vizient®

Electrophysiology, cardiac rhythm management and heart failure technologies

Technology Watch | 2018 Volume 1

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Disclaimer: Members of the Vizient cardiovascular staff attend clinical sessions at important cardiovascular meetings throughout the year. The staff meets with suppliers, reviews new technologies and monitors data from pertinent clinical trials. The information is consolidated into this overview of product and practice trends in the various cardiovascular segments. This document is intended to educate nonclinical hospital staff by offering them insights into new and innovative technologies. Vizient staff members have no personal financial connections with the suppliers and no conflicts of interest in the development of this document. The products and trends presented are for educational purposes. Vizient does not endorse any of the products described in this document.

Introduction

The Vizient® Cardiovascular Technology Watch is intended to educate and provide insights into new and innovative technologies that support delivery of the highest-quality cardiovascular care. This issue highlights the latest products and pharmaceuticals available in the market as well as emerging technologies. The Cardiovascular Technology Watch also features a Vizient-contracted supplier of innovative products for pediatric patients and Vizient pricing projections for both products and pharmaceuticals.

Market watch

The cardiac rhythm management (CRM) and electrophysiology (EP) segments of the cardiovascular market remain dynamic. Similar to other cardiovascular segments, new technologies are being developed, such as leadless pacing, left atrial appendage closure and advanced ablation systems. Within the heart failure segment, innovative devices are being developed to augment or supplant existing devices and therapies. The pace of evolutionary product development within the cardiac rhythm devices environment continues its pace. Today, all the major U.S. suppliers now sell a full line of magnetic resonance imaging (MRI)-conditional devices; these have been heavily promoted and there has been a respective rise in their use. Vizient data shows the use of these MRI-conditional devices has almost tripled in less than a year. Hospitals can expect their overall cost for cardiac rhythm devices to rise dramatically; cost increases estimated at 18 to 22 percent are directly attributable to the use of premium-priced MRI devices, even as average selling prices for MRI-conditional devices are beginning to decline. The increased use of left atrial appendage devices and the shift to advanced ablation and mapping catheters in the EP lab are also driving supply costs higher. The result is better care—at a price.

These markets are experiencing other dynamics. In the EP market, sales practices by some suppliers are increasing their control of both the procedure and device cost, while the physicians' ability to choose what type of device to use for a procedure is slowly being limited. In addition, device reprocessing limitations are increasing. In the CRM market, hospitals that do not track device warranties or properly bill Medicare run the risk of being audited in the future. Hospital supply chain leaders need to remain vigilant and work closely with their clinicians to help the health care system to develop solutions and continue to provide better patient care.

Economic watch

Price projections for the CRM and EP segments of the cardiovascular market are shown in tables 1a and 1b. The pricing trends reflect the change in price over the past 12 months comparing the average 2016 versus 2017 prices (Table 1a).

Table 1a. Changes in pricing trends over the last 12 months

Category	Change (%)
CRM	
Pacemakers	↓ 7.0
Implantable defibrillators	↑ 1.2
Resynchronization therapy	↑ 6.0
Implantable cardiac monitors	Flat
EP	
Advanced ablation catheters	↓ 1.1
Ablation catheters	↓ 10.3
Mapping catheters	↓ 1.4
Diagnostic catheters	↓ 4.5

Abbreviations: CRM = cardiac rhythm management; EP = electrophysiology.

Table 1b shows the current average market pricing by product segment. All prices listed include the average prices for that category of products, rather than sale prices for specific products. Individual hospital pricing may vary depending on considerations such as rebates, quality and volumes that are not included in these estimates.

Table 1b. Pricing trends: average prices

Supplier	Average price
CRM devices	
Resynchronization therapy	
Abbott	$16,580
Biotronik	$16,690
Boston Scientific	$16,870
Medtronic	$19,140
Implantable defibrillators	
Abbott	$11,990
Biotronik	$13,790
Boston Scientific	$14,550
Medtronic	$14,230
Pacemakers – MRI	
Abbott	$3,910
Biotronik	$4,210
Boston Scientific	$4,390
Medtronic	$4,390
Pacemakers – non-MRI	
Abbott	$3,360
Biotronik	$3,240
Boston Scientific	$3,290
Medtronic	$3,250

Supplier	Average price
EP devices	
Advanced ablation catheters	
Abbott	$2,220
Biosense Webster	$2,780
Boston Scientific	N/A
Medtronic	N/A
Ablation catheters	
Abbott	$775
Biosense Webster	$1,110
Boston Scientific	$1,080
Medtronic	$1,090
EP diagnostic catheters	
Abbott	$660
Biosense Webster	$975
Boston Scientific	$615
Medtronic	$140

Supplier	Average price
Heart occlusion device average prices	
Septal occluders	
Abbott	$6,460
WL Gore	$5,320
Left atrial appendage occluders	
Atricure	$3,340
Boston Scientific	$16,160
SentreHeart	$6,950

Abbreviations: CRM = cardiac rhythm management; EP = electrophysiology; MRI = magnetic resonance imaging.

All estimated selling pricing is the averaged pricing over a category of products. These are not selling prices for specific products. Your pricing may vary given considerations such as rebates, quality and volumes that are not included.

Supplier watch

Innovative Health

Innovative Health offers reprocessed products and services, with a focus on cardiovascular products. The company was formed in 2015 by the same individuals who worked with the U.S. Food & Drug Administration (FDA) in the early 2000s to develop regulations that ensures reprocessed products are safe and effective. The company's executive leadership understands the market and how to reprocess products. With its focus on cardiovascular products, Innovative Health hopes to close the gap between the products being used and those that can be reprocessed, and addresses the growing needs of the rapidly changing cardiovascular medical device market.

Cardiovascular products, and especially EP products, are among the fastest evolving of all medical products. Reprocessed products must keep pace; however, to ensure patient safety and efficacy, each reprocessed family of products must be FDA 510(k) cleared. Reprocessing companies have not kept pace with technology development and market demand, allowing a gap to form.

Reprocessing is a safe and effective practice, and many hospitals use reprocessed products to manage supply chain costs. The word "reprocessing," however, can elicit varied reactions from hospitals and the supplier community. A report from the General Accountability Office to Congress reported:

"After reviewing the available evidence — including [the] FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed Single Use Devices (SUDs), peer-reviewed studies published since 2000, and the results of our and [the] FDA's consultations with hospital representatives — we found no reason to question [the] FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs. That is, the available information regarding safety, while not providing a rigorous safety comparison between reprocessed SUDs and other devices, does not indicate that reprocessed SUDs currently in use pose an increased safety threat."[1]

By expanding its portfolio of reprocessed cardiovascular products, Innovative Health helps hospitals by increasing the number of device options and giving clinicians more choices.

Reprocessed devices

Reprocessed devices must receive FDA 510(k) clearance and detailed data on cleaning, sterilization and functional performance must demonstrate that each device will remain substantially equivalent to a predicate device until reaching the designated maximum number of times it can be reprocessed. Daniel Schultz, MD, director of the FDA's former Center for Devices and Radiological Health, told the House Committee on Government Reform that "Single-use devices that meet [the] FDA's regulatory requirements are as safe and effective as a new device."[2] Not all products can be reprocessed, but each product that can goes through cleaning as well as functional and sterility testing before being allowed to be reused. The FDA has cleared the reuse of about 70 device families, dividing them into the following three categories:

- High-risk (e.g., EP catheters, balloon angioplasty catheter, implanted infusion pumps) – reprocessed only if sufficient evidence of safety and efficacy is available and if the reprocessing facility has been inspected
- Medium-risk (e.g., ultrasound catheters, laparoscopic equipment) – requires the same evidence of safety and efficacy as high-risk devices with no requirement for facility inspection
- Low-risk (e.g., EP cables, elastic bandages, tourniquet cuffs) – can be reprocessed without having to submit any evidence

Most importantly, commercial reprocessors for devices originally labelled for single use must meet the same requirements as the manufacturers of new devices. Reprocessed devices must be functionally tested to ensure product performance and tested for sterility prior to being released for use. This differs from new device manufacturing, in which functional testing is done by manufacturing lot sampling and can be released into a company's distribution system prior to the lot sterility testing being completed. This means that reprocessed devices have been found to fail *less* frequently than new devices.[3]

Hospital impact

The economic impact of using reprocessed cardiovascular medical devices can be significant, but will vary by hospital based on its use of reprocessed devices and product mix. A 2015 study of reprocessed products found that for each device, one reprocessing instance was associated with more than 26 percent in savings, and five reprocessing instances (FDA regulatory maximum) was associated with more than 56 percent in savings.[4]

Technology watch

Cardiac rhythm management devices

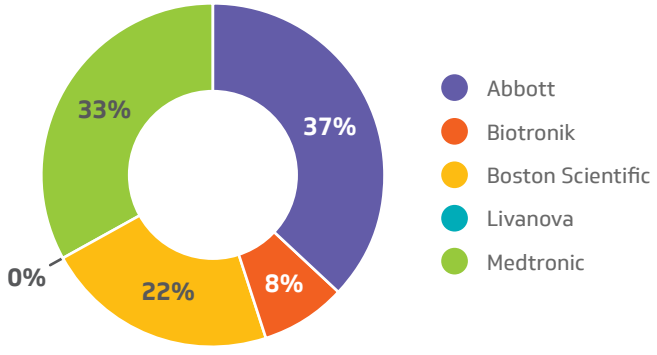
The CRM market continues to be an important product segment, although technological advancement in this market has been mixed. With the exception of the leadless pacemaker introduced in 2016, there hasn't been an emergence of any technologically significant device since the introduction of cardiac resynchronization therapy devices in 2006. CRM devices are evolving, however, and reductions in device size, improved battery life and specifically, the MRI compatibility indication have become the norm over the past 10 years. The introduction of multielectrode left ventricular pacing can be seen as an evolutionary advancement, since it provided incremental patient care allowing for a 53 percent lower hospitalization rate[5] and lower patient readmission risk at 30 days.[6] Technologies produced by various competitors have converged, and today all major manufacturers produce high-performance devices with minimal differences.

