MassMEDIC
THE HEART OF HEALTHTECH

Cardiology Medical Devices Market Trends 2023

AliraHealth

Disclaimer

- Alira Health makes no representations or warranties, either expressed or implied, as to the accuracy of the information in this report. Alira Health has collected and compiled the presented information on a best effort basis under time and budget constraints. In no event will Alira Health be held liable for any direct, indirect, incidental or consequential damages arising out of the use of the information in this report.
- Unless otherwise explicitly stated, all information is copyrighted by Alira Health, irrespective of whether a copyright symbol and statement is present. All trademarks are acknowledged.

AliraHealth

1 Grant Street Framingham, MA USA

Deepak Sahu
Managing Partner, USA
deepak.sahu@alirahealth.com

Akash Karopadi
Principal, USA
akash.nayakkaropadi@alirahealth.com

Bill Schulz
Senior Consultant, USA
bill.schulz@alirahealth.com

Authors' Note

AUTHORS' NOTE

- This 2023 report investigates the current landscape and trends in the U.S. and European Cardiology Medical Devices industry. It is the outcome of proprietary research tools and methodologies.
- The Cardiology Medical Devices industry is among the largest and most competitive within MedTech, with market leaders Medtronic, Abbott, Boston Scientific, Edwards Lifesciences, Johnson & Johnson, and countless innovators pioneering solutions for the most pressing cardiac needs.
- The industry is experiencing fundamental shifts in patient and provider needs, sites of care, technological innovation, and macro-economic shocks lingering from COVID-19 that are expected to impact the delivery of solutions in the future.
- An aging and increasingly overweight population necessitates continued commitment from industry stakeholders to fulfill patient needs, in parallel with support for providers facing staff shortages and cost constraints.
- The industry must also face the increasing shift of Cardiology procedures to outpatient and ambulatory care settings expected to continue based on the favorable outcomes and economics of surgeries performed in these settings.
- Pipeline innovation and industry consolidation are expected to continue, albeit more modestly compared to the accelerated pace instigated by the pandemic.
- While the incidence of heart disease is expected to grow in the foreseeable future, innovation and increased investment in novel solutions offer promise to address emerging patient needs and improve health outcomes.
- Within the pages of this report, Alira Health seeks to provide an in-depth market analysis, detailed examination of the patient population and market players, and insight on deal activity and the development of novel cardiology medical devices.

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

3. Cardiology Market Outlook 49

4. Key Takeaways 55

5. About Authors 61

Table of Contents

1. Cardiology Market Foundations 5
   - 1.1 Market Overview & Segmentation 6
   - 1.2 Epidemiology of the Cardiology Patient Population 13
2. Cardiology Clinical & Market Landscape Today 21
3. Cardiology Market Outlook 49
4. Key Takeaways 55
5. About Authors 61

Table of Contents

1. Cardiology Market Foundations 5

1.1 Market Overview & Segmentation 6

1.2 Epidemiology of the Cardiology Patient Population 13

2. Cardiology Clinical & Market Landscape Today 21

3. Cardiology Market Outlook 49

4. Key Takeaways 55

5. About Authors 61

Overview of the Cardiology Medical Devices Market and Segmentation

Market Overview & Segmentation

The Cardiology Medical Devices Market includes the solutions used to address or monitor diseases or conditions of the heart and blood vessels. The five market segments are comprised of implantable and non-implantable devices to improve the patient journey.

OVERVIEW

- The **Cardiology Medical Devices market** is comprised of devices that support **heart function, treat cardiological diseases, or maintain cardiac rhythm.**
- The market can be **divided into 5 segments by application:** cardiac rhythm management, peripheral vascular, interventional cardiology, electrophysiology, and structural heart.
- Cardiac rhythm management (CRM) includes **implantable devices** that aid in **lifesaving monitoring and control** over a patient's heart rhythm.
- The peripheral vascular segment is the **largest segment in terms of number of devices** and includes implantable devices as well as devices that aid in surgery or delivering therapies to patients.
- The **Interventional Cardiology** segment includes implantable devices and technologies that enable interventional procedures to be performed.
- Electrophysiology focuses specifically on a procedure called an **electrophysiology study** using two different innovative catheters to detect and treat abnormal heart rhythms at the source.
- The **structural heart** segment includes implantable devices critical to the **care and maintenance of the heart and its valves or the aorta.**

SEGMENTATION OF CARDIOLOGY MEDICAL DEVICES BY APPLICATION

CARDIOLOGY MEDICAL DEVICES

Cardiac Rhythm Management	Peripheral Vascular	Electrophysiology	Interventional Cardiology	Structural Heart
• Pacemakers • Implantable Cardioverter-Defibrillator (ICD) • Cardiac Resynchronization Therapy (CRT) • Implantable Loop Recorders (ILR)	• Peripheral Guidewires • Stents (Peripheral Vascular) • Carotid and Renal Artery, Venous) • Catheters (PTA[1] Balloon, Renal Denervation) • Peripheral Protection Devices / Arteriotomy Closure Devices • Vascular Embolization Plugs and Coils	• Electrophysiology Diagnostic Catheters • Electrophysiology Ablation Catheters	• Coronary Stents • PTA[1] Balloon Catheters • Intravascular Ultrasound (IVUS) • Coronary Guidewires • Cardiac Catheters	• Prosthetic Heart Valves • Cardiac Valve Repair Devices • Transcatheter Aortic Valve Replacement (TAVR) • Transcatheter Mitral Valve Implantation (TMVI) • Transcatheter Mitral Valve Repair (TMVR)

ALIRA HEALTH COMMENTS

- **Alira Health identified 22 devices across 5 segments of the Cardiology Medical Devices Market** in the United States and EU.
- **Alira Health reviewed the Cardiology Medical Devices Market** to understand the current status of the market and anticipate changes over the next five years.

Note: [1]PTA, Percutaneous transluminal angioplasty.

Source: LSI Global MD&D Data; GlobalData; Alira Health analysis.

Understanding of the Cardiac Rhythm Management Segment

Market Overview & Segmentation

The Cardiac Rhythm Management segment of the cardiology medical devices market includes four implantable devices that regulate and manage heart function and rhythm. These include pacemakers, ICDs, CRT machines, and ILRs.

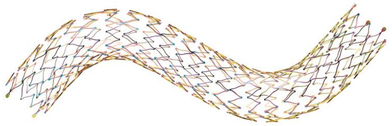
Device	Pacemakers	Implantable Cardioverter-Defibrillator	Cardiac Resynchronization Therapy	Implantable Loop Recorders
Description	A pacemaker is a small, surgically implanted device placed in the chest to help control a patient's heartbeat. It controls the heartbeat through electrical pulses and prevents the heart from beating too slowly. A pacemaker helps the heart pump blood through a patient's cardiovascular system.	An ICD is a small, surgically placed, battery- powered device. The ICD, connected to the heart through wires, continuously monitors the heartbeat. It detects and stops irregular heartbeats (arrythmias) by delivering electric shocks when it detects abnormal rhythms.	CRT is a treatment to restore, or resynchronize, a patient's heartbeat when irregularities occur. A pacemaker is surgically implanted and then wires connect the CRT device to the patient's heart, allowing electrical currents to correct the beat and timing of the heart. CRT uses the natural rhythm of both the atria and the ventricles to ensure the heart is pumping blood as it should.	An ILR is a heart recording device surgically placed atop a patient's heart, under the skin of the chest. An ILR can last as long as three years and continuously monitors a patient's heart rate, allowing for irregular or abnormal rhythms to be detected and, if necessary, treated.
Clinical Applications	A pacemaker is implanted to help control a patient's heartbeat. Patients experiencing a slowed or irregular heartbeat are most likely to be prescribed a pacemaker.	Patients with an enlarged heart, history of coronary artery disease, those with genetic heart conditions, and those at-risk of dangerously fast heart rhythms are the most likely candidates for monitoring by an ICD.	CRT is meant for use in patients experiencing arrythmia and severe heart failure symptoms, or in patients whose ventricles are not pumping or working together.	ILRs may be implanted in patients experiencing abnormal heartbeat (arrhythmia) or hidden heart rhythms that may arise as a sign of stroke, heart palpitations, or unexplained fainting.

Sources: Abbott; Aesculap; American Heart Association; DAIC; GlobalData; JAMA Cardiology; Johns Hopkins Medicine; Mayo Clinic; Medscape; National Heart, Blood, and Lung Institute; University of Michigan Health; Alira Health analysis.

Understanding of the Peripheral Vascular Segment

Market Overview & Segmentation

The Peripheral Vascular segment includes devices intended for use in cardiovascular procedures that deliver vascular embolization plugs and coils, stents, and grafts into the vein with guidewires or catheters.



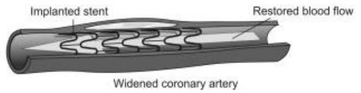
Device	Peripheral Guidewires	Stents	Catheters	Vascular Embolization Plugs and Coils
Description	A guidewire is used to navigate through the body and necessary vessels to ensure the catheter is properly placed and that therapy can be administered appropriately. Key factors of effective guidewires include: torqueability, trackability, flexibility, durability, and lubricity.	There are three major kinds of stents and grafts related to peripheral vascular devices and procedures: peripheral vascular, carotid and renal artery, and venous. Stents are implanted devices that hold open a blocked or clogged artery or vein, allowing blood flow. Stents are small, wire-mesh tubes that are permanent implantations.	Catheters, or the use of catheters through procedures called catheterization, requires surgery during which a long, thin, flexible tube is inserted into a blood vessel or artery. Dye is injected through the tube under x-ray to allow for a visual of the arteries in the heart muscle. The procedure of catheterization allows providers to have a more comprehensive view of a patient's heart and any blockages or plaque buildup the patient may have.	Coil embolization is a procedure that allows physicians to precisely stop abnormal blood flow in a blood vessel. The procedure requires a catheter with a metal coil to be implanted into an artery. The metal coil is lodged into position within the blood vessel where a blood clot will form and eventually turn into a scar, providing a permanent fix once healed. A vascular plug embolization works similarly but is ideal for medium-to-large- flow blood vessels, which would require multiple coils to address the problem.
Clinical Applications	Peripheral guidewires are used to deliver therapies to necessary areas of the peripheral vascular system, such as in the cases of Peripheral Artery Disease and Critical Limb Ischemia, or during procedures such as an angioplasty or atherectomy.	Stents are used by doctors in the treatment of patients with peripheral vascular complications to hold open a vein or artery.	Catheterization is most often a treatment for patients showing symptoms of Peripheral Artery Disease, which can occur as a result of abnormal healing of a wound or poor circulation.	Patients experiencing abnormal blood flow in a blood vessel, excessive bleeding, or who show signs of having a vascular malformation are most likely to require vascular embolization treatment.

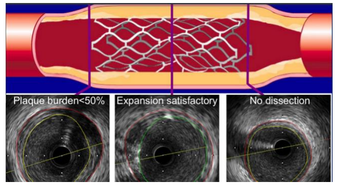
Sources: Abbott; American Heart Association; Asahi Intecc; Chinatown Cardiology; Cleveland Clinic; DeltaMed; Endovascular Today; GlobalData; HeartPlace; Hunterdon Cardiovascular; National Heart, Blood, and Lung Institute; MedicalExpo; Medscape; MemorialCare; The Heart and Vascular Center; The Jackson Clinic; UCSF Department of Surgery; Alira Health analysis.

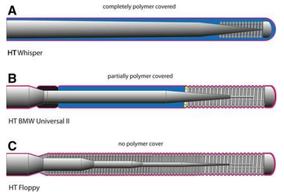
Understanding of the Interventional Cardiology Segment

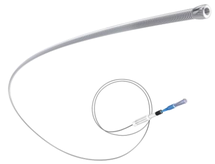
Market Overview & Segmentation

Five devices were identified in the Interventional Cardiology segment that are either implantable, such as coronary stents, or designed to aid in procedures such as PTA balloon catheters, IVUS, coronary guidewires, and cardiac catheters.









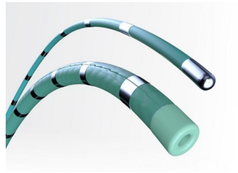
Device	Coronary Stents	PTA Balloon Catheters	Intravascular Ultrasound	Coronary Guidewires	Cardiac Catheters
Description	Coronary stents are small devices designed specifically to be used to hold open the coronary artery. Coronary stents are most seen in one of three types: bare metal stents, drug-eluting stents, or biodegradable stents.	Percutaneous transluminal coronary angioplasty is a procedure to open blocked coronary arteries and improve or restore blood flow to the heart and through the cardiovascular system. A PTA balloon catheter is a polymer constructed device that follows a guidewire to the part of the blood vessel that has become narrowed, then the balloon catheter is inflated to open the narrow vessel.	An IVUS uses ultrasonic sound waves to create computer images of blood vessels. IVUS allows for direct visualization and measurement of the blood vessels from different angles, including inside the vessel, which also means narrowing and blockages can be more easily found.	Coronary guidewires are used to deliver therapies to different diseased parts of the coronary arterial system. For procedures in and around the vascular pathways of the heart, coronary guidewires lay the pathway for therapies to be delivered, including opening restricted blood flow in occluded vessels. Key factors of effective coronary guidewires include: torqueability, trackability, flexibility, durability, and lubricity.	Cardiac catheterization is the process of injecting contrast dye into coronary arteries via an inserted catheter so a doctor can better see the blood flow through those arteries. Cardiac catheterization can be used to conduct heart tests, deliver treatments, measure pressure in different chambers, or even test oxygen levels in different areas of the heart.
Clinical Applications	Coronary stents are used in patients who need treatment for narrowed coronary arteries. They may also be used to treat aneurysms, which occurs when a bulge forms in the wall of an artery.	PTA balloon catheters are used in procedures to treat Coronary Artery Disease (CAD) which may lessen a patient's symptoms of angina. They are also used in angioplasty procedures.	Using IVUS, doctors can more accurately diagnose and treat their patients. Doctors might choose to use IVUS on patients thought to have narrowing arteries or chronic blood clots.	Patients undergoing procedures such as angioplasty, atherectomy, or thrombectomy might have a coronary guidewire inserted as part of the procedure.	Cardiac catheters can be used to conduct tests in patients who may be experiencing heart failure, those prone to or diagnosed with any number of heart diseases, or to better see the flow of blood through the heart.

Sources: Acrostak; American College of Cardiology; American Heart Association; Asahi Intecc; Boston Scientific; Cardiovascular Research Foundation; Cleveland Clinic; FDA; GlobalData; Mass Device; Mayo Clinic; MedStar; National Heart, Blood, and Lung Institute; National Library of Medicine: MedlinePlus; RadiologyInfo.org; Science Direct; Stanford Medicine; The Texas Heart Institute; Washington Regional Medical Center; Alira Health analysis.

Understanding of the Electrophysiology Segment

Market Overview & Segmentation

The two devices needed to perform an electrophysiology (EP) study and treat abnormal rhythms found in an EP Study are an electrophysiology diagnostic catheter and an electrophysiology ablation catheter.



Device	Electrophysiology Diagnostic Catheters	Electrophysiology Ablation Catheters
Description	An electrophysiology study is performed by inserting an electrophysiology diagnostic catheter into a patient's blood vessel which leads to their heart. Through this catheter, electrodes are placed in the heart to receive signals, and the electrical activity of the heart can then be measured.	An electrophysiology ablation catheter is really two catheters: one placed in the neck, which allows access to the top of the heart, and one through the groin, allowing access to the bottom of the heart.
Clinical Applications	An electrophysiology diagnostic catheter is the key component to an EP study, conducted to diagnose arrythmia or abnormal heart rhythms. An EP study allows doctors a closer look into how electrical signals move though a patient's heart and may be conducted if a patient had recently fainted unexpectedly, is at-risk of sudden cardiac death, experiences arrhythmia, or needs a cardiac ablation.	After an electrophysiology study has been conducted, any number of rhythm concerns or arrhythmia could be raised. The treatment for many of these concerns uses an electrophysiology ablation catheter as a delivery method for therapies, or to allow doctors to have a clearer view of the issue. By having these two opposite angles, doctors are best able to manipulate the catheters, identify the source of the abnormal rhythm, and destroy it.

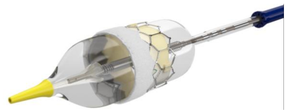
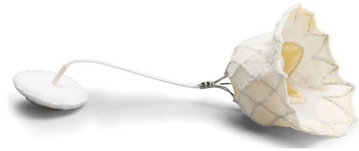
Sources: American Heart Association; Boston Scientific; DAIC; GlobalData; Mayo Clinic; UCSF Benioff Children's Hospitals; UCSF Health; Alira Health analysis.

Understanding of the Structural Heart Segment

Market Overview & Segmentation

The Structural Heart segment includes five devices intended for either implantation, such as prosthetic heart valves, TMVI, or TAVR, or for heart valve procedures, such as cardiac repair devices or TMVR.




Device	Prosthetic Heart Valves	Cardiac Valve Repair Devices	Transcatheter Aortic Valve Replacement	Transcatheter Mitral Valve Implantation	Transcatheter Mitral Valve Repair
Description	Prosthetic heart valves are used to replace damaged or malfunctioning “native” heart valves. There are three main types used, but the most used is the mechanical heart valve which lasts for a long time, usually throughout the remainder of a patient’s life. A prosthetic valve can be placed through a chest incision (open heart surgery) or through a transcatheter approach, in which the valve is placed through a catheter inserted into the femoral artery.	In cases where a valve is damaged or malfunctioning, but not so much so that it warrants an entirely new valve through replacement or use of a prosthetic valve, a native valve can be repaired. A common repair of a valve is in the use of a ring to support the damaged valve. Like the way prosthetic heart valves are placed, this procedure is done either through open heart surgery or through a transcatheter approach.	TAVR is a minimally invasive procedure to replace a thickened aortic valve through use of a catheter. The artificial valve is compressed onto a catheter and then delivered to the thickened aortic valve through a large blood vessel where a doctor using x-ray technology places it. It then expands to where the diseased valve was. The new, artificial valve immediately begins working as a valve should and allows healthy blood flow to be restored.	TMVI is the therapy best suited for treating severe mitral regurgitation. The goal of TMVI is to restore mitral valve function without the need for open heart surgery. TMVI is a procedure conducted through a transcatheter approach in which an implanted bioprosthetic valve is placed to support the stenotic valve.	TMVR is a minimally-invasive procedure to repair the valve between the heart’s left chambers when it is not closing correctly. The procedure uses a catheter inserted into the femoral artery. Through the catheter, a doctor can clip together the parts of the valve that do not properly close, preventing backflow of blood.
Clinical Applications	Prosthetic heart valves can be necessary treatment for patients with certain heart diseases or congenital abnormalities.	Heart valves need to be replaced occasionally from normal wear and tear from blood flow through the heart, or from being weakened by disease or age.	Patients with severe aortic stenosis, biologically weak aortic valve tissue, or comorbidities that make open heart surgery risky are most likely to undergo a TAVR procedure.	A TMVI procedure is a therapy most intended for patients who experience mitral regurgitation, have a failing bioprosthetic valve, or have mitral annular calcification.	Mitral regurgitation patients are most likely to experience a TMVR procedure to properly close a valve and prevent the backflow of blood.

Sources: Abbott; Aesculap; American Heart Association; DAIC; GlobalData; JAMA Cardiology; Johns Hopkins Medicine; Mayo Clinic; Medscape; National Heart, Blood, and Lung Institute; University of Michigan Health; Alira Health analysis.

Table of Contents

1. Cardiology Market Foundations 5

   1.1 Market Overview & Segmentation 6

   1.2 Epidemiology of the Cardiology Patient Population 13

2. Cardiology Clinical & Market Landscape Today 21

3. Cardiology Market Outlook 49

4. Key Takeaways 55

5. About Authors 61

Heart Failure Overview & Disease Segmentation

Epidemiology of the Cardiology Patient Population

Heart failure syndromes encapsulate a wide array of underlying disease states that stress proper cardiac function to cause gradual or rapid change in cardiac output. Interventions are focused on mitigation and early prevention to reduce morbidity and mortality.

