

Do Medical Device Monopolies Impact Safety And Quality? Analysis of Adverse Events for Abiomed Impella(R) Heart Pumps

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Abstract - Monopolistic market conditions eliminate competition and reduce incentives for product improvement. This research investigates the safety and performance of a life-saving cardiovascular medical device when one manufacturer monopolises the market. The Abiomed Impella(R) heart pump provides hemodynamic support for the heart. As there are no other manufacturers of similar devices, Abiomed maintains a monopoly on these medical devices. The Food and Drug Administration (FDA) Manufacturer and Use Facility Device Experience (MAUDE) database lists adverse events for medical devices, and provides insights into adverse event types and occurrences. This study analysed adverse events, including deaths, injuries, and malfunctions, for Abiomed Impella(R) devices from 2008 to 2021. The data reveal a striking increase in reported malfunctions over the decade from 2011 to 2021, during which annual malfunctions rose nine-fold from 10 to 90. Of the 285 total malfunctions reported for Abiomed Impella(R) devices in the decade 2011 to 2021, almost one-third of malfunctions occurred in 2021. Reported injuries for Abiomed Impella(R) devices rose even more dramatically, from one annual injury to 374 annual injuries between 2008 and 2021. Reported deaths for Abiomed Impella(R) devices also rose from 2 annual deaths to 17 annual deaths between 2012, and 2021. Most concerning, many patient deaths were misreported as injuries or malfunctions. Only 33% of deaths associated with Abiomed Impella(R) devices were accurately reported as deaths. These results highlight the need for continuous improvement and transparent reporting for medical devices; it can mean the difference between life and death.

Keywords: Medical devices, heart pump, cardiology, adverse events

1. Introduction

The Impella 2.5® and Impella CP® devices are U.S. FDA PMA approved to treat certain advanced heart failure patients undergoing elective and urgent percutaneous coronary interventions (PCI) such as stenting or balloon angioplasty, to re-open blocked coronary arteries [2]. All Impella models are placed across the aortic valve by employing fluoroscopic/echocardiographic guidance [4]. Impella heart pumps are currently the **ONLY** FDA PMA approved minimally invasive hemodynamic support devices for high risk percutaneous coronary interventions or cardiogenic shock [3].

The FDA Manufacturer and User Facility Device Experience (MAUDE) database, lists adverse reports from manufacturers, distributors, clinicians, and other voluntary reporters and is publicly accessible [1]. Mandatory reporters include manufacturers, importers, and device user facilities. Voluntary reporters include healthcare professionals, patients, and consumers.

2. Methods

The Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database was searched using the search term 'Abiomed' in the manufacturer field, with the event types 'death', 'injury', and 'malfunction' over the time period from 2008 to 2021.

