Affected Account #
Account Name
Account Address

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

URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Solero Microwave Tissue Ablation (MTA) System Generator

July 20, 2021

Attention: Consignee Representative

AngioDynamics, Inc., the manufacturer of the Solero Microwave Tissue Ablation (MTA) Generator is conducting a field safety corrective action (FSCA) to the end user level on specific serial numbers of these devices. The FSCA requires servicing of the Solero MTA Generator to upgrade the software to help reduce the incidence of Error Code "Error 0001", which can occur during system start-up. The software upgrade reduces the risk of potential patient harm that could result from a delay in performing a procedure/treatment. AngioDynamics has received multiple complaints, and no reports of patient injury that have resulted from this issue.

AngioDynamics has confirmed that generators affected by this FSCA have been distributed to end users worldwide. AngioDynamics began distributing product affected by this issue on February 28, 2017.

Our records indicate that your health care facility has the following Solero Generator(s) that have not been updated to the upgraded software and are therefore subject to this FSCA.

Product Description:	Product No.:	Ref./ Catalog No.:	Serial No.	Date Shipped	Sales Order Number

To upgrade these devices, you will need to return the generator to AngioDynamics for service. The AngioDynamics Hardware Service Department will contact you to schedule the upgrade, which may include the shipment of a replacement generator to your facility if needed to be used during the upgrade of your devices.

In the interim, while this upgrade is being scheduled, you may continue to use the Solero generator and are instructed to adhere to the following Warning in the current product labelling (User Manual).

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

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 treatment.

1. **Actions to be taken IMMEDIATELY:**
    - Confirm the location within your facility of the Solero Generator (Part #/Serial Number) listed above.

- If the generator(s) are no longer at your facility, or cannot be located, please contact AngioDynamics via the following methods.
    - ☐ Email (preferred): hardwareservices@angiodynamics.com
    - ☐ Phone: 1-866-883-8820 (Hardware Service)
- Forward a copy of this Field Safety Notification to all sites to which you have distributed affected product.

2. **Scheduled Service to Upgrade:**
    - You will be notified by AngioDynamics Hardware Service when (date) your Solero generator has been scheduled for the upgrade
    - Shipping materials (Pelican Case/ Corrugated Shipper Box) will be provided to return the Solero generator for upgrade.
        - AngioDynamics will provide a loaner Solero generator loaner unit, if needed, to your facility.
        - Upon receipt of the loaner unit (if provided), carefully unpack and place the loaner unit into service
    - A return shipper label will be included with the loaner/Packaging materials
    - Pack-up the Solero Generator requiring upgrade
        - Utilize the packaging material provided by AngioDynamics
    - Apply the return shipping label to the outside of the shipper.
    - Once AngioDynamics returns the upgraded Solero Generator to you, please follow this same process for return of the Solero loaner unit, if applicable.
        - A return shipper label will be included with your returned upgraded Generator
3. **Distributors:**
    - You will be contacted by your AngioDynamics relationship manager and the necessary arrangements will be made to implement this upgrade on affected Solero Generators in your possession and with your customers.

We regret any inconvenience that this issue may have caused, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction. AngioDynamics has implemented corrective actions 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, Inc. This FSCA is being conducted with the knowledge of the appropriate regulatory agencies.

Sincerely,

Warren Nighan
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