DEFINITION

- The American Heart Association (AHA) defines **heart failure** (HF) as a **chronic, progressive condition in which the heart muscle is unable to pump enough** blood to meet the body's needs for blood and oxygen.
- HF signs & symptoms are **primarily caused by severe pulmonary congestion** due to elevated filling pressure and/or **concurrent cardiovascular diseases**.
- The AHA **classifies HF in four stages:** A, B, C, and D, **specified through** the **symptoms** and **objective evidence of cardiovascular disease.**

KEY RISK FACTORS[1]

Most Common Risk Factors Leading to HF

- Coronary Artery Disease
- High Blood Pressure
- Previous Heart Attack
- Heart Muscle Disease or Abnormal Heart Valves

HF can occur in **otherwise healthy patients** when they have low red blood cell count (**severe anemia**), an overactive thyroid gland (**Hyperthyroidism**), or an abnormal heart rhythm (**arrythmia or dysrhythmia**).

Chronic Risk Factors

- Previous Hospitalization for Heart Attack
- Metabolic Disorders
- Diabetes
- Chronic Kidney or Lung Disease

Biomarkers assist in the diagnosis of HF by indicating signs of myocardial injury, inflammation, oxidative stress, and vascular dysfunction to provide insight into direct causes of disease and prognosis.

Physiological Risk Factors

- Hypertension
- Family History
- Arrhythmias
- Structural CVD

Hospitalizations for decompensated HF are **not all exclusively acute**, but rather may follow from a **pattern of chronic stress** on the cardiovascular system.

Key **CHF** **AHF**

STAGING

There are **four stages of HF** which **distinguish the development and progression of disease up to reduced risk of survival**. Therapeutic protocols are associated to each stage, with **stage A** aimed at early intervention and mitigation, **stage B** for treatment and correction of structural abnormalities, and **stages C and D** for reduction of symptoms, morbidity, and mortality.

Stage A – At-Risk
Patients at-risk for HF but without current or previous symptoms/signs of HF or abnormal biomarkers

Stage B – Pre-HF
Patients without current or previous symptoms of HF but with evidence of structural heart disease or other risk factors

Stage C – Symptomatic
Patients with current or previous symptoms of HF

Stage D – Advanced
Marked HF symptoms that interfere with daily life and with recurrent prior hospitalizations

EPIDEMIOLOGY

Around **6.2 million adults** in the US have HF per year

Lifetime **risk of HF remains 20-45% after 45 years** of age across ethnic groups

>90% of annual HF hospitalizations[3] are due to fluid accumulation symptoms – indicating acute HF

1 in 4 HF patients are readmitted within 30 days

Note: 1Non-exhaustive list; 2Left ventricle; 3Data on annual hospitalizations for HF are only available for the USA and Europe and exceed one million in both regions. Source: Heidenreich et al., 2022 AHA/ACC/HFSA Guideline for the management of heart failure, Circulation (2022); American Heart Association, What Causes Heart Failure?; CDC.gov, Heart Failure; Arrigo et al., Acute heart failure, Nature (2021); Gheorghiade et al., Acute heart failure syndromes, Circulation (2005); Cleveland Clinic, Acute Heart Failure; Tsao et al., Heart disease and stroke statistics, Circulation (2022); Williams et al., Changes in cardiac physiology after severe burn injury, ABA (2011); Hernandez et al., Outcomes in heart failure patients after major non-cardiac surgery, ACC (2004); Khan et al., Trends in 30- and 90-day readmission rates for heart failure, Circulation (2021); Čerlinskaitė et al., Acute heart failure management, KCJ (2018); Alira Health analysis.

Heart Failure Staging & Prevalence by Stage

Epidemiology of the Cardiology Patient Population

HF affected an estimated 6.2 million Americans in 2020 and is expected to affect over 8 million by 2030. HF is most often classified into four stages by the AHA, each determined by symptoms and having a different prognosis.

HEART FAILURE QUICK FACTS

- **The heart** is the **most important organ in the human body** and the **normal functions of other organs** or systems in the body are **contingent on the heart** pumping blood to the body's cells.
- **HF** occurs when the heart **cannot keep up with its workload, preventing the body from getting** the needed oxygen and nutrients.
- **Classifications of HF:** HF is widely classified in one of two ways: the AHA classifies HF in stages A-D while the New York Heart Association (NYHA) classifies HF in phases I-IV.
- **Types of HF:** left-side HF including systolic and diastolic failure; right-sided heart failure; and congestive heart failure, as identified by the AHA.
- **Prevalence:** The prevalence of HF is expected to increase from 6.5 million Americans in 2020 to over 8 million by 2030.
- This expectation can be attributed to the aging population and the increase of major risk factors such as hypertension, improved survival after a heart attack, and improved survival with HF.
- **Care and Treatments:** No two patients with HF have the same pathways. Each patient diagnosed or at risk for HF has unique comorbidities that allow the progression of the stages to occur at different rates.
- While **68% of cases** were accounted for in **Stages A-D** in the study highlighted, 32% of participants **were in Stage 0,** meaning they were **not identified as at-risk for HF.**

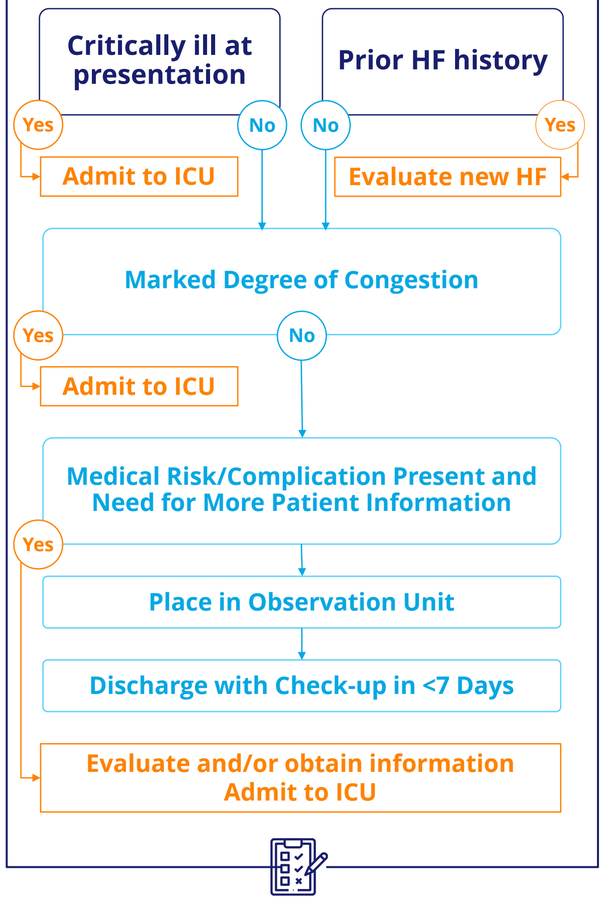
STAGE CLASSIFICATIONS	DESCRIPTION AS STATED BY THE AHA	PREVALENCE WITHIN SAMPLE POPULATION	SYMPTOMS AND PROGNOSES
STAGE A	At high risk for HF but without structural heart disease or symptoms of HF.	 **22%**	Patients with Stage A HF do not experience symptoms but are at-risk for developing a more fatal stage of HF. However, if they have strong renal function, commit to living a healthy lifestyle and controlling their blood glucose, they can reduce their chances of being diagnosed with a later stage of HF.
 **STAGE B/PHASE I**	Structural heart disease but without signs or symptoms of HF.	 **34%**	Stage B patients experience mild symptoms and have some physical limitations in their normal daily activities. The prognoses in stage B depends on the underlying cause of the structural heart disease and care of any comorbidities the patient may be living with.
 **STAGE C/PHASE I-IV**	Structural heart disease with prior or current symptoms of HF.	 **12%**	In stage C, patients present with visible symptoms of cardiovascular disease, including noticeable hindrance on their previous lifestyle and daily activities. Patients in stage C generally have worse prognoses than those in stages A or B and are at higher risk for mortality. Symptoms can improve through uses of medication, device therapy, or lifestyle adjustments prolonging the life of the patient.
 **STAGE D/PHASE IV**	Refractory HF requiring specialized interventions.	 **0.2%**	Patients with Stage D HF live uncomfortably, even when they are at rest. Symptoms severely alter the way they previously lived their lives, and they show obvious signs of severe cardiovascular disease. There is a high risk for hospitalization and mortality in stage D and care is often palliative rather than for the improvement of outcomes.

Source: Alira Health analysis.

US Heart Failure Triage & Diagnostic Algorithm

Epidemiology of the Cardiology Patient Population

TRIAGE ALGORITHM



DIAGNOSTIC ALGORITHM

Stage A

Support for At-Risk Patients

Patient is at-risk but not currently exhibiting HF signs or symptoms

Diagnosis-Specific Treatment

Establish healthy and prevention-focused lifestyle, medication as appropriate

Monitoring

Keep BP regulated at <130/180 mmHg for those with a CVD[1] risk of >10%, utilize remote BP and other lifestyle management monitoring systems

Stage B

NYHA[2] I

No limitation of physical activity & without fatigue, palpitations, and/or dyspnea

Support for Pre-HF

Patient is qualified as Pre-HF; continue protocol from Stage A, adding intervention as appropriate

Diagnosis-Specific Treatment

Medication | Surgery

Monitoring

Check left ventricle ejection fraction (LVEF) ≤40% and note patients with a recent MI and LVEF ≤40%

Stage C

NYHA I-IV

Slight to elevated limitation of physical activity but comfortable at rest

Support for HF

Patient exhibits signs and symptoms of HF (such as edema, high filling pressures, orthopnea)

Clinical Severity Assessment

Diagnostic

ECG detects HR and heart rhythm; Thoracic ultrasound examines mediastinum; Chest CT detects enlarged heart, fluid; Chest X-ray detects infection, embolism

Intervention and Monitoring

Continue with Guideline Directed Medical Therapy (GDMT) with serial reassessment and optimize dosing

Stage D

NYHA IV

Unable to carry out physical activity & HF symptoms are present at rest

Specialty Referral

Patient may be referred for advanced HF to consider and undergo advanced therapies, or to access a broader team knowledge for better potential outcomes.

Indicators

Peak VO_2 <14 mL/kg/min, furosemide equiv. dose >160 mg/d, SBP ≤90 mmHg, serum sodium <134 mEq/L

Clinical Severity Assessment

Assess suitability for LVAD[6], cardiac transplantation, palliative care

"Our staff conducts one-on-one patient education if time allows. Patient education on lifestyle management is, I think, the number one facet to bring congestive HF down." – **Intensivist, 600 Bed Hospital, Missouri**

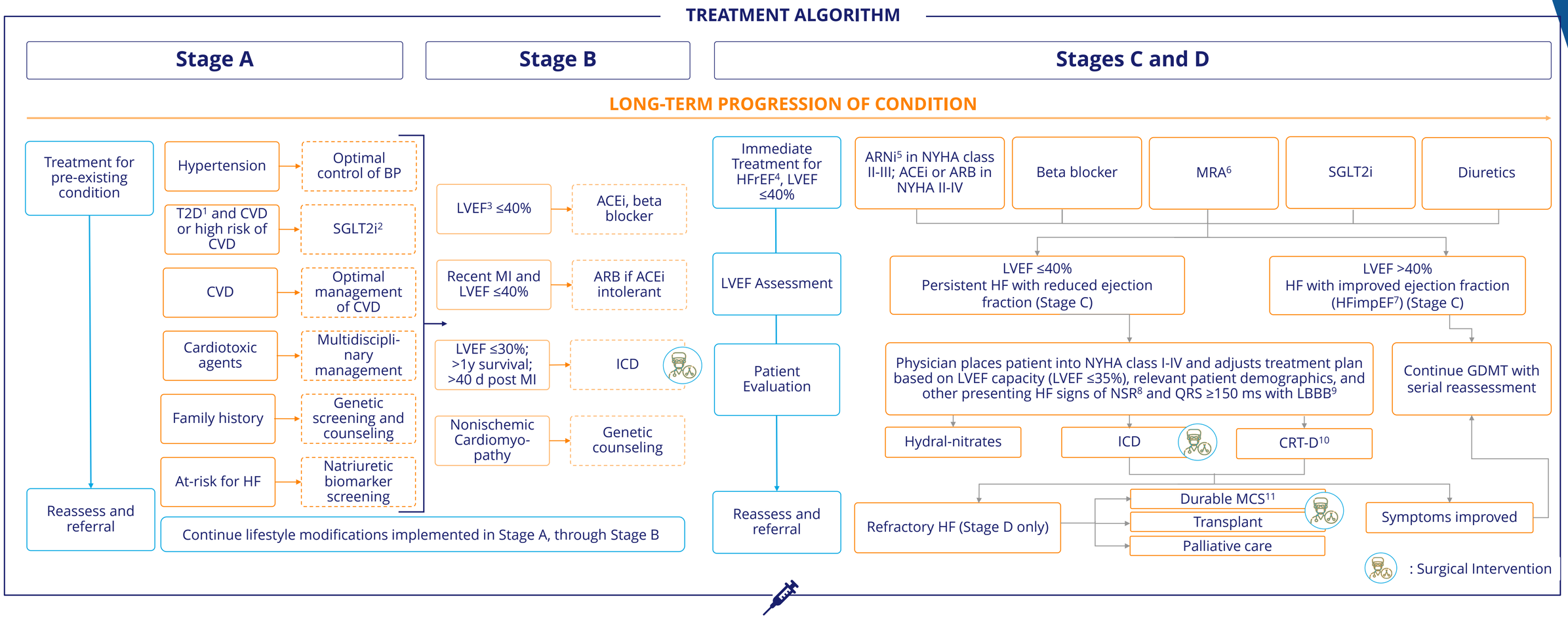
"Shortness of breath in AHF has either a pulmonary cause or cardiac cause. Once it is clear to be cardiac-related, the patient will be moved to the ICU or discharged on diuretics." – **Surgeon, 450 Bed Hospital, Maryland**

"Determining the cause of shortness of breath is done through a chest x-ray and physical exam. The patient's response to non-invasive oxygen treatment is another indicator." – **Surgeon, 450 Bed Hospital, Maryland**

Note: [1]Cardiovascular disease; [2]New York Heart Association; [3]Angiotensin-converting enzyme inhibitors; [4]Angiotensin II receptor blocker; [5]Implantable cardioverter-defibrillator; [6]Left ventricular assist device. Source: Abbott, Recognizing the Stages of Heart Failure; Čerlinskaitė et al., Acute heart failure management, KCJ (2018); Heidenreich et al., 2022 AHA/ACC/HFSA Guideline for the management of heart failure, Circulation (2022); Hollenburg et al., 2019 ACC Expert consensus decision pathway on risk assessment, management, and clinical trajectory of patients hospitalized with heart failure, ACC(2019); Alira Health analysis.

US Heart Failure Treatment Algorithm

Epidemiology of the Cardiology Patient Population



"Communication between ER nurses and the ICU staff sets the basis for medication reconciliation for a patient in the ICU receiving further evaluation."
– Intensivist, 120 Bed Hospital, New York

"We typically do a workup to find the source of HF and then start diuretic or blood pressure support medications, then consult with the cardiologist on these patients."
– Intensivist, 600 Bed Hospital, Missouri

"Patients are started on a medication regimen when they initially present. When the EKG, vital signs, fever, and appearance are stabilized, the patient can be followed-up in outpatient." **– ER NP, 500 Bed Hospital, Maryland**

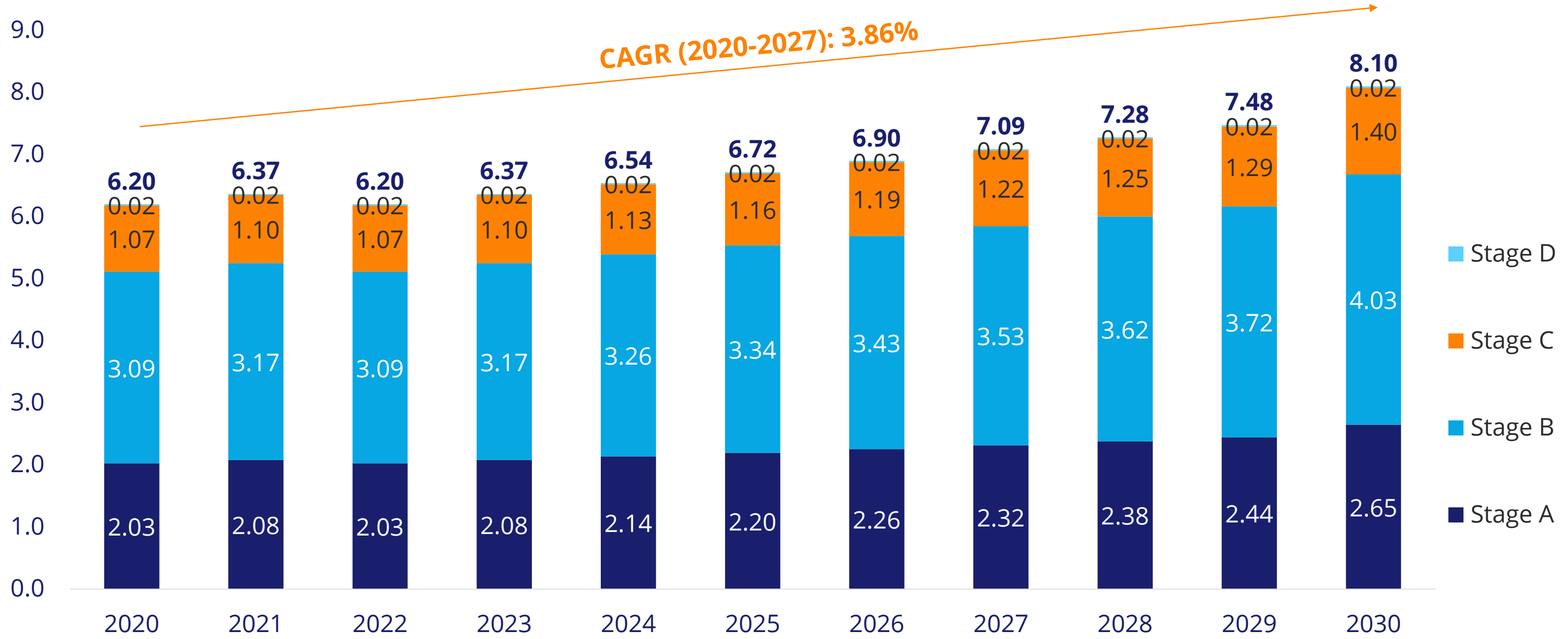
Note: 1Diabetes mellitus type II; 2Sodium-glucose cotrnsporter-2 inhibitor; 3Left ventricle ejection fraction; 4Heart failure with reduced ejection fraction; 5Angiotensin Receptor-Neprilysin Inhibitor; 6Mineralocorticoid receptor antagonists; 7Heart failure with improved ejection fraction; 8Normal sinus rhythm; 9Left bundle branch block; 10Cardiac resynchronization therapy defibrillator; 11mechanical circulatory support.

Source: Abbott, Recognizing the Stages of Heart Failure; Čerlinskaitė et al., Acute heart failure management, KCJ (2018); Heidenreich et al., 2022 AHA/ACC/HFSA Guideline for the management of heart failure, Circulation (2022); Hollenburg et al., 2019 ACC Expert consensus pathway on risk assessment, management, and clinical trajectory of patients hospitalized with heart failure, ACC (2019); Alira Health Analysis.

Epidemiology of the US Heart Failure Population

Epidemiology of the Cardiology Patient Population

TOTAL ADDRESSABLE US HEART FAILURE PATIENT POPULATION METHODOLOGY (IN MILLIONS)



METHODOLOGY

1. Using the **current total US population** as published by the **United States Census Bureau and World Bank**, and the current compound average growth rate for the population, **CAGR**, as published by the World Bank, **Alira Health forecasted** the US population to year 2030.

2. **The AHA** published a projection that **8.1 million Americans will have HF by 2030**. With this information and the number of HF patients in 2020, AH determined the forecasted CAGR for number of HF patients and the corresponding prevalence in the overall population.

3. **Through publications from the AHA,** Alira Health was able to determine the **normalized prevalence by stage** of:
   - Stage A: 32.7%
   - Stage B: 49.78%
   - Stage C: 17.23%
   - Stage D: 0.29%

ALIRA HEALTH ANALYSIS

> The AHA published a projection that 8.1 million Americans would have HF by 2030. The largest portion of this 8.1 million is projected to be 4.03 million patients in stage B.

> The transition from Stage C to Stage D showed to have the smallest growth rate at only 0.29%. Because this growth rate is so small, the overall change in expected patients to have stage D HF year over year remains the smallest segment of the patient HF population and only grows by and estimated 5,500 patients from 2020 to 2030 while the number of Stage A is expected to grow from 2.03 million patients in 2020 to an expected 2.65 million patients in 2030.