3. Results

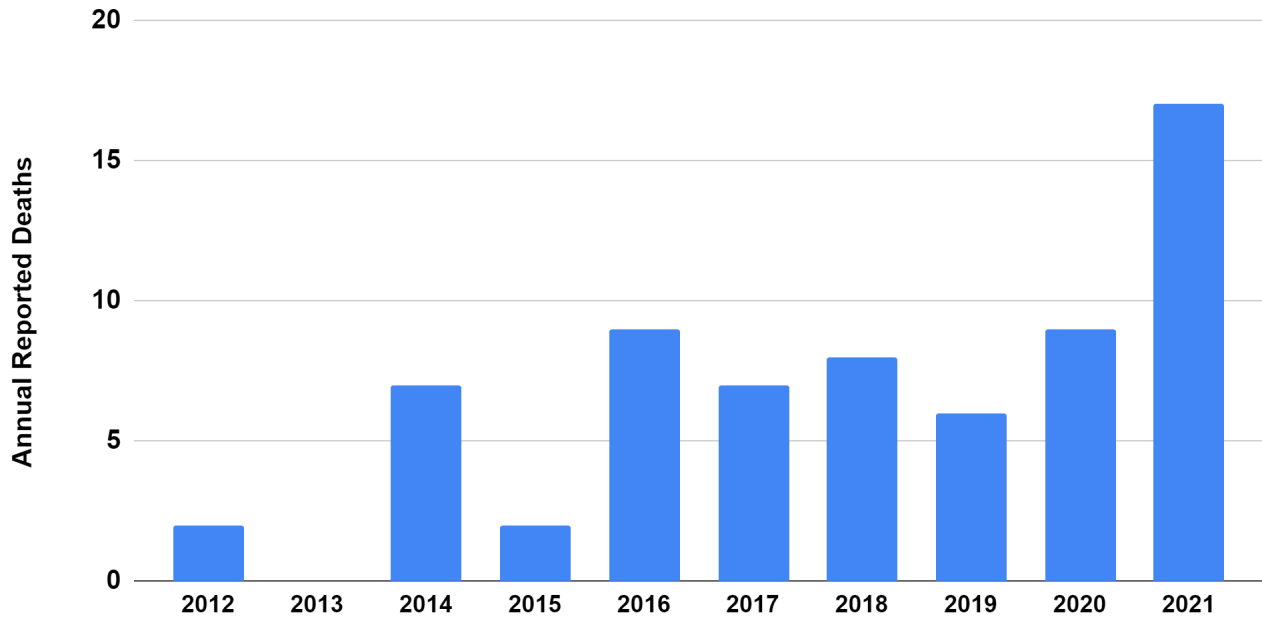


Fig. 1: Annual reported deaths for Abiomed Impella(R) heart pump devices.

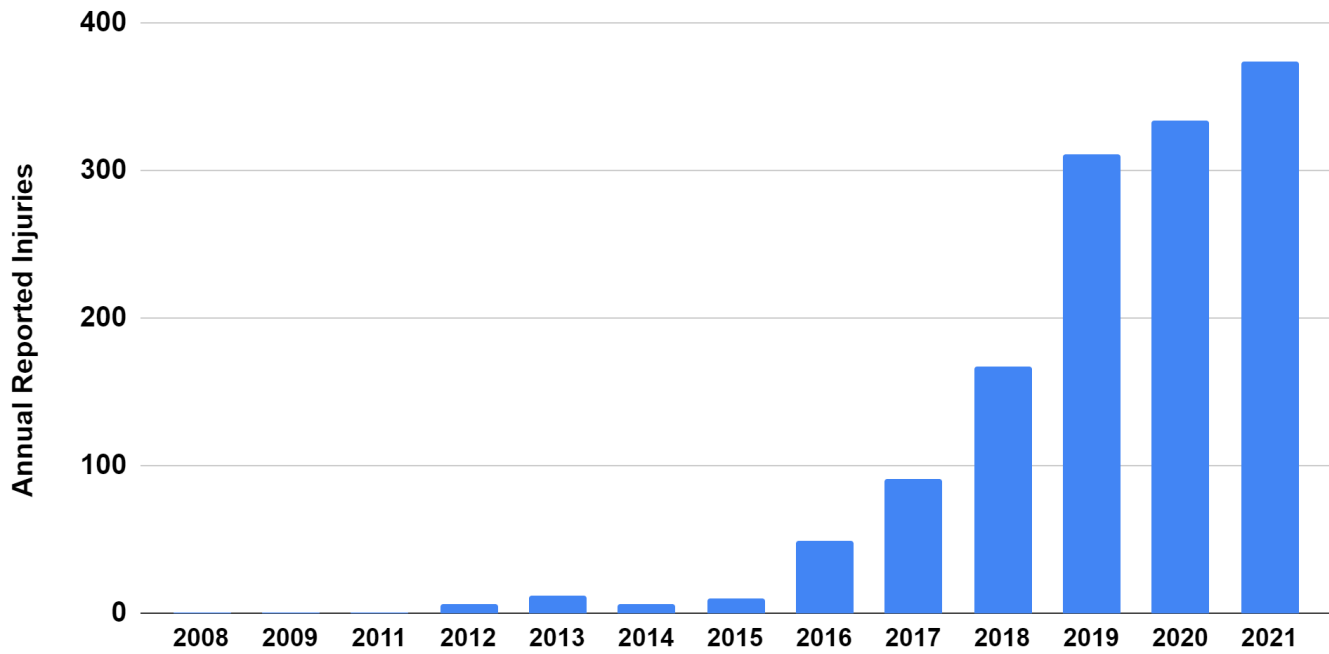


Fig. 2: Annual reported injuries for Abiomed Impella(R) heart pump devices.

