be taken:**
   - Immediately remove the recall product from your inventory (whether in labs, Central Supply, Shipping and Receiving or ANY other location).
   - Segregate this product in a secure location for return to Navilyst Medical.
   - Immediately 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.**

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- If affected product is located in your institution, please call Navilyst Medical 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.

  □ Fax Reply Verification Tracking Form:
  Attn: PASV Valve Recall Coordinator
  Fax number 1-800-782-1357

  ☑ Email Reply Verification Tracking Form:
  rdenino@angiodynamics.com or sbaxter@angiodynamics.com

3. **Package and Return the Recalled Product.**
   - Package any product that is being returned in an appropriate shipping box.
   - Affix enclosed shipping label to the outside of the shipping box.
   - Please use our UPS Account Number (F021E0) to return this package via second day delivery.
   - Write the RMA number on the box. (Provided on the Recall Verification Tracking Form)
   - Seal the box and return to:

     Navilyst Medical, Inc. (An AngioDynamics Company)
     603 Queensbury Avenue
     Queensbury, NY 12804
     Attn: PASV Valve 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 Navilyst Medical. This medical device recall action is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Sincerely,

[redacted]

Michael Duerr
Director Corporate Compliance
Tel: 1-518-742-4571
Fax: 1-800-782-1357