Source: American College of Cardiology: Progression to Stage D Heart Failure); American Heart Association, Circulation: (Heart Disease and Stroke Statistics- 2022 Update), (Heart Failure: Forecasting the Impact of Heart Failure in the United States), (Prevalence and Prognostic Significance of Heart Failure Stages), (Progression of Preclinical Heart Failure: A Description of Stage A and B Heart Failure in a Community Population); National Library of Medicine: (ACCF/ AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America), (Epidemiology of Heart Failure), (Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association), (Heart Disease and Stroke Statistics- 2022 Update); US Census Bureau; World Bank, ; Alira Health analysis.

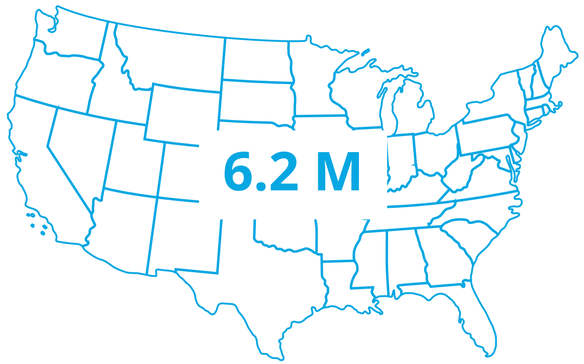
Epidemiology in the US

Epidemiology of the Cardiology Patient Population

The AHA expects the number of HF cases in the United States to grow from 6.2 million in 2020 to 8.1 million in 2030, yielding an expected compound annual growth rate of 2.71%.

HEART FAILURE US EPIDEMIOLOGY KEY FACTS & FIGURES

2020 HEART FAILURE PREVALENCE



- The American Heart Association (AHA) published a report that said 6.2 million Americans had HF in 2020 and 8.1 million were expected to have HF by 2030. Using these assumptions Alira Health was able to determine the growth rate of the prevalence of HF in the American population between 2020 and 2030.

GROWTH RATE

+2.71%

- The compound annual growth rate (CAGR) of HF in the United States was calculated using the AHA data that said 6.2 million Americans had HF in 2020 and 8.1 million would have heart failure by 2030.

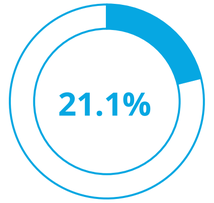
HEART FAILURE PREVALENCE BY AGE

18-44 yo	45-64 yo	≥65 yo

- Data is from a National Health Interview Survey conducted in 2020 by the National Center for Health Statistics. Respondents in the study were asked if they had ever been told by a doctor or other health professional that they had heart disease, angina pectoris, or myocardial infarction, and had to have responded positively to at least one of those to be included in the study.

UNDIAGNOSED RATE

Reported in 2019



- According to a 2019 JAMA Cardiology study, 1 in 5 patients who had self-reported having heart disease had undiagnosed HF.

Source: American College of Cardiology: Progression to Stage D Heart Failure); American Heart Association, Circulation: (Heart Disease and Stroke Statistics- 2022 Update), (Heart Failure: Forecasting the Impact of Heart Failure in the United States), (Prevalence and Prognostic Significance of Heart Failure Stages), (Progression of Preclinical Heart Failure: A Description of Stage A and B Heart Failure in a Community Population); National Library of Medicine: (ACCF/ AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America), (Epidemiology of Heart Failure), (Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association), (Heart Disease and Stroke Statistics- 2022 Update); US Census Bureau; World Bank, ; Alira Health analysis.

Epidemiology in the EU

Epidemiology of the Cardiology Patient Population

In 2017, the European Heart Network (EHN) published their yearly statistics which showed that 37% of EU deaths were attributed to Cardiovascular Disease. The CAGR of CVD was found to be 3.14% in men and 2.9% in women across Europe.

HEART FAILURE EU EPIDEMIOLOGY KEY FACTS & FIGURES

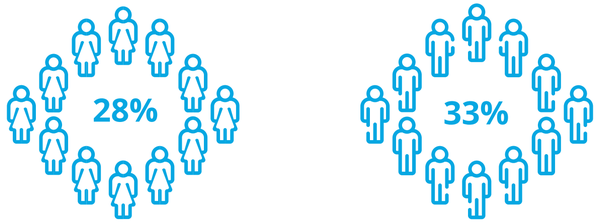
2020 HEART FAILURE PREVALENCE

> The EHN published a Network Paper in 2019 that reported a 1-2% prevalence of HF in the European population which they calculated as meaning more than 10 million people in the EU could be affected by HF.

GROWTH RATE OF CARDIOVASCULAR DISEASES

> The CAGR of CVD among men and women in Europe was calculated using a EHN report published in 2019. The report read that between 1990 and 2015, CVD rose 26% among women and 32% among men.

LIFETIME RISK OF HEART FAILURE FOR PEOPLE AGED 55 YEARS+

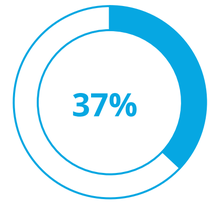


> Data is from the “Burden on Society” subsection of an EHN Paper entitled “Heart Failure and Cardiovascular Disease” published in April of 2019. While data for the entire population was not included in this report, the breakdown of men and women, and their respective likelihood of diagnosis with HF with age was published.

CVD ACCOUNTS FOR

of all EU deaths

According to data from 2017



> According to the 2017 European Cardiovascular Disease statistics published by the EHN, CVD deaths make up, on average, 37% of all yearly deaths in the EU.

Source: European Heart Network: Heart Failure and Cardiovascular Diseases- A European Heart Network Paper; Alira Health Analysis.

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

   2.1 Clinical Approaches & Applications 22

   2.2 Clinical Unmet Needs 25

   2.3 Market Size & Growth Dynamics 27

   2.4 Competitive Landscape & Profiles 37

   2.5 Deals Flow Assessment 45

3. Cardiology Market Outlook 49

4. Key Takeaways 55

5. About Authors 61

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

2.1 Clinical Approaches & Applications 22

2.2 Clinical Unmet Needs 25

2.3 Market Size & Growth Dynamics 27

2.4 Competitive Landscape & Profiles 37

2.5 Deals Flow Assessment 45

3. Cardiology Market Outlook 49

4. Key Takeaways 55

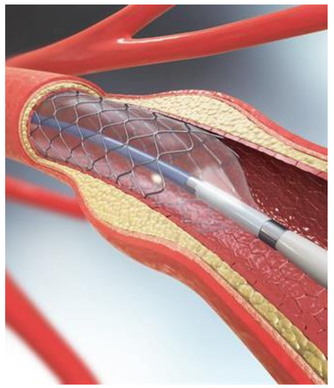
5. About Authors 61

Most Common Interventional Cardiology Clinical Applications

Clinical Approaches and Applications

Interventional Cardiology is a subsection of Cardiology in which patients with various cardiovascular diseases and complications are treated with minimally-invasive catheter procedures rather than traditional open heart surgeries.

DEFINITION



- **Interventional Cardiology** is a category of care for **cardiovascular diseases and complications** in which **catheter-based therapies** are used to treat a patient rather than surgical therapies.
- Interventional Cardiology is most commonly used to **repair damaged vessels, clear clogged or narrowed arteries,** treat **heart failure** patients, or treat cardiovascular diseases such as **congenital heart disease, coronary artery disease, valvular heart disease**, and **structural heart disease**, among others.
- As a practice, **Interventional Cardiology began with** the first Percutaneous Transluminal Coronary Angioplasty **(PTCA)** in the **late 1970's** and has since expanded to include many minimally invasive procedures using **catheters.**

KEY RISK FACTORS

Previous Hospitalization for Heart Attack	
Metabolic Disorders	Diabetes
Chronic Kidney or Lung Disease	
Smoking	Family History
Arrhythmias	Structural CVD
Age	Race and Ethnicity
Diet	Exercise
Common Comorbidities	
Atrial Fibrillation	Hypertension
High Blood Pressure	Chronic Inflammation
Metabolic Disorders	Diabetes
Chronic Kidney or Lung Disease	

- While some of the physiological risk factors are out of a patient's control, some of the habitual risk factors can be addressed and even minimized by a patient's lifestyle choices. For example, giving up smoking, reducing sodium intake, and exercising regularly can help reduce a patient's risk of cardiovascular complications.

DIAGNOSES AND PROGNOSES OF INTERVENTIONAL CARDIOLOGY

Coronary Artery Disease (CAD)	Valvular Heart Disease	Peripheral Artery Disease (PAD)	Structural Heart Disease
CAD is a condition in which the arteries that supply blood to the heart become narrowed or blocked, which can cause chest pain (angina), shortness of breath, and even heart attacks.	Valvular heart disease occurs when the valves in the heart do not function properly, which can cause fatigue, shortness of breath, and chest pain.	PAD is a condition in which the arteries that supply blood to the legs become narrowed or blocked, which can cause pain, cramping, and reduced mobility.	Structural heart disease refers to abnormalities or defects in the structures of the heart, such as the walls or valves.
Procedures such as coronary angioplasty, stenting, and atherectomy can be used to restore blood flow to the heart.	Procedures such as TAVR and balloon valvuloplasty can be used to repair or replace damaged valves.	Procedures such as angioplasty, stenting, and atherectomy can be used to restore blood flow to the legs and improve symptoms.	Procedures such as atrial septal defect closure and patent foramen ovale closure can be used to repair these structural abnormalities.

Source: American Heart Association; AMS Cardiology; CDC.gov, Heart Failure; Cleveland Clinic; Cleveland Clinic, Heart Disease: Prevention & Reversal (2022); Columbia Cardiology; Alira Helath analysis.

Cardiology Specialization & Provider Characteristics

Clinical Approaches and Applications

The number of Cardiac Specialties has grown with the prevalence of various cardiovascular diseases and complications. While all Cardio-specialists undergo extensive education, Interventional Cardiologists have some of the most rigorous training.

TYPES OF CARDIO-SPECIALISTS

- The heart is a complex organ, and the most important in the human body. Without the heart functioning properly, the rest of the body cannot carry out its necessary duties. The importance of the heart does not go unnoticed.
- The US NIH allocated an estimate $2.9B on cardiology research in 2021. With this large amount of funding for research, many specialties and sub-specialties have risen, and with them, specialized treatments for the various patient complications that may arise.

Clinical Cardiologists | **Preventive Cardiologists** | **Cardiac Surgeons** | **Interventional Cardiologists**

DEEP DIVE INTO INTERVENTIONAL CARDIOLOGISTS

- **Interventional Cardiology** is a subspecialty of Cardiology and one of the most focused and time-intensive specialties to pursue. Similar to other highly focused sub-specialties, Interventional Cardiology **takes 3 to 4 years of additional training and certification** after medical school and the Internal Medicine Residency.
- **Cardiology students and fellows wishing to become Interventional Cardiologists** are required to have additional training and a fellowship program outside of the minimum 3 years of cardiology fellowship that is required to become a licensed cardiologist.
- Coronary artery stenting is where Interventional Cardiology was born, but the field has expanded into repairment and replacement of valves and aorta with recent innovations.

PATIENT POPULATION AND PROVIDERS

Specialist	Clinical Cardiologist	Preventive Cardiologist	Cardiac Surgeon	Interventional Cardiologist
Clinician Role / Patient Characteristics	**Clinical Cardiologists** are responsible for the **continuous management** of patients with **heart disease, arrythmias, who have experienced a heart attack**, or who have begun to develop symptoms.	**Preventive Cardiologists** work with patients who experienced **cardiac episodes at a young age or who are predisposed to heart disease**. They will work a plan to minimize the likelihood of heart failure or cardiovascular complications.	**Cardiac Surgeons** address **urgent repairs on patients' hearts and major blood vessels**. They conduct procedures such as **coronary artery bypass grafting** and **repairment or replacement of valves or aorta** that cannot be done with a catheter.	**Interventional Cardiologists** treat patients through **minimally-invasive catheter procedures**. These procedures can be planned well in advance or be used to **treat emergent cardiac complications**.
Setting	**Outpatient/ Primary Care Setting**	**Outpatient/ Primary Care Setting**	**Cardiac ICU/ OR**	**Cardiac ICU/ Cardiac Cath Lab**

Source: American College of Cardiology, (For the FITs | Interventional Heart Failure: Insight into an Evolving Training Pathway), (New Advanced Training Statement on Interventional Cardiology: Key Points); American Heart Association, Circulation: Cardiovascular Interventions (Certification and Competency in Interventional Cardiology); American Medical Association: Freida, Interventional Cardiology; Castle Connolly Top Doctors, What is Interventional Cardiology?; Cleveland Clinic, Cardiac Surgeon (2021), "What Type of Cardiologist Should You See for Specialized Heart Care?" (2019); National Library of Medicine, Epidemiology of Heart Failure; Alira Health analysis.

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

2.1 Clinical Approaches & Applications 22

2.2 Clinical Unmet Needs 25

2.3 Market Size & Growth Dynamics 27

2.4 Competitive Landscape & Profiles 37

2.5 Deals Flow Assessment 45

3. Cardiology Market Outlook 49

4. Key Takeaways 55

5. About Authors 61

Clinical Unmet Needs Within Cardiology Medical Devices

Clinical Unmet Needs

The Cardiologist shortage and global microprocessor shortage are likely to have the most significant impact on the markets in the EU and US, while proper training for physicians on new techniques is expected to have a lesser impact on the markets in coming years.

Unmet Need	Description	Impact on Affected Region
Cardiologist Shortage	In 2021 the Cardiometabolic Heath Congress published a projection that there could be a shortage of 29,000 cardiologists by the year 2025. The rapidly rising age of physicians, with nearly 60% of Cardiologists aged 55 or older, contributes to this shortage as well.	EU: HIGH; US: HIGH
Global Microprocessor Shortage	Since the start of the 2020 COVID-19 pandemic, medical device companies have had to compete with many other industries for microprocessor chips, such as electronics manufacturers responsible for computers, smartphones, cameras, and auto manufacturers, lowering the availability of microprocessors for cardiology devices such as pacemakers, ICDs, and CRTs, among others.	EU: HIGH; US: HIGH
Stringent Regulation on Medical Devices	The Medical Device Regulations (MDR) in the EU significantly increased requirements in May of 2021 to launch new devices, which has resulted in a shortage of certain medical devices. Survey results from the European Society of Cardiology say that 57% of these cases are affecting the care of high-risk patients or children.	EU: HIGH; US: MEDIUM
Patient Cost Drivers	HF is expensive for payers, accounting for over 30% of the costs to Medicare. A large portion of these costs come from high readmission rates of patients, for which the Centers for Medicare & Medicaid Services (CMS) has begun penalizing providers.	EU: MEDIUM; US: HIGH
Growing Heart Failure Patient Population	The rapidly aging population in both the US and EU has contributed to the epidemic of HF around the world and has given rise to sub-specializations such as interventional cardiology.	EU: MEDIUM; US: HIGH
Proper Training for Clinicians on New Tools and Techniques	Given this emergence of sub-specialties in recent years, the need for specialty clinicians and practitioners to be trained on new practices and procedures to ensure proper treatment of their patients has grown.	EU: LOW; US: LOW

> *"Connectivity and wiring patients, post discharge (pressure to discharge early patients), and avoiding re-admissions in the hospital are the major unmet needs to address"*
> **- Emergency Department Head**

> *"It's about resource management. These hospitals have limited resources - like nurses, doctors, et cetera"*
> **- Former Director of Marketing**

> *"Having some insights for at-risk patients is particularly important among patients who are older and harder to get a full history"*
> **- Cardiologist**

> *"Teach back techniques and educational level on their condition can indicate the overall outcome of the heart failure patient."*
> **- ER NP**

Source: Primary interviews; Alira Health analysis.

Legend: EU US HIGH MEDIUM LOW

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

   2.1 Clinical Approaches & Applications 22

   2.2 Clinical Unmet Needs 25

   2.3 Market Size & Growth Dynamics 27

   2.4 Competitive Landscape & Profiles 37

   2.5 Deals Flow Assessment 45

3. Cardiology Market Outlook 49

4. Key Takeaways 55

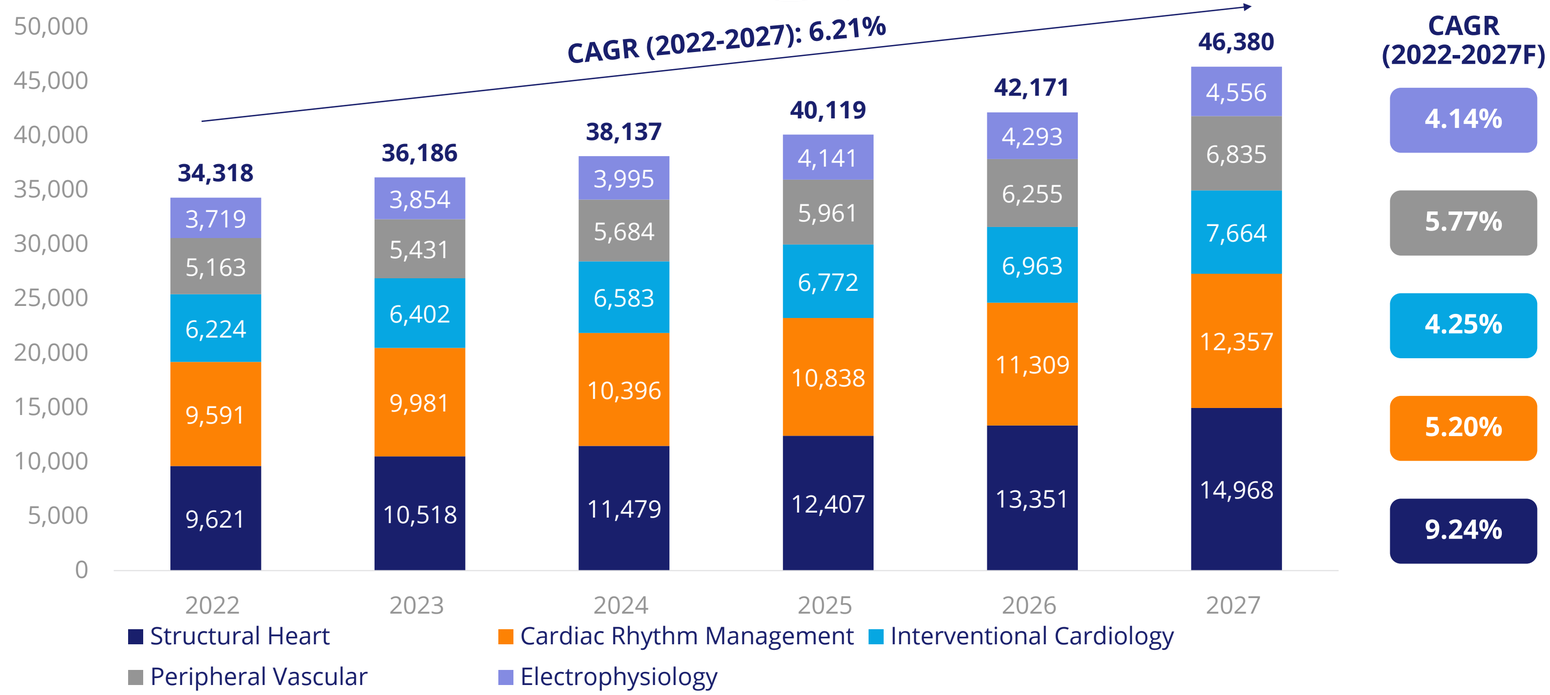
5. About Authors 61

Cardiology Medical Devices Market Size & Growth

Market Size & Growth Dynamics

The US & EU Cardiology Medical Devices Market was worth $34.3B in 2022, forecasted to grow at an 6.21% CAGR '22-'27F to reach $46.4B in 2027F. Structural Heart was the largest segment at $9.6B in 2022 and is also expected to be the fastest growing segment.

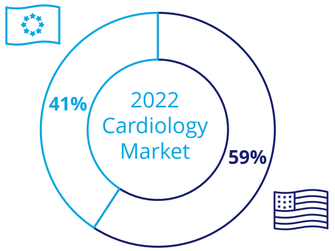
CARDIOLOGY US & EU MARKET SIZE & GROWTH, $B, (2022-2027F)

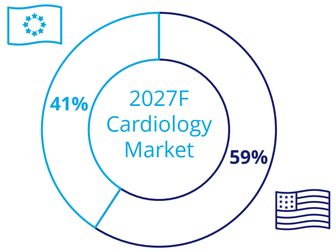


CAGR (2022-2027F)
4.14%
5.77%
4.25%
5.20%
9.24%

COMMENTS

- The **structural heart** segment **is expected to be the fastest growing** with a **CAGR of 9.24% between '22 and '27F**, taking it from **a total of $9.62B in 2022** to an **expected $14.97B** in **2027F**.
- **Electrophysiology is the smallest segment** in the cardiology medical devices market but is **expected to grow** at an annual compound growth rate of **4.15% between 2022 and 2027F.**
- There is **no change expected** in market share for the US and EU between 2022 and 2027F.





