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Ventricular Assist Device Market Size & Share, Industry Report, 2022

Ventricular Assist Device Market Analysis By Product (Left, Right, Bi-Ventricular Assist Devices), And Segment Forecasts To 2022

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Industry Insights

Global Ventricular Assist Device (VAD) market was valued at USD 762.9 million in 2014 and is expected to witness positive growth over the forecast period. VAD’s are specifically used in Class III and IV advanced heart failure patients as defined by the New York Heart Association (“NYHA”) or in those patients who are awaiting heart transplantation. Key factors attributing to the market growth include increasing the prevalence of cardiovascular diseases such as hypertension, coronary artery disease, and heart failure.

In 2013, according to the data published by the American Heart Association it has been estimated that in the U.S. nearly 6.6 million people suffered from heart failure and nearly 600,000 new cases are diagnosed each year.

As per data published by the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR), in 2014, approximately 2,431 heart transplants were conducted and as of February 2015, the number of people awaiting the heart transplantation reached 3,986.

Furthermore, increasing the prevalence of diabetes, genetic factors, lifestyle factors such as junk food, tobacco consumption, substance abuse, alcohol addiction are also expected to significantly contribute to the end-stage cardiovascular disease population.

The above-mentioned disease prevalence rates, coupled with a wide gap in the number of organ donors available and the number of people awaiting a heart transplant, project a positive growth trend for ventricular assist device over the forecast period.

U.S. ventricular assist device market, by product, 2012 - 2022 (USD Million)
Product Insights

Left ventricular assist device (LVAD), Right ventricular assist device (RVAD), Bi-ventricular assist device (BI-VAD) are amongst key product segments included in the scope of the study. VADs replicate the functions of the heart by pumping blood throughout the body and allow the heart to recover to its normal functioning capacity. In cases, where the heart cannot recover to its normal function these devices act as long-term treatment options and significantly improve healthcare outcomes. VADs can be used as bridge-to-transplant (BTT), bridge-to-recovery or destination therapies (DT).

These products provide cardiac support for patients with late-stage heart failure (HF) and are waiting for a donor's heart. It has been estimated that nearly 40% to 50% of the patients who are on the organ transplant waiting list in the U.S. are treated using a VAD i.e bridge-to-transplant therapy. However, due to an increasing number of patients on the waiting list for organ transplantation, use of these products for destination therapy is expected to witness lucrative growth over the forecast period.

Technology advancements in product design, development, raw material, and manufacturing have significantly contributed to the industry expansion since the launch of first generation device which were equipped with pulsatile volume displacement pumps are were powered using pneumatic or electrical drive systems. To overcome certain limitations and defects second generation products with continuous flow were developed.

These products are light weight, more efficient and compact. The continuous flow device includes axial flow and centrifugal pumps. Some of the key products in this category are Jarvik 2000, the Impella Pump System, and Thoratec Heartmate II. Furthermore, the third generation products such as Dura Heart, Ventr Assist, Heart Mate III LVAD are expected to be commercialized post clinical trials and regulatory approvals in the near future.

In 2014, LVAD accounted for the maximum market share of 74% owing to a high number of cases with left ventricular damage. Usage of LVAD is higher due to cardiomyopathy, heart
stroke, and heart failure conditions across the globe. These products support the systolic function of the heart and help in maintaining adequate blood flow to rest of the body. Furthermore, this segment is expected to retain the high market share over the forecast period.

**Regional Insights**

The industry is segmented on the basis of the region as North America, Europe, Asia Pacific, MEA and Latin America. The North America held the largest market share of over 50% in 2014. This may be attributed to increasing prevalence of cardiovascular diseases such as hypertension, stroke, coronary heart disease, and heart failure. Furthermore, the presence of high-quality healthcare infrastructure, high patient awareness levels and better reimbursement policies for implantation procedures are expected to propel the usage rates over the forecast period.

Asia Pacific is expected to be the fastest growing regional market with a CAGR of over 15% over the next seven years. Rising prevalence of cardiovascular disease which in turn leads to stroke, heart failure, and other end-stage CVD diseases and constantly improving healthcare infrastructure are key factors driving the industry growth. Furthermore, increasing out of pocket healthcare expenditure along with the expansion of health insurance services across major tier-I, tier-II cities, and rural centers are expected to promote the growth of this industry. High promotion of medical tourism activities by various governments and disproportionate increase in waiting list for organ transplants compared to a number of organs donors are some of the other key factors expected to significantly boost the VAD market over the forecast period.

**Competitive Insights**

Key players operating in the industry include Abiomed, Heart Ware International, Thoratec, Berlin Heart, Cardiac Assist, Jarvik Heart, and Reliant heart. Thoratec accounts for the maximum share of over 71.00% and is followed by HeartWare International. Entry of new players and technological advancements are expected to further intensify competition over the forecast period.
Jarvik Heart Sees A Future In The U.S.

