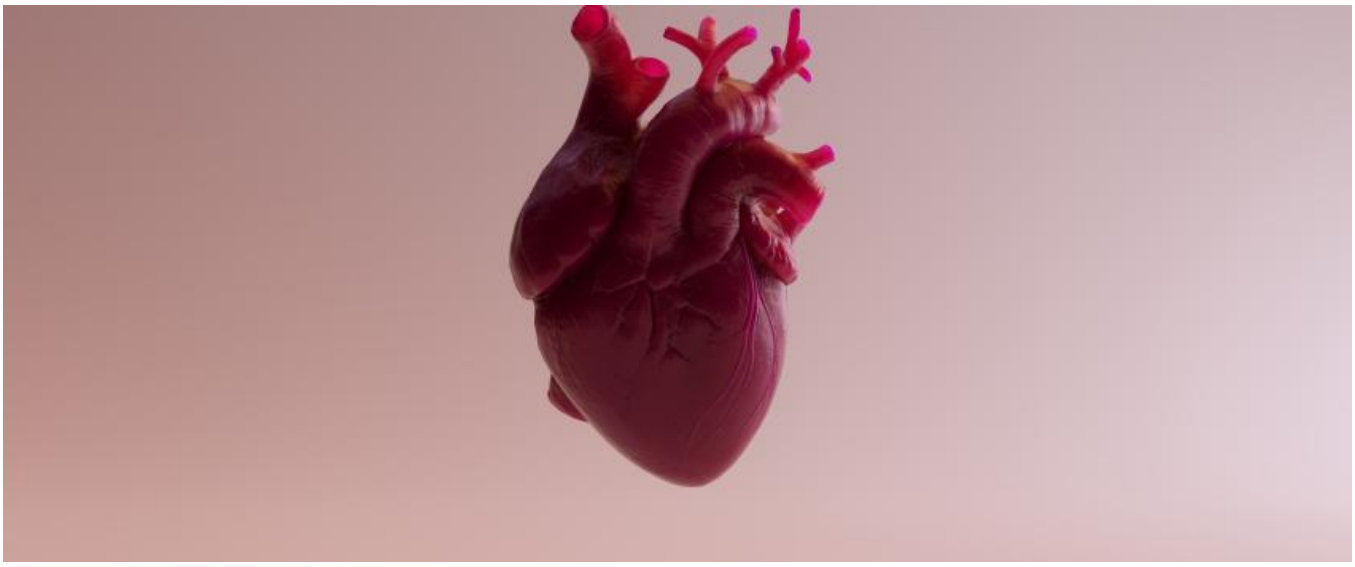
Evaluate Vantage

June 07, 2021

Medtronic bows to the inevitable

Elizabeth Cairns



Paying $1.1bn for Heartware five years ago was not the company's smartest move.

Medtronic's decision last week to stop selling its ventricular assist device HVAD was a long time coming. The implanted heart pump had been the subject of over 100 complaints to the US FDA stating that it takes too long to restart or fails to restart altogether, including reports of 14 deaths and 13 cases where the device had to be explanted.

The company's withdrawal leaves Abbott the only occupant of the ventricular assist device (VAD) space. Abbott believes that it can meet the expanded demand for these pumps with its own device, called HeartMate. Both groups acquired their technologies by buying the devices' makers – and though Abbott's deal cost rather more than Medtronic's it appears to have been the wiser choice.

The patients who receive VADs are very ill. The devices are used to temporarily assist a failing heart to pump blood as the patient awaits a heart transplant, or in some cases as a permanent implant in those unsuitable for transplant. Without a VAD, these patients would not have long to live.

Back in 2015 the cardiology-focused group St Jude Medical bought the VAD maker Thoratec for $3.4bn, thus obtaining the HeartMate device. St Jude was acquired by Abbott in a $25bn deal a year later. Two months after the Abbott-St Jude deal was announced, Medtronic made a defensive move by buying Heartware, the originator of the HVAD, for $1.1bn.

Trouble

Since then the VAD market has been split between the world's two largest medtech companies. But Medtronic has been running into trouble for some time. Searching an FDA database reveals that since the HVAD was approved in the US in 2012 it has been subject to 15 class I recalls – the designation the agency uses where there is a "reasonable probability" that use of the product will cause serious adverse health consequences or death.

Abbott's Heartmate has only had two class I recalls, in 2017 and 2018.

Medtronic does not recommend removal of the HVAD in the 4,000 or so patients who already have one, since explantation is itself very risky. But any new patients requiring a VAD will be guided towards Abbott's device, which Medtronic admits is associated with lower rates of stroke and death.

Though Medtronic's exit from the market will benefit Abbott, it will benefit Medtronic, too. The HVAD line was unprofitable, according to Leerink analysts, and Medtronic had said that it would have continued to sell the

device while making a loss, had it not become clear that it was less safe than Abbott's rival product.

In any case HeartMate outsold the HVAD nearly fivefold last year, and the sellside saw the gap widening, according to consensus data from *Evaluate Medtech*. HeartMate had been expected to become a billion-dollar product in 2025 – but if Abbott absorbs all Medtronic's forecast VAD sales from now on, HeartMate could reach that milestone next year.