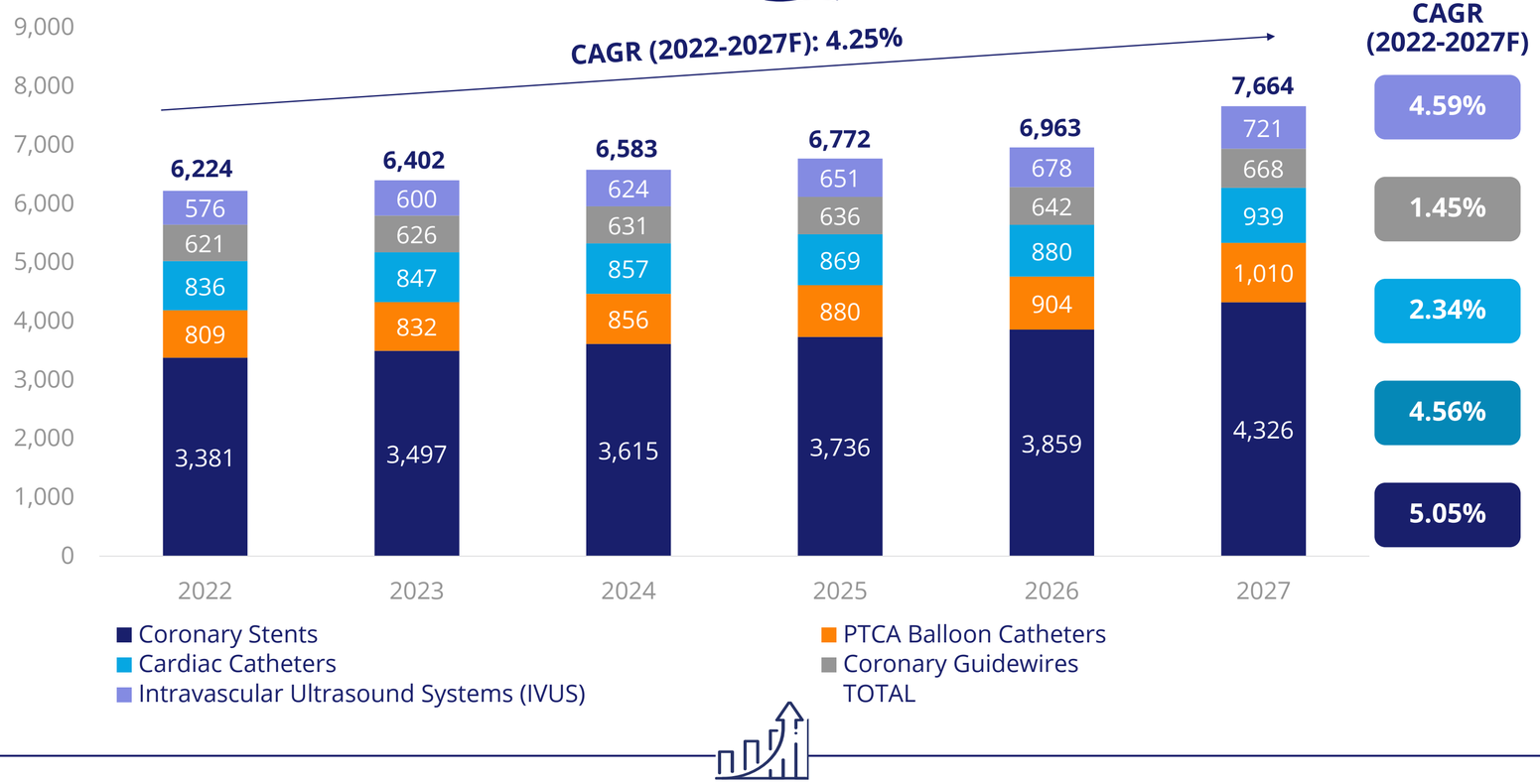
Source: GlobalData; LSI MD&D Report 2021; Alira Health analysis.

US & EU Market Breakdown: Interventional Cardiology

Market Size & Growth Dynamics

The Interventional Cardiology segment is expected to grow at an annual rate of 4.25%. Worth $6.22B in 2022 (18% of the market), it is expected to be worth $7.66B by 2027 (17% of the market).

INTERVENTIONAL CARDIOLOGY US & EU MARKET SIZE & GROWTH, $B, (2022-2027F)



COMMENTS

- The total **US & EU interventional cardiology segment made up 18%** of the cardiology medical devices market **in 2022** and **is expected to make up 17% of the market in 2027F.**
- The **Interventional Cardiology segment was worth $6.22B in 2022** and has an **expected revenue of $7.66B in 2027F**.
- The **forecasted CAGR for the 2022-2027 period is 4.25% for the interventional cardiology segment.**
- **Coronary** Stents make up the **largest portion of the Interventional Cardiology segment.**
- **Coronary stents, PTCA Balloon Catheters, and IVUS** all have **a CAGR of 5%.**
- **Coronary guidewires** have the **smallest CAGR of the segment at 1.45%.**

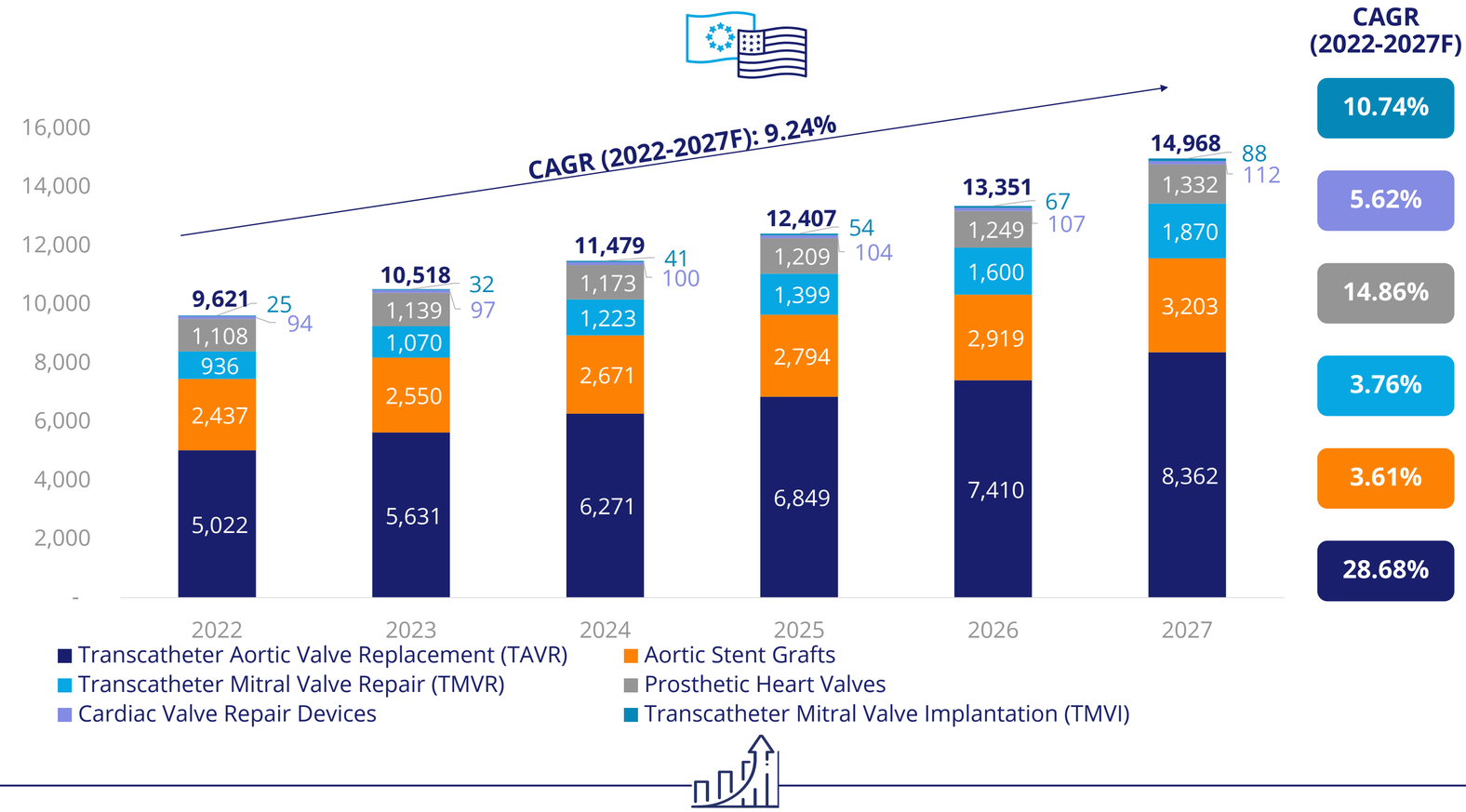
Source: GlobalData; LSI MD&D Report 2021; Alira Health analysis.

US & EU Market Breakdown: Structural Heart

Market Size & Growth Dynamics

Structural Heart was the largest segment of the Cardiology Medical Devices market at $9.6B in 2022 and is also expected to be the fastest growing segment. While it made up 28% of the market in 2022, it is expected to make up 32% in the 2027F.

STRUCTURAL HEART US & EU MARKET SIZE & GROWTH, $M, (2022-2027F)



CAGR (2022-2027F)

10.74%
5.62%
14.86%
3.76%
3.61%
28.68%

COMMENTS

- The **Structural Heart segment was worth $9.62B in 2022** and has a **CAGR of 9.24%** ('22-'27F).
- Making up **28% of the market in 2022, Structural Heart was one of the largest segments** equaled only by Cardiac Rhythm Management. **It is expected to be the largest segment by 2027F, forecasted to hold 32%** of the cardiology medical devices market.
- **TAVR** makes up the **largest portion** of the **Structural Heart Segment.**
- **TAVR** has the **second largest expected CAGR at 11%. TMVI has the largest expected CAGR of 29%.**
- **TMVI is the sub-segment with the largest CAGR (28.68%)** of the Structural Heart segment.

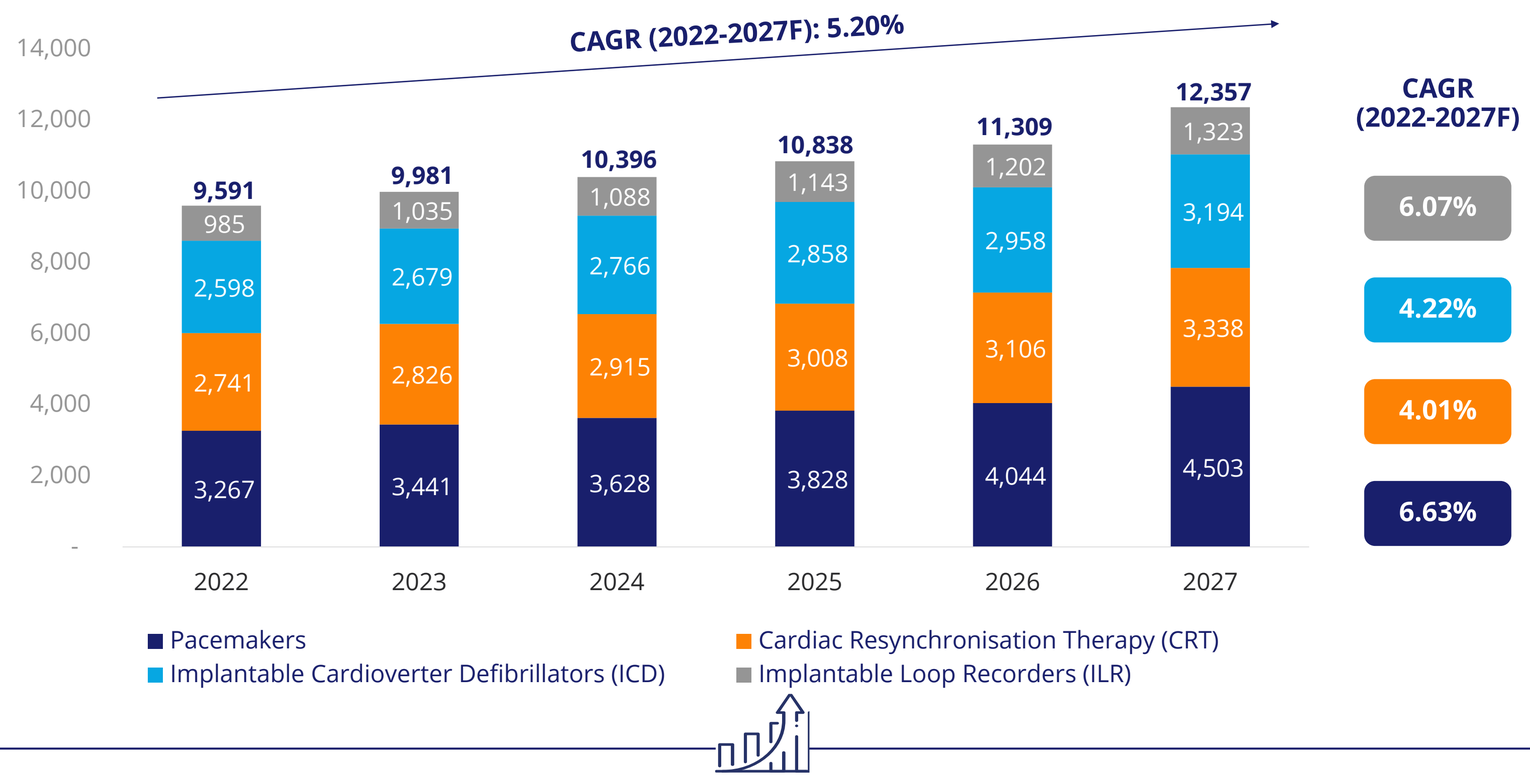
Source: GlobalData; LSI MD&D Report 2021; Alira Health analysis.

US & EU Market Breakdown: Cardiac Rhythm Management

Market Size & Growth Dynamics

The Cardiac Rhythm Management segment was the second largest in the cardiology medical devices market in 2022, making up 28% of the market and worth $9.59B in 2022. The segment has a forecasted CAGR of 5.20% between 2022 and 2027F.

CARDIAC RHYTHM MANAGEMENT US & EU MARKET SIZE & GROWTH, $M, (2022-2027F)



CAGR (2022-2027F)
6.07%
4.22%
4.01%
6.63%

COMMENTS

- The **Cardiac Rhythm Management segment was worth $9.59B in 2022** and has a **CAGR of 5.20%** ('22-'27F).
- **Cardiac Rhythm Management** was the **second largest segment** of the cardiology medical devices market **in 2022** and **is expected to be worth $12.36B in 2027F.**
- **Pacemakers** make up the **largest portion of the Cardiac Rhythm Management segment** and also have the **largest CAGR** in the segment at **7% ('22-'27F).**
- **The second largest sub-segment** of the cardiac rhythm management segment **was ILRs in 2022, making up 10%,** and it is **expected to grow at a CAGR of 6.07% ('22-'27F), making up a forecasted 11%** of the segment **in 2027**.
- **Cardiac Rhythm Management** was **one of the two largest segments** of the cardiology medical devices market **in 2022** and is **expected to be the second largest in 2027F.**

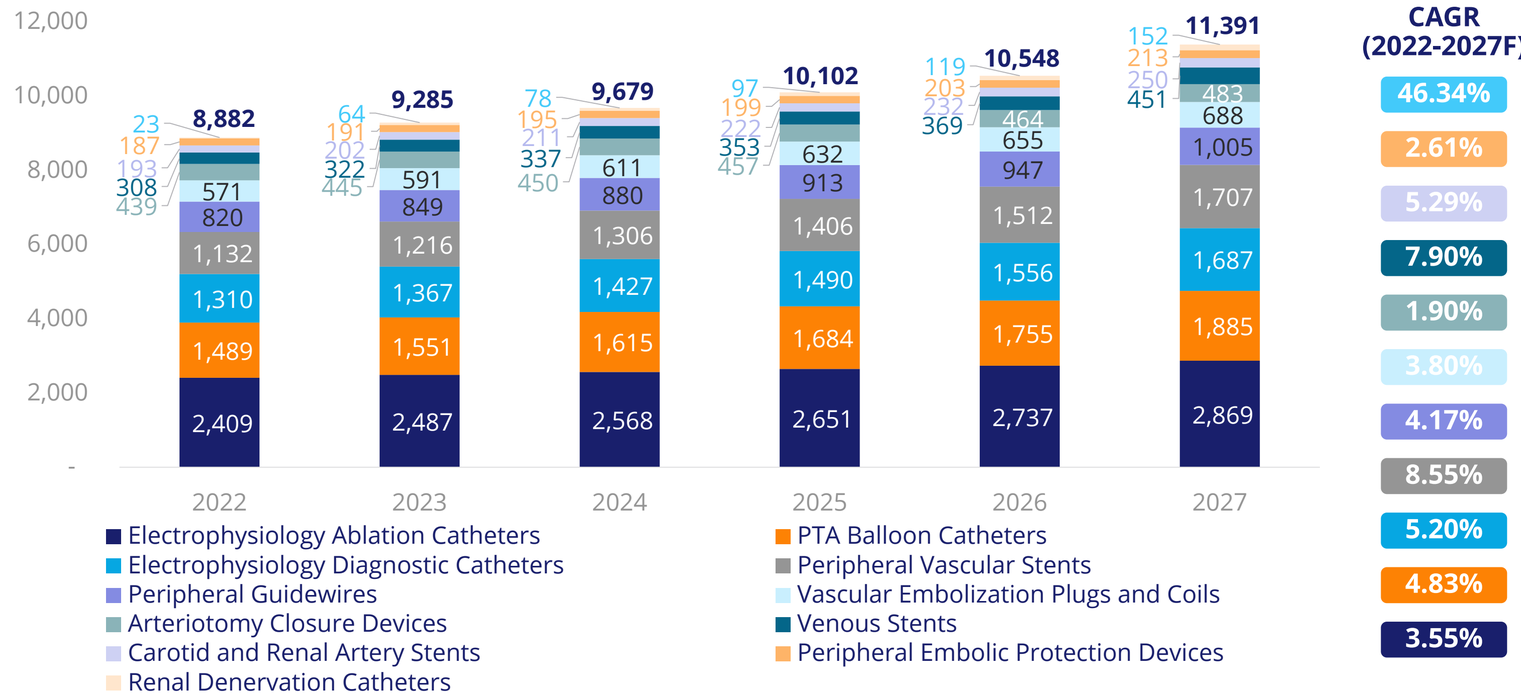
Source: GlobalData; LSI MD&D Report 2021; Alira Health analysis.

US & EU Market Breakdown: Electrophysiology/Peripheral Vascular

Market Size & Growth Dynamics

Together, the Electrophysiology and Peripheral Vascular segments made up 26% of the market in 2022. Electrophysiology has a forecasted CAGR ('22-27) of 4.15% and Peripheral Vascular has a CAGR of 5.77% forecasted for the same period.

