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310071
SISK HEALTHCARE T A SYNAPSE MEDICAL
Main Stores UNIT 1D
Dublin 9, IE 0

URGENT MEDICAL DEVICE RECALL – IMMEDIATE ACTION REQUIRED

UNI*FUSE™ INFUSION SYSTEM WITH COOPER WIRE™

August 6, 2014

Attention: Risk Management Department:

AngioDynamics Inc., the manufacturer of Uni*Fuse™ Infusion Systems, is notifying you that certain kits/lots of 90cm Uni*Fuse™ Infusion System with Cooper Wire™ have been packaged with an incorrect occlusion wire. The occlusion wires provided with the affected products are not the appropriate length (too long) and will not properly connect to the proximal fitting of the catheter with the distal tip occluded. To date, no patient injuries have been reported as a result of this issue.

As a result, AngioDynamics is recalling a specific number of product/lot numbers of 90cm Uni*Fuse™ Infusion Systems with Cooper Wire™.

The specifics about the scope of this notification are identified in the table below. No other products/lots are affected. The Ref./Catalog number and lot number are located on both the inner pouch and box label.

Uni*Fuse™ Infusion System with Cooper Wire™			
Product Description:	Product No.:	Ref./Catalog No.:	Batch/Lot No.:
5F x 90cm x 10cm	H787124018065	12401806	4731639
5F x 90cm x 30cm	H787124018085	12401808	4731641
5F x 90cm x 40cm	H787124018095	12401809	4762513

Our records indicate that your health care facility has received one or more of these affected products.

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 AngioDynamics, Inc.
   - 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.**
   - If affected product is located in your institution, please call AngioDynamics, Inc. 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 Form.

  □ Fax Reply Verification Tracking Form:
  Attn: Uni*Fuse™ Infusion System with Cooper Wire™ Recall Coordinator
  Fax number 1-800-782-1357
  □ Email Reply Verification Tracking Form:
  rdenino@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:

  AngioDynamics, Inc.
  603 Queensbury Avenue
  Queensbury, NY 12804
  Attn: Uni*Fuse™ Infusion System with Cooper Wire™ 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,

_____

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

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Reply Verification Tracking Form

UNI*FUSE™ INFUSION SYSTEM WITH COOPER WIRE™

Instructions: Complete, Sign and Return:
Attn: UNI*FUSE™ INFUSION SYSTEM WITH COOPER WIRE™ Recall Coordinator
Fax: **1-800-782-1357**
Email: rdenino@angiodynamics.com
Rocco Denino – Phone: 518-795-1358

Note: Please Return Immediately Upon Completion
Only products/lots identified below are affected by this recall action.

Uni*Fuse™ Infusion System with Cooper Wire™							
Product Description:	Product No.:	Ref./ Catalog No.:	Batch/ Lot No.	Quantity Shipped	Date Shipped	Sales Order Number	Quantity to be returned
5F x 90cm x 30cm	H787124018085	12401808	4731641	2	31-May-14	5014502	

☐ We do NOT have any affected product
☐ We have found affected product and are returning the quantity (eaches) indicated above
Return Authorization Number: *87RU112* 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: _____