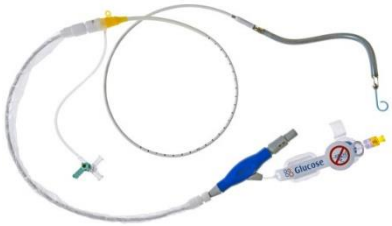
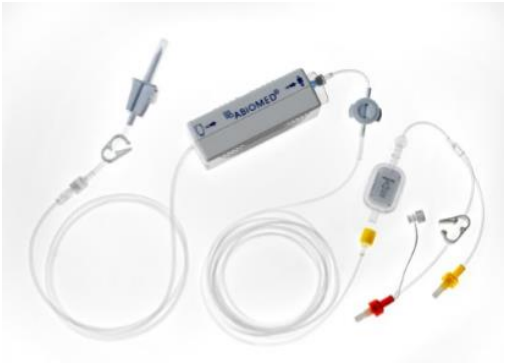
المركز الوطني للبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication

Increased Rate of Mortality in Patients Receiving Abiomed Impella RP System

Device/ Product Name:	Impella RP® System
Lot numbers/Serials:	Not specific
Manufacturer:	Abiomed, Inc.
Problem:	The SFDA wants to ensure that all Cardiologists, Cardiothoracic Surgeons and Transplant Surgeons, to be aware of the mortality rate that has been observed in the ongoing Post-Approval Studies (PAS) on Impella RP System. The high mortality rate observed in the PAS may be primarily related to differences in pre-implant characteristics of the patients. Specifically, before getting the Impella RP system implanted, patients in the PAS were more likely to have been in cardiogenic shock for longer than 48 hours, experienced an in-hospital cardiac arrest, been treated with an intra-aortic balloon pump, or suffered a pre-implant hypoxic or ischemic neurologic event It is important to note that the evaluation into this issue are ongoing, the root cause for the high mortality rate is still unknowing and the results are not adjusted for potential confounders. You can read the complete Safety Alert that includes recommendations from HERE.
Recommendation/Actions:	• These clinical events may not preclude a clinical decision to use the device, physicians should be aware that the occurrence of one or more of these events prior to Impella RP implantation may decrease expected survival rate. • Carefully consider these interim survival results from the ongoing Impella RP PAS when making treatment decisions and discuss the risks and benefits of the Impella RP System with patients and their caregivers.

	• Report any adverse events or suspected adverse events experienced with the use of Impella RP® System and through National Center for Medical Devices Reporting (NCMDR) Or Saudi Vigilance Prompt reporting of adverse events can help the SFDA identify and better understand the risks associated with medical devices.
Devices/Products photo:	 The Impella RP Catheter  Automatic Impella Controller  The Impella Purge Cassette

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 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: 2406, 2412
Fax: +966 (11) 2757245

Or

Saudi Vigilance

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Sincerely,
NCMDR Team