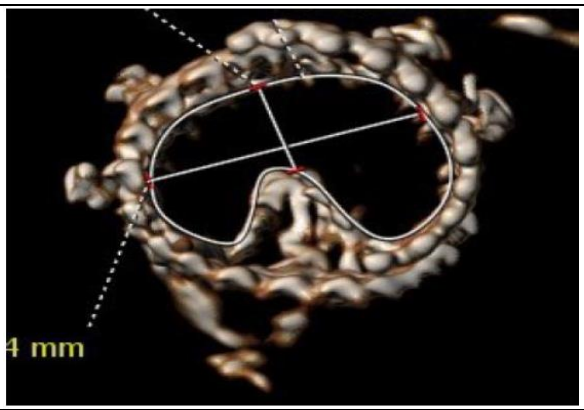
المركز الوطني للبلاغات عن الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Urgent Safety Communication

Possibility of stent folding in Perceval Sutureless Heart Valve

Device/ Product Name:	Perceval Sutureless Heart Valve
Lot numbers/Serials:	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
Manufacturer:	LivaNova
Problem:	Possibility of stent folding due to Perceval valve oversizing.
Recommendation/Actions:	**Prevention** - Decalcification, to avoid uneven surfaces; - Correct sizing, using available information in the IFU; and - Ballooning, with the recommendation to pour warm sterile saline (at 37°C) while ballooning. **Early detection** - Visual inspection, checking that the Perceval stent is correctly deployed; and - 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.

Devices/Products photo:		
Authorized Representative Details	**Company name:**	cigalah group
	Contact Person:	Hammad Alrowaili
	Phone:	+966 11 4603575 +966 505404345
	Email:	a-naif9@hotmail.com

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2904
Fax: +966 (11) 2757245

Or

Saudi Vigilance
https://ade.sfda.gov.sa/Home/Report

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team