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Health innovation that matters

URGENT FIELD SAFETY NOTICE

FSCA identifier: HV-SAL-2018-001

Affected Product: Perceval Sutureless Heart Valve

Type of action: Advice given by the Manufacturer regarding the use of the device

Date: June 18, 2018

Attention: Implanting Surgeons

Reason: Possibility of stent folding due to Perceval valve oversizing

Dear Doctor:

You are receiving this letter because according to our records, you are an implanter of Perceval Sutureless Aortic Heart Valve[1]:

Item #	REF	Product Description
ICV1208	**PVS21**	Perceval Sutureless Aortic Heart Valve size S
ICV1209	**PVS23**	Perceval Sutureless Aortic Heart Valve size M
ICV1210	**PVS25**	Perceval Sutureless Aortic Heart Valve size L
ICV1211	**PVS27**	Perceval Sutureless Aortic Heart Valve size XL

Description of the issue

LivaNova[2] has recently become aware, through its post-market surveillance processes, of more than anticipated cases of valve insufficiency, primarily caused by oversizing leading to “stent folding”.

In the past 10 years, 49 complaints related to Perceval folding were reported, with an increase in the number of cases in 2017. Although this event has been observed with all prosthesis sizes, it has been more frequently reported with sizes S and M.

[1] Perceval is a sutureless bioprosthetic valve indicated for use in adult patients who are diagnosed with aortic valve stenosis or steno-insufficiency. The prosthesis consists of a bovine pericardium tissue component and a flexible, self-expandable Nitinol stent, which has the dual role of supporting the valve and fixing it in place without the need for sutures. Prior to implantation, the prosthesis’ diameter is reduced to a suitable size to load it onto the holder. The valve is then positioned and released in the aortic root, where the stent design and its ability to apply a radial force to the annulus allows stable anchoring of the device.

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

Stent folding is defined as an inward deformation of the stent at the annulus level (see Figure 1).

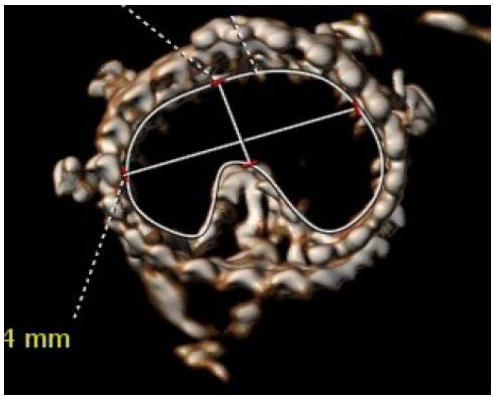

Figure 1. Stent folding

The main root cause identified for stent folding is valve oversizing, associated with other factors such as:

- extremely eccentric aortic annulus;
- highly calcified portion of the annulus, or uneven decalcification (concentrated bulky calcium protrusion);
- aortic root anatomy deviating from the tri-symmetrical physiological geometry (bicuspid valve, or absence of one of the Valsalva sinuses);
- severe hypertrophic septum.

Moreover, patients with an implanted Perceval valve may experience valve folding when emergency cardiovascular procedures, such as cardiopulmonary resuscitation (CPR), are administered post-implant.

How does this affect patients?

Valve folding could result in paravalvular or central leakage, in some cases associated with high gradient, which may be significant enough to require a reoperation.

Actions to be taken following this communication

By means of this voluntary action, LivaNova will be providing clarifications about this potential adverse event related to the Perceval valve and recommendations to prevent its occurrence. We would like to follow this letter with an *in-person* meeting with you and all the physicians implanting Perceval in your hospital, to discuss key procedural steps to be followed to reduce the occurrence of stent folding, and to provide further information for an early detection of the phenomenon.

You will be contacted by your LivaNova representative to discuss the logistics of scheduling a meeting, and we kindly ask you to facilitate such meeting.

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In the meantime, LivaNova reminds you of the importance of the following key points, as indicated in the IFUs, for prevention and early detection of stent folding:

Prevention

1) Decalcification, to avoid uneven surfaces;
2) Correct sizing, using available information in the IFU; and
3) Ballooning, with the recommendation to pour warm sterile saline (at 37°C) while ballooning.

Early detection

1) Visual inspection, checking that the Perceval stent is correctly deployed; and
2) Performing an intraoperative echographic evaluation after Perceval implant to confirm correct positioning and verify valve functionality under beating heart conditions.

There are no required actions for patients already implanted with Perceval outside of normal monitoring and treatment.

If you have additional questions or urgent request for clarification, please contact the reference person reported below, your LivaNova representative.

Transmission of this Field Safety Notice

Please ensure that this Field Safety Notice is communicated to all personnel who need to be aware of it within your organization. In case you have transferred products to a third party, please communicate this information to them.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agencies, who are aware of these actions.

Contact reference person:
[Add local contact information: Name / organization, address, contact details]

LivaNova is committed to provide quality products and services to its customers and we rely on your collaboration. If you have any questions regarding this notice, please contact your local LivaNova representative listed above.

Sincerely,

Joan Ceasar
Director, Customer Quality and Safety