The CRM market is forecast to be flat to slightly declining through the end of this decade. Pacemaker implantation is anticipated to decline approximately 1.9 percent, but that decline is offset by an increase in cardiac resynchronization therapy devices at approximately the same rate (1.7 percent), resulting in an overall market decline of 1.0 percent.[7] The decline in defibrillator implantation is the most important contributing factor to the market's overall modest decline. By 2020, the implantation of cardiac resynchronization therapy devices will outpace those of implantable cardiac defibrillators. Average selling prices should continue to decline due to a lower patient population, increased competition for market share and hospital consolidation, including large hospital systems consolidating suppliers.

Cardiac rhythm management device expenses are expected to significantly increase for most hospitals in 2018, with adoption of MRI-compatible devices as the cause. Prior to 2018, the market limited the use of MRI-compatible devices; however, with suppliers now aggressively marketing these devices, sales are surging. The premium for an MRI-compatible device is 31.5 percent, 18.1 percent and 21.6 percent for pacemakers, implantable defibrillators and cardiac resynchronization therapy devices, respectively. From 2016 to 2017, data showed the penetration of MRI-compatible systems was 57.2 percent, 19.8 percent and 22.8 percent for pacemakers, implantable defibrillators and cardiac resynchronization therapy devices, respectively. Overall prices for MRI-compatible devices are trending down, but for many hospitals, the product mix change to these premium devices will result in significant increases to supply costs. Currently, Medtronic has dominant market share in all segments of the MRI-compatible device sector.

The CRM market is currently being led by Abbott (Figure 1 and Table 2). Abbott's 2016 introduction of its multipoint left ventricular pacing device catapulted it past Medtronic in the cardiac resynchronization segment. However, Medtronic is the first company to receive FDA approval for MRI compatibility on all its cardiac rhythm devices. Medtronic's dominant market position in all of the MRI market subcategories and the rapid market shift will return the company to the leading market share position in 2018.

Figure 1. Total cardiac rhythm management market



Source: Vizient Intellisource, PSC Price Benchmark, January 2018.

Table 2. Cardiac rhythm management market

	Pacemakers	Defibrillators	Resynchronization
Abbott	1st	3rd	1st
Biotronik	4th	4th	4th
Boston Scientific	3rd	2nd	3rd
Livanova	5th	5th	5th
Medtronic	2nd	1st	2nd

Source: Vizient Intellisource, PSC Price Benchmark, January 2018.

Another rapidly growing market segment is implantable cardiac monitoring. These monitors have existed for some time; however, with the introduction of the Medtronic Reveal LINQ device, usage has grown and positively supported the company's U.S. sales. Medtronic stated in its fourth quarter 2017 earnings call that the Reveal LINQ device showed mid-single digit growth on a constant currency basis as the adoption of the device continued.[8] Estimates forecast device growth at a compounded annual growth rate of 7.4 percent beginning 2017 and into 2023.[9] The success of Medtronic's device has resulted in other suppliers entering the implantable cardiac monitoring market segment.

Pressure on average selling prices will continue. Once average selling prices reset at an estimated 18 to 22 percent higher level due to the rapid shift toward using MRI-compatible devices, prices will stabilize and resume their downward pricing trend.

Potential new devices

CRM devices that are in development and are likely to enter the U.S. market are shown below.

Leadless pacemakers

Nanostim (Abbott)

The Nanostim is a single chamber, leadless pacemaker. It does not need a connector, pacing lead or pulse generator pocket. A distal nonretractable, single-turn helix affixes the device to the wall of the right ventricle. The tip electrode includes dexamethasone sodium phosphate that is intended to promote low acute and chronic stimulation thresholds by suppressing the local inflammatory response to a foreign body. The pacemaker has a length of 42 mm and a maximum outer diameter of 6 mm. Sensing and pacing information can be communicated with an external programmer. Despite its small size, the device battery is expected to have an average lifespan of more than 9 years at 100 percent pacing, or more than 13 years at 50 percent pacing. The device is fully retrievable so that it can be repositioned during the implant procedure and later retrieved if necessary; for example, if the battery needs to be replaced. The device is not currently available commercially or for distribution or sale in the U.S.

The LEADLESS Pacemaker IDE Study (Leadless II) (NCT02030418)

Vivik Reddy (U.S., Mount Sinai Hospital [New York]), principal investigator

Study size: 1,567 patients

Prospective, nonrandomized, single-arm, international multicenter study

This global multicenter study is designed to evaluate the safety and function of the Abbott leadless pacemaker. Based on the primary data of patients, the primary effectiveness endpoint and primary safety endpoint were both met. The device was successfully implanted in 95.8 percent of patients and 93.3 percent of patients met the safety endpoint. The company has presented its data to the U.S. FDA but due to device redesign issues, the study has been suspended. The setback continues to delay getting U.S. PMA premarket approval.

Empower MPS (Boston Scientific)

The Empower MPS is a leadless pacemaker similar in design and size (volume of 0.78 cc) to other pacemakers already available. It is being designed to work alone or in tandem with the company's subcutaneous implantable defibrillator. The pacer might be used in any of three situations: 1) defibrillator patients who later need pacing therapy; 2) leadless pacemaker patients who later need an implantable defibrillator; and 3) patients who might need both a defibrillator and a pacemaker placed at the same time. A clinical trial is targeted to start in 2019. The pacemaker is not currently available commercially or for distribution or sale in the U.S.

Leadless pacemaker (Biotronik)

Biotronik has a program underway to develop a leadless pacemaker. No further details are available at this time.

WiSE Wireless Cardiac Stimulation System (EBR Systems)

The WiSE CRT System is a wireless technology for cardiac resynchronization therapy. This technology is the only wireless pacing system designed to stimulate the heart's left ventricle, and consists of a tiny electrode implanted in the left ventricle. With every heartbeat, it receives a synchronized ultrasound signal from a small transmitter placed between two ribs. Those sound waves are converted to electrical energy, providing cardiac pacing. The device received a Conformité Européene (CE) mark in 2015. The device is not currently available commercially or for distribution or sale in the U.S.

Stimulation of the Left Ventricle Endocardium–CRT study (SOLVE-CRT) (NCT02922036)

Company-sponsored study

Study size: 350 patients

Prospective, multicenter, randomized, controlled, double blinded, pivotal trial U.S. study

This pivotal study is designed to evaluate the safety and function of the WiSE System. The study began enrolling patients in late 2017. No clinical data is available.

MRI-compatible devices

Resonate family of CRM Systems (Boston Scientific)

Boston Scientific, which launched the Resonate family of implantable cardioverter defibrillator and cardiac resynchronization therapy defibrillator systems, is the last major U.S. supplier to receive approval from the FDA for the MRI conditional clearance. With this approval, the shift to promoting MRI conditional systems will increase. Unique to this family clearance is that prior FDA-cleared systems already on the market also received the MRI conditional clearance. The MRI conditional labeling allows patients implanted with specific models of the company's Resonate family of devices to receive full-body MRI scans in 1.5 Tesla environments when conditions of use are met. This capability extends beyond the Resonate family and includes patients who were previously implanted with Autogen, Dynagen and Inogen devices.

Implantable cardiac monitors

Confirm Rx Implantable Cardiac Monitor (Abbott)

The Confirm Rx is an implantable cardiac monitor that is designed to detect irregular heartbeats. A unique feature of the monitor is that it uses Bluetooth to sync to the patient's smartphone. Cardiac recordings pass from the device to the smartphone and then onto the company's online portal, where cardiologists can view the data at any time. A schedule is set to move saved data from the device to the phone and to the online portal. All the data transfers are encrypted to ensure privacy. The device measures 49 mm x 9.4 mm x 3.1 mm, similar to the market-leading device. The device was cleared by the FDA in October 2017.

