LivaNova

Health innovation that matters

Customer Reply Form

1. FSN information	
FSN Reference	CRM-SAL-2017-002
FSN Date	July 24, 2017
Device(s)	Platinium ICDs and CRT-Ds

2. Customer Details	
Account Number	
Organization Name	
Organization Address	
Department/Unit	
Shipping address if different from above	
Contact Name	
Telephone number	
Email	

3. Customer action undertaken		
☐	I confirm receipt of the Field Safety Notice. The information and required actions have been brought to the attention of all relevant users.	*Customer to fill in or enter N/A*
☐	I have identified and/or quarantined affected devices - enter number of devices and date complete	*Customer to fill in or enter N/A*
☐	I have returned affected devices - enter number of devices returned and date complete	*Customer to fill in or enter N/A*
☐	I do not have any affected devices	*Customer to fill in or enter N/A*
☐	I have a query please contact me	*Customer to enter contact details if different from above and brief description of query*

Print Name	Signature	Date
Customer print name here	*Customer sign here*	*Date here*

4. Return acknowledgement to Manufacturer / Supplier / Distributor	
Email	*Pre-filled by manufacturer*
Fax	*Pre-filled by manufacturer*
Customer Helpline	*Pre-filled by manufacturer*
Postal Address	*Pre-filled by manufacturer*

Sorin CRM SAS
Filiale de LivaNova PLC

Tél : +33 (0)1 46 01 33 33
Fax : +33 (0)1 46 01 34 58

SAS au Capital de 120 000 000 €
RCS Nanterre 309 786 481
N° Intracommunautaire FR 30 309 786 481
Code APE (NAF) : 2660Z

Siège Social
4, avenue Réaumur
92140 Clamart – France

www.livanova.com

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5. Distributors/Suppliers Only			
☐	I have checked my stock and quarantined affected inventory	*Distributor/Supplier to enter quantity and date, or enter N/A*	
☐	I have identified customers that received or may have received this device and attached a list of customers	*Distributor/Supplier to fill in or enter N/A*	
☐	I have attached a list of customers that have confirmed receipt of the FSN	*Distributor/Supplier to fill in or enter N/A*	
☐	Neither I nor any of my customers has any affected devices in inventory	*Distributor/Supplier to fill in or enter N/A*	
Print Name *Distributor print name here*		Signature *Distributor sign here*	Date *Date here*

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence that we need to monitor the progress of the corrective actions.

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URGENT FIELD SAFETY NOTICE

Overconsumption following ElectroStatic Discharge or MRI scan

FSCA identifier:	**CRM-SAL-2017-002**
Affected Devices:	Platinium Implantable Cardiac Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)
Date:	July 24, 2017
Attention:	Physicians, Medical centers, Healthcare professionals
Reason:	LivaNova[1] is initiating a correction and removal of a subset of Platinium devices and notifying physicians of the possibility of overconsumption following an ElectroStatic Discharge during the implant surgery or a Magnetic Resonance Imaging scan.

Dear Doctor,

Details on affected devices:

You are receiving this notification because our records indicate that your facility has received a specific hardware version of Platinium ICD or CRT-D which is affected by the issues described here below. You may have some patients who are implanted with potentially affected Platinium ICDs or CRT-Ds.

Description of the problem:

There are two issues discussed in this letter:

1. An electronic component used in a specific hardware version of Platinium devices has been found to be sensitive to electrostatic discharge (ESD) potentially generated during the implant surgery. The discharge can trigger overconsumption of current, leading to reduced device longevity (5% longevity loss per month). The overconsumption is detectable upon interrogation of the device during follow-up visit and it can be stopped by resetting the device. Although the overconsumption is stopped after this reset, the residual longevity displayed by the programmer may temporarily be underestimated.

[1] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries including Sorin Group Italia srl. In this document, we refer to all entities using the brand name LivaNova.

2. Although Platinium devices are not currently approved as MRI conditional and are therefore contraindicated for MRI, LivaNova is aware that some patients implanted with a Platinium device have undergone an MRI scan based upon medical judgment weighing the benefits and risks of the procedure. When exposure to an MRI's magnetic field occurs, overconsumption can occur and the battery voltage will decrease to 2.80V. At this level, the device remaining longevity is 25% of the initial longevity.

