# Abiomed Recalls the Instructions for Use for Impella Left Sided Blood Pumps due to Perforation Risks

Please be aware, this recall is a correction, not a product removal.

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

## Recalled Product

- US Available Product Names: Impella 2.5; Impella CP; Impella CP with SmartAssist; Impella 5.0; Impella 5.5 with SmartAssist ; Impella LD
- Product Codes: See Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=205357)
- Distribution Dates: October 10, 2021 to October 10, 2023
- Devices Recalled in the U.S.: 66,390
- Date Initiated by Firm: December 27, 2023

## Device Use

Impella Left Sided Blood Pumps are used for short term support of the pumping chambers of the heart (ventricles) during high-risk catheter-based procedures called percutaneous coronary interventions (PCI). Impella Left Sided Blood Pumps also are used when there is ongoing cardiogenic shock (https://medlineplus.gov/ency/article/000185.htm) that occurs less than 48 hours after a severe heart attack (acute myocardial infarction), open-heart surgery, or when the heart is not functioning well due to a condition called cardiomyopathy (https://medlineplus.gov/cardiomyopathy.html). Impella therapy aims to reduce the work of the heart's ventricles and provide support for the circulatory system so the heart has time to recover. There are several types of Impella pumps that are used for different therapeutic reasons.

## Reason for Recall

Abiomed is recalling its Impella Left Sided Blood Pumps because the pump catheter may perforate (cut) the wall of the left ventricle in the heart. During operations, the Impella device could cut through the wall of the left ventricle.

The use of the affected Impella pumps may cause serious adverse health consequences, including left ventricle perforation or free wall rupture, hypertension, lack of blood flow, and death.

There have been 129 reported serious injuries, including 49 reports of death.

## Who May be Affected

- People who are undergoing procedures with the Impella Left Sided Blood Pumps
- People who have anterior infarction (heart disease)
- Elderly people and women

## What to Do

On December 27, 2023, Abiomed sent all affected customers an Urgent Medical Device Correction letter.

The letter requested customers to adhere to new and revised warnings:

- Carefully position the pump catheter during operative procedures
- Use imaging when advancing or torquing the pump catheter
- Use special care when inserting the pump catheter in patients with certain high risk conditions or during active CPR
- Review the updated warnings in the device Instructions for Use
- Notify everyone at your facility who needs to be informed of this recall correction
- Notify any other facilities where the products have been forwarded of the updated Instructions for Use

## Contact Information

Customers in the U.S. with questions about this recall should contact Abiomed, Inc at (978) 646-1400.

## Additional Resources

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=205357)

## How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.