Implantable ICM (Boston Scientific)

The currently unnamed implantable cardiac monitor will provide unique features that no other currently available devices have. The device is also being designed with algorithms to detect atrial arrhythmia, pause, bradycardia and tachycardia. The company envisions a seamless patient interface and back-end monitoring that links to its existing remote monitoring system. The company anticipates the device will be available in the U.S. market in the first half of 2019.

Other products

Universal Cardiac Implant Platform (Murj, Inc.)

The Universal Cardiac Implant Platform is a cloud-based, Health Insurance Portability and Accountability Act-compliant application that consolidates data from all implantable cardiac device types and manufacturers into a single review platform. The platform is intended to ease the growing burden of implantable cardiac device data transmission and analysis. The company claims the application improves workflow and reduces a routine device check to less than two minutes, with just two clicks. Physicians can review and approve all device impressions with a patient's prior event data immediately accessible. Data is collected and stored in the company's off-premise data warehouses. The platform uses dashboards and other visualization tools to boost productivity and track and measure care benchmarks for cardiovascular implantable electronic device management. The platform launched in the U.S. in May 2017.

Carnation Ambulatory Monitor (Bardy Diagnostics, Inc.)

The Carnation Ambulatory Monitor is a single patient use, continuous recording ambulatory electrocardiogram (ECG) monitor that records for up to seven days. The electronics allow single-channel, P-wave centric electrocardiogram recordings of the small signals that come from the upper heart chambers. The device is comprised of two parts: a reusable monitor/recorder and an adhesive securement band aid-like device that contains the two electrodes. The device, which weighs 18 grams, measures seven inches long, with a 1 ½-inch hourglass-shaped width and a thickness of three-eighths. It is water-resistant and designed to be easily worn for extended periods. Data collected is stored within the monitor and can be downloaded by a physician or clinician. The monitor is reusable, thus enabling a reduction in hospital costs. The device is available for sale in the U.S.

QardioCore (Qardio, Inc.)

The QardioCore monitor is a single channel ECG designed to provide continuous medical grade data on heart rate and heart rate variability, skin temperature, respiratory rate and activity tracking. The device sampling rate is 600 samples per second with a 16-bit sampling resolution. The device connects via Bluetooth to a patient's smartphone, during which time data storage is practically unlimited; up to 10 hours of data can be stored when not connected to a smartphone or tablet, depending on usage conditions. The monitor is splash- and rain-resistant. The device has not received FDA clearance and is not currently available commercially or for distribution or sale in the U.S.

MagLense Technology (Cambridge Consultants)

MagLense is an innovative "through the body" wireless power transfer system that provides flexible, efficient and safe wireless power transfer to devices inside the body without having to worry about precise alignment with the implant, or the size and body shape of the patient. The system uses multiple uniquely shaped flexible coils to shape the applied magnetic field so that it intelligently targets an implant. This configuration and control architecture enables more efficient power transfer to the implant. The system works from up to about 19 inches from the implanted device, and is self-calibrating to deliver the optimum power for different implant locations, orientations, body sizes and shapes. The design targets only the desired implant, potentially avoiding any heat damage to surrounding tissue or other implants. The system may free up patients from the time spent recharging their implant batteries, and may also reduce the need for device changes in implants with permanent batteries. The technology is ready for integration into medical devices.

Economic impact

The economic impact of CRM devices will continue to increase. The aging population and growing prevalence of heart failure will continue to be the main engine increasing the expenditure on these devices. In 2018, hospitals should budget for an 18 to 22 percent increase in supply chain expense for CRM devices, due to a shift in the use of MRI-compatible devices. While data shows that the average selling price for all types of CRM devices continues to decline, related prices for MRI devices compared with their non-MRI counterparts—as well as the use of these devices—are up significantly (Table 3).

Table 3. MRI devices: types, pricing and market penetration

Device type	Price premium (%)	Market penetration (%)
Pacemakers	31.5	75.2
Implantable defibrillators	18.1	19.8
Cardiac resynchronization therapy devices	21.6	22.8

Source: Vizient Intellisource, PSC Price Benchmark, January 2018.
Abbreviation: MRI = magnetic resonance imaging.

A clinical benefit to the MRI-compatible devices exists. Hospitals need to develop a strategy for their use and budget appropriately for their higher cost.

Reimbursement

As innovative devices are introduced, suppliers can work with the federal government to develop unique reimbursement coding. The last innovation technology, leadless pacing, gained reimbursement from the Centers for Medicare & Medicaid Services (CMS) within nine months of its market introduction. In this category, hospitals should anticipate continual reimbursement coverage. Based on past trends, reimbursement rates should increase at a moderate 1 to 2 percent annually. In the longer term, this will be beneficial; in the shorter term, hospitals should budget for lower profits.

Medical device warranty management

Medical device warranty tracking and management represents a potential risk for hospitals in the U.S. Most hospitals are aware of the government regulations regarding tracking requirements outlined in 21 Code of Federal Regulations (CFR) Part 821, which requires medical device manufacturers to track their products in the event of a recall. The list of devices covers 48 product families.

Medical device recalls happen rarely. What happens when one of these medical devices is explanted, which is a more common occurrence? For many hospitals, the device is simply returned to the manufacturer for evaluation and a possible warranty credit. It may be logged into the hospital's system, but is the final disposition tracked? For most hospitals, a comprehensive system linking the department, supply chain and billing does not exist, exposing the hospital to risk. A robust warranty credit tracking process should be implemented. Third party providers are beginning to develop solutions to manage device tracking. At the heart of the issue is the CMS requirement that hospitals properly track their medical devices for billing purposes. The CMS policy states that:

"Medicare is not responsible for the full cost of the replaced device if the hospital is receiving a partial or full credit, either due to a recall or service during the warranty period. Therefore, effective for discharges on or after October 1, 2008, hospitals are required to bill the amount of the credit in the amount portion for value code, FD, 'Credit Received from the Manufacturer for a Replaced Medical Device,' when the hospital receives a credit for a replaced device that is 50% or greater than the cost of the device."[10]

The current list of medical devices that must be tracked for CMS warranty credit purposes is shown in Table 4.

Table 4. Medical devices that must be tracked for CMS credit

Device HCPCS code	Device description
C1721	AICD, dual chamber
C1722	AICD, single chamber
C1728	Catheter, brachytherapy seed administration
C1764	Event recorder, cardiac
C1767	Generator, neurostim, implant
C1771	Repair device, urinary, incontinence, with sling graft
C1772	Infusion pump, programmable
C1776	Joint device, implantable
C1777	Lead, AICD, endo single coil
C1778	Lead, neurostimulator
C1779	Lead, pacer, transvenous VDD
C1785	Pacer, dual, rate-response
C1786	Pacer, single, rate-response
C1789	Prosthesis, breast, implant
C1813	Prosthesis, penile, inflatable
C1815	Prosthesis, urinary sphincter, implantable
C1818	Integrated keratoprosthesis
C1820	Generator, neurostim, implantable, with rechargeable battery and charging system
C1840	Lens, intraocular (telescopic)
C1881	Dialysis access system
C1882	AICD, other than single/dual
C1891	Infusion pump, non-program, permanent
C1895	Lead, AICD, endo dual coil
C1896	Lead, AICD, non single/dual
C1897	Lead, neurostim, test kit
C1898	Lead, pacer, other than transvenous

Device HCPCS code	Device description
C1899	Lead, pacer/AICD combination
C1900	Lead coronary venous
C2619	Pacer, dual, non rate-response
C2620	Pacer, single, non rate-response
C2621	Pacer, other than single/dual
C2622	Prosthesis, penile, non-inflatable
C2626	Infusion pump, non-program, temp.
C2631	Repair device, urinary, incontinence, without sling graft

Source: Federal Register. U.S. Government Publishing Office website. 79(217):66873. https://www.gpo.gov/fdsys/pkg/FR-2014-11-10/pdf/2014-26146.pdf. Published November 10, 2014.
Abbreviations: AICD = automatic implantable cardioverter defibrillator; CMS = Centers for Medicare & Medicaid Services; HCPCS = Healthcare Common Procedure Coding System; VDD = virtual device driver.

Approximately 40 percent of the list involves CRM devices. A large integrated health system audited its departments and found that while the EP and catheterization laboratory services were mostly compliant, the other services had no idea that the requirement existed. The CMS expects hospitals to know federal regulation 42 CFR § 419.45, account for every warranty credit and evaluate whether the credit is 50 percent+ (triggering FB modifier; FB refers to an item provided without cost to the provider, supplier or practitioner, or a credit is received for a replacement device [do not use for services provided on or after Jan. 1, 2014]) (hospital owes) or > 50 percent (triggering the FC modifier; FC refers to a partial credit received for a replacement device [do not use for services provided on or after Jan. 1, 2014]) (hospital retains) of the device credit. The CMS assumes the device contributes to the bulk of the hospital procedure's cost for replacement and reduces the Medicare reimbursement appropriately. In some cases, the FB modifier reduction results in a hospital payment that does not cover the cost to perform the procedure. Determining if an explanted device is under warranty and if the hospital is entitled to a credit is not a clear or standardized process. When a manufacturer provides a credit for a recalled device, CMS reduces a hospital's payment when the hospital receives a credit equal to 50 percent or more of the device cost.