Neither of the issues described above affect the therapeutic functions of the device. All sensing, pacing and shock delivery capabilities will remain functional.

How did this affect patients?

No permanent injury or death has occurred as a result of these issues.

As of June 16th, 2017, LivaNova has received eighteen (18) reports of overconsumption associated with ESD exposure at implant (issue #1), out of the 9386 devices that can be affected by this issue (i.e. 0.19%). Specifically:

- The device associated with the first issue reported was explanted before it could be corrected by reset;
- Twelve (12) were corrected by reset within the 3 months after implant, resulting in less than 15% reduction in longevity; and
- Five (5) were corrected by reset in the 4 to 10 month time frame post-implant, resulting in a greater longevity reduction.

As of June 16th, 2017, LivaNova has received four (4) reports of overconsumption and premature device replacement attributed to MRI scans (issue #2), out of the 9386 devices that can be affected by this issue (i.e. 0.04%). The overconsumption led to premature device replacement in the four (4) cases reported after the MRI scans. In one (1) of these four cases, the patient reported feeling a sensation of heat in the area of device.

Actions taken by LivaNova to address these issues:

1. Since May 18th 2017, LivaNova has stopped releasing Platinium devices with the electronic component that can potentially adversely react to either an ESD generated at implant or the MRI's magnetic field. Platinium devices with a new version of this electronic component have been made available.

2. LivaNova is initiating a correction of the affected implanted devices and a removal of the non implanted affected devices.

3. To eliminate the risk of overconsumption caused by interaction with the MRI's magnetic field, LivaNova developed a new software version[2] that has been approved and will be deployed shortly. All implanted devices will be automatically upgraded upon interrogation by a programmer updated with the new software. Your LivaNova representative will inform you as soon as the new software is available and will assist you in upgrading your programmer.

[2] SmartView 2.56 in Europe and SmartView 2.56J in Japan

Advise on action to be taken by the user:

1. Identify and quarantine affected Platinium devices that are still in your inventory. To determine if a device is subject to this advisory and could potentially present with a risk of overconsumption, please go and check its serial number on the following website: www.livanova.com/platinium-fsn. Your LivaNova representative can assist you in the identification of these products as necessary.

2. Return Platinium devices that are subject to this advisory to LivaNova by contacting your LivaNova representative or your local Customer Service at [*local phone number or email to be inserted*] and referencing this communication to initiate a return and credit of unused product. Your LivaNova representative can assist you in the return of these products as necessary.

3. In order to mitigate the potential risks associated with both triggering events (ESD at implant or MRI scan), LivaNova recommends physicians follow-up the patients at the periodicity already stated in the implant manual[3], especially:
   - Before the patient is discharged and at each subsequent follow-up, it is advisable to check the battery status and the occurrence of system warnings;
   - It is recommended that a routine follow-up examination be done one month after discharge, and then every three months until the device nears the replacement date.

4. LivaNova does not recommend anticipating patient visits, provided that the instructions for use are followed.

5. If the warning "[A3] Technical issue" is displayed, then this indicates that the device is affected by the overconsumption caused by an ESD at implant. Without delay, please contact your LivaNova representative who will organize the reset of the device. A second reset may be necessary in order to correct the estimation of the residual longevity displayed by the programmer. It will be organized at the next scheduled patient visit.

Transmission of this Field Safety Notice:

Please complete and return the Customer Reply Form as soon as possible to acknowledge that you have read and understand this Field Safety Notice. Returning the Customer Reply Form will also prevent repeat notifications of this notice.

Please ensure that all personnel involved in the management of patients implanted with Platinium ICDs or CRT-Ds in your organization are aware of the information outlined in this letter.

[3] For instance, Implant Manual reference U456C (section 8) in Europe.

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LivaNova has communicated this information to the Competent Authority of your country.

If you need further information, please contact your local LivaNova representative or contact LivaNova at [*local phone number to be inserted*]. We appreciate your assistance in this matter.

Sincerely,

[*Local Company Representative*]

Enclosed: Customer Reply Form