[redacted]

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

URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

ANGIODYNAMICS MINI STICK MAX COAXIAL MICROINTRODUCER KIT

January 30, 2024

Attention: Risk Management Department

AngioDynamics, Inc., is conducting a medical device Field Safety Corrective Action (FSCA) to the end user level based on the non-conformance of a supplied component included within the AngioDynamics Mini Stick Max Coaxial Microintroducer Kit. This non-conformance may prevent the guidewire from passing through the introducer hub during a surgical procedure. The inability of the guidewire to pass through the introducer is due to the presence of voids in the internal lumen of the sheath hub.

AngioDynamics became aware of this issue upon receipt of multiple reported complaints associated with the affected Mini Stick Max Kits. To date, AngioDynamics has not received reports of patient injury as a result of this issue. The potential risk of the non-conformance is a delay in procedure, wherein the user may need to exchange the sheath to complete the case.

AngioDynamics has confirmed that the Mini Stick Max kits affected by this FSCA were distributed globally to end-users. AngioDynamics began distributing the affected lots of Mini Stick Max Kits affected by this FSCA on June 13, 2023. Our records indicate that your health care facility has received one or more of the Mini Stick Max kits subject to this FSCA.

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

NOTE: The Ref./Catalog numbers and lot/batch numbers are located on the labeling of the Mini Stick Max Kits.

1. Actions to be taken:

- IMMEDIATELY
  - Stop using the product subject to FSCA.
  - Remove any affected (recalled) 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.
  - Forward a copy of this FSN 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: Mini Stick Max Recall Coordinator
Fax number 1-855-273-0519

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.
- Seal the box and return to:

AngioDynamics, Inc.
24 Native Drive
Queensbury, NY 12804
Attn: Mini Stick Max 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. Corrective actions have been implemented by AngioDynamics to prevent further distribution of affected product due to this issue. We are committed to continuing to offer products that meet the highest quality standards that you expect from AngioDynamics. This medical device FSCA (recall) action is being conducted with the knowledge of the appropriate regulatory agencies and the U.S. Food and Drug Administration (FDA).

Sincerely,

[redacted]

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

[redacted]

Contact Category

- ☒ Initial Contact
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REPLY VERIFICATION TRACKING FORM

URGENT VOLUNTARY MEDICAL DEVICE RECALL
IMMEDIATE ACTION REQUIRED

AngioDynamics Mini Stick Max Coaxial Microintroducer Kit

January 30, 2024

Instructions: Complete, Sign and Return
Attn: Mini Stick Max Recall Coordinator
E-mail (preferred): **recall@angiodynamics.com**
Fax: 1-855-273-0519
Rocco Denino - Phone: 518-795-1358 or Stefanie Petteys - Phone: 518-795-1657
Return Products via FedEx to:
AngioDynamics, Inc.
24 Native Drive
Queensbury, NY 12804
Attn: **Mini Stick Max Recall Coordinator**

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

Product Description:	Product No.:	UDI No.:	Ref./ Catalog No.:	Batch/ Lot No.:	Qty Shipped: (boxes)	Date Shipped:	Sales Order Number:	Qty to be Returned (ea):
MINI STICK MAX 4F X 10 CM STD .018 SS/PD ECHO 2.75" PG	H965457491	15051684022927	45-749	5805056	9	17-Nov-2023	41123881	
MINI STICK MAX 4F X 10 CM STD .018 SS/PD ECHO 2.75" PG	H965457491	15051684022927	45-749	5805056	9	11-Dec-2023	41141298	

[redacted]

Select all that apply and return to **recall@angiodynamics.com.**

☐ We do **NOT** have any affected product

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

Return Authorization Number: 87MSM0967 Product Return Date: _____

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

Name of facility / Contact: _____

Address: _____

Telephone Number: _____ Fax Number: _____

☐ We have received complaints of adverse effects associated with the use of the product.

If so, please provide details to AngioDynamics as soon as possible.
Report any injuries/illnesses associated with recalled devices to US FDA via MedWatch.

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

Print Contact Name: _____ Title: _____

Facility Name: _____ Department: _____

City and State: _____

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

Contact Signature: _____ Date: _____

[redacted]