As many as 25 percent of pacemakers and 32 percent of implantable cardioverter defibrillators are explanted and replaced annually.[11] Since no standardized procedure exists to manage the mandated implant reporting and explant warranty credit processes, it can be confusing; however, the responsibility for doing so rests with the hospital. In an audit, the hospital is at risk. The Office of the Inspector General (OIG) reviewed this issue, and concluded:

"With just fifty $10,000 devices (explanted), $2 million dollars could be lost if the devices are replaced and the warranty is not used. With $500,000 in lost revenue, the threat of another $500,000 to $1 million in damages and $500,000 in legal fees, not to mention reputation damage."[12]

The risk of a hospital not properly managing medical device warranty credits exists. As the population of CRM and neurostimulation devices increases, the risk of improper tracking and reporting also increases.

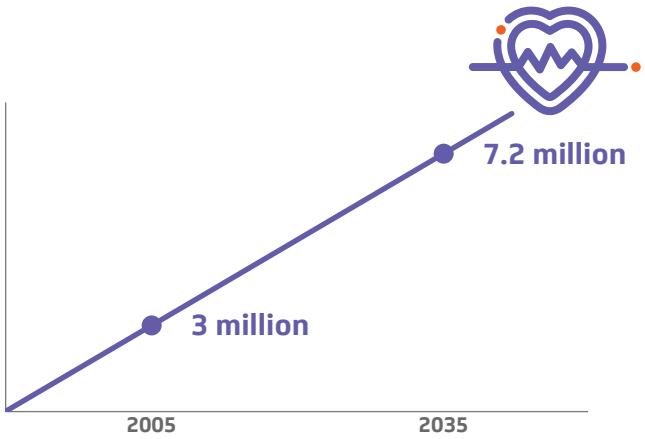
Electrophysiology devices

An EP study is a test that records the electrical activity and pathways of the heart. The studies are done to help determine what is causing the heart's irregular heartbeat or atrial fibrillation. If abnormal electrical activity is coming from an area or group of heart cells that is causing the irregular heartbeat, an electrophysiologist can use a variety of catheters to map and treat the cells. The goal is to achieve a normal heartbeat. With some conditions, an EP procedure may not improve the heart's function; in these cases, an implantable device such as a pacemaker or cardiac resynchronization therapy device will be implanted.

Approximately 2 percent of people younger than age 65 have atrial fibrillation, while about 9 percent of people aged 65 years and older have the condition, costing the U.S. about $6 billion each year[14] and doubling the incidence of the condition by 2035 (Figure 2). The EP market is expected to remain healthy, experiencing growth across all product segments at a higher rate than other cardiovascular market segments over the forecast period. Growth in the mid- to high-single digits is forecasted. Estimates from several market research sources place the compounded annual market growth between 3.7 to 6.9 percent over the next five years.[15-17] This growth is the result of both increasing procedural trends estimated at 6.9 percent and technology introductions that increase the cost of procedures. An example is the introduction of the irrigating, pressure-sensing ablation catheter. Pricing for this device is anticipated to remain relatively flat. While there are few suppliers in this market, these suppliers have used multiple strategies to maintain control of both procedure and device average selling prices. Adopting a strategy from the orthopedic market, suppliers have embedded clinical support personnel into the procedure, resulting in hospitals becoming reliant on this support. This support is so important that if a supplier clinical representative is not available, procedures are often rescheduled. Reprocessing of EP catheters is being used to maintain procedural profitability. Suppliers are actively fighting the use of reprocessed catheters with tactics such as threatening to void equipment warranties, developing newer technologies that cannot be reprocessed and requiring company clinical support to leave the procedure if a reprocessed catheter is being used, unless it is being reprocessed by the EP supplier. These tactics have allowed the suppliers to slow down the pricing pressures seen in other cardiovascular and orthopedic markets.

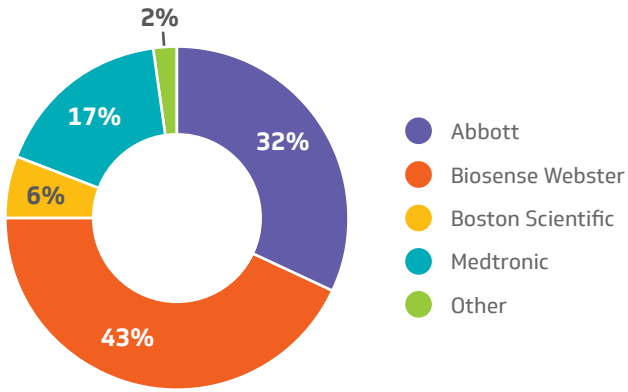
Competitively, the EP market is dominated by only a handful of suppliers. For this market segment, Biosense Webster is the market leader. In the emerging left atrial appendage segment, Boston Scientific is the leader. Figures 3 and 4 show the current market shares by manufacturer.

Figure 2. Atrial fibrillation is expected to increase



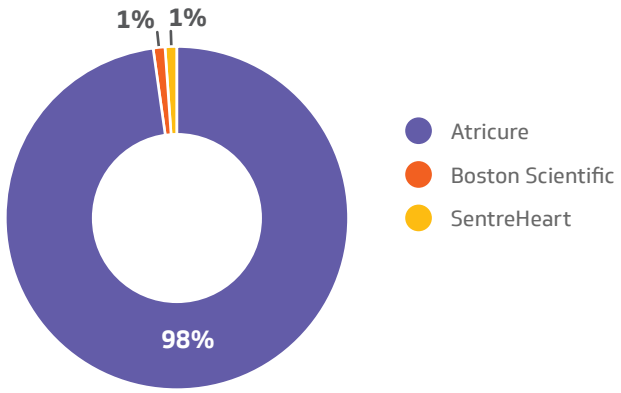
Source: American Heart Association.[13]

Figure 3. EP device market



Source: Vizient Intellisource, PSC Price Benchmark, January 2018.
Abbreviation: EP = electrophysiology.

Figure 4. Left atrial appendage device market



Source: Vizient Intellisource, PSC Price Benchmark, January 2018.

The product development in this market segment will remain robust. The combination of an increasing prevalence of heart failure and the high profitability for suppliers will drive continued technology innovation. Some of the new devices currently available in development and in clinical trials are presented next.

Mapping systems

CardioInsight Noninvasive 3D Mapping Vest (Medtronic)

The CardioInsight system uses a 252-electrode sensor vest that is worn by the patient to pair body surface electrical data with heart-torso anatomy. The noninvasive technology creates 3-D electro-anatomic maps of the heart by collecting ECG signals from the chest and combining these signals with data from a computed tomography scan. The vest technology contours to the patient`s body and allows for continuous and simultaneous panoramic mapping of both atria or both ventricles, which cannot be achieved with current invasive methods. The 3-D cardiac maps can be created by capturing a single heartbeat and enable rapid mapping of these heart rhythms. The device received FDA 510(k) clearance in February 2017.

AcQMap High Resolution Imaging and Mapping System (Acutus Medical)

The AcQMap High Resolution Imaging and Mapping System uses a basket catheter with 48 electrodes combined with 48 tiny ultrasound transducers. The basket can be manually rotated around inside the atrium to rapidly produce a very accurate electrical and anatomical map in about five minutes. Conventional EP mapping systems can take 20 minutes or longer to complete the mapping process. The electrodes in the AcQMap System do not need to contact the walls of the heart because they can detect the electrical field created by cardiac contractions. The system was approved in Europe in 2016 and the company said it will soon be submitting it for FDA 510(k) approval.

Advanced ablation catheters

Apama Radiofrequency Ablation Balloon Catheter System (Boston Scientific)

The Apama Radiofrequency Balloon Catheter is a single-shot, multi-electrode catheter that uses a 28-mm balloon with 12 proximal and six distal electrodes wrapped on the extremity of a compliant balloon designed to isolate the pulmonary vein in a single inflation. The catheter features a built-in camera allowing for real-time visualization of electrode tissue contact; customization of energy delivery around the circumference of the balloon; and integrated pacing and sensing electrodes that eliminate the need for a separate diagnostic catheter. This enables physicians to ensure effective energy delivery and provides them with the ability to customize the amount of energy delivered around the circumference of the balloon, while further reducing procedure times when compared to existing balloon technologies. This catheter system is in the clinical trial stage and is not available for sale anywhere in the world.

