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URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

AngioDynamics Solero Microwave Tissue Ablation (MTA) System: Generator and Applicator

April 17, 2019

Attention: Risk Management Department

AngioDynamics, Inc., the manufacturer of the AngioDynamics Solero Microwave Tissue Ablation (MTA) System, Generator and Applicators, is conducting a field safety corrective action (FSCA), to the end user level on specific serial numbers and batch/lots of these devices. The FSCA requires replacement of the Operator's Manual/Directions for Use provided with the product to reduce the risk of potential patient harm due to a delay in performing a procedure.

This Field Safety Notification (FSN) is being sent to all consignees of the Solero Generator and Applicator and includes the revised Operator's Manual/Directions for Use. The instructions and warnings have been clarified to ensure the Solero System is functioning properly prior to starting a procedure.

The current Solero Microwave Tissue Ablation System Generator Operator's Manual ('System Manual') and the Solero Microwave Tissue Ablation Applicator Directions for Use ('Applicator DFU') include the following indications for use:

> **"The Solero Microwave Tissue Ablation (MTA) System and Accessories are indicated for the ablation of soft tissue during open, laparoscopic, or percutaneous procedures. The Solero MTA System is not intended for cardiac use."**

The Solero System Manual and Applicator DFU both include the following warning statement:

> **WARNING: Do not place the applicator in the patient until the applicator has been connected, primed, and the generator status bar indicates "Ready."**

This above-referenced warning is intended to ensure that the Solero System properly starts-up and is fully functional prior to placement into the patient. However, based on field reports, we have determined that this warning could more clearly articulate the use of applicators when used in open procedures. The warning is being revised as follows to ensure the system is properly functioning prior to the surgical preparation of patients. This will reduce the potential for patient harm (e.g., prolonged exposure to anesthesia and/or premature initiation of surgery) resulting from a delay in providing therapy.

> **(Revised) WARNING: Do not initiate the procedure/anesthesia until the applicator has been connected, primed, and the generator status bar indicates "Ready."**

Please review the System Manual and Applicator DFU included within this packet to note the amended statement in the warning section. There is no need to remove from service, or return, any Solero Generators/Applicators as part of this correction.

In addition to the changes to the Operator's Manual and Directions for Use, AngioDynamics will also install a software update to help reduce the incidence of 'Error 0001' which can occur during initial start- up. This improvement will be implemented on the next servicing of the Solero Microwave Tissue Ablation System Generator.

AngioDynamics has confirmed that generators and applicators affected by this correction have been distributed to end users worldwide. AngioDynamics began distributing product affected by this correction on February 28, 2017. Our records indicate that your health care facility has received one or more of the devices subject to this correction.

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

NOTE: The Ref./Catalog numbers and lot/batch numbers are located on the labeling. The serial number of the Generator is located on the back panel of the unit.

1. Actions to be taken:

- Identify if any of the affected product is in your inventory (whether in labs, Central Supply, Shipping and Receiving or ANY other location).
- Solero Generator: Remove the operator's manual originally supplied with the generator and discard. Utilize the revised operator's manual included with this FSN for all procedures.
- Solero Applicator: Review the revised DFU with the personnel that utilize the Solero System(s). Please note that future shipments of the applicators will contain the revised DFU.
- Forward a copy of this correction notification to all sites to which you have distributed affected product.
- Solero Generator software to be updated at next scheduled service

2. Complete and return the Reply Verification Tracking Form.

- If you have any questions regarding the corrective action as stated above, 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).
- If additional Operators Manuals/DFUs are required, please note the quantity needed on the enclosed Reply Verification Tracking Form.
- Promptly complete, sign, and return the enclosed Reply Verification Tracking Form (even if you do not have any product affected by this FSCA).

  □ Email Reply Verification Tracking Form (preferred): **recall@angiodynamics.com**
  □ Fax Reply Verification Tracking Form:
  Attn: Solero Correction Coordinator
  Fax number 1-800-782-1357

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 FSCA is being conducted with the knowledge of the appropriate regulatory agencies.

Sincerely,

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