ELECTROPHYSIOLOGY/ PERIPHERAL VASCULAR US & EU MARKET SIZE & GROWTH, $M, (2022-2027F)



CAGR (2022-2027F)

46.34%
2.61%
5.29%
7.90%
1.90%
3.80%
4.17%
8.55%
5.20%
4.83%
3.55%

COMMENTS

- The **Electrophysiology segment was worth $3.72B in 2022.**
- **Electrophysiology made up 11% of the** cardiology medical devices **market in 2022 and** is **expected to make up 10%** of the market **in 2027F.**
- The **Electrophysiology segment** has an expected **CAGR of 4.15% ('22-'27F).**
- **Electrophysiology ablation catheters** accounted for **65% of the electrophysiology segment.**
- The **Peripheral Vascular segment was worth $5.16B in 2022** and has a **CAGR of 5.77%** ('22-'27F).
- The **Peripheral Vascular Segment made up 15%** of the entire market **in 2022** and is **expected to remain constant,** making up **the same percentage in 2027F.**
- **Renal Denervation Catheters,** in the Peripheral Vascular segment, has a **CAGR of 46%** ('22-'27F), **the largest CAGR in the segment.**

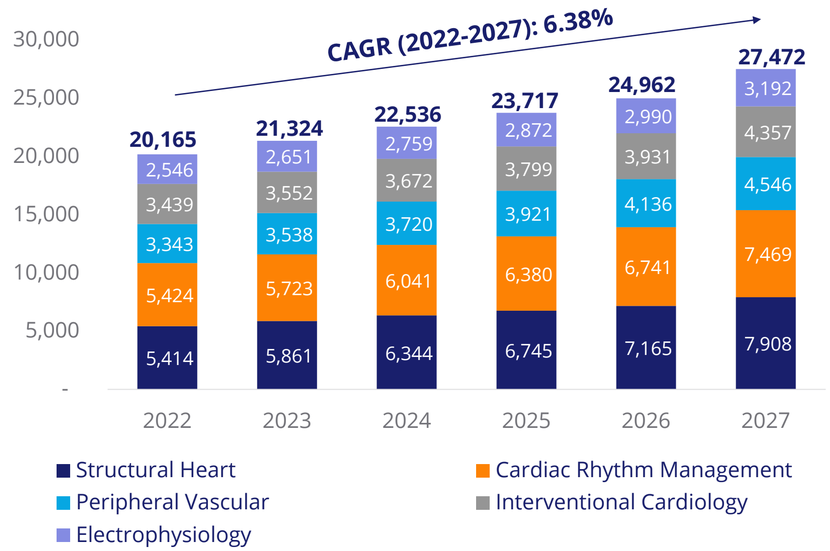
Source: GlobalData; LSI MD&D Report 2021; Alira Health analysis.

Cardiology Medical Devices Market in the US

Market Size & Growth Dynamics

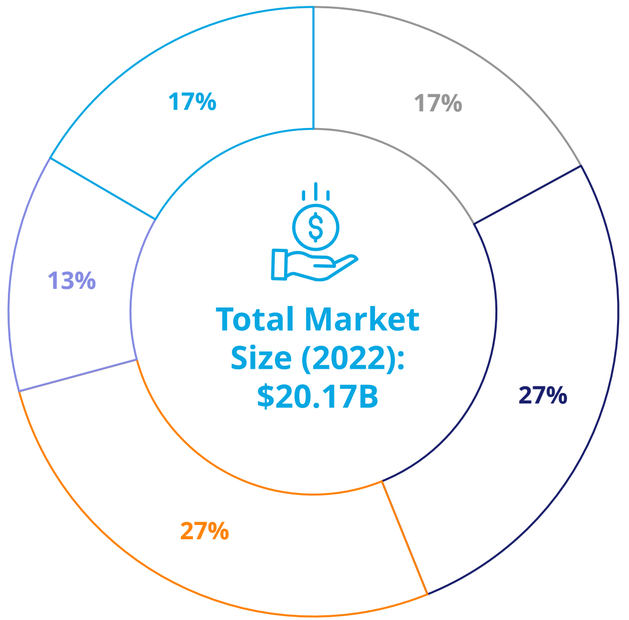
The US cardiology medical devices market was valued at $20.17B in 2022, projected to reach $27.47B in 2027 with a forecasted CAGR '22-'27 of 6.38%. Structural heart is expected to be the fastest growing segment at 7.87% CAGR for the period.

US CARDIOLOGY MEDICAL DEVICES MARKET SIZE ($B) & GROWTH



- **The Structural Heart segment is expected to remain the largest and most profitable segment** during the '22-'27F period.
- **While the Electrophysiology** segment is the smallest and **is expected to remain the smallest through 2027,** it has an **expected CAGR of 4.62%,** signifying the **immense growth the whole market is expected to see.**
- **Cardiac rhythm management** made up **27% of the US Cardiology** medical devices market in 2022 and is expected to remain constant, making up **27% of the market in the forecast of 2027** as well.

Market Size Split by Application (2022)



- Interventional Cardiology — CAGR '22-'27e: 4.85%
- Structural Heart — CAGR '22-'27e: 7.87%
- Cardiac Rhythm Management — CAGR '22-'27e: 6.61%
- Electrophysiology — CAGR '22-'27e: 4.62%
- Peripheral Vascular — CAGR '22-'27e: 6.34%

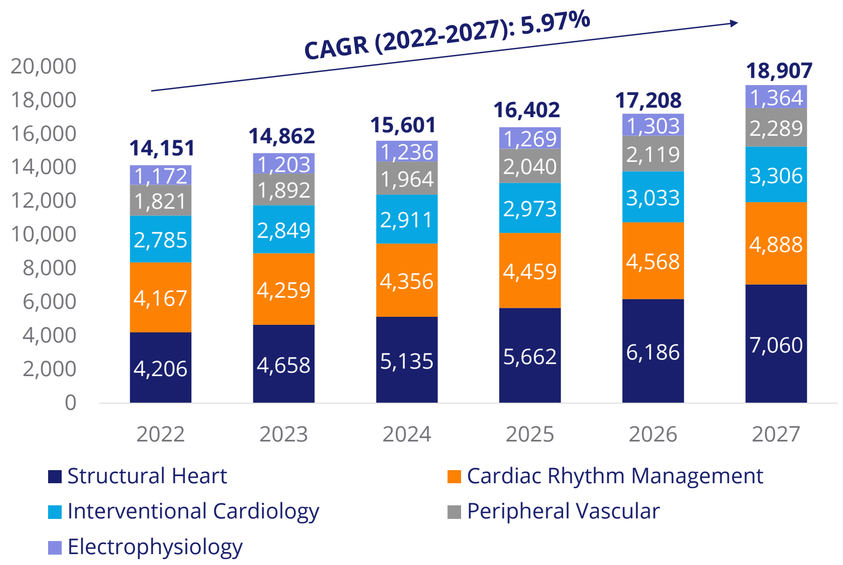
Source: GlobalData; LSI MD&D Report 2021; Alira Health analysis.

Cardiology Medical Devices Market in the EU

Market Size & Growth Dynamics

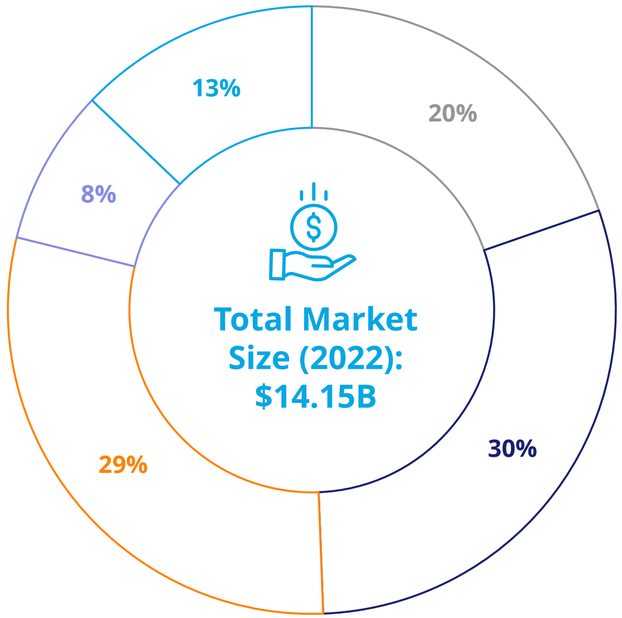
The cardiology medical devices market in the EU was valued at $14.15B in 2022 and is projected to reach $18.91B in 2027 with a forecasted CAGR '22-'27 of 5.97%. Structural heart is expected to be the fastest growing segment at 10.91% CAGR for the period.

EU CARDIOLOGY MEDICAL DEVICES MARKET SIZE ($B) & GROWTH



- **The Structural Heart segment is expected to remain the largest and most profitable segment** throughout the '22-'27F period.
- While **structural heart made up 30% of the market in the EU in 2022**, it is **forecasted to make up 37% of the market by 2027** given its impressive **CAGR of 10.91%.**
- **Peripheral Vascular is the segment with the second largest CAGR of 4.69% and is expected to see a growth from $1.82B in 2022 to $2.29B by 2027F.**

Market Size Split by Application (2022)



Interventional Cardiology	CAGR '22-'27e: 4.85%
Structural Heart	CAGR '22-'27e: 7.87%
Cardiac Rhythm Management	CAGR '22-'27e: 6.61%
Electrophysiology	CAGR '22-'27e: 4.62%
Peripheral Vascular	CAGR '22-'27e: 6.34%

Source: GlobalData; LSI MD&D Report 2021; Alira Health analysis.

Key Market Drivers and Restraints

Market Size & Growth Dynamics

The cardiology medical devices market will maintain moderate growth through 2026 driven by growing prevalence of heart disease & the trend toward minimally-invasive surgery. Obstacles to growth include price pressure & strict MDR regulation of Class III devices.

Drivers

Market Drivers and Restraints	Impact
> **Prevalence & Awareness of Heart Disease** – The WHO reports 17.9M annual deaths globally from cardiovascular disease, an estimated 32% of all deaths worldwide. The growing obese and geriatric population is likely to increase prevalence of heart disease in the future. Initiatives and awareness campaigns by governments and the private sector are also driving market growth.	EU: MEDIUM; US: MEDIUM
> **Shift Toward Minimally-Invasive Surgery in Cardiology** – The trend across specialties toward performing more minimally-invasive surgery is particularly true in Cardiovascular, where many procedures can be done faster, more efficiently, and safer through minimally-invasive techniques. Already, 40% of structural heart procedures in the US and EU are minimally-invasive. This is likely to maintain market growth through 2026.	EU: MEDIUM; US: MEDIUM
> **Improved Regulatory Approval Process** – The significant improvement in the US FDA's approval speed, matching or surpassing the EU's MDR process, has reduced the waiting time for American patients to receive life-saving interventions, driving market growth. This improvement has increased advances in technology, such as the use of drug-eluting stents and intravascular imaging, have increased the success rates of interventions and reduced complications, contributing to market growth.	EU: MEDIUM; US: MEDIUM
> **Rise in Unhealthy Lifestyle Habits** - One of the comorbidities most seen with cardiovascular disease is obesity. 41.9% of Americans and nearly 60% of adults in the European Region are obese or overweight. Another factor that has been found to lead to CVD is smoking or the use of tobacco products. In 2020, 12.5% of Americans and 18.5% of Europeans smoked.	EU: HIGH; US: LOW
> **Increasing prevalence of structural heart disease** – The rising incidence of aortic and mitral valve disease, combined with the aging population, is expected to drive significant growth in interventional cardiology, particularly in the field of structural heart disease. The aging population is expected to be the most important factor in increasing cardiovascular diseases, particularly coronary heart disease. This demographic shift drives the demand for cardiology interventions.	EU: MEDIUM; US: MEDIUM
> **Expansion of clinical trials** – The growing number of clinical trials, particularly for procedures like TAVR, stimulates market growth by driving innovation and improving patient outcomes.	EU: MEDIUM; US: MEDIUM
> **Growth of cardiac intervention procedure training programs** – The expansion of specialized training programs, where cardiologists are trained in advanced procedures, has increased the number of skilled professionals capable of performing interventions, supporting market growth.	EU: MEDIUM; US: LOW
> **Interdisciplinary approach and technological advancements** – The involvement of engineering, design, and other specialist fields, along with the integration of big data and artificial intelligence (AI), is driving advancements in cardiology and expanding the potential for innovative interventions.	EU: MEDIUM; US: MEDIUM

Legend: EU, US, LOW, MEDIUM, HIGH

Note: [1]TAVR, Transcatheter aortic valve replacement; [2]TMVR, Transcatheter mitral valve replacement; [3]TTVR, Transcatheter tricuspid valve replacement; [4]MDR, Minimum device regulation. Source: WHO; GlobalData; CDC; EuroStat; Benjamin EJ, Virani SS, Callaway CW, et al. Heart disease and stroke statistics—2018 update: a report from the American Heart Association. Circulation Journal. 2018;137(12):e67-e492; Diagnostic and Interventional Cardiology; Primary research; Alira Health analysis.

Key Market Drivers and Restraints

Market Size & Growth Dynamics

The cardiology medical devices market will maintain moderate growth through 2026 driven by growing prevalence of heart disease & the trend toward minimally-invasive surgery. Obstacles to growth include price pressure & strict MDR regulation of Class III devices.

Restraints

Market Drivers and Restraints	Impact
> **Price Pressure from Competition & Bundled Payment Systems** – High competition at the original equipment manufacturer (OEM) level combined with highly restrictive regulatory specifications for critical cardiology devices in structural heart and interventional cardiology create challenges for OEMs to keep prices the same while maintaining quality. Additionally, margins for cardiac procedures, particularly those with fixed Diagnosis-Related Group (DRG) reimbursement, pose challenges to market growth. However, the implementation of incentive-linked programs and the improvement of value-based care models are expected to alleviate this restraint.	
> **Strict Regulation in EU** – Cardiology is among the most regulated healthcare markets due to its invasiveness and high acuity. Heart valves, stents, and grafts are considered Class III devices by the FDA and Class IIa and III by CE Marking. Additionally, effective as of May 2021, new MDR4 in the EU significantly increased requirements to launch new devices. OEMs have therefore prioritized the US for initial market launch through FDA clearance.	
> **Reimbursement Driving Transition to Lower Cost Care Settings** – Payers increasingly are shifting cardiology procedures to care settings that can deliver treatment or surgery at lower cost, such as ambulatory surgical centers and infusion clinics. Shifting case volume to these settings, which are often more cost constrained than large hospitals, could decrease adoption of innovative devices as a result of cost pressures, slowing market growth.	
> **Operator Dependency for Cardiac Procedures** – Cardiac procedures still heavily rely on operator skill and experience, leading to variations in outcomes. Despite the potential of AI and big data to reduce operator dependency, skepticism and insufficient training hinder their widespread adoption, limiting market growth.	
> **Interventional Device Size Limitations** – The current size of cardiac devices often hinders their easy use, particularly in certain patient populations such as women. However, ongoing innovations in device design are expected to address this limitation and improve accessibility.	
> **Slow Establishment of Centers of Excellence** – The growth of cardiology interventions is hindered by the slow establishment of centers of excellence in the field. The process of building and expanding such programs is time-consuming, resulting in a limited number of programs in the US. This constraint restricts the availability and accessibility of specialized care, thereby impeding market expansion.	
> **High Cost of Diagnosis & Treatment in Emerging Economies** – Of the estimated 32% of all deaths worldwide attributed to cardiovascular disease, ~80% of the burden occurs in developing and emerging economies. This is due in part to the high cost of diagnosis and treatment for cardiovascular disease and other heart conditions in regions across the globe. This high-cost burden will likely continue to restrain market growth in the future.	

Legend: EU US LOW MEDIUM HIGH

Note: [1]TAVR, Transcatheter aortic valve replacement; [2]TMVR, Transcatheter mitral valve replacement; [3]TTVR, Transcatheter tricuspid valve replacement; [4]MDR, Minimum device regulation. Source: WHO; GlobalData; CDC; EuroStat; Benjamin EJ, Virani SS, Callaway CW, et al. Heart disease and stroke statistics—2018 update: a report from the American Heart Association. Circulation Journal. 2018;137(12):e67-e492; Diagnostic and Interventional Cardiology; Primary research; Alira Health analysis.

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

   2.1 Clinical Approaches & Applications 22

   2.2 Clinical Unmet Needs 25

   2.3 Market Size & Growth Dynamics 27

   2.4 Competitive Landscape & Profiles 37

   2.5 Deals Flow Assessment 45

3. Cardiology Market Outlook 49

4. Key Takeaways 55

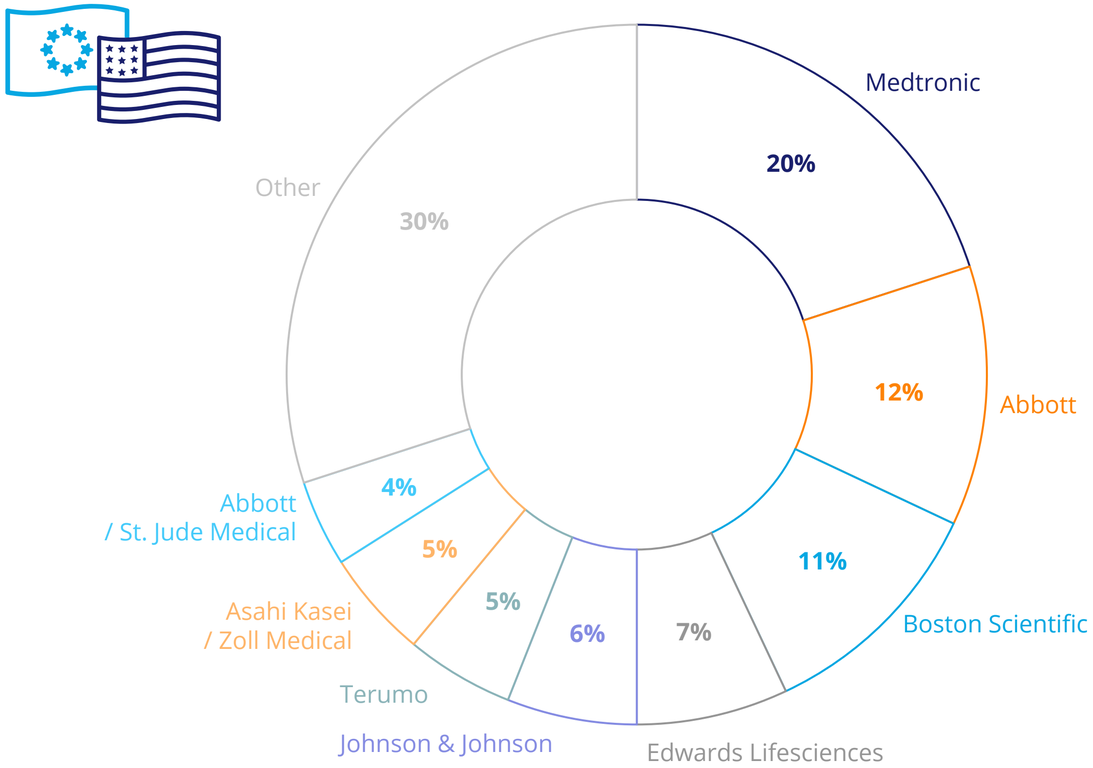
5. About Authors 61

Overview of Key Market Players

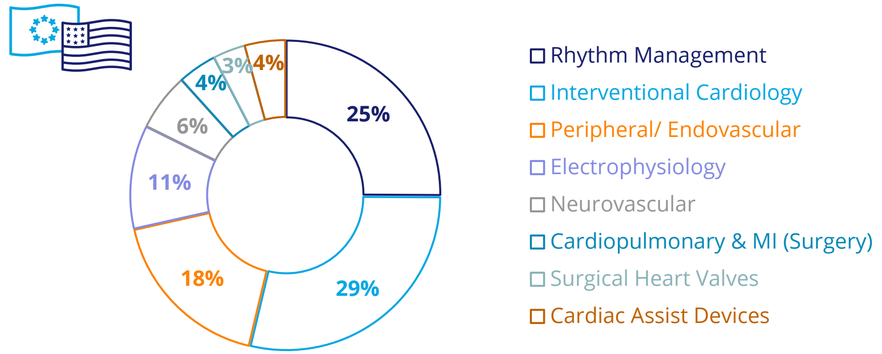
Competitive Landscape & Profiles

The 8 companies with the greatest share in the Cardiology Medical Devices Market collectively had more than 30% in each segment of the market; 43% of the overall market was controlled by Medtronic (20%), Abbott (12%) and Boston Scientific (11%) in 2020.

COMPANIES WITH THE GREATEST MARKET SHARE OF THE CARDIOLOGY MEDICAL DEVICES MARKET IN 2020



CARDIOLOGY MEDICAL DEVICES MARKET SEGMENTATION BY TOP 8 SEGMENTS



ALIRA HEALTH COMMENTS

- The **largest segment of the market in 2020** was **Interventional Cardiology** with a **total of $14.301B** in sales.
- **79% of the sales in the Cardiology Medical Devices Market were attributed to the 7 top-performing companies.**
  - **Abbott** was responsible **for 20% of sales** in **the Cardiology Medical Devices Market in 2020.**
- **Rhythm Management was the second largest segment** in terms of sales **in the Cardiology Medical Devices Market in 2020.**
  - **Medtronic was responsible for over 30% of the Rhythm Management segment** with a total **sales number** of **$3.925B in 2020.**

Source: LSI Global MD&D Data; GlobalData; Alira Health analysis.

