Class 1 Device Recall Arrow AutoCAT2

See Related Information[22]

Date Initiated by Firm	May 20, 2020
Date Posted	June 26, 2020
Recall Status[1]	Terminated [3] on January 07, 2023
Recall Number	Z-2410-2020
Recall Event ID	85684[23]
510(K)Number	K060309[24]
Product Classification	System, balloon, intra-aortic and control[25] - **Product Code** DSP[26]
Product	Arrow AutoCAT2 Intra-Aortic Balloon Pump AUTOCAT2 WAVE, Product Code IAP-0500
Code Information	Serial Number Ranges: AUTOCAT2 WAVE IAP-0500 140861W through 140865W 140910W through 140913W 150101W 150103W through 150105W 150108W through 150109W 150114W 150119W 150202W through 150219W 150303W Arrow AutoCAT 2 Intra-Aortic Balloon Pump AUTOCAT2 WAVE IAP-0500 150306W 150310W 150404W through 150406W 150410W 150501W through 150506W 150515W 150606W through 150607W 150612W through 150622W 150701W 150706W 150708W through 150712W 150717W through 150719W 150803W through 150820W 150822W through 150823W 150825W 150913W through 150918W 150924W 150940W 151001W through 151008W 151017W through 151018W 151020W 151028W 151109W 151112W 151115W through 151120W 160104W 160110W through 160111W 160121W 160123W through 160125W 160127W through 160130W 160210W 160212W 160215W 160218W 160220W 160301W through 160304W 160307W through 160311W 160315W 160324W 160328W through 160330W 160332W through 160340W 160411W Arrow AutoCAT 2 Intra-Aortic Balloon Pump AUTOCAT2 WAVE IAP-0500 160413W through 160417W 160423W through 160424W 160428W 160501W through 160502W 160504W through 160507W 160520W through 160524W 160526W through 160528W 160601W through 160604W 160606W through 160613W 160615W through 160617W 160620W through 160629W 160632W through 160633W 160701W through 160702W 160704W 160706W through 160713W 160716W through 160717W 160719W 160721W through 160725W 160727W 160734W through 160742W 160744W through 160745W 160801W through 160803W 160805W through 160823W 160825W through 160827W 160829W through 160830W 160901W through 160917W 160920W through 160945W 170201W through 170203W 170207W through 170208W 170211W through 170220W 170222W through 170230W 170301W 170303W through 170307W 170309W through 170327W 170329W through 170330W 170606W through 170610W 170921W through 170927W 170929W through 170930W 170941W through 170950W 171101W through 171104W 171118W 171202W through 171205W Arrow AutoCAT 2 Intra-Aortic Balloon Pump AUTOCAT2 WAVE IAP-0500 180111W through 180119W 180302W through 180308W 180310W 180331W through 180332W 180334W through 180340W 180501W through 180510W 180531W through 180540W 180611W through 180620W 180721W through 180730W 180751W through 180760W 180831W through 180839W 180932W through 180938W 180940W through 180941W 181051W through 181053W 181055W 190111W through 190118W 190222W 190227W through

	190228W 190230W 190321W through 190330W 190511W 190513W 190515W through 190518W 190520W through 190530W 190621W through 190630W 190634W through 190640W 190849W through 190860W 191043W through 191046W 191048W 200213W through 200236W
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
For Additional Information Contact	610-378-0131
Manufacturer Reason for Recall	A potential issue with a component within the above-referenced IABPs may impact the ability of the devices to operate. A Component within the IABP is susceptible to vibration failure resulting in fretting, charring, and discoloration of motor connector wires, which may result in pump alarms for System Error 3 and High Baseline presented on the screen of the IABP, and potential abrupt cessation of function or inability to start the IABP.
FDA Determined Cause [2]	Component design/selection
Action	Urgent Medical Device Correction notification letters dated 5/20/20 were sent to customers. ACTIONS TO BE TAKEN BY FACILITIES (Immediate): Please immediately check your inventory of Arrow AutoCAT2 and Arrow AC3 Optimus IABPs, whether stored or in use, and determine if you have an IABP with a model number listed above. Please see Appendix 1 for product codes and serial numbers. If an IABP in the scope of this Medical Device Correction displays a System Error 3 or High Baseline alarm, now or at any point in the future until the Long-Term Corrective Action detailed below occurs, immediately quarantine the device and contact Teleflex at 1-855-419-8507 or recalls@teleflex.com to receive support for inspection and servicing of the impacted device. We recommend against using an IABP for ground or air transport between medical facilities pending implementation of the Customer Action (Long Term). For IABP use during ground or air transport prior to implementation of the Customer Action (Long Term), it is recommended that the risks and benefits of using the IABP be assessed by the medical team treating the patient and that alternative circulatory support devices be considered. Customer Action (Subsequent): Teleflex will contact each impacted facility to schedule inspection and servicing of all IABP units that contain this internal component. This inspection and servicing will be performed onsite at facilities, for all IABP units. Facilities should adhere to the following instructions pending implementation of the Teleflex Long-Term Corrective Action described later in this letter: 1. Ensure that a backup IABP is available as instructed within the Operator Manual. If no such replacement IABP is immediately available, it is recommended that the risks and benefits of using the IABP be assessed by the medical team treating the patient and that alternative circulatory support devices be considered. 2. IABP units should be closely monitored during delivery of IAB
Quantity in Commerce	2123 total
Distribution	Worldwide distribution.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29].

510(K) Database	510(K)s with Product Code = DSP[30]

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22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=85684
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K060309
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DSP
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DSP
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28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
29. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
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FDA

U.S. Food and Drug Administration
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Ph. 1-888-INFO-FDA (1-888-463-6332)
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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=85684
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K060309
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DSP
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27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DSP
28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
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