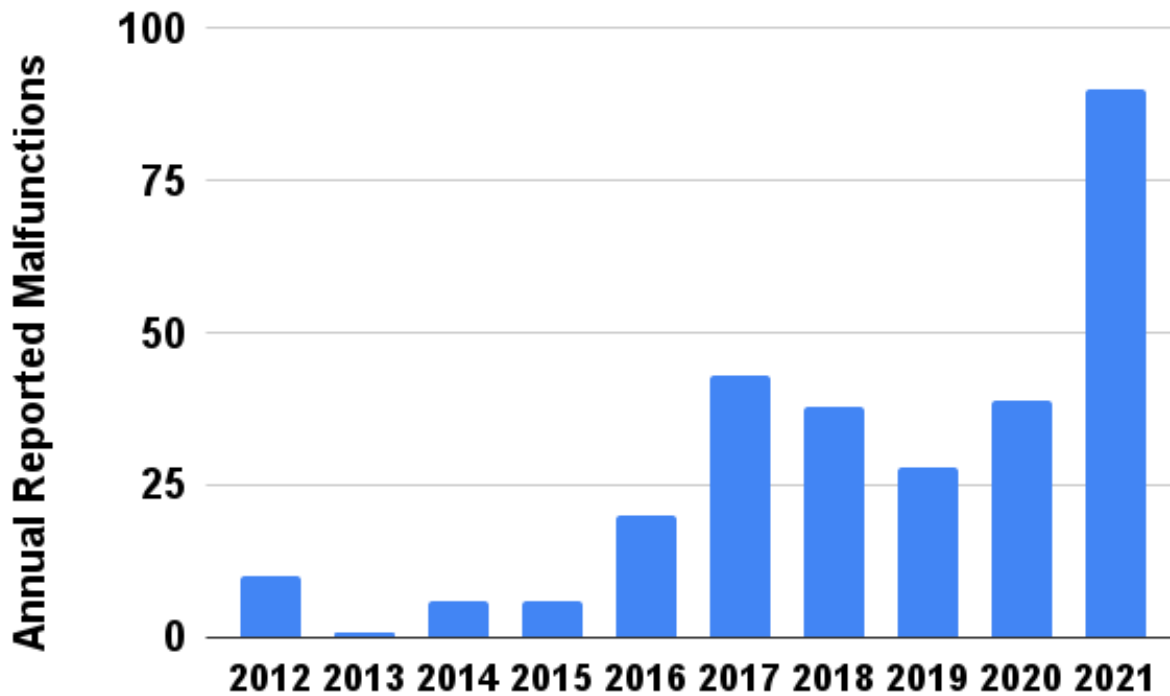


Fig. 3: Annual reported malfunctions for Abiomed Impella(R) heart pump devices.

4. Conclusion

In conclusion, the data from the FDA MAUDE database reveal a significant increase in reported malfunctions, injuries, and deaths for Abiomed Impella(R) heart pump devices during the decade from 2012 to 2021. The reported deaths in figure 1 increased from 2 in the year 2012 to 17 in the year 2021, which is a 750% increase. The reported injuries in figure 2 increased from 1 in the year 2008 to 374 in the year 2021: a steady and alarming increase. The malfunctions across the years varied but generally had an upwards trend.

The upwards trend of the adverse events and continuation of problematic procedures/materials highlights Abiomed's indifference towards its patients. The placement of all Impella devices (across the aortic valve) can pose numerous issues. One such issue is cardiac perforation. Once the Impella is implanted, it uses a motor current to operate [5]. A well known risk of a motor current is cardiac perforation. Cardiac perforation can be caused by mechanical trauma due to CATHETER manipulation [6]- the Impella device is a CATHETER based ventricular assist device [7]. Extensive catheter manipulation (especially in areas with thin walls: aortic valve) can cause the chamber wall to tear. Furthermore, cardiac perforation was one of the leading causes of the adverse events. For example, cardiac perforation accounted for 14% of the injuries. Abiomed's ignorance of this repeated issue proves it's apathy

Moreover, the results indicate that only 33% of deaths that occurred with Abiomed Impella(R) heart pump devices were accurately reported as deaths. Most of the misreported deaths were disguised as injuries and malfunctions. These results indicate a need for continuous improvement of medical devices, as well as timely reporting of adverse events, particularly when one manufacturer has a monopoly on the market. The rise in malfunctions, injuries, and deaths also indicates a need for incentives to encourage competitors to enter the market.

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