Medtronic at a Glance

Competitive Landscape & Profiles

Medtronic

Medtronic is a global leader in the cardiology industry, offering technology-driven devices and solutions through collaborations and acquisitions, allowing them to use AI and Real-World Clinical Data to improve patient outcomes.

COMPANY SNAPSHOT

Headquarters:
Dublin, Ireland

Ownership:
Public

Revenue (2022):
$30.81B

Employees (2022):
~95,000

> **Medtronic is a global health technology company** that operates **in the medical device, care management services, patient engagement solutions, and data analytics industries.**

> Medtronic operates through 12 therapy areas: Airway & Lung, Brain, Mouth & Dental, Diabetes, Digestive and Gastrointestinal, ENT, **Heart & Vascular**, Pain, Spine & Orthopedic, Urinary, Weight Loss and Obesity, and Women's Health.

> Within Medtronic's Heart & Vascular therapy area, there are 15 subsections for patients and healthcare providers to utilize for information and care guidelines.

MEDTRONIC BUSINESS UNITS

Cardiovascular	**Structural heart, CRM**, vascular, mechanical & circulatory support
Diabetes	Therapies and services for Type I and Type II diabetics
Medical Surgical	Patient monitoring, surgical robotics, gastrointestinal, respiratory
Neuroscience	Neuromodulation, neurovascular, ENT, cranial & spinal tech

Business Unit containing relevant Cardiology Medical Devices

KEY MILESTONES RELEVANT TO INTERVENTIONAL CARDIOLOGY

Apr 2022 — **Medtronic and GE Healthcare** announce a collaboration focused on the expected increase in **outpatient cardiology and peripheral vascular procedures** in Ambulatory Surgery Centers (ASCs) and Office Based Labs (OBLs).

Apr 2022 — Medtronic acquired a **portfolio of cardiac-device products** from **Acutus Medica**l to enhance its offerings **in the field of cardiac care**.

Jan 2022 — **Medtronic acquired Affera** to expand its portfolio of surgical solutions and enhance its position as a leader in **minimally-invasive surgical technology**.

Sep 2021 — **Medtronic** and **Mpirik** announced a **collaboration** in a **pilot program** to **address disparities** in care of patients who are at-risk of experiencing **Sudden Cardiac Arrest** using **real-world clinical data/real-world evidence (RWE)** and **AI** to provide more **insightful and sophisticated care** than has been available.

May 2021 — **Medtronic revolutionized Open Heart surgery** by taking away the need to open a patient's chest with their **Harmony Transcatheter Pulmonary Valve**.

Aug 2014 — **Medtronic acquires Covidien**, incorporating Covidien's portfolio of surgical products, navigation systems and patient monitoring platforms. With the acquisition, Medtronic greatly expands its ability to **treat patients globally**.

ALIRA HEALTH COMMENTS

> Medtronic is a leader in the cardiology medical devices market though their strong technology-driven patient care devices and platforms, and more recently with collaborations that further strengthening their cardiac care portfolio using RWE[1] and AI technology[2].

AliraHealth

Notes: 1 Real-World Evidence; 2 Artificial Intelligence. Source: Medtronic website & product catalog; Medtronic press releases; Alira Health analysis.

MassMEDIC THE HEART OF HEALTHTECH

Abbott Laboratories at a Glance

Competitive Landscape & Profiles

Abbott Laboratories is a diversified healthcare company that offers a wide range of products and services in the cardiology industry, including cardiac rhythm management devices, diagnostic equipment, and catheter-based technologies.

COMPANY SNAPSHOT

Headquarters:
Chicago, IL

Ownership:
Public, The Vanguard Group, Inc owns the most shares

Revenue (2022):
$43.7B

Employees (2022):
~ 115,000

> **Abbott Laboratories** was founded in 1888 with the intention of producing more targeted and effective therapies. Since then, they have grown to serve people in over 160 countries with their **leading technologies**.

> Abbott is primarily focused in 6 business areas: **Cardiovascular**, Diabetes Care, Diagnostics, Neuromodulation, Nutrition, and Medicines.

ABBOT BUSINESS UNITS

Cardiovascular	**LVADs, remote heart failure monitoring, heart valve disease, CAD**
Diabetes Care	Therapies and services for Type I and Type II diabetics
Diagnostics	Molecular diagnostics, point of care and rapid diagnostics
Neuromodulation	Pain and movement disorders, spinal cord stimulation
Nutrition	Adult, pediatric, sports, and metabolic nutrition
Medicines	Gastroenterology, respiratory, vaccines, women's health, pain

Business Unit containing relevant Cardiology Medical Devices

KEY MILESTONES RELEVANT TO INTERVENTIONAL CARDIOLOGY

Jan 2023 — Abbott introduced their **newest generation TAVI system** called **Navitor**, bolstering their **Structural Heart Portfolio** and making it the **most comprehensive in the US.**

Aug 2022 — Study data from **Abbott's HeartMate3 LVAD** for use in **patients with advanced HF** showed **promising early results** for **furthering patient lives 5+ years.**

Oct 2021 — The **FDA approved two new Abbott devices**: a **minimally-invasive Left Atrial Appendage called Amulet** and **Portico, a minimally-invasive TAVR system**. These two devices contributed to Abbott's most comprehensive Structural Heart portfolio.

Apr 2019 — **Abbott presented promising data** on four of their active studies to the **American College of Cardiology** (ACC) at the 68th annual **Scientific Session** that pointed to an **expanding line of Medical Devices in Abbott's future** which would ultimately lead to **further improved patient care.**

Apr 2016 — **Abbott acquired St. Jude Medical,** drastically **expanding their cardiovascular offerings** and **strengthening their position** in the **cardiology medical devices market globally.**

ALIRA HEALTH COMMENTS

> **Abbott** was responsible for **12% of the overall Cardiology Medical Devices market sales** in 2020 and **20% of the entire Interventional Cardiology segment.** Abbott Laboratories has long been a **cardiology market leader** and their position in the market was strengthened with their **acquisition of St. Jude Medical in 2016.**

Source: Abbott Laboratories website & product catalog; Abbott Laboratories press releases; Alira Health analysis.

Boston Scientific at a Glance

Competitive Landscape & Profiles

Boston Scientific is focused on developing and manufacturing devices that treat cardiovascular and peripheral vascular diseases. With acquisitions, they have expanded their offerings, strengthened their position in the market, and reached more patients.

COMPANY SNAPSHOT

Headquarters:
Marlborough, MA

Ownership:
Public

Revenue (2022):
$12.7B

Employees (2022):
~45,000

> **Boston Scientific is a global healthcare company** with locations in 115 countries and over 17,000 products in the market. There is a **strong focus in the cardiology space.**

> Boston Scientific is primarily focused in 6 business areas: Endoscopy, **Interventional Cardiology**, Neuromodulation, **Peripheral Interventions, Rhythm Management**, and Urology and Pelvic Health.

BOSTON BUSINESS UNITS

Interventional Cardiology	**CAD**[1], **Structural Heart**, mechanical & circulatory support
Peripheral Interventions	**Peripheral Artery Disease**, **Pulmonary Embolism**, certain cancers
Rhythm Management	**Heart Rhythm Disorders**, **SCA**[2], **HF**, **Arrythmias**
Endoscopy	Digestion & nutrition, Pancreatitis, GI pathology & diseases, tumors
Neuromodulation	Deep Brain Stimulation, chronic pain, Dystonia, cranial & spinal tech
Urology and Pelvic Health	Kidney stones, prostate cancer, pelvic floor disorders

Business Unit containing relevant Cardiology Medical Devices

KEY MILESTONES RELEVANT TO INTERVENTIONAL CARDIOLOGY

Aug 2022 — **Boston Scientific acquired Obsidio**, allowing Boston Scientific to expand its offerings in the field of interventional venous care and provide a complete suite of solutions for treating venous conditions.

Feb 2022 — **Boston Scientific** closed their **acquisition of Baylis Medical Company**, **strengthening their position in the Electrophysiology market** and broadening their guidewire and transseptal access platform offering.

Jun 2020 — **Boston Scientific launched their DIRECTSENSE Technology** designed as a tool for **monitoring** the effect of **radiofrequency** during **cardiac ablation** procedures.

Jan 2016 — Using **Accenture's analytics insight platform**, **Boston Scientific and Accenture** introduced an **innovative digital health solution** called **ADVANTICS** that is both **cloud-based and data-driven**. It will offer healthcare providers **actionable insights** into **care coordination** and **patient population health patterns.**

Apr 2015 — **Boston Scientific** announced **two strategic collaborations** with **MedAxiom** and **TogetherMD** to **advance efforts in reducing cost of cardiovascular care delivery** and **improving outcomes** using a **value-based care** approach.

ALIRA HEALTH COMMENTS

> **Boston Scientific is a major player in the Cardiology Medical Devices market** and was **responsible for 11% of the overall sales** in 2020. Through many **strategic collaborations and acquisitions** over the years, they have expanded positioning in interventional cardiology, structural heart, and cardiac monitoring.

Note: 1 Coronary Artery Disease; 2 Sudden Cardiac Arrest. Source: Boston Scientific website & product catalog; Boston Scientific press releases; Alira Health analysis.

GE Healthcare at a Glance

Competitive Landscape & Profiles

GE Healthcare

GE Healthcare is a global leader in the Cariology Medical Devices Market and offers a wide range of medical imaging and diagnostic equipment, including products for cardiology such as MRI and CT scanners, ultrasound machines, and ECG machines.

COMPANY SNAPSHOT

Headquarters:
Chicago, IL

Ownership:
Public

Revenue (2022):
$18.3B

Employees (2022):
~51,000

- GE Healthcare is a **worldwide healthcare leader** in medical technologies, pharmaceutical diagnostics, and digital solutions innovation.
- GE Healthcare is a **global medical device provider** present in over 160 countries that **designs, develops, manufactures, and distributes health tech solutions and therapies** for 17 different specialties and settings.
- The company **spun off from General Electric Company** in January 2023 and **officially began trading as GE HealthCare independently** on January 4, 2023.

GE HEALTHCARE BUSINESS UNITS

- **Surgery**
- **MRI**
- **Detection and Guidance Solutions**
- **Life Care Solutions**
- **Ultrasound**
- **Molecular Imaging & Computed Tomography**
- **Healthcare IT**
- **Global Services**
- **Life Sciences**

Business Unit containing relevant Cardiology Medical Devices

KEY MILESTONES RELEVANT TO INTERVENTIONAL CARDIOLOGY

Feb 2023 — **GE Healthcare** announced they will **acquire Caption Health**, a **leader in AI healthcare** whose technology can help **detect signs of heart failure quicker** and allow patients to be treated earlier to **slow the progression** of the disease.

Jan 2023 — **Strengthening their interventional guidance offerings**, **GE HealthCare announced their plan to acquire IMACTUS**, a company that created CT-Navigation, assisting physicians with **needle guidance** and **enabling more precise care.**

Jan 2023 — **GE HealthCare completes spin-off from General Electric Company** and **begins trading independently** on Nasdaq.

July 2018 — **Aurora Health Care** and **GE** announced their **partnership** to **build a new hybrid Operating Room (OR)** that would allow the hospital to handle a doubled case load average per day, **address capacity issues**, and **increase both efficiency and productivity.**

Nov 2017 — **GE introduced Drawbridge Health**, a **collaboration** between **GE Global Research, GE Healthcare, and GE Ventures** to **aid providers in offering** an **improved patient experience** by eliminating the need for phlebotomy and **streamlining the process of receiving accurate and reliable results**.

ALIRA HEALTH COMMENTS

- **GE HealthCare,** since the completion of its spin-off from General Electric Company, has continued to **strengthen its position in the Cardiology Medical Devices Market** through the **acquisitions** of such companies as **IMACTUS and Caption Health.**

AliraHealth

Source: GE Healthcare website & product catalog; GE Healthcare press releases; *Los Angeles Times* Archives; Alira Health analysis.

MassMEDIC THE HEART OF HEALTHTECH

Philips Healthcare at a Glance

Competitive Landscape & Profiles

Philips is a multinational company focused on healthcare. They offer a wide range of medical equipment and patient therapies, including cardiology products such as diagnostic imaging, ultrasound machines, and patient monitoring devices.

COMPANY SNAPSHOT

Headquarters:
Amsterdam, Netherlands and Andover, MA

Ownership:
Public

Revenue (2022):
$18.8B

Employees (2022):
~77,200

- **Philips NV is a global company,** based in the Netherlands, that was formerly an industry leader in five different areas but **began divesting certain areas of its business in 2016 to focus on healthcare.**
- Philips Healthcare is focused on delivering technology for use across various clinical applications. The mission of these platforms is **to help clinicians manage seamless** and **efficient workflows, make informed decisions** about care delivery, **improve patient outcomes, and lower costs.**

PHILIPS BUSINESS UNITS

Cardiovascular care	**Cardiology Informatics, Image-Guided Therapy,** Emergency Care
Diagnostic Technologies	Digital Pathology, Genomics data platform
Imaging	Tomography, MRI, molecular imaging, radiography, ultrasound
Healthcare Informatics	Cardiology, critical care and anesthesia, perinatal, radiology
Monitoring	Patient-worn monitors, mobile monitoring, data integration

Business Unit containing relevant Cardiology Medical Devices

KEY MILESTONES RELEVANT TO INTERVENTIONAL CARDIOLOGY

Feb 2023 — **Philips announced a multi-year partnership with TriHealth Heart & Vascular Institute** allowing for Philip's technologies to educate TriHealth physicians **resulting in higher quality healthcare for patients**.

Mar 2021 — **Philips announced the sale of their Domestic Appliances business** to Hillhouse Capital as a move to **strengthen their focus and energy on the healthcare business.**

May 2019 — **Philips** announces **collaboration with Medtronic** to **further advance treatment of atrial fibrillation** by providing an **innovative, integrated image guidance solution** for cryoablation procedures.

Jan 2017 — Philips announced a **global collaboration with HeartFlow** aiming to improve access to tools that will aid in **determining extent of coronary artery disease.**

Aug 2017 — **Philips and Bon Secours Charity Health System (BSCHS)** announced a **long-term strategic partnership** to support **transformation of patient care** and build **healthier communities** in New York's Hudson Valley by making Philips solutions available to BSCHS.

Mar 2015 — **Philips** announced their decision to **split** the long-time industry leader and Dutch electronics company **into two companies**, with **one focusing on lighting** and the **other focused on healthcare and technology**.

ALIRA HEALTH COMMENTS

- Philips' recent deal activity has focused on **supporting public health initiatives relating to cardiovascular diseases** and partnerships or collaborations that leverage the **Company's technological capabilities** to further their reach in **improving patient outcomes**.

Source: Philips website & product catalog; Philips press releases; Alira Health analysis.

Edwards Lifesciences at a Glance

Competitive Landscape & Profiles

Edwards Lifesciences is a medical device company that specializes in developing and manufacturing devices such as heart valves, transcatheter aortic valves, and transcatheter mitral valves that treat structural heart diseases.

COMPANY SNAPSHOT

Headquarters:
Irvine, CA

Ownership:
Public

Revenue (2022):
$5.4B

Employees (2022):
~16,000

- Edwards Lifesciences is a multinational medical device company **focused on health technology for structural heart disease, critical care, and surgical monitoring.**
- Edwards is a leader in delivering technology for use in patient monitoring, **heart valve replacement, and cardiac surgery.**
- Their mission is to work with clinicians to **innovate products** that will allow for **successful treatment of patients with cardiac and hemodynamic conditions** allowing them to **live longer and more fruitful lives.**

EDWARDS BUSINESS UNITS

Critical Care	Hemodynamic monitoring systems and sensors
Surgical Structural Heart	**Tissue heart valves, surgical heart valve repair therapies**
Transcatheter Heart Valves	**Heart valve replacements** for minimally-invasive implants
Transcatheter Mitral & Tricuspid Therapies	**Transcatheter valves** to treat **mitral and tricuspid diseases**

Business Unit containing relevant Cardiology Medical Devices

KEY MILESTONES RELEVANT TO INTERVENTIONAL CARDIOLOGY

Sep 2022 — **Edwards Lifesciences** received **FDA approval** for their innovative **PASCAL Precision transcatheter valve repair system for transcatheter edge-to-edge repair (TEER)** in patients with degenerative mitral regurgitation **(DMR).**

Dec 2020 — In their **RESTORE clinical trial**, **Edwards treated the first degenerative mitral valve regurgitation patient in the US** with the **investigational HARPOON system**, while the **heart continued beating**, using only a small incision.

July 2020 — Edwards receives **FDA approval** for KONECT RESILIA Aortic Valved Conduit **for complex aortic valve surgeries**. This the first ever **ready-to-implant solution** for **bio-Bentall procedures** which involves the **replacement of a patient's aortic valve, root, and ascending aorta.**

Apr 2019 — **CAS Medical Systems was acquired by Edwards** for $98 Million. The companies had been working together on **CAS's non-invasive oxygenation** measurement device and Edward's hemodynamic monitoring system.

Mar 2019 — Edwards announced a **strategic investment plan** to acquire **Corvia Medical**, the company responsible for developing the world's **first transcatheter device designed to treat heart failure with preserved mid-range ejection fraction.**

Dec 2017 — **Edwards Lifesciences** announced their **acquisition of Harpoon Medical**, significantly **strengthening their structural valve portfolio.**

ALIRA HEALTH COMMENTS

- **A market leader in heart valve technology and development**, Edwards Lifesciences has strengthened their positioning through their own research and development and through acquisitions of companies such as Harpoon and Corvia, holding steady in their goal to **improve patient outcomes**.

Source: Edwards website & product catalog; Edwards press releases; Alira Health analysis.

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

   2.1 Clinical Approaches & Applications 22

   2.2 Clinical Unmet Needs 25

   2.3 Market Size & Growth Dynamics 27

   2.4 Competitive Landscape & Profiles 37

   2.5 Deals Flow Assessment 45

3. Cardiology Market Outlook 49

4. Key Takeaways 55

5. About Authors 61

2022 Deal Flow in the Cardiology Medical Devices Market

Deals Flow Assessment

The recent deals activity in the interventional cardiology industry highlight the ongoing investment of companies in this space, and the potential for added value through partnerships and M&A.

Timeline	Partner	Target	Deal Rationale	Deal Type
December 2022*	PAVmed	Novosound	PAVmed licensed Novosound's proprietary ultrasound tech to improve its medical devices & diagnostic capabilities for its customers.	Partnership
December 2022	Maxwell Biomedical	Cardialen	Maxwell Biomedical wanted to expand its portfolios to include Cardialen's cardiac arrhythmia and heart failure technology, which treats areas of significant unmet need.	Acquisition
November 2022	CompuGroup Medical	Medicus	CompuGroup Medical acquired Medicus Laboratory Information Systems to expand its presence in the laboratory market and provide a comprehensive cloud-based laboratory information system (LIS) solution to its customers.	Acquisition
November 2022*	TriSalus Life Sciences	LAVA Medtech Acquisition Corp.	TriSalus Life Sciences merged with MedTech Acquisition to combine respective expertise and resources to accelerate growth, improve operational efficiency, expand into new markets, and provide more comprehensive solutions.	Merger
November 2022	profusa	NorthView Acquisition Corp.	Profusa entered into a partnership agreement with NorthView Acquisition Corp to gain funding to develop and commercialize cutting-edge medical tissue monitoring products.	Merger
November 2022	Johnson & Johnson	Abiomed	Johnson & Johnson acquired Abiomed to expand its presence in the rapidly growing market for medical devices that support heart function.	Acquisition
November 2022	mmt Medical Manufacturing Technologies	Confluent	Medical Manufacturing Technologies (MMT) acquired an equipment line from Confluent Medical to enhance production capabilities and secure a long-term supply of a key component equipment of MMT's production process.	Asset Transaction
October 2022	sebia	ZEUS Scientific	Sebia acquired Zeus Scientific to augment their offering portfolio with Zeus Scientific's strong expertise in autoimmunity and infectious diseases.	Acquisition

*Announced but not yet closed

Note: Data includes US + EU5, only announced and completed deals. Seed, VC, debt financing, and equity raises were excluded. Only deals completed in 2022 or 2023 + announced but not yet closed were included. Ordered by announcement date.

Source: GlobalData; Publicly available press releases; Alira Health analysis.

2022 Deal Flow in the Cardiology Medical Devices Market

Deals Flow Assessment

The recent deals activity in the interventional cardiology industry highlight the ongoing investment of companies in this space, and the potential for added value through partnerships and M&A.