AF-FICIENT

Matthew Daly (New Zealand, Christchurch Hospital), principle investigator

Study size: 19 patients

Prospective, nonrandomized, multicenter, single-arm, first-in-human feasibility outside the U.S. (OUS) trial

The study was a 19-patient first-in-human study for the radiofrequency balloon technology. It showed the device could uniformly achieve pulmonary vein isolation in all patients without the need for "touch-up" with a focal ablation catheter. Patients underwent pulmonary vein isolation where radiofrequency energy was delivered simultaneously from all electrodes (up to 30 seconds posteriorly and 60 seconds anteriorly). The study demonstrated the device was safe, and additional clinical studies are planned.

Radiofrequency Balloon Ablation Catheter (Biosense Webster)

The Biosense Webster Radiofrequency Ablation Balloon Catheter is being developed to treat patients with atrial fibrillation. The system uses a balloon that is lined with 10 irrigated, flexible gold surface electrodes that are designed to independently deliver varying amounts of power. The energy level for each electrode can be tailored to prevent damage to neighboring nerves or tissue. The irrigation improves the therapy while keeping surrounding tissue cool. This catheter is in the clinical trial stage and not available for sale in the U.S.

PV Isolation with a Novel Multi-electrode Radiofrequency Balloon Catheter that Allows Directionally-Tailored Energy Delivery (RADIANCE)

Vivek Y. Reddy (U.S., Mount Sinai Hospital [New York]), principle investigator

Study size: 39 patients

Prospective, nonrandomized, multicenter, single-arm, first-in-human feasibility OUS trial

The study was a 39-patient first-in-human study for the radiofrequency balloon technology. It showed the device could uniformly achieve pulmonary vein isolation in all patients without the need for "touch-up" with a focal ablation catheter. The study showed the catheter could deliver directionally-tailored energy using multiple electrodes in patients with paroxysmal atrial fibrillation. Patients underwent pulmonary vein isolation where radiofrequency energy was delivered simultaneously from all electrodes (up to 30 seconds posteriorly and 60 seconds anteriorly). The study demonstrated the device was safe. Additional clinical studies are planned.

Excalibur Laser Ablation Balloon Catheter (CardioFocus Inc.)

The Excalibur Laser Ablation Balloon Catheter uses a laser to ablate cells in the pulmonary vein. The system consists of a compliant balloon that seats in the ostia of the pulmonary veins, with a laser inside the catheter that can be rotated around to ablate the tissue. A 2Fr endoscope camera inside the catheter directly visualizes the ablation and location of the laser, eliminating the need for electro-mapping systems and reducing procedure time. The lesions are created with 20- to 30-second ablations. About 25 ablations are needed to isolate a pulmonary vein with lesion overlap. Another advantage of the system is that it can deliver variable energy, which can be dialed down to prevent damage to surrounding tissue. This enables durable lesion creation in a range of pulmonary vein anatomies with one balloon. With extended positioning at hand, physicians can quickly establish wide areas of contact outside of the pulmonary veins. The catheter is a second generation device that optimizes the speed and magnitude of target tissue contact during pulmonary vein isolation procedures, which makes the balloon highly responsive to a range of user techniques and amounts of pressure. The device was CE mark approved in October 2017. The catheter is not available commercially or for distribution or sale in the U.S.

DirectSense Rx and ForceSensing Catheter (Boston Scientific)

Boston Scientific is developing a family of pressure-sensing ablation catheters. Studies found the contact force of an ablation catheter against tissue is a big factor in determining whether the lesion created will be effective in blocking conduction. This has led to the rapid adoption of force-sensing catheters that can show the amount of pressure being applied during ablations, which has led to improved outcomes and fewer repeat procedures. These catheters are anticipated to be available in the U.S. in mid-2018.

Pulmonary Vein Ablation Catheter GOLD (Medtronic)

The Pulmonary Vein Ablation GOLD catheter uses gold electrodes for improved thermal efficiency, as compared to the platinum electrodes of the first-generation system, to help optimize radiofrequency ablation therapy. By delivering radiofrequency energy through nine electrodes (either all simultaneously or using a subset of electrodes), the catheter helps physicians safely and efficiently create consistent lesions to effectively block the erratic electrical atrial fibrillation currents coming from the pulmonary veins. The gold electrodes provide four times the thermal conductivity of platinum electrodes, offering the potential for more accurate temperature measurement and improved power delivery. The catheter features an over-the-wire design and an anatomic shape to help physicians safely position and stabilize it in different patient anatomies. A 20-degree forward-tilted array helps physicians find optimal placement, and is designed to improve uniformity of contact with the tissue. Following an ablation, the catheter can verify pulmonary vein isolation through its ability to pace and map. The system is not approved for use in the U.S.

Advanced mapping catheters

Advisor HD Grid Mapping Catheter (Abbott Vascular)

The Advisor HD Grid Mapping Catheter has a 16-electrode array at its distal end. Its unconventional, slotted spoon-like shape produces high-quality, high-density maps of the electrical activity within the heart. The catheter's shape provides simultaneous coverage in the horizontal and vertical planes, which may minimize signal problems. The catheter is indicated to pinpoint sources of cardiac arrhythmias that are difficult to diagnose in order to locate targets for therapeutic ablation procedures. The catheter connects to the Ensite Precision Cardiac Mapping System.

AcQMap 3D Imaging and Mapping Catheter (Acutus Medical)

The AcQMap 3D Imaging and Mapping Catheter is used with the company's imaging system. The diagnostic technology reveals the electrical conduction of the whole heart chamber in extraordinarily high resolution, along with the functional structure of the heart. While existing contact voltage-based technologies have shown static, geometric representations of the heart, this system simultaneously uses intra-chamber ultrasound and dipole density mapping to display highly accurate real-time physical mechanics and electrical activity. It can also remap within seconds to confirm successful substrate modification via ablation therapy. The catheter and system were cleared by the FDA for use in October 2017.

Left atrial appendage closure devices

Following the success of the Boston Scientific Watchman left atrial appendage closure system, a number of other companies are developing devices to treat left atrial appendages (Table 5).

Table 5. Devices under development

Vendor name	Device name	Material	Regulatory status
Aegis Medical Innovations	Sentinel	Ligating loop	In development
Biosense Webster	WaveCrest	Nitinol	CE mark approved
Boston Scientific	Watchman FLX	Nitinol and polyester	CE mark approved
Cardia	Ultrasept LAA	Nitinol and polyester	In development
Custom Pediatric Medical Devices	Sideris	Frameless balloon covered with polyurethane	In development
Lifetech Scientific	LAmbre	Nitinol and polyester	CE mark approved
Occlutech	Occlutech	Nitinol mesh and nanomaterial cover	CE mark approved
Pfm Medical	Pfm	Nitinol mesh	In development
Abbott Vascular	Amplatzer Amulet	Nitinol mesh	CE mark approved, FDA IDE ongoing

Abbreviations: CE = Conformité Européene; FDA = Food and Drug Administration; IDE = investigational device exemption.

Watchman FLX (Boston Scientific)

The Watchman FLX is the next generation of the Watchman left atrial appendage closure system. The new implant is completely repositionable and removable. The device uses a closed-end nitinol cage and the capture screw is recessed to minimize clot formation in the screw head.

Evaluation of the Watchman FLX LAA Closure Technology (PINNACLE FLX) (NCT02702271)

TBD, co-principle investigator

Study size: 481 patients

Prospective, nonrandomized, multicenter U.S. trial

The study is a prospective, nonrandomized, multicenter investigation to establish the safety and effectiveness of the Watchman FLX Left Atrial Appendage Closure Device for subjects with non-valvular atrial fibrillation who are eligible for long-term anticoagulation therapy to reduce the risk of stroke but who have a rationale to seek a non-pharmacologic alternative. The study has yet to begin enrolling patients.

Amplatzer Amulet Left Atrial Appendage Occluder (Abbott Vascular)

The Amplatzer Amulet Left Atrial Appendage Occluder design is based on the Amplatzer occluder technology. The device is a two part, self-expanding, nitinol mesh disc and lobe delivered via a transcatheter system. The two parts are connected by a central waist. Like other left atrial devices, this implant is designed to completely occlude the left atrial appendage at the ostium and block any blood clots. The end screw is flush with the disc to create a smooth surface within the left atrium. The device is offered in eight sizes (16 to 34 mm) to accommodate varying anatomies, with landing zone ranges from 11 to 31 mm in diameter. The implant is not available commercially or for distribution or sale in the U.S.

Amplatzer Amulet LAA Occluder Trial (Amulet IDE) (NCT02879448)

Dhanunjaya Lakkireddy (U.S., University of Kansas), co-study chair

Study size: 1,600 patients

Prospective, randomized, multicenter active control worldwide trial

The Amulet device will be evaluated for safety and efficacy by demonstrating that its performance is non-inferior to the commercially available Boston Scientific Watchman left atrial appendage closure device in patients with non-valvular atrial fibrillation. Patients will be randomized in a 1:1 ratio between the Amulet LAA occlusion device (treatment) and the Watchman LAA closure device (control). The trial will be conducted at up to 150 sites worldwide. Patients will be followed for 5 years after device implant. The trial began enrolling U.S. patients in September 2016 with updated data from the trial not available.

