Johnson&Johnson MedTech

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URGENT MEDICAL DEVICE RECALL (REMOVAL)

AIC Purge Retainer Fixation Correction

Product Code(s)	Product Description(s)	UDI-DI(s)
0042-0000-US	Impella Controller, Packaged, US	00813502010022
0042-0010-US	Impella Optical Controller, Packaged, US	00813502010985
0042-0040-US	Optical, AIC, Impella Connect, Pkgd, US	00813502011401
1000432	AIC w/Impella Connect for ECP	00813502013030
1000201	Dbl optical, AIC Impella Connect, Phg US	00813502010442

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT THAT IS THE SUBJECT OF THIS NOTICE

Dear Valued Customer,

Please be advised that Abiomed, Inc ("Abiomed") has initiated a device recall (removal) and is informing customers of a correction for the Automated Impella Controller (AIC) purge retainer fixation and implementing this change to identified customers through device servicing at the Abiomed Service Center. Abiomed servicing team will contact you to coordinate the return of the device(s) to implement this change. To ensure continuity of care, hospital inventory can continue to be used.

REASON FOR NOTIFICATION:

Abiomed identified a rate of 0.61% (660 complaints / 98,861 cases from February 2022 to July 2024) AIC purge pressure issues due to purge retainer failures. Currently this rate is 0.19% (105 complaints / 55,471 cases from August 2024 to June 2025). Complaints review determined that there have been no deaths and 5 serious injuries directly related to this failure. When this issue arose, it was determined that force applied during purge disc insertion/removal was determined to be a factor contributing to the purge retainer failures. Failures impacting purge pressure and detection of the purge disc may lead to errors, alarms, and potential interruptions in hemodynamic support when the AIC may need to be replaced. In unusual circumstances, (i.e. purge system failure), this failure may result in a pump stop with resultant loss of hemodynamic support which is considered a life-threatening injury with the potential for permanent impairment or death.

Abiomed identified a design change to correct the AIC purge retainer fixture that will be implemented through device servicing at the Abiomed Service Center. This design change involves the addition of a third mounting screw for the purge retainer, improving fixation.

Ninety-one percent (91%) of global AIC consoles that have been serviced by Abiomed since April 2024 have been corrected with the design change, and nine percent (9%) of AIC consoles globally still require the correction. Customers with consoles that have already been corrected are not receiving this notification. If you are receiving this letter, Abiomed's records indicate you are in possession of an AIC console that requires the correction. A list of US impacted AIC console serial numbers may be found in Attachment 1 of this letter.

Customers are reminded of the ongoing Abiomed AIC related field action in June 2025 for a potential Automated Impella Controller (AIC) intermittent detection issue during Impella pump transfer when the pump is connected. This purge retainer fixation correction is a different recall.

RECOMMENDATIONS:

To ensure continuity of care, hospital inventory can continue to be used.

Abiomed has identified customers with AIC product subject to the update and will implement the applicable correction for these identified customers through device servicing at the Abiomed Service Center. Abiomed servicing team will contact you to coordinate the return of the device(s) to implement this update.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Hospital inventory can continue to be used to ensure continuity of care.
- Upon contact from Abiomed's field servicing team, please work with them to return the identified device(s) for the change to be implemented. Refer to Attachment 1 for list of impacted AIC serial numbers.
- Review this notice carefully, and forward to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products).
- If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.
- Review, complete all fields, sign, and return the business response form (BRF) provided to impacted customers and send it to abiomed8660@sedgwick.com.
- As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting Program as per below instructions:
    - Complete and submit the report online: www.fda.gov/medwatch/report.htm or
    - Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact ra-abm-fieldaction@its.jnj.com or your local clinical field staff. Thank you for your cooperation.

