SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

URGENT FIELD SAFETY NOTICE

Tissue Heart Valves: Pericarbon More and Perceval manufactured at Sorin Group Italia

Affected Devices:	24 PVS27/XL, Perceval Sutureless Heart Valves, 4 PS25 Pericarbon More Heart Valves and 1 PS33 Pericarbon More Heart Valve
Date:	11 August 2014
Reference No:	FSCA 2014-001
Attention:	Risk / Safety Managers, Distributors, Clinicians and other users of these devices
Reason:	Possible bacterial contamination
Type of action:	Return of the Affected Devices

Dear Valued Customer, Distributor, Sorin Subsidiary,

This communication is to notify you that Sorin Group Italia has identified a potential risk associated with some units of Perceval S Aortic and Pericarbon More Mitral prosthetic heart valves and is voluntarily recalling them.

Description of the Problem

Sorin Group Italia identified the presence of Corynebacterium spp. in the pre-sterile bioburden monitoring of Tissue Heart Valve test samples in July 2014.
Corynebacterium spp. has never previously been identified during the presterile bioburden testing or in in-process devices or in other environmentally controlled areas of the manufacturing facility. The bacteria identification performed by VITEK® 2 Compact system (based on biochemical reactions) showed that the contamination is from Corynebacterium (C. jeikeium, C. urealyticum, C. pseudodiphterycum) that are common microbial flora found on human skin and mucosal membranes.
All the valves released have been sterilized with a validated sterilization process conforming to the specifications and passed a final sterility test. However, Corynebacteria were not included in the validation study and the final sterility test is only indirect indicator of sterility. Consequently Sorin Group Italia assessed that the risk of having finished product contaminated by Corynebacteria is not negligible and decided to recall the devices possibly affected.

Potential risk

If a contaminated valve is implanted there is the potential for development of infectious endocarditis with all attendant complications including death, while treatment may require intravenous antibiotic therapy and reoperation for valve explantation or other measures as determined necessary by medical personnel.

Sorin Group Italia S.r.l.

Sede Legale:
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Sede Amministrativa:
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Tel.+39 0535 29811 Fax +39 0535 25229
Stabilimento di Mirandola:
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Stabilimento di Saluggia:
Via Crescentino sn - 13040 SALUGGIA (VC) Italy
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Tel. +39 02 69465.211 - Fax +39 02 69465.300

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International Customer Service: +39 02 37027030

Capitale Sociale: € 8.550.034,00
Registro Imprese di Milano N. 10556980158
R.E.A. MILANO 1767776 - N.Mecc. Imp./Exp. MI 352423
Cod. Fisc. 10556980158 - Part. IVA 02109510368
ISO CODE IT02109510368
Registro Nazionale Produttori AEE N. IT08020000000823

Società soggetta all'attività di direzione e coordinamento da parte del capogruppo Sorin S.p.A.

Affected units

This Field Safety Notice is related to the devices identified in the table below.

Item #	Product Description	Serial Number
ICV0769	PS25 PERICARBON MORE	PA6490A
ICV0773	PS33 PERICARBON MORE	PA6320A
ICV0769	PS25 PERICARBON MORE	PA6337A
ICV0769	PS25 PERICARBON MORE	PA6357A
ICV0769	PS25 PERICARBON MORE	PA6517A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6358A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6458A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6457A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6418A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6384A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6419A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6391A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6417A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6576A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6667A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6593A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6623A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6383A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6670A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6647A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6466A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6583A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6620A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6645A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6669A

ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6629A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6492A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6524A
ICV1211	PVS27/XL VALV.AORT.PERCEVAL S	PA6648A

This recall does not include any product other than the specified serial numbers listed in the table above.

Advice on action to be taken:

1. Action to be taken by Subsidiaries and Distributors

Identify if any of the affected products is in inventory, if so please contact us immediately to arrange the return of the product to:

Sorin Group Italia S.r.l
Via Crescentino, sn
13040 Saluggia (VC)
Italy

If any of the affected products has been distributed, contact the customer immediately requesting to not use the device.
Send to the customer the present letter filling in the first section of the Customer Response Form in the Appendix. Then arrange the return of the product to Group Italia S.r.l.
Note: It is the Subsidiary's or Distributor's responsibility to contact each customer in writing, providing translation in the local language if necessary.

2. Action to be taken by Customer if the affected product is in stock

If any of the affected products is in your stock do not use it.
Please fill in the second section of the Customer Response Form and return it to Sorin or Distributor. You will be contacted to arrange the return of the product to Sorin Group Italia S.r.l.

3. Action to be taken if the affected product has been utilized

Immediately notify Cardiac Surgeons and/or Cardiologists primarily responsible for care of the affected patient to ensure informed decision making regarding the need for further diagnostic evaluation and treatment. The medical literature suggests that these organisms may cause endocarditis and may exhibit multiple antibiotic resistance, therefore, consultation with Infectious Disease specialists should also be considered to determine the most appropriate evaluation and treatment. The responsible physicians should inform and closely monitor the patient and perform further diagnostic evaluations as needed to rule out the presence of endocarditis.
Further evaluation and treatment may be indicated as determined by the responsible physician(s) and Infectious Disease specialists.

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Contact reference person:

For questions regarding this Urgent Field Safety Notice, please contact

Giovanni Gaviglio, Director Industrial QA, Sorin Group Italia S.r.l.

Phone: +39 (0) 161 487812
Fax: +39 (0)161 487599
Email: SGI.fsca@sorin.com

A copy of this Urgent Field Safety Notice has been provided to the appropriate Regulatory Agency who are aware of these actions.

Thank you for your cooperation in this matter. Sorin Group is committed to providing quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,

[redacted]

Giovanni Gaviglio
Director Industrial Quality Assurance

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Appendix - Customer Response Form

FIELD SAFETY NOTICE: Tissue Heart Valves - Reference # FSCA 2014-001

Section 1

According to our records you have the following affected products:

<< Fill in the customer related codes and serial numbers only- Use Product Trace list (Excel File)>>

Product Code	Affected Serial Number

Please return this completed form to:

Sorin Site/ Distributor Name: <<Print Your Company name here>>

Country: <<Print Your Country here>>

Contact Name: << Print Your Contact Name here>>

E-mail: <<Print Your E-mail address here>>

Fax No.: <<Print Your Fax No. here>>

Phone Number: <<Print Your Phone No. here>>

Please Complete (Section 2):

1. We HAVE reviewed and understand the FIELD SAFETY NOTICE ☐
2. Yes - We do have the listed affected products and we will follow the indication ☐
3. We DO NOT have the listed products /or/ Products were implanted /or/ We request more information (please specify) _____ ☐

Please contact us: Email: SGI.fsca@sorin.com

Customer Name: <<Print Your Company name here>>

Country: <<Print Your Country here>>

Contact Name: << Print Your Contact Name here>>

E-mail: <<Print Your E-mail address here>>

Fax No.: <<Print Your Fax No. here>>

Phone Number: <<Print Your Phone No. here>>

Submitted by .....

Signature .....

Date ...../...../.....