WaveCrest Left Atrial Appendage Occlusion System (Biosense Webster)

The WaveCrest Left Atrial Appendage Occlusion System is a transcatheter self-expanding device constructed from a nitinol mesh and polyester patch. The mesh was selected for its unique ability to minimize undesired thrombus formation on the outside of the occluder and to demonstrate closure during the implant procedure. The device most closely resembles the Boston Scientific Watchman. The device is CE mark approved and available in other parts of the world. The implant is not available commercially or for distribution or sale in the U.S.

WaveCrest vs. Watchman Transseptal LAA Closure to Reduce AF-Mediated Stroke 2 (WAVECREST2) (NCT03302494)

Vivek Reddy (U.S., Mount Sinai Hospital [New York]), co-principle investigator

Study size: 1,250 patients

Prospective, randomized, multicenter active control U.S. trial

The study will evaluate the safety and effectiveness of the WaveCrest Left Atrial Appendage Occlusion System in closure of the left atrial appendage and evaluate reduction of embolic stroke in atrial fibrillation patients who cannot tolerate chronic oral anticoagulation therapy.

Subjects will be randomized in a 1:1 ratio to the treatment arm (WaveCrest) or the control arm (Watchman). The trial is designed to demonstrate that safety and effectiveness of the WaveCrest device are non-inferior to the Watchman device. Study results will be used for the U.S. market approval submission. The study began enrolling patients in January 2018.

LAmbre Left Atrial Appendage Occlusion System (Lifetech Scientific)

The LAmbre Left Atrial Appendage Occlusion System combines the features of both the Watchman (Boston Scientific) and the Amplatzer Amulet (Abbott Vascular). The device has two connected parts: a cover and an umbrella. The titanium nitride-coated cover uses a mesh design with recessed hub to promote faster endothelialization and reduce delayed thrombus formation. The umbrella features eight frames, a polyethylene terephthalate membrane and eight hooks for multiple capture and repositioning points, and has three anchoring hooks. The double-membrane design seals the left appendage. The device only requires a small sheath (8F to 10F) and will be available in sizes from 16 to 36 mm. The implants are not available commercially or for distribution or sale in the U.S.

Potential new devices

Radiation ablation technique

A novel radiation ablation technique was reported in *The New England Journal of Medicine* in late 2017. The researchers used noninvasive imaging techniques to identify the scarred area of the ventricle, and then treated it with a short burst of radiation to burn off the damaged cells, causing the heart to electrically malfunction. The basic procedure used stereotactic body radiation therapy, which is most commonly used to target tumors in cancer patients. While this was the first in-man trial, the results of the experimental therapy almost completely eliminated ventricular tachycardia—in which the heart beats excessively fast and out of sync with its upper chambers—in five patients who experienced a combined 6,577 episodes in the three months leading up to the treatment. After a six-week "blanking" period, during which the patients' hearts recovered from the procedure, the patients had just four tachycardia episodes over the next 46 patient-months—a 99.9 percent reduction from pretreatment levels. A clinical trial is needed to verify these early results.

Economic impact

The economic impact of new EP devices will create increased demand on hospital infrastructure and increase hospitals' supply chain expenses. Over the past several years, new catheters and mapping systems have been designed with technology to prevent reprocessing, which has resulted in an increase in procedure cost.

Reimbursement

Reimbursement for EP studies and ablation procedures has increased, but not at a pace to keep up with the higher prices of emerging devices. The result is a slow erosion of hospital procedural profitability.

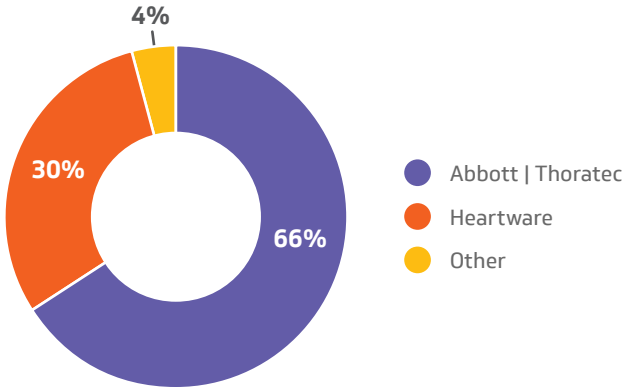
Other heart failure devices

Congestive heart failure (CHF) is the inability of the heart to maintain proper cardiac output to meet the metabolic demands of body tissue and organs. CHF is marked by the failure of the ventricles to pump a sufficient volume of blood to the body organs. This report has already discussed devices that maintain heart rhythm; however, ventricular assist devices (VAD) and novel assist devices are also designed to improve ventricular function.

The American Heart Association estimates about 5.7 million people[18] live with some degree of heart failure. For FDA-cleared products and their indications, it is estimated that only 9 percent[19] of people actually receive these devices. Projections forecast the U.S. CHF market will grow at an estimated annual compound rate of 2 to 3 percent over the next five years, due to the majority of sales existing in the CRM market. For cardiac assist devices—whether left ventricular assist, percutaneous circulatory support or counter pulsation therapy—the market segment is forecast to grow at an annual compound rate of 8.1 percent.[20] Product development in this segment will focus on percutaneous circulatory support and left ventricular assist devices (LVAD). With long development cycles and stringent FDA premarket approval requirements, new products will be introduced slowly. Outside these more traditional segments, companies are developing innovative technologies to treat both acute and chronic heart failure. Several devices, some of which may soon be approved for use in the U.S., are described below.

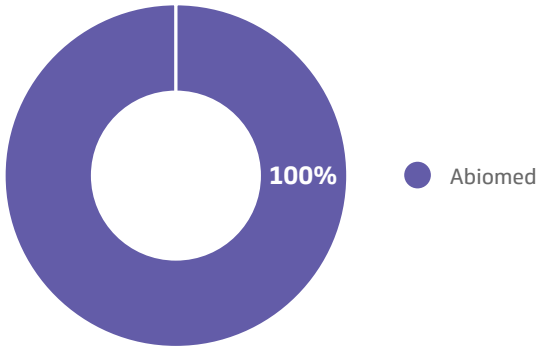
The competitive environment is divided. Each segment has a different set of suppliers, with many having a dominant market share. This has resulted in minimal pressure on device price. The various market shares are shown in Figures 5 through 7.

Figure 5. Ventricular assist therapy



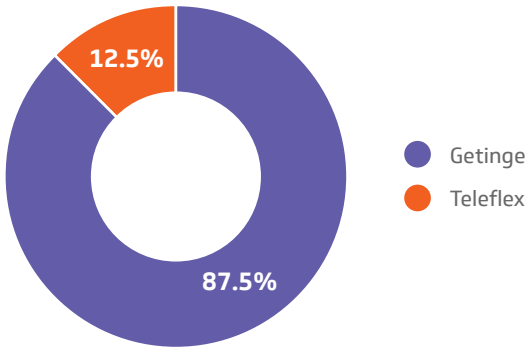
Source: Vizient Intellisource, PSC Price Benchmark, January 2018.

Figure 6. Percutaneous circulatory support



Source: Vizient Intellisource, PSC Price Benchmark, January 2018.

Figure 7. Counter pulsation therapy



Source: Vizient Intellisource, PSC Price Benchmark, January 2018.

Ventricular assist devices

HeartMate 3 Left Ventricular Assist System (Abbott | Thoratec)

The HeartMate 3 Left Ventricular Assist System is the most recently approved LVAD. The device uses a centrifugal pump (continuous flow) to provide up to 10 liters of blood per minute. The pump uses improved flow technology, enabling the device's rotor to be suspended by magnetic forces. There is no friction, which reduces damage to the patient's blood. The system is indicated for providing short-term hemodynamic support (e.g., bridge to transplant or bridge to heart recovery) in patients with significant left ventricular heart failure. The FDA cleared the device for use in August 2017.

Shield II MOMENTUM 3 U.S. IDE Clinical Trial (HM3) (NCT02224755)

Poornima Sood, MD, MBA (U.S., St Jude Medical), study coordinator

Study size: 1,028 patients

Prospective, multicenter, unblinded randomized U.S. trial

The objective of the study is to evaluate the safety and effectiveness of the HM3 Left Ventricular Assist System (LVAS) by demonstrating non-inferiority to the HMII LVAS when used for the treatment of advanced, refractory, left ventricular heart failure. Data reported in *The New England Journal of Medicine* showed that of 294 patients, 52 percent were assigned to the centrifugal-flow pump group and 142 to the axial-flow pump group. In the intention-to-treat population, the data showed non-inferiority (absolute difference, 9.4 percentage points; 95 percent lower confidence boundary, −2.1 [$P < .001$]). There were no significant between-group differences in the rates of death or disabling stroke, but reoperation for pump malfunction was less frequent in the Heartmate 3 group than in the traditional pump group (0.7 percent vs. 7.7 percent). No suspected or confirmed pump thrombosis occurred in the Heartmate 3 pump group and in 10.1 percent in the traditional pump group. The positive data from this trial assisted in the product being approved for use in the U.S.

aVAD (ReliantHeart, Inc.)