Attachments:
Attachment 1 – Table of US Impacted Serial Numbers

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Attachment 1 - Table of US Impacted Serial Numbers

IC1029	IC2561	IC3975	IC5549	IC6846	IC8529	IC10098	IC10859	IC11311	IC11558
IC1072	IC2562	IC3976	IC5598	IC6962	IC8617	IC10221	IC10879	IC11316	IC11559
IC1073	IC2575	IC4041	IC5605	IC7002	IC8710	IC10227	IC10900	IC11353	IC11561
IC1075	IC2635	IC4042	IC5661	IC7003	IC8808	IC10237	IC10915	IC11362	IC11565
IC1080	IC2664	IC4045	IC5662	IC7026	IC8852	IC10254	IC10926	IC11373	IC11567
IC1096	IC2665	IC4060	IC5720	IC7036	IC8906	IC10271	IC10961	IC11380	IC11568
IC1122	IC2691	IC4201	IC5721	IC7213	IC9081	IC10294	IC10980	IC11384	IC11569
IC1161	IC2692	IC4202	IC5745	IC7214	IC9082	IC10297	IC11012	IC11389	IC11572
IC1190	IC2720	IC4250	IC5749	IC7239	IC9158	IC10327	IC11035	IC11423	IC11573
IC1202	IC2739	IC4259	IC5750	IC7241	IC9160	IC10332	IC11043	IC11429	IC11574
IC1203	IC2840	IC4295	IC5828	IC7344	IC9198	IC10338	IC11051	IC11471	IC11581
IC1224	IC2841	IC4339	IC5984	IC7482	IC9227	IC10362	IC11054	IC11480	IC11582
IC1231	IC2913	IC4430	IC6042	IC7483	IC9247	IC10383	IC11059	IC11492	IC11583
IC1238	IC2976	IC4431	IC6199	IC7507	IC9513	IC10455	IC11068	IC11524	IC11584
IC1373	IC2977	IC4616	IC6321	IC7509	IC9629	IC10470	IC11069	IC11525	IC11585
IC1511	IC3009	IC4640	IC6322	IC7558	IC9632	IC10478	IC11073	IC11526	IC11586
IC1708	IC3010	IC4641	IC6328	IC7616	IC9633	IC10493	IC11075	IC11528	IC11597
IC1741	IC3154	IC4692	IC6329	IC7677	IC9635	IC10497	IC11087	IC11529	IC11600
IC1771	IC3155	IC4708	IC6359	IC7787	IC9636	IC10526	IC11147	IC11530	IC11606
IC1852	IC3244	IC4715	IC6360	IC7880	IC9637	IC10530	IC11158	IC11531	IC11609
IC1853	IC3246	IC4716	IC6403	IC7912	IC9641	IC10531	IC11159	IC11532	IC11611
IC1944	IC3337	IC4831	IC6501	IC7991	IC9657	IC10549	IC11168	IC11533	IC11613
IC1964	IC3342	IC4832	IC6559	IC8017	IC9813	IC10557	IC11203	IC11534	IC11614
IC2029	IC3347	IC4884	IC6571	IC8024	IC9814	IC10566	IC11238	IC11536	IC11615
IC2069	IC3351	IC4893	IC6596	IC8036	IC9815	IC10568	IC11239	IC11537	IC11616
IC2071	IC3512	IC4895	IC6597	IC8179	IC9816	IC10578	IC11241	IC11538	IC11617
IC2154	IC3513	IC4964	IC6622	IC8185	IC9817	IC10606	IC11242	IC11539	IC11618
IC2199	IC3714	IC4966	IC6623	IC8200	IC9818	IC10607	IC11243	IC11540	IC11619
IC2314	IC3715	IC5056	IC6632	IC8216	IC9819	IC10653	IC11249	IC11549	IC11621
IC2315	IC3772	IC5120	IC6637	IC8349	IC9820	IC10717	IC11251	IC11550	IC11622
IC2321	IC3773	IC5151	IC6673	IC8390	IC9821	IC10722	IC11268	IC11551	IC11624
IC2428	IC3806	IC5201	IC6825	IC8393	IC9887	IC10769	IC11273	IC11552	IC11635
IC2429	IC3822	IC5497	IC6834	IC8415	IC9888	IC10811	IC11274	IC11555	IC11637
IC2521	IC3823	IC5500	IC6835	IC8418	IC9987	IC10837	IC11294	IC11556	IC11638
					IC10097	IC10855	IC11310	IC11557	IC11639