LivaNova
Health innovation that matters

Urgent New Field Safety Notice

Perceval single use accessory kit models assembly error
HV-SAL-2020-001

Type of action: Device removal

July 29, 2020

To Attention of: Vigilance responsible, Health care professionals involved in Perceval Sutureless heart valve stock management and implantation

Dear Madam, dear Sir:

Purpose of this Letter

The purpose of this letter is to advise you that LivaNova ("LivaNova" or "the Company") is executing a field safety corrective action for specific lots of Perceval single use accessory kit intended to be used with Perceval Sutureless heart valves (Perceval S and Perceval PLUS).

According to our traceability, you were supplied of one or more Perceval single use accessory kit potentially affected by the issue described below, and/or one or more of these device(s) may remain in your inventory.

Description of the Issue

The Dual Collapser is a component of the Perceval single use accessory kits.
The Dual Collapser is used to reduce the Perceval Sutureless heart valve diameter, thus allowing the Perceval implantation.

Due to an assembly error, the Dual Collapser size S/M may present misaligned collapser segments arrays and this may cause the inability to collapse the inflow ring of Perceval(s) valve sizes S and M.
The issue affects specific models and lots of Perceval single use accessory kit as reported below in table 1.

Risk to Health

The risk associated with the use of an affected Dual Collapser is the potential increase of Extra Corporeal Circulation (ECC) time due to the difficulties to complete the valve collapsing.

The probability of increased ECC to cause patient harm has been assessed as Remote.

Accordingly, no health consequence for the patients have been reported for a prolonged cross

clamp time nor in relation to collapsing failure events.

It should be noted, as of July 21, 2020, no patient injury has been reported as a result of this issue.

Which Device(s) are Potentially Affected?

The issue affects a subset of Dual Collapser size S/M belonging to a specific production lot and assembled into different Perceval single use accessory kit models, as listed in Table 1.

Model (item)	Device description	lots
ICV1345	PVS single use accessory kit size S	2002060216; 2002060218
ICV1346	PVS single use accessory kit size M	2002060219; 2002060220
ICV1349	PVS single use accessory kit MICS size S	2001300339; 2002130159; 2002200196
ICV1350	PVS single use accessory kit MICS size M	2001300341; 2002060224; 2002130160; 2002130161; 2002130162; 2002200198; 2002200199

Table 1: Potentially affected Perceval single use accessory kits models

Detailed list of potentially affected Perceval single use accessory kit lots supplied to your facility is provided in Attachment 1 to this communication.

Other Perceval single use accessory kit lots in your inventory not listed in Attachment 1 are not affected by this issue and can be used.

What Actions Should Health Care Professionals Take?

LivaNova is coordinating the removal of all potentially affected Perceval single use accessory kit lots in your inventory.

Please ensure timely execution of the following actions:

1. Using the list provided in **Attachment 1**, please check your inventory for potentially affected devices supplied at your facility;
1. All potentially affected devices listed in Attachment 1 and still in inventory **should not be used and should be quarantined**, pending return to LivaNova;
2. Please complete and return the **Attachment 1** by e-mail to LivaNova.FSCA@livanova.com to initiate the removal/replacement process of the Perceval single use accessory kit(s).

Your LivaNova Representative will contact you to coordinate replacement of the potentially

defective device(s) if they have not already been used

What Actions Is the Manufacturer Taking?

1. Notification of the potentially affected devices removal via letter to inform users of the issue and advise them not to use and quarantine the potentially affected devices immediately
2. Coordinating and providing information to the user on product replacement.

Transmission of this Communication

Please ensure that this notice is communicated **to all personnel within your organization who need to be aware and transfer this notice to other organizations on which this action has an impact**. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Your country's Heath Competent Authority is informed about this communication to customers, and this action is being reported to other applicable regulatory agencies. Follow-up FSN is not planned for this issue.

Please report all device-related incidents to LivaNova or your local representative, and the national Competent Authority if appropriate, as this provides important feedback.

If you have transferred any of the affected devices to a third party, please communicate this information to them and inform the LivaNova Quality Assurance Team at LivaNova.FSCA@livanova.com.

Contact reference person

For questions regarding the information in this letter or regarding the device return and replacement, please contact your usual representative or LivaNova Customer Quality via e-mail at LivaNova.FSCA@livanova.com.

Thank you for your cooperation in this matter. LivaNova is diligently working to resolve this issue. We remain committed to providing quality devices and service to our customers, and we apologize for any inconvenience this situation may have caused.

Sincerely,

Enrico Milani
Director Heart Valve Quality Engineering and Cardiovascular Customer Quality
LivaNova

Attachment list
Attachment 1: Customer Response Form and Potentially Affected Devices List

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Attachment 1:
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By signing and returning this Customer Response Form, you are acknowledging you have read and understood the notification and it has been distributed to all users involved in the use of potentially affected Perceval single use accessory kit(s).

To prevent repeat notifications of this notice, please complete all information, sign and return all pages of this Attachment 1 **no later than August 31st, 2020** by e-mail to LivaNova.FSCA@livanova.com.

Customer Information:

Customer/Facility Name	
City	
Country	

Using **Table 2 - Affected Product Information on next page**, please check your inventory for potentially affected Perceval single use accessory kits, and indicate the result of your check:

☐ **No** : all affected products have been used and no further action is required.

☐ **Yes** : I have affected products in my facility, and they have been quarantined. I am **indicating all required information in Table 2 - Affected Product Information on next page** so that the entire corrective action can be completed appropriately at my facility.

☐ **Other**: Please provide details in **Comment** section, after your signature.

Name/Title	
Signature	
Contact details (e-mail/Phone number)	
Comment / Question	

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Attachment 1:
Perceval single use accessory kit models assembly error
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You have potentially affected devices in your inventory. Please:
- Fill each line in Table 2
- Please contact your LivaNova Representative or Customer Quality via e-mail at LivaNova.FSCA@livanova.com if you need any assistance.

Table 2 - Affected Product Information for _____

Model (item)	Device description	Lot Number	Quantity received	Quantity in inventory To be returned (*)	Quantity no longer available	Other important information

(*) RMA# description for Device Return: FSCA HV-SAL-2020-001

Name/Title

When your Response has been processed, LivaNova will contact you to coordinate replacement of the potentially defective device(s).