The aVAD is an early stage intraventricular heart pump. The pump is small, measuring 2.48 cm in diameter. A larger 1.2-cm inner channel transports blood safely. The company anticipates the system will facilitate a less invasive surgical technique. The system is being designed to provide 24/7 remote monitoring of pump speed and power. It is anticipated the new pump will have less of the power consumption and run 30 percent longer than other VADs, resulting in the use of smaller batteries. In the U.S., the system is in preclinical testing and is expected to enter an FDA investigational device exemption (IDE) trial in the near future.

50cc Total Artificial Heart (SynCardia)

The 50cc Total Artificial Heart is designed to fit adult patients of smaller stature and adolescents. The system is designed to be used as a bridge to a donor heart transplant, and replaces both failing heart ventricles and the four heart valves. It also restores blood flow—pumping up to 9.5 liters per minute—and eliminates complications associated with the patient's failing heart. The intent is to help vital organs recover more quickly and allow patients to be better transplant candidates. The device is investigational and not for sale in the U.S.

Miniaturized ventricular assist device (Medtronic | Heartware)

This is the company's next-generation LVAD. The PedVAD—a pediatric version for infants with heart failure—was planned, but recent recalls have resulted in delays in the development of these newer pumps. The MVAD is smaller, and uses the company's centrifugal pump technology. A patented, wide-blade impeller features three blood flow paths, which are designed to enhance blood flow and reduce blood trauma while decreasing the time blood travels through the device. The new pump is designed to be implanted completely within the pericardial space, which results in a less complex system that eliminates friction, heat and component wear. The unique integrated inflow cannula design offers the flexibility to fit into smaller-framed patients and treat more complex conditions.

Percutaneous circulatory support devices

Impella RP (Abiomed)

The Impella RP is a percutaneous, single vascular access pump designed for right heart support. It features a mini heart pump mounted at the end of a thin, flexible catheter, a console that drives the pump and an infusion system that flushes the pump. The pump is indicated for providing temporary right ventricular support for up to 14 days in patients who have acute right heart failure or decompensation following LVAD implantation, myocardial infarction, heart transplant or open-heart surgery. The pump functionality is similar to prior company devices, and is inserted percutaneously through the femoral vein and into the pulmonary artery. It can deliver up to 4 liters of blood per minute from the inferior vena cava into the pulmonary artery. The pump has a specially designed 22 Fr cannula that is sized to fit through the vessels and hearts of pediatric and adult patients. The cannula of the pump has five openings at its distal tip that allow blood to exit. A differential blood pressure sensor measures the pressure difference between the inside and outside of the cannula. This pressure measurement is used to adjust the pump flow needed to compensate for right heart failure. The pump is inserted into the right side of a patient's heart through a small incision in the femoral vein in the leg, eliminating the need for surgery. The pump was approved for use in the U.S. in September 2017.

HeartMate Percutaneous Heart Pump (Abbott | Thoratec)

The HeartMate Percutaneous Heart Pump system is a catheter-based heart pump that provides hemodynamic left ventricular support. It is designed to be a competitive alternative to existing percutaneous circulatory support systems. The device can be inserted into the femoral artery via an integrated 13F introducer sheath. The covered nitinol cannula and integrated impeller expand to 24F across the aortic valve after insertion. The system is designed to facilitate rapid insertion. A three-blade impeller delivers 4 to 5 liters per minute of blood while minimizing shear stress on blood moving through the device. The pump collapses to its original 13F dimension if the device needs to be removed. The device is investigational and not for sale in the U.S.

iVAC2L Percutaneous Ventricular Assist Device (PulseCath BV)

The iVAC2L is an extracorporeal membrane pump, and is indicated for patients with impaired left ventricular function who require a mechanical circulatory support as bridge-to-decision or bridge-to-bridge (left ventricle assist device). A 17 Fr single lumen, nitinol braided catheter with a proprietary bidirectional rotating valve and an extracorporeal membrane pump ensures efficient pump performance. The pump can increase cardiac output up to 2 liters per minute and helps to maintain coronary and end-organ perfusion. It is inserted via the femoral artery, and is designed to work with conventional intra-aortic balloon pump drivers. The device is investigational and not for sale in the U.S.

Reitan Catheter Pump (Cardiobridge GmbH)

The 10F-Reitan Catheter Pump is a short-term intra-aortic percutaneous circulatory support device that is inserted through a 10F sheath in the femoral artery. The pump addresses the two major issues of heart failure: declining renal and cardiac function. A foldable pump head is closed during insertion and removal. During operation the pump head is open to an expanded diameter of 15 cm. The cage and propeller are visible under fluoroscopy. The power system is portable (18 pounds) and includes battery backup. The device is investigational and not for sale in the U.S.

Aortix (Procyrion, Inc.)

The Aortix heart pump is an intra-aortic pump designed for ambulatory use. About 3 inches long with a diameter thinner than a No. 2 pencil, the pump can deliver approximately 6 liters per minute. The pump takes about 10 minutes to implant into the descending thoracic aorta through the femoral artery in the groin. It is placed in the descending thoracic aorta, which is downstream of the carotid arteries and thereby reduces thrombotic stroke risk. When in place, small anchors that look like slim, metal fingers spring out and hold the device in the aorta. The pump uses impeller technology to accelerate native blood flow, and is designed for younger and less sickly heart failure patients who are no longer responding to medication or who are resistant to cardiac resynchronization therapy. The device is investigational and not for sale in the U.S.

Other interesting heart failure devices

Revivent Myocardial Anchoring System (BioVentrix)

The Revivent Myocardial Anchoring System is the second generation of the CE-marked device designed for the treatment of CHF. The anchoring system consists of two polyester fabric-covered anchor heads made of titanium. A flexible tether made of polyetheretherketone functions as a type of zip tie and is used to squeeze the anchors together and hold them in place. Increased ventricular wall tension is the underlying cause of left ventricular enlargement and causes worsening of heart failure symptoms. The implant lessens wall tension by directly reducing the left ventricular radius and preventing further left ventricular enlargement, thereby slowing the progression of the disease. The device is investigational and not for sale in the U.S.

BioVentrix Revivent TC System for Treatment of Left Ventricular Aneurysms (NCT02931240)

Andrew S. Wechsler (U.S., Drexel University College of Medicine), principal investigator

Study size: 126 patients

Prospective, randomized, multicenter, dual-arm trial

The pivotal study of the Revivent TC System is designed as a 2:1 study versus active concurrent control group allocation ratio. This study will include 126 patients, of which 84 will be treated with the investigational device and 42 will be included in an active control group. The trial is designed to demonstrate the safety and effectiveness of the system. This is accomplished by implanting micro-anchoring pairs in the left ventricle to exclude scarred myocardium from the healthy tissue. The trial endpoints include positive effects on volume reduction, ejection fraction, quality of life, New York Heart Association (NYHA) class, six-minute walk test and rehospitalization. The study began enrolling in mid-2016. No study results are available.

Parachute ventricular partitioning device (CardioKinetix, Inc.)

The Parachute catheter-based partitioning device is deployed within the left ventricle for patients who have developed ischemic heart failure following a heart attack, and is designed to be a treatment for heart disease. The implant partitions the damaged muscle, isolating the nonfunctional muscle segment from the functional segment, decreasing the overall volume and restoring a more normal geometry and function in the left ventricle. The implant, composed of a fluoropolymer membrane stretched over a nitinol frame, is deployed into the apex of the left ventricle. The device will be available in 65-, 75-, 85- and 95-mm sizes. It will be delivered through either a 14F or 16F system, depending on size. The device is investigational and not for sale in the U.S.

A Pivotal Trial to Establish the Efficacy and Long-term Safety of the Parachute Implant System (PARACHUTE IV) (NCT01614652)

William T. Abraham (U.S., The Ohio State University), co-principal investigator

Study size: 560 patients

Prospective, nonrandomized, multicenter, open-label trial

The Parachute IV clinical trial is a 1:1 randomized, multicenter trial designed to evaluate the Parachute implant. The primary objective is to assess the safety and efficacy of the Parachute implant and delivery system in partitioning the left ventricle in patients with heart failure due to ischemic heart disease. The event-driven primary endpoint includes all-cause mortality and hospitalization for worsening heart failure. Other key endpoints include hemodynamic measures by echocardiography and imaging measures by computed tomography. The trial had enrolled more than half the required patients as of early 2016. No data is currently available. This is the U.S. IDE trial, being conducted at 78 U.S. sites.