Timeline	Partner	Target	Deal Rationale	Deal Type
October 2022	microbot medical	Nitiloop CROSSING THE LIMITS	Microbot Medical, a medical device company, acquired FDA-cleared devices from Nitiloop to expand its product portfolio and increase its presence in the market for minimally-invasive medical devices.	Asset Transaction
September 2022	secant group	Nationwide Children's Hospital	Secant Group entered into an agreement with the Abigail Wexner Research Institute at Nationwide Children's Hospital to collaborate on research and development projects.	Partnership
September 2022	Ra Medical Systems	Catheter Precision	Ra Medical Systems merged with Catheter Precision to combine Ra Medical Systems' expertise in developing laser-based solutions for treating peripheral artery disease with Catheter Precision's experience in developing catheter-based solutions for the same condition.	Merger
August 2022	Boston Scientific	OBSIDIO	Boston Scientific acquired Obsidio, allowing Boston Scientific to expand its offerings in the field of interventional venous care and provide a complete suite of solutions for treating venous conditions.	Acquisition
July 2022	MICRO-TECH ENDOSCOPY	Thoracent	Micro-Tech Endoscopy entered into a distribution partnership with Thoracent, allowing Micro-Tech to distribute Thoracent's products and expand its presence in the market for medical devices and supplies.	Partnership
June 2022	Teleflex	Traverse Vascular	Teleflex acquired Traverse Vascular, a medical device company that develops and markets solutions for treating peripheral arterial disease, in order to expand its offerings in the field of interventional vascular care.	Acquisition
May 2022	Occlutech	B BRAUN SHARING EXPERTISE	Occlutech Holding entered into a distribution agreement with B. Braun Interventional Systems to expand its presence in the US market while B. Braun increases its portfolio focus in congenital and structural heart.	Partnership
May 2022	LivaNova	ALUNG	LivaNova acquired a 97% stake in ALung Technologies, allowing LivaNova to expand its offerings in the field of respiratory care and provide a complete suite of solutions for treating respiratory conditions.	Acquisition

Note: Data includes US + EU5, only announced and completed deals. Seed, VC, debt financing, and equity raises were excluded. Only deals completed in 2022 or 2023 + announced but not yet closed were included. Ordered by announcement date.

Source: GlobalData; Publicly available press releases; Alira Health analysis.

2022 Deal Flow in the Cardiology Medical Devices Market

Deals Flow Assessment

The recent deals activity in the interventional cardiology industry highlight the ongoing investment of companies in this space, and the potential for added value through partnerships and M&A.

Timeline	Partner	Target	Deal Rationale	Deal Type
April 2022	Medtronic	ACUTUS MEDICAL	Medtronic acquired a portfolio of cardiac-device products from Acutus Medical to enhance its offerings in the field of cardiac care.	Asset Transaction
April 2022	Undisclosed	Nido Surgical	NIDO Surgical has sold its SEPIA device to an undisclosed acquirer who will hasten the product development and subsequent distribution.	Asset Transaction
April 2022	CASTLE BIOSCIENCES	ALTHEADx	Castle Biosciences acquired AltheaDx, a genomics-based diagnostic company that develops and markets diagnostic tests for cancer, in order to expand its offerings in the field of cancer diagnostics.	Acquisition
March 2022	DSM	svelte medical systems	DSM and Svelte Medical entered into a licensing agreement granting Svelte the right to use DSM's proprietary bioerodible amino acid-based drug carrier in the design of a non-thrombogenic, non-inflammatory drug-eluting stent.	Partnership
February 2022*	CSI CARDIOVASCULAR SYSTEMS, INC.	INNOVA VASCULAR INNOVATORS IN VASCULAR TECHNOLOGIES	Cardiovascular Systems, Inc. entered into a partnership with Innova Vascular to expand its market reach and provide patients with a wider range of treatment options for peripheral artery disease (PAD).	Partnership
January 2022	BioVentrix	MateraCor	BioVentrix acquired MateraCor to expand its product portfolio and offer a more comprehensive range of solutions for patients with HF.	Acquisition
January 2022	Medtronic	AFFERA	Medtronic acquired Affera to expand its portfolio of surgical solutions and enhance its position as a leader in minimally invasive surgical technology.	Acquisition
January 2022	VITALPATH	MODERN CATHETER TECHNOLOGIES	VitalPath acquired Modern Catheter Technologies to expand its portfolio of medical devices, specifically to include innovative catheter-based solutions for the treatment of a variety of medical conditions.	Acquisition

*Announced but not yet closed

Note: Data includes US + EU5, only announced and completed deals. Seed, VC, debt financing, and equity raises were excluded. Only deals completed in 2022 or 2023 + announced but not yet closed were included. Ordered by announcement date.

Source: GlobalData; Publicly available press releases; Alira Health analysis.

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21
   - 2.1 Clinical Approaches & Applications 22
   - 2.2 Clinical Unmet Needs 25
   - 2.3 Market Size & Growth Dynamics 27
   - 2.4 Competitive Landscape & Profiles 37
   - 2.5 Deals Flow Assessment 45

3. Cardiology Market Outlook 49

4. Key Takeaways 55

5. About Authors 61

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

3. Cardiology Market Outlook 49

   3.1 Market Player Pipeline Assessment 50

   3.2 Emerging Macro Market Trends 53

4. Key Takeaways 55

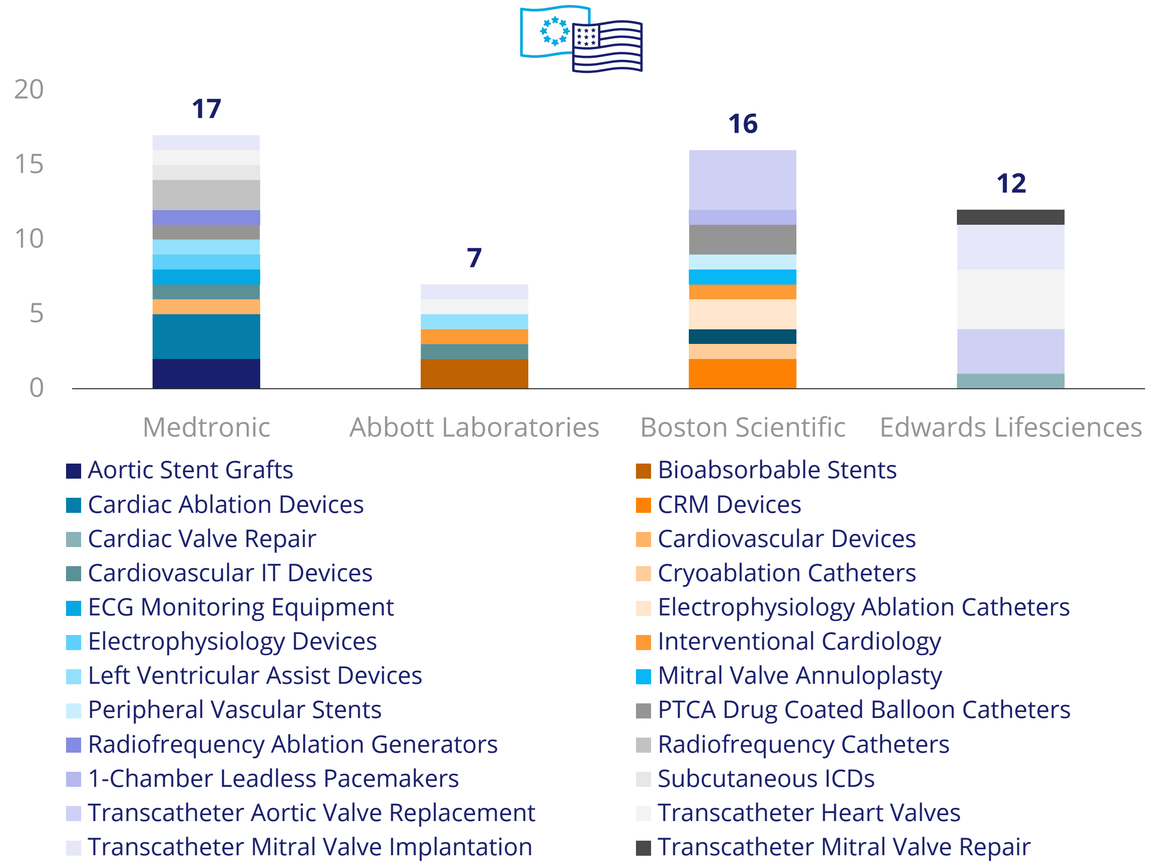
5. About Authors 61

Cardiology Medical Devices Pipeline Analysis

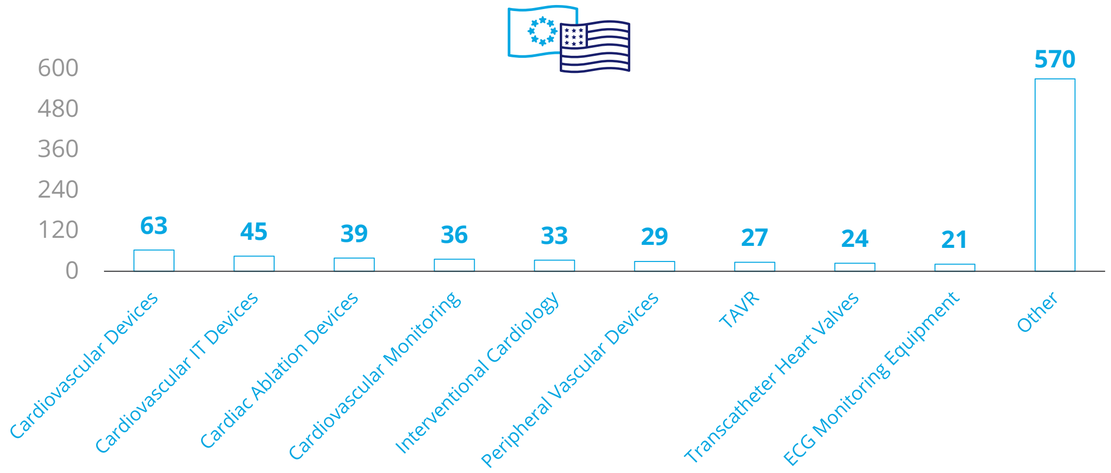
Market Player Pipeline Assessment

Medtronic, Boston Scientific, and Edwards are among the largest contributors to cardiology device development in the pipeline. 4 of the top 6 companies currently have 52 solutions in development, with a strong focus on valve repair, stents & grafts, and IT.

PIPELINE CARDIOLOGY DEVICE SOLUTIONS BY MARKET LEADERS



PIPELINE CARDIOLOGY SOLUTIONS BY DEVICE TYPE*



ALIRA HEALTH COMMENTS

- **Market leaders currently own 52 cardiology medical device solutions in the pipeline,** with Medtronic and Boston Scientific owning the most diversified pipelines across segments.
- Among the **leading pipeline cardiology segments were cardiovascular devices and IT, cardiac ablation devices, interventional devices, peripheral vascular, and TAVR1.**
- **570 additional devices are under development across the remaining segments** of the cardiology medical devices market.

Notes: *Other includes Left Ventricular Assist Devices, ECG Monitoring Equipment, PTA Peripheral DCB Catheters, Cardiac Valve Repair Devices, Electrophysiology Devices, Cardiac Catheters, Cardiovascular Surgery Devices, Thrombectomy Systems (Catheters), Transcatheter Mitral Valve Implantation (TMVI), Bioabsorbable Stents (BAS), PTCA Drug-Coated Balloon (DCB) Catheters, Vascular Grafts, Transcatheter Mitral Valve Repair (TMVR), and others. Sources: GlobalData; Alira Health Analysis.

Cardiology Medical Devices Pipeline & Technological Trends

Market Player Pipeline Assessment

The innovation level in cardiology devices is high, including promising trends of innovation in both the manufacturing of devices and the product pipeline. The pipeline is dominated by US-based programs with the largest targeted focus in Interventional Cardiology.

CARDIOLOGY DEVICES PIPELINE OVERVIEW

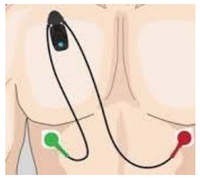
PIPELINE SUMMARY (AS OF MAR 2023)

Total US and EU Pipeline Programs	**926**	
Pipeline Programs Regional Breakdown		**887** (96%)
		16 (1.5%)
		23 (2.5%)

TOP PLAYERS & DEVICE SEGMENTS

Top Companies with Pipeline Devices in the US	OrbusNeich	**18** (2%)
	Medtronic	**17** (1.8%)
	Boston Scientific	**16** (1.7%)
	CSI Cardiovascular Systems, Inc.	**15** (1.6%)
	Edwards Lifesciences	**12** (1.4%)
Top Device Segments	Interventional Cardio	**158** (17%)
	Peripheral Vascular	**104** (11%)
	Cardiac Assist	**81** (9%)
	Cardio Monitoring	**78** (8%)
	Transcatheter Heart Valves	**78** (8%)

PIPELINE SUMMARY (AS OF MAR 2023)



- **Cardiac Ablation Device Innovation –** Ablation is a treatment option for patients with cardiac arrhythmias of many varieties that involves the use of a catheter to create lesions and destroy heart tissue that creates abnormal rhythms. Innovative catheters and components (e.g., Abbott's TactiFlex™ Ablation Catheter, Sensor Enabled™ which earned both FDA approval and the CE mark in February 2023) are addressing the growing demand for minimally-invasive ablation procedures.
- **Wearable Devices –** Wearable devices like smartwatches and trackers collect long-term health data and can provide a more comprehensive view of a patient's health. They have potential clinical applications in arrhythmia screening and remote management of chronic conditions.
- **AI / Machine Learning –** AI is a computer science field that studies the problem of building agents which take the best possible course of action in a specific situation. AI is being used in cardiology to analyze large amounts of data and identify patterns that can help predict and prevent heart disease. AI can also help healthcare professionals make more accurate diagnoses, treatment decisions, and predictions of outcomes for heart failure patients.

MANUFACTURING INNOVATIONS & TRENDS

- **Minimally-Invasive procedures –** Minimally-invasive surgical (MIS) procedures, especially in the cardiovascular discipline, have continued to gain favor over the years due to myriad benefits like minimal damage to the body, less pain, and lower risk of complications as compared to open surgeries.
- **Miniaturization –** With the increased MIS procedure demand comes need for miniaturized tools. MIS procedures are enabled by the miniaturization of devices such as catheters and guidewires that increase accuracy, speed, and precision.
- **Increasing complexity and customizability –** Tailor-made complex devices allow for higher efficiency and fewer devices in surgery. In Cardiology, this is particularly relevant for catheters and delivery devices designed for procedures like PTA1 and IVUS2.
- **Precision Medicine -** Precision medicine can transform cardiovascular disease treatment by customizing care based on a patient's unique profile. It considers genetics, lifestyle, and exposures for individualized prevention and treatment and uses advanced molecular interaction networks for deep phenotyping and personalized pharmacotherapy.
- **Polymer-Free Drug-Eluting Stents -** Polymer-free drug-eluting stents (PF-DES) have emerged as a promising alternative to traditional polymer-coated stents due to their reduced risk of inflammation and thrombosis. They utilize innovative coatings that avoid the potential long-term side effects of polymer coatings.

Notes: [1]Percutaneous Transluminal Angioplasty; [2]Intravascular Ultrasound. Source: Abbott Press Releases; American College of Cardiology; American Heart Association; Boston Scientific Press Releases; European Society of Cardiology; Frontiers; GlobalData; Journal of Cardiovascular Translational Research; Journal of Clinical Medicine; Journal of Invasive Cardiology; MedTech Intelligence; National Library of Medicine (National Center for Biotechnology Information); Alira Health analysis.

Table of Contents

1. Cardiology Market Foundations 7

2. Cardiology Clinical & Market Landscape Today 23

3. Cardiology Market Outlook 49

   3.1 Market Player Pipeline Assessment 50

   3.2 Emerging Macro Market Trends 53

4. Key Takeaways 55

5. About Authors 61

Key Trends Impacting Cardiology Medical Devices

Emerging Macro Market Trends

Trends towards technological advancement, miniaturized and implantable devices, increased home care, and minimally- or non-invasive procedures will help cardiology patients receive safer, more effective, and more convenient care.

GROWING CARDIOLOGIST SHORTAGE

- In 2021, the **Cardiometabolic Heath Congress published a projection that there could be a shortage of 29,000 cardiologists by the year 2025.**
- The rapidly rising age of physicians, with **nearly 60% of Cardiologists aged 55 or older,** contributes to this shortage as well.

High

MINIATURIZATION OF DEVICES

- **Cardiac interventional devices are increasingly miniaturized to improve device use, access, & patient outcomes.**
- **Pacemakers, ICDs, catheters, and stents** have all seen significant innovation in miniaturization, making it easier for providers to use or place them, and increasing the patient outcomes associated with these devices.

High

SHIFT OF CARDIAC PROCEDURES TO ASC

- Cardiology procedures are shifting toward more efficient ambulatory surgery centers (ASCs) that, according to a report by Health Affairs, **ASCs can be up to 57% less expensive than hospital outpatient departments for certain procedures.**
- Advances in technology & anesthesia have made it possible to perform more complex procedures in ASCs, including **angioplasty, stenting, and implantable cardioverter-defibrillator (ICD) placement**

High

FOCUS ON NON-INVASIVE PROCEDURES

- There is **growing preference for minimally-invasive procedures, such as catheter-based interventions, over traditional open surgery methods.** This is driving growth of the interventional devices segment.
- Non-invasive procedures **offer patients a lower risk of infection, faster recovery times, and lower pain/discomfort.**

High

Magnitude of Impact: Low  High

Source: Grand View Research; Insight Partners; Centers for Medicare & Medicaid Services (CMS); Primary interviews; Alira Health analysis.

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

3. Cardiology Market Outlook 49

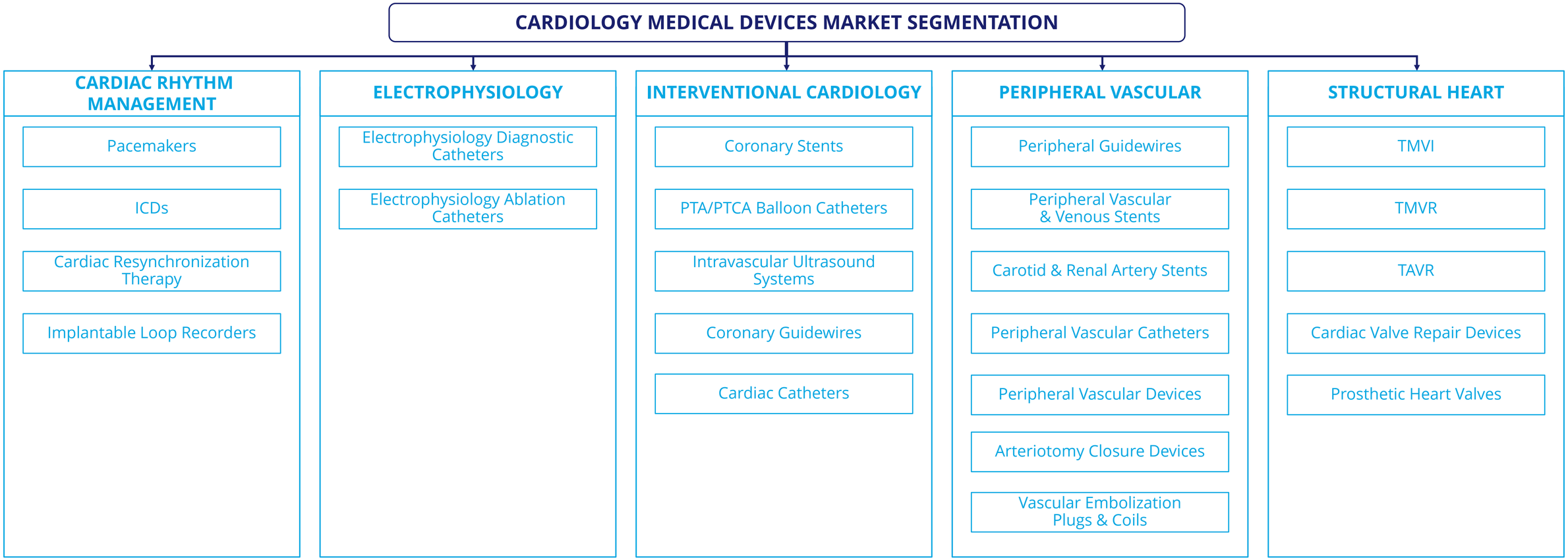
4. Key Takeaways 55

5. About Authors 61

Cardiology Medical Devices Market Segmentation

Key Takeaways

The Cardiology Medical Devices Market includes the solutions used to manage diseases of the cardiovascular system. The market is comprised of CRM, electrophysiology, interventional cardiology, peripheral vascular, and structural heart solutions.

