Account #
Consignee Name
Consignee Address
City, Zip, Country

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

URGENT FIELD SAFETY NOTICE

URGENT VOLUNTARY MEDICAL DEVICE RECALL

IMMEDIATE ACTION REQUIRED

NANOKNIFE DISPOSABLE SINGLE ELECTRODE PROBES

April 24, 2020

Attention: Risk Management Department

AngioDynamics, Inc., is conducting a medical device recall to the end user level upon awareness that a specific batch of NanoKnife Disposable Single Electrode Probes was not programmed in accordance with specification. The programming affects the RFID function and does not allow the NanoKnife probes to be recognized by the NanoKnife generator. This issue is identified once the probe is connected to the generator, and prevents the generator from delivering energy to the affected probes.

Affected Product:

Product No. / DI :	Product Description:	Ref. / Catalog No.:	Batch / Lot No.:
H787204001030	15 cm IRE Single Electrode RFID Activation, Packaged Good	20400103	5577754

AngioDynamics has confirmed that the NanoKnife Disposable Single Electrode Probes affected by this recall have been distributed to end users. Our records indicate that your health care facility has received one or more of the devices subject to this recall.

AngioDynamics has received several complaints associated with the probes under recall; however, there have been no reports of patient injury as a result of this issue.

AngioDynamics began distributing product affected by this recall on February 26, 2020.

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 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.

1. Actions to be taken:

- IMMEDIATELY
  - Stop using the product subject torecall.
  - Remove any affected (recalled) product from your inventory (whether in labs, Central Supply, Shipping and Receiving or ANY otherlocation).
  - 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) toobtain a replacement or credit for your returned product.
- Promptly complete, sign, and return the enclosed Reply Verification Tracking Form (even if youdo 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: NK Probe 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.
- Seal the box and return to:

  AngioDynamics, Inc.
  24 Native Drive
  Queensbury, NY 12804
  Attn: NK Probe 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.

Sincerely,

……..

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Consignee Name
Consignee Address
City, Zip, Country

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REPLY VERIFICATION TRACKING FORM

URGENT VOLUNTARY MEDICAL DEVICE RECALL

IMMEDIATE ACTION REQUIRED

NANOKNIFE DISPOSABLE SINGLE ELECTRODE PROBE

April 24, 2020

Instructions: Complete, Sign and Return:

Attn: NK Probe Recall Coordinator

E-mail (preferred): **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 to:

AngioDynamics, Inc.
24 Native Drive
Queensbury, NY 12804
Attn: NK Probe 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 (boxes):	Date Shipped:	Sales Order Number:	Quantity to be returned
15 cm IRE Single Electrode RFID Activation, PG	H787204001030	20400103	5577754	#	DD-MMM-YYYY	#	

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

☐ We have found affected product and are returning the quantity (eaches) indicated above
Return Authorization Number: 87NPP0_ _ **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 received 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: _____

City and State: _____

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

Contact Signature:_____ Date: _____

Consignee Name
Acct #