Harmony Neuromodulation Heart Failure System (Enopace Biomedical)

The Harmony Neuromodulation Heart Failure System is designed to stimulate the aortic vagal afferents in the upper part of the descending aorta to restore the heart's autonomic balance and improve cardiac performance. The system is composed of two parts: the endovascular implant is a self-expandable nitinol stent housing both a receiving antenna and a four-electrode endostimulator, and the patient control wirelessly powers the endovascular implant, manages the therapy and records treatment information. The implant is delivered via an arterial catheter. The system functions by simulating the nerve to alter the left ventricular mechanism and left ventricle aorta coupling, which reduces left ventricular pressure.

InterAtrial Shunt Device (Corvia Medical)

The InterAtrial Shunt Device (IASD) is the first transcatheter device designed to treat heart failure with preserved ejection fraction. The "barrel" implant is a self-expanding nitinol star-shaped stent with a 19-mm outer diameter and 8-mm internal diameter. After a small opening is created in the atrial septum, the implant is deployed through a 14F delivery catheter, forming a passage between the left and right atria that enables the left atrium to decompress, allowing for the reduction of left atrial pressure. The goals are to improve heart failure symptoms and quality of life, decrease heart failure hospitalization rates and reduce the overall cost burden of managing heart failure patients. The device is investigational and not for sale in the U.S.

REDUCE LAP-HF II Trial (REDUCE LAP-HF II) (NCT03088033)

Sanjiv Shah (U.S., Northwestern Memorial Hospital [Vizient member hospital]), co-principle investigator

Study size: 380 patients

Prospective, multicenter, randomized, controlled, blinded, multinational trial, with a non-implant control group

The Reduce LAP-HF II study is designed to evaluate the safety and efficacy of the IASD System to reduce elevated left atrial pressure in patients with heart failure with preserved ejection fraction. This is the pivotal trial for U.S. product approval. The study will enroll patients at up to 70 sites in the U.S. and up to 30 sites outside the U.S. The study began enrolling patients in November 2017. No data is currently available.

V-Wave Shunt (V-Wave Ltd.)

The V-Wave Shunt is an interatrial shunt device for patients with advanced heart failure. It is similar to Corvia Medical's IASD, which is meant to improve left atrial pressure in patients with diastolic heart failure. The shunt is implanted venously and placed in the atrial septum. Within the shunt is a porcine tissue valve that ensures only left to right shunting of blood and reduces the probability of blood clot formation. The device regulates left atrial pressure by shunting excess blood volume away from the left ventricle. The shunt is intended to relieve symptoms, improve quality of life and reduce the need for acute hospitalization due to worsening episodes of heart failure. The device is investigational and not for sale in the U.S.

Reducer Coronary Sinus Stent (Neovasc, Inc.)

The Reducer is a balloon-expandable hourglass-shaped metal stent. The stent is implanted in the coronary sinus, creating a narrowing of the coronary sinus to modulate flow and elevate pressure. Increasing the blood flow to the heart muscle reduces recurrent and severe heart pain (refractory angina). The implant provides relief of angina symptoms by altering blood flow in the heart's venous system, thereby increasing the perfusion of oxygenated blood to ischemic areas of the heart muscle. The implant is not available commercially or for distribution or sale in the U.S.

REDUCER-I: An Observational Study of the Neovasc Reducer System (NCT02710435)

Stefan Verheye (Belgium, ZNA Middelheim Hospital), principal investigator

Study size: 400 patients

Prospective, randomized, multicenter, multiarm European trial

This study is a multicenter, multicountry three-arm prospective and retrospective investigation in up to 400 subjects conducted at a maximum of 40 investigational centers. Arm 1 will include eligible prospective subjects. Arm 2 will include subjects who were previously enrolled and treated with the Reducer during the Coronary Sinus Reducer for Treatment of Refractory Angina (COSIRA) study. Arm 3 will include subjects who received a Reducer under CE mark.

Transcatheter Renal Venous Decongestion System (Magenta Medical)

Magenta Medical has developed a temporary venous catheter–based therapy for hospitalized patients with acute decompensated heart failure. The therapeutic principle is aimed at addressing a pathophysiological core element of acute heart failure—renal venous congestion and its deleterious effects on renal and cardiac function. The device is not available commercially or for distribution or sale in the U.S.

ROX Coupler (Rox Medical, Inc.)

The ROX Coupler is a small vascular implant for patients with stage 2, treatment-resistant hypertension. The device is intended for use in patients with uncontrolled hypertension and may lower blood pressure by shifting a modest amount of arterial blood to the venous system. The self-expanding nitinol device permits a controlled shunt volume. The shunt is placed between the artery and vein in the upper thigh to allow 800 to 1,000 ml per minute of blood to flow between them. The device is not available commercially or for distribution or sale in the U.S.

Remote Dielectric Sensing Technology ReDS Technology (Sensible Medical Innovations Ltd.)

ReDS technology is a novel noninvasive electromagnetic energy-based technology (Remote Dielectric Sensing, ReDS) that quantifies changes in lung fluid content providing an accurate, actionable and absolute measurement of lung fluid content located at the right mid-lobe of the lung. Data collected will be used to track fluid status and guide medical management in heart failure patients. The technology is incorporated in a vest using radar technology to see through the chest and track the amount of fluid in the lungs. Patients put on the vest

and connect it to a tablet for about 90 seconds each day. Patients' fluid readings are then uploaded for a cardiologist to review. The technology is a miniaturized version of what the military uses to search for survivors through rubble. The device is investigational and not for sale in the U.S.

Continuous Perineneal Ultrafiltration (Paragate Medical LTD)

Paragate is developing an implantable device programmed to continuously remove the excess fluids produced in patients with heart failure or kidney disease so that the fluids do not accumulate and cause breathing difficulties and other serious complications. By using a membrane and through a unique absorption element (a patented design), our fully implantable and minimally invasive device is capable of removing the excess extracellular fluid from the body at a rate of 1 liter per day. In addition to enabling an efficient approach to heart failure patient management, the device offers a therapeutic benefit by reducing blood volume and pressure overload. The device is investigational and not for sale in the U.S.

Cordella HF System (Endotronix, Inc.)

The Cordella System is an implantable device providing accurate, on-demand measurements of pulmonary artery pressure. The device and monitoring system is similar to the Abbott Cardiomens system. The system combines the implanted monitor with a portable handheld reader that allows patients to transmit data at their convenience. The system extends clinical care into the home through remote physiologic monitoring and heart failure guideline-directed assessments. A clinical trial began enrolling patients in 2017. The device is investigational and not for sale in the U.S.

Moderato pacemaker (Backbeat Medical)

The Moderato pacemaker uses the company's programmable hypertension control therapy. The therapy comprises proprietary pacing algorithms that are incorporated into standard pacemakers using standard leads and standard lead placement. The system offers a new potent device-based therapeutic alternative for the treatment of patients with hypertension. The system's algorithm reduces ventricular filling to lower blood pressure while modulating the response of the baroreflex to prevent activation of the autonomic nervous system. The company manufactures its own pacemaker incorporating the program and therapy. Current clinical trial efforts are focused on gaining CE mark approval. The device is investigational and not for sale in the U.S.

Optimizer Smart (Impulse Dynamics)

The Optimizer Smart device provides innovative therapy to patients with a narrow QRS complex, reduced ejection fraction and advanced heart failure. The proprietary cardiac contractility modulation technology delivers non-excitatory electric pulses to the cardiac muscle enhancing the contractility of the myocardium. The assumption is that the therapy will enable the heart to operate more efficiently. The first in-man clinical trial began in 2017. The device is investigational and not for sale in the U.S.

Left Atrial Pressure System (Vectorious Medical Technologies)

The currently unnamed device is a wireless left atrial pressure monitoring device that, if introduced into the market, will compete directly with CardioMEMS. The main difference is that the Vectorious Medical device will enable daily "push button" readings of left atrial pressure versus readings of pulmonary pressure with the CardioMEMS device. The company believes left atrial pressure monitoring will enable earlier detection of CHF symptoms and the ability to respond sooner. The system consists of a wireless device that is affixed to the interatrial septum, allowing it to directly measure left atrial pressure. Because the device measures left atrial pressure, it can also be used to optimize the performance of LVADs. A first in-man clinical trial is underway. The device is not available for sale anywhere in the world.

Economic impact

The economic impact of the newer generation ventricular assist systems will be minimal. Advancement in performance and smaller sizing will improve clinical outcomes, but cost will remain high and reimbursement is not expected to change. It is too soon to forecast the impact of increasing competition in the percutaneous circulatory support category. Recent innovative device introductions by the suppliers in this category have not resulted in price declines.

Reimbursement

Reimbursement for the various heart failure assist devices exists. Reimbursement codes are not anticipated to change in terms of ventricular assist, percutaneous circulatory assist or counterpulsation therapy. However, uncertainty exists with the various miscellaneous heart failure devices. It is unknown whether these will be reimbursed under existing or new reimbursement codes until the devices are cleared for use in the U.S.

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Notes

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