AUTONOMIC TECHNOLOGIES

Urgent Field Safety Notice

Pulsante® SPG Microstimulator System
Manufacturer's Reference Number: HHA-17-001
MHRA ref : 2017/004/004/299/008
Field Safety Corrective Action (FSCA), return of devices to the manufacturer

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Date: April 7, 2017

Attention: [CUSTOMER NAME]

Details on affected devices:
Autonomic Technologies Inc., the manufacturer of the Pulsante® SPG Microstimulator System, is conducting a voluntary recall of all distributed lots of Pulsante® SPG Microstimulator Systems for product that has **not** been implanted.

Description of the problem:
A change was made to the Pulsante® SPG Microstimulator (the implantable component) which was not properly validated. This change requires further validation to ensure patient safety. There have been no reported patient adverse events associated with this change, but it is appropriate to remove product from the field until all required testing is completed. Upon successful completion of testing, Autonomic Technologies will resume shipping Pulsante® SPG Microstimulator Systems.

Advise on action to be taken by the user:

- There is no action required at this time for patients who have already been implanted with the Pulsante® SPG Microstimulator System.
- Hospitals which stock the Pulsante® SPG Microstimulator System will identify, quarantine, and return all product to Autonomic Technologies Inc. using the attached Customer Acknowledgement Form. All lots of all components of the Pulsante® SPG Microstimulator System are included.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the devices have been transferred.

Contact reference person:
Ian G. Welsford, Ph.D.
Senior Vice President of Technical Operations

Direct Dial: +1.650.395.4222 X1006 Mobile Number: +1.603.235.7123
Email: quality@ati-spg.com

The undersigned confirms that this notice has been submitted as notification to the appropriate Regulatory Agency.

We are contacting you to ensure you are aware of this activity and the impact on your patients who have been implanted with a Pulsante® SPG Microstimulator System or have been recommended for Pulsante® Therapy. Autonomic Technologies Inc. anticipates that all required testing will be conducted by July 31, 2017 at the latest. The company will resume product supply when the testing is successfully completed.

Yours sincerely,

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