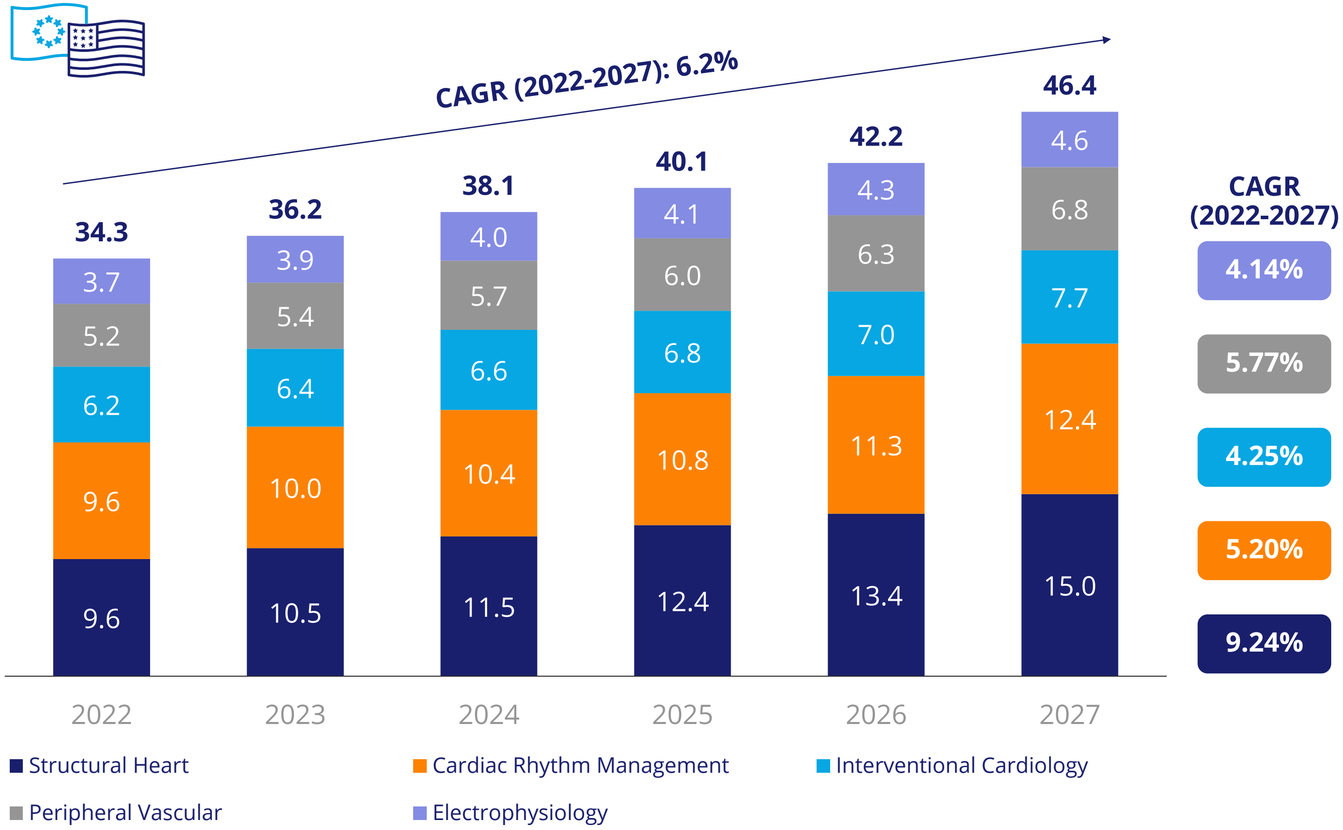


Market Size & Growth

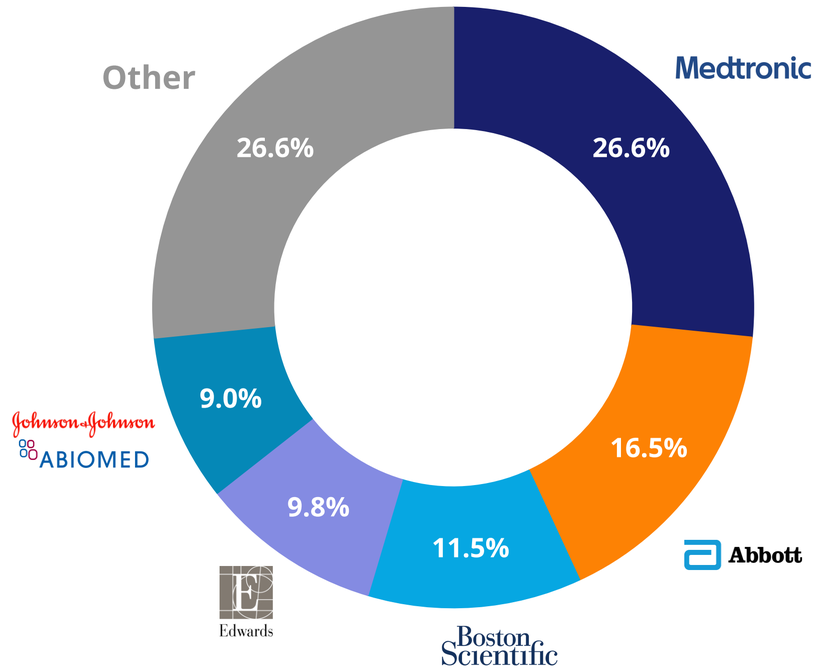
Key Takeaways

The US & EU Cardiology Medical Devices Market was worth $34.3B in 2022, forecasted to grow at an 6.2% CAGR '22-'27 to reach $46.4B in 2027. Structural Heart was the largest segment at $9.6B in 2022 and is also expected to be the fastest growing segment.

CARDIOLOGY MEDICAL DEVICES MARKET SIZE, US & EU, 2022 - 2027 ($B)



CARDIOLOGY MEDICAL DEVICES MARKET LEADERS (%)



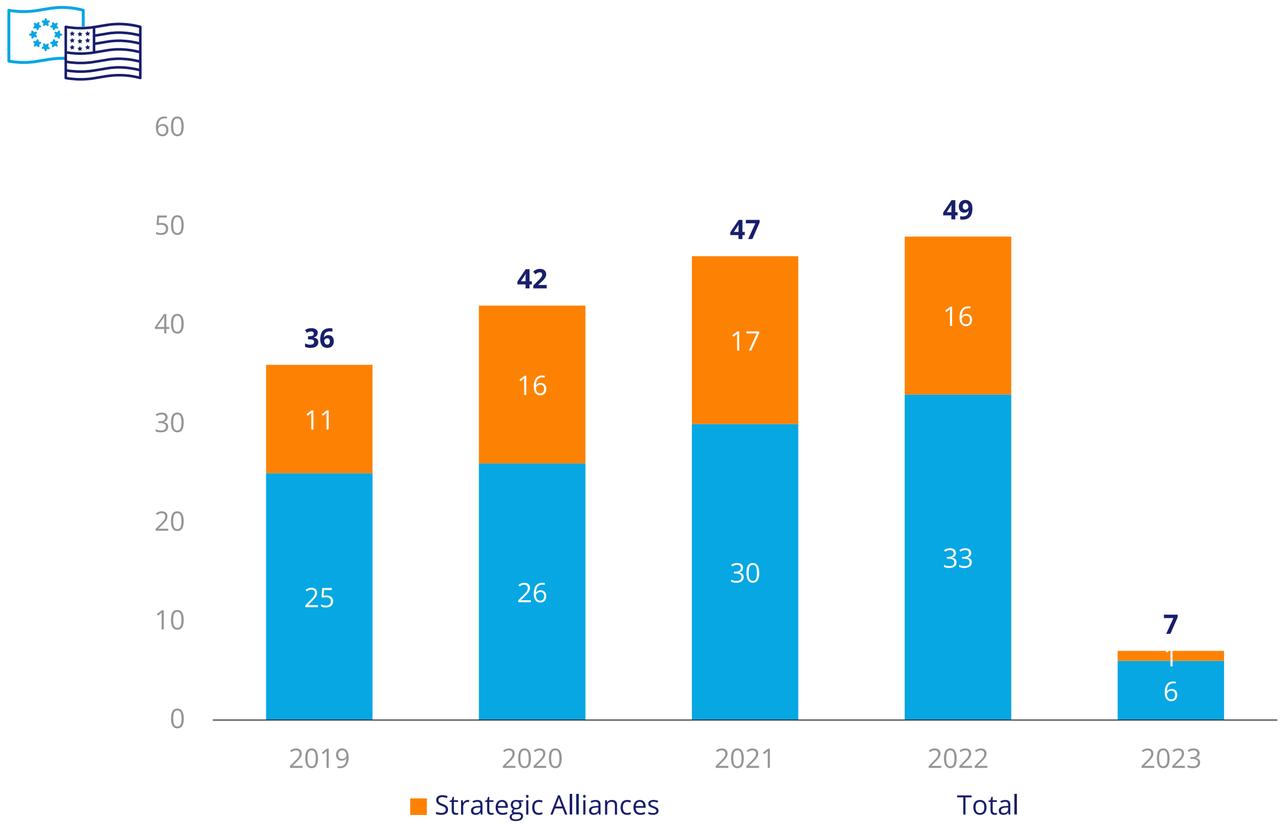
Source: GlobalData; Alira Health analysis.

Deal Flow & Pipeline

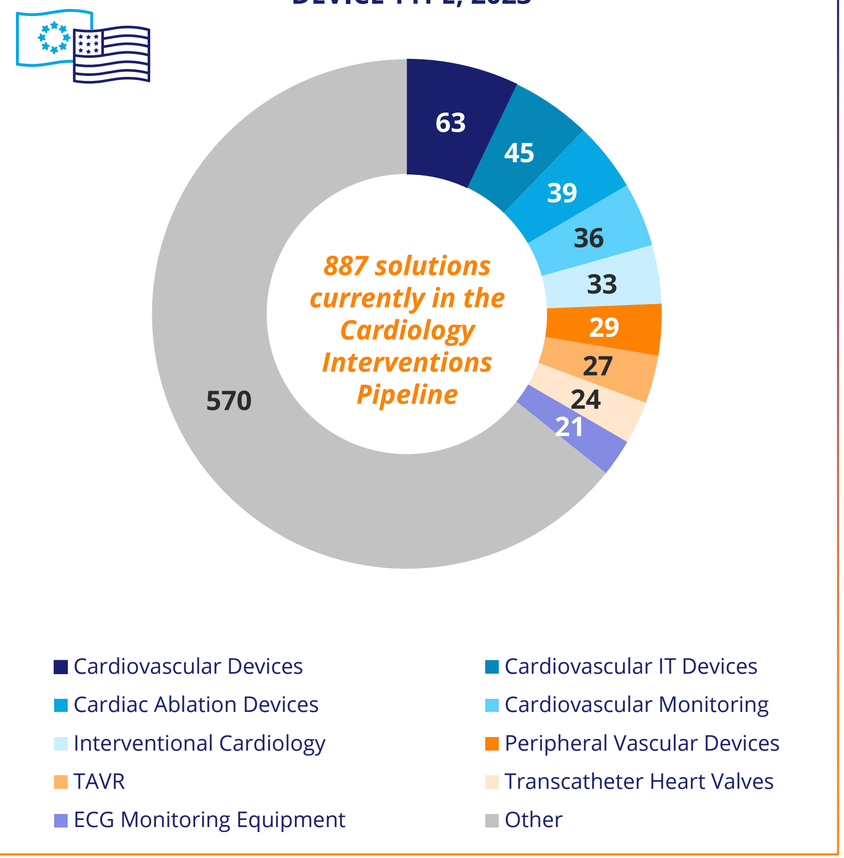
Key Takeaways

The Cardiology Medical Devices Market has experienced consistent deal flow since 2019, both from M&A and strategic alliances. The pipeline is highly fragmented across market subsegments, with TAVR, cardio IT, and heart valves being segments of high innovation.

CARDIOLOGY MEDICAL DEVICES DEAL FLOW, 2019 – 2023 (#)



CARDIOLOGY MEDICAL DEVICES PIPELINE BY DEVICE TYPE, 2023



Source: GlobalData; Alira Health analysis.

Key Trends Impacting Cardiology Medical Devices

Key Takeaways

Trends towards technological advancement, miniaturized and implantable devices, increased home care, and minimally- or non-invasive procedures will help cardiology patients receive safer, more effective, and more convenient care.

GROWING CARDIOLOGIST SHORTAGE

- In 2021, the **Cardiometabolic Heath Congress published a projection that there could be a shortage of 29,000 cardiologists by the year 2025.**
- The rapidly rising age of physicians, with **nearly 60% of Cardiologists aged 55 or older,** contributes to this shortage as well.

High

MINIATURIZATION OF DEVICES

- **Cardiac interventional devices are increasingly miniaturized to improve device use, access, & patient outcomes.**
- **Pacemakers, ICDs, catheters, and stents** have all seen significant innovation in miniaturization, making it easier for providers to use or place them, and increasing the patient outcomes associated with these devices.

High

SHIFT OF CARDIAC PROCEDURES TO ASC

- Cardiology procedures are shifting toward more efficient ambulatory surgery centers (ASCs) that, according to a report by Health Affairs, **ASCs can be up to 57% less expensive than hospital outpatient departments for certain procedures.**
- Advances in technology & anesthesia have made it possible to perform more complex procedures in ASCs, including **angioplasty, stenting, and implantable cardioverter-defibrillator (ICD) placement**

High

FOCUS ON NON-INVASIVE PROCEDURES

- There is **growing preference for minimally-invasive procedures, such as catheter-based interventions, over traditional open surgery methods.** This is driving growth of the interventional devices segment.
- Non-invasive procedures **offer patients a lower risk of infection, faster recovery times, and lower pain/discomfort.**

High

Magnitude of Impact: Low  High

Source: Grand View Research; Insight Partners; Centers for Medicare & Medicaid Services (CMS); Primary interviews; Alira Health analysis.

Conclusion

The Cardiology Medical Devices Market is comprised of devices that support heart function, repair heart structure, treat cardiological diseases, or maintain cardiac rhythm. The market can be divided into 5 segments by application: cardiac rhythm management, peripheral vascular, interventional cardiology, electrophysiology, and structural heart**. Devices across these segments are critical to completing cardiological surgeries**, either by helping surgeons access the cardiovascular system, implanting within the body to support heart function, or monitoring the function of the heart.

Cardiology medical devices are used to diagnose, treat, and manage a wide range of clinical diagnoses. However, in general, **the patient population experiencing heart disease is expected to experience strong growth (3.86% CAGR '20 – '27)** relative to other adjacent patient populations **due to the aging US and EU population, and the increasing obese and overweight population in both regions.** Each of these comorbidities (i.e., age and BMI) are associated with an increased risk of heart disease and are expected to continue driven incidence growth through the decade.

The US & EU Cardiology Medical Devices Market was worth $34.3B in 2022, forecasted to grow at a 6.21% CAGR '22-'27 to reach $46.4B in 2027F. Structural Heart was the largest segment at $9.6B in 2022 and is also expected to be the fastest-growing segment. The US cardiology medical devices market was valued at $20.17B in 2022, projected to reach $27.47B in 2027 with a forecasted CAGR '22-'27 of 6.38%. Likewise, The market in the EU was valued at $14.15B in 2022 and is projected to reach $18.91B in 2027 with a forecasted CAGR '22-'27 of 5.97%.

The US & EU Cardiology Medical Devices Market is led by many of the largest medical device companies in the world, given the significant size of the market and breadth of medical devices within it. The 8 companies with the greatest share in the Cardiology Medical Devices Market collectively had more than 30% share in each segment of the market. **43% of the overall market was owned by Medtronic (20%), Abbott (12%) and Boston Scientific (11%) in 2020.**

Future innovation in the market is expected to be driven by technological advancements, miniaturization of devices and the associated shift toward minimally/non-invasive surgery, and the adoption of AI and machine learning technologies. Areas of significant investment in the pipeline include heart valve repair devices such as transcatheter aortic valve repair, cardiac ablation devices, and cardiovascular monitoring devices.

Table of Contents

1. Cardiology Market Foundations 5

2. Cardiology Clinical & Market Landscape Today 21

3. Cardiology Market Outlook 49

4. Key Takeaways 55

5. About Authors 61

At Alira Health, **our mission is to humanize healthcare**

We complement your expertise with a full spectrum of patient-centric data and tech-enabled services to uncover opportunity, accelerate innovation, and improve outcomes for patients around the world.

- PRODUCT DEVELOPMENT
- REGULATORY
- CLINICAL
- BIOMETRICS
- MARKET ACCESS
- MANAGEMENT CONSULTING
- TRANSACTION ADVISORY
- PATIENT ENGAGEMENT
- REAL-WORLD EVIDENCE

Research and Clinical Development Solutions

PRODUCT DEVELOPMENT

IP Development (Structured IP™)

Alira Health Ventures: Incubation of Breakthrough Technologies

In-VITRO and In-VIVO Testing

CMC Manufacturing Strategy and Operations

CMC Process Development and Optimization

CMC Outsourcing Support

CMC GMP Facility Design

CMC Project Integration

CMC Technical & GMP Training

REGULATORY

Strategy and Roadmap Development

Submission Management

Regulatory Framework Navigation

Health Authority Interactions

FDA and EMA Liaison Officer for Foreign Companies

Lifecycle Maintenance Support

CMC Quality and Regulatory Affairs

CLINICAL

Study Design and Protocol Writing

Site Selection and Feasibility

Investigator Training

Subject Recruitment & Retention

Trial Management and Clinical Operations

Pharmacovigilance

BIOMETRICS

Data Management

Biostatistics and Statistical Programming

Statistical Consulting

CDISC Conversion

ISS/ISE Reporting

Medical Writing

Biometrics Optimization Solution (B.O.S)

Centralized Biometrics

AliraHealth

Technology Powered Consulting and Real-World Evidence Solutions

MANAGEMENT CONSULTING

Market Opportunity Assessment

Portfolio Management

Commercial / Vendor Due Diligence

Commercial Excellence

Corporate Strategy Planning

Commercial Strategy and Go-to-Market Model Development

Integrated Launch Planning

Healthcare Optimization

MARKET ACCESS

Global Market Access, Pricing and Reimbursement Strategy

Evidence Generation Strategy and Plan

Indication Prioritization

Value Communication

Mock Negotiations and Payer Consultations

Health Economics and Outcomes Research Strategy

Value Based Healthcare Pilots

Market Access Diagnostic MAP™

Accelerated Coverage Pathways for Innovation

PATIENT ENGAGEMENT

Patient Centricity Strategy

Patient Advisory Board

Patient Knowledge Center

Patient Mobilization Program

Patient Support Program

TRANSACTION ADVISORY

M&A Sell-Side

M&A Buy-Side

Business Development and Licensing

Carve-Out

REAL-WORLD EVIDENCE

Data Strategy

Real-World Studies

Real-Time Data

AliraHealth

In Collaboration With MedTech Community Partner

MassMEDIC
THE HEART OF HEALTHTECH

Founded in 1996, the Massachusetts Medical Device Industry Council (MassMEDIC) is the largest regional medtech association in the United States, with over 300 members representing manufacturers, product developers, suppliers, research institutions and academic health centers.

For more than a quarter of a century, MassMEDIC has been the voice of the groundbreaking medical technology industry in New England, advocating for sound public policy that supports innovation and fostering a community built on a shared purpose.

MassMEDIC members are part of a community of innovators that believe in collaboration and collective success. Our network and resources help you navigate today's evolving healthcare ecosystem and strengthen your goals through connection, education, awareness, and advocacy.

Learn more at www.massmedic.com

info@massmedic.com

AliraHealth

Contact Us

LET'S KEEP IN TOUCH

www.alirahealth.com

info@alirahealth.com

NORTH AMERICAN OFFICES

Toronto | Canada
Boston | US
San Francisco | US

EUROPEAN OFFICES

Vienna | Austria
Paris, Bordeaux | France
Munich | Germany
Bologna, Milan, Verona | Italy
Zevenbergen | Netherlands
Barcelona | Spain
Basel | Switzerland
London | UK

ASIAN PACIFIC OFFICES

Sydney | Australia
Singapore