Nov. 9, 2016 3:49 PM ET
by: EP Vantage

With almost no sales and marketing operation Jarvik Heart has quietly managed to snare 25% share of the heart pump market in France and Italy, and 40% in Japan. Considering that its competitors include Medtronic (NYSE:MDT) and Abbott (NYSE:ABT), this is impressive. The question is whether it can replicate the feat in the US.

The company is starting pivotal US trials for an entirely new, much smaller left ventricular assist device (LVAD) designed for use in children awaiting a heart transplant. “Ours is the only one that is going to be approved for infants,” says Peter Hinchliffe, Jarvik Heart’s president. He explains that, should it gain FDA approval in this setting, the company will expand its use into adult patients. This technology could be a major success in heart failure – either for Jarvik itself or for any company that acquires it.

An acquisition is clearly the best way to expand sales of Jarvik’s devices. The private group – it is owned by the artificial heart developer Robert Jarvik – is expecting sales of around $15m this year and while its manufacturing base in downtown Manhattan is coping well at the moment, it will not be sufficient for commercial demand should widespread use be permitted.

The Jarvik 2000 LVAD is CE marked and has been on the market in Europe since 2005; around 130 are implanted each year. It is the smallest commercial-stage pump in the world, and unlike the other offerings, it can be implanted without cracking the chest. But the new device the company is working on is smaller still.

Tiny

This device is called the Jarvik 15mm LVAD. Mr. Hinchliffe says it is the size of an AA battery and is suitable for patients who weigh 5kg or more – roughly those aged around two months and up. That said, the enrollment criteria for the pivotal Pumpkin trial specifies patients who weigh 8-20kg.

Pumpkin will enrol 88 patients, half of whom will be treated with a Jarvik 15mm and half the only assist system for children available in the US: Berlin Heart’s Excor. But this is not an implanted device, and Excor patients cannot leave the hospital. Many cannot leave their bed.
The study’s endpoints concern adverse event rates and survival at six months. “We’ve had people live nine and a half years on the Jarvik 2000,” Mr. Hinchliffe says, “It’s the identical design, it’s just downsized. We feel very confident that this pump will perform as well as its larger brother.”

The Jarvik 2000 and the smaller Jarvik 15mm

One of the most common adverse events associated with LVADs is infection, and here Mr. Hinchliffe says the larger, marketed Jarvik 2000 has an advantage over other devices on the market.

All other implanted LVADs have a drive line – a power supply – that exits the patient’s skin at the abdomen. Infection rates in these drive lines are around 30% or 40%, Mr. Hinchliffe says, and they have a deleterious effect on quality of life, with patients unable to bathe or swim as they cannot immerse themselves above the level of the drive line.

The power supply to the Jarvik 2000 does not exit via the abdomen. Instead the wires are fed up through the neck to a small titanium post that is screwed to the skull and comes out through the skin behind the patient’s ear.

“That has been proven, in cochlear implants, to have extremely low infection rates, and because the post is attached to the skull there’s very little movement that could tear tissue,” Mr. Hinchliffe says. The infection rate with this drive line is around 2%, he says.

The 2000 is in a pivotal US trial as a permanent implant, known as destination therapy. The 350-patient trial started in 2013 but so far only 50 or 60 patients have been enrolled, and data will not be released until 2018, so the Jarvik 2000 will likely be overtaken by the 15mm thanks to shorter follow-up in the pediatric study.

Resources

Mr. Hinchliffe says that the technological advantages of the 2000 explain how it has come to occupy such a big slice of the market. Though Medtronic and Abbott are its most powerful competitors, they are not the only ones – Berlin Heart and ReliantHeart have CE marked LVADs too (ReliantHeart relies on tech to lure buyer, August 17, 2016). The devices do not compete on cost, he says, with the Jarvik 2000 being sold in Europe at much the same price level as the others.

But growing sales in Europe and expanding onto the US will be tricky without the kind of investment Jarvik cannot afford.
The best chance for Jarvik Heart to grow is to become part of a bigger company that has those resources – sales and marketing, clinical – that can support a device like this within their infrastructure,” says Mr. Hinchliffe. “If, say, Boston Scientific or one of the large companies in heart failure were to buy Jarvik Heart … that would make a lot of sense.”

Doubtless potential acquirers would want to look at pivotal data – or even wait until one or both devices gains US approval – before jumping.

<table>
<thead>
<tr>
<th>Study</th>
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<td>Pivotal US trial of Jarvik 15mm in 88 paediatric patients (Pumpkin)</td>
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<td>Pivotal US trial of Jarvik 2000 in 350 adult patients</td>
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