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Attachment 1: Customer Reply Form

1. FSN information	
FSN Reference	CRM-SAL-2017-001
FSN Date	March 16, 2018
Device(s)	PLATINIUM ICDs and CRT-Ds DF4 models: VR 1240, DR 1540, CRT-D 1741, SonR CRT-D 1841, 4LV CRT-D 1744, 4LV SonR CRT-D 1844

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

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4, avenue Réaumur
92140 Clamart – France

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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

PLATINIUM: risk of intermittent contact in the DF4 connectors

FSCA identifier:	**CRM-SAL-2017-001**
Affected Devices:	Platinium Implantable Cardiac Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) DF4 models: VR 1240, DR 1540, CRT-D 1741, SonR CRT-D 1841, 4LV CRT-D 1744, 4LV SonR CRT-D 1844
Date:	March 16, 2018
Attention:	Physicians, Medical centers, Healthcare professionals
Reason:	LivaNova[1] is initiating a removal of a limited subset of Platinium devices that may present with intermittent loss of contact in the DF4 connectors

Dear Doctor,

Details on affected devices:

You are receiving this notification because our records indicate that your Center or Hospital has in its inventory Platinium ICDs or CRT-Ds which may be affected by the issue described below.

Description of the problem:

On a subset of Platinium ICDs or CRT-Ds DF4 models, a component of the DF4 connector was identified as potentially defective leading to intermittent loss of contact. As a consequence, high values of continuity measures on the defibrillation coils or noise on the right ventricular channel may be observed. This issue could also lead to absence of ventricular pacing therapy and/or inappropriate shock. Delivery of defibrillation shock is unaffected.

How did this affect patients?

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

As of January 31st, 2018 LivaNova has received six (6) reports on Platinium devices about this issue out of the 6947 Platinium devices equipped with a DF4 connector distributed over the same period of time (0.09%). All six events were detected within the first month after implantation.

- There were three (3) reports of high intermittent RV coil continuity, and
- Three (3) reports of right ventricular noise and/or inappropriate shock.

Five (5) devices out of six (6) were explanted.

[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.

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Actions taken by LivaNova to address these issues:

LivaNova is initiating a recall of non implanted Platinium devices that may present with a defective DF4 connector.

Advice on action to be taken by the user:

1. Identify and quarantine affected Platinium devices that are in your inventory. Refer to Attachment 2 to determine if a device from your inventory is subject to this advisory. Your LivaNova representative will 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 or replacement of unused product. Your LivaNova representative will assist you in the return of these products as necessary.

3. LivaNova does not recommend anticipating patient visits, provided that the instructions for use are followed[2]. Standard follow-up practices allow the detection of high values of continuity measures or right ventricular noise.

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 inventory of Platinium ICDs or CRT-Ds in your organization are aware of the information outlined in this letter.

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:
- Attachment 1: Customer Reply Form
- Attachment 2: List of devices in the center inventory

[2] 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. For instance, refer to the Implant Manual reference:
- U902A for Europe, sections 5.12 and 8.1
- U904A for US, sections 14.12 and 17.1

Attachment 2: List of devices in the center inventory

[*to be filled in*]