State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Abiomed, Inc. Impella Intravascular Series for Destruction of Blades

Recall Date	Product Description	Recalling Firm	Recall Reason
7/26/2023	**Impella 2.5 intravascular micro axial blood pump** Product Number 005042	**Abiomed, Inc.** Danvers, Massachusetts	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system. Systemic embolization of the fractured impeller material is a possibility.
7/26/2023	**Impella 5.0 intravascular micro axial blood pump** Product Number 005062	**Abiomed, Inc.** Danvers, Massachusetts	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades.
7/26/2023	**Impella LD intravascular micro axial blood pump** Product Number 005082	**Abiomed, Inc.** Danvers, Massachusetts	There is a potential risk for unintentional interaction of the Impella motor

			housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades.
7/26/2023	**Impella 5.5 with SmartAssist intravascular micro axial blood pump** Product Numbers 0550-0008 and 1000100	**Abiomed, Inc.** Danvers, Massachusetts	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR).
7/26/2023	**Impella CP intravascular micro axial blood pump** Product Number 0048-0032	**Abiomed, Inc.** Danvers, Massachusetts	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR).
7/26/2023	**Impella CP with SmartAssist intravascular micro axial blood pump** Product Numbers 0048-0024, 0048-0045, 1000080	**Abiomed, Inc.** Danvers, Massachusetts	There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR).

Recall Class	Product Identification	Distribution	Affected Dates
I	**Impella 2.5 intravascular micro axial blood pump** UDI-DI: 00813502011081.	9252 Units Nationwide	June 2023 and Prior
I	**Impella 5.0 intravascular micro axial blood pump** UDI-DI: 00813502011180	9252 Units Nationwide	June 2023 and Prior

I	**Impella LD intravascular micro axial blood pump** UDI-DI: 00813502011227	9252 Units Nationwide	June 2023 and Prior
I	**Impella 5.5 with SmartAssist intravascular micro axial blood pump** UDI-DI: 00813502011531, 00813502012828	9252 Units Nationwide	June 2023 and Prior
I	**Impella CP intravascular micro axial blood pump** UDI-DI: 00813502011388	9252 Units Nationwide	June 2023 and Prior
I	**Impella CP with SmartAssist intravascular micro axial blood pump** UDI-DI: 00813502011371, 00813502011876, 00813502012279.	9252 Units Nationwide	June 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov