ANGIODYNAMICS®

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

ABBOTT AG / LOGISTIKCENTER 2
GAUERHOF KANTONSSTRASSE 2
ALTISHOFEN 6246
SWITZERLAND

Urgent Medical Device Recall – Immediate Action Required

Soft-Vu® Angiographic Catheter

June 18, 2012

Attention: Risk Management Department

AngioDynamics, Inc., the manufacturer of the Soft-Vu® Angiographic Catheter, is conducting a medical device recall. We have identified a potential for the product to be mislabeled.

The outer box is labeled as Soft-Vu® Angiographic Catheter, JB (1) Non-Braided 5F x 100cm x .035"; however, the potential exists that the pouch within may be labeled as a Soft-Vu® Angiographic Catheter Kerns with (1) Side Hole Braided 4F x 65cm x .035"

The specifics about the recalled products are identified in the table below. No other AngioDynamics, Inc. products/lots are affected.

Product Description	Catalog Number:	Lot Number(s)
Soft-Vu® Angiographic Catheter JB(1) Non-Braided 5F x 100cm x 0.035"	10734201	564325

Our records indicate that you have received affected products. Refer to the attached Reply Verification.

Please carefully read this recall notification in its entirety. If you have any questions about this recall action, your local Sales Representative is available to assist you or contact Julie Blair, Customer Service Manager, AngioDynamics, Inc. at 1-800-772-6446 or by email at customerservice@angiodynamics.com.

1. IMMEDIATELY DISCONTINUE USE OF AND SEGREGATE RECALLED PRODUCT.

- Immediately remove the 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.
- Immediately forward a copy of this recall notification to all sites to which you have distributed affected product.

ANGIODYNAMICS®

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 arrange for 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:

Soft-Vu® Angiographic Catheter Recall Coordinator

Fax number: **1-518-798-1360**

☐ 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: Soft-Vu® Angiographic Catheter 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,

Teri Juckett
Regulatory Affairs Manager

Enclosure: Reply Verification Form

ANGIODYNAMICS®

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

PROMEDICA sklad Jazlovice
ZDEBRADSKA 249/33
RICANY U PRAHY 251 01
CZECH REPUBLIC

Urgent Medical Device Recall – Immediate Action Required

Soft-Vu® Angiographic Catheter

June 18, 2012

Attention: Risk Management Department

AngioDynamics, Inc., the manufacturer of the Soft-Vu® Angiographic Catheter, is conducting a medical device recall. We have identified a potential for the product to be mislabeled.

The outer box is labeled as Soft-Vu® Angiographic Catheter, JB (1) Non-Braided 5F x 100cm x .035"; however, the potential exists that the pouch within may be labeled as a Soft-Vu® Angiographic Catheter Kerns with (1) Side Hole Braided 4F x 65cm x .035"

The specifics about the recalled products are identified in the table below. No other AngioDynamics, Inc. products/lots are affected.

Product Description	Catalog Number:	Lot Number(s)
Soft-Vu® Angiographic Catheter JB(1) Non-Braided 5F x 100cm x 0.035"	10734201	564325

Our records indicate that you have received affected products. Refer to the attached Reply Verification.

Please carefully read this recall notification in its entirety. If you have any questions about this recall action, your local Sales Representative is available to assist you or contact Julie Blair, Customer Service Manager, AngioDynamics, Inc. at 1-800-772-6446 or by email at customerservice@angiodynamics.com.

1. IMMEDIATELY DISCONTINUE USE OF AND SEGREGATE RECALLED PRODUCT.

- Immediately remove the 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.
- Immediately forward a copy of this recall notification to all sites to which you have distributed affected product.

ANGIODYNAMICS®

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 arrange for 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:

Soft-Vu® Angiographic Catheter Recall Coordinator

Fax number: **1-518-798-1360**

☐ 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: Soft-Vu® Angiographic Catheter 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,

Teri Juckett
Regulatory Affairs Manager

Enclosure: Reply Verification Form

ANGIODYNAMICS®

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

June 18, 2012

Account Number 302277
ABBOTT AG / LOGISTIKCENTER 2
GAUERHOF KANTONSSTRASSE 2
ALTISHOFEN
SWITZERLAND

Reply Verification Tracking Form

Soft-Vu® Angiographic Catheter

Instructions: Complete, Sign and Return:

Attn: **Soft-Vu® Angiographic Catheter Recall Coordinator**
Fax: **1-518-798-1360**
Email: rdenino@angiodynamics.com

Note: Please Return Immediately Upon Completion

Only products/lots identified below are affected by this recall action.

Product Description	Catalog Number:	Lot Number(s):	Qty Shipped	Date Shipped	Invoice Number	Quantity to be Returned:
Soft-Vu® Angiographic Catheter JB(1) Non-Braided 5F x 100cm x 0.035"	10734201	564325	5	10 April 2012	22222222	

☐ We do NOT have any affected product
☐ We have found affected product and are returning the quantity (eaches) indicated above

Return Authorization Number: _84016418_____ 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: _____

Tel #: _____ _____**Fax #:**_____

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

Print Contact Name: _____Title _____

Facility Name _____ Dept_____

Tel: ____-____-_____ Fax: ____-____-_____ E-mail:_____

Contact Signature: _____Date: _____

ANGIODYNAMICS®

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

June 18, 2012

Account Number 308066
PROMEDICA sklad Jazlovice
ZDEBRADSKA 249/33
RICANY U PRAHY 251 01
CZECH REPUBLIC

Reply Verification Tracking Form

Soft-Vu® Angiographic Catheter

Instructions: Complete, Sign and Return:

Attn: **Soft-Vu® Angiographic Catheter Recall Coordinator**
Fax: **1-518-798-1360**
Email: rdenino@angiodynamics.com

Note: Please Return Immediately Upon Completion

Only products/lots identified below are affected by this recall action.

Product Description	Catalog Number:	Lot Number(s):	Qty Shipped	Date Shipped	Invoice Number	Quantity to be Returned:
Soft-Vu® Angiographic Catheter JB(1) Non-Braided 5F x 100cm x 0.035"	10734201	564325	10	06 March 2012	90893713	

☐ We do NOT have any affected product
☐ We have found affected product and are returning the quantity (eaches) indicated above

Return Authorization Number: _84016414_____ 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: _____

Tel #: _____ _____**Fax #:**_____

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

Print Contact Name: _____Title _____

Facility Name _____ Dept_____

Tel: ____-____-_____ Fax: ____-____-_____ E-mail:_____

Contact Signature: _____Date: _____