Account #
Account Name
Account Address

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

URGENT VOLUNTARY MEDICAL DEVICE RECALL

IMMEDIATE ACTION REQUIRED

Accu2i pMTA Applicator

June XX, 2017

Attention: Risk Management Department:

AngioDynamics, Inc., the manufacturer of the Accu2i pMTA Applicator, is conducting a medical device recall on specific lots of these devices. AngioDynamics is recalling product that has the potential to not function during use. The product affected by this recall will not deliver the desired microwave energy due to coolant ingress in an electrical connection; this condition results in an error code 'High Reflective Power' displayed on the microwave generator. Please note that not all 'High Reflective Power' error codes are a result of this failure mode, as this error code results from any instance where the microwave energy is not efficiently transmitted to the tissue.

Although the specific failure mode of the applicator not delivering the desired microwave energy would not result in any direct harm to the patient; the inserted applicator will need to be removed and replaced in order to continue the procedure.

Our records indicate that your health care facility has received one or more of the AngioDynamics products subject to this recall.

AngioDynamics began distributing product affected by this recall on August 13, 2015.

AngioDynamics has received several complaints from users, but to date, there have been no reports of patient injuries (MDRs) as a result of this issue. This recall will need to be carried out to the end user level.

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
    - 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 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: Accu2i Applicator 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: Accu2i Applicator 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]