Pioneering Innovations in Cardiology

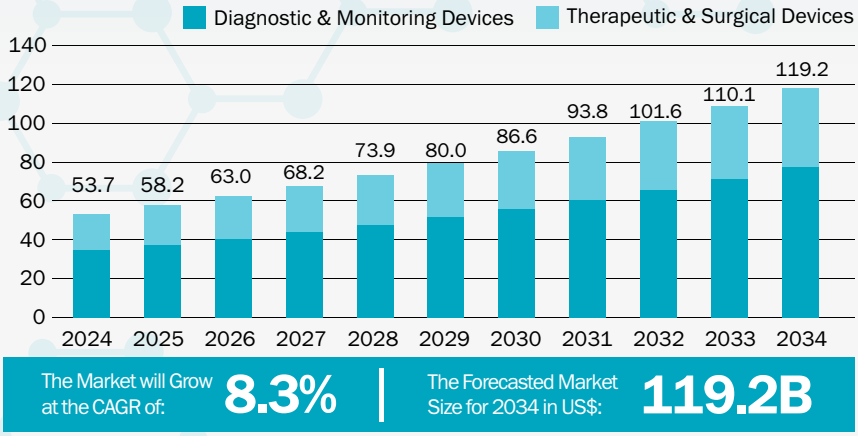
TRENDS, TECHNOLOGIES AND STRATEGIES SHAPING THE FUTURE OF CARDIOVASCULAR CARE

WHITEPAPER

Introduction

The cardiology sector is undergoing a period of profound transformation, driven by rapid technological advancements and evolving patient needs. Medical devices are highly innovative, playing a critical role in diagnosing, monitoring and treating cardiovascular diseases. From wearable ECG monitors to advanced pulsed field ablation (PFA) catheter technologies, these devices have revolutionized patient care, enabling earlier detection and more precise interventions. The global cardiovascular device market size was valued at USD 53.67 billion in 2024 and is anticipated to grow at a CAGR of 8.4 percent from 2025 to 2030[1].

Cardiovascular Market
Size by Product Type, 2024-2034(US$ Billion)



This whitepaper provides an in-depth overview of the dynamic shifts within cardiology, spotlights the latest trends, breakthroughs in technology and the outlook for cardiology devices and therapies. It explores the challenges and opportunities facing medical original equipment manufacturers (OEMs) and discusses the critical role that contract design and manufacturing (CDM) partners play in navigating this complex landscape. This paper aims to provide a clear roadmap for developing and delivering the pioneering innovations that will define the next era of cardiovascular treatment.

Reasons for Growth in the Cardiology Medical Device Market

- Human behavioral factors such as insufficient physical activity, high sodium intake, excessive alcohol consumption and tobacco use
- Metabolic factors such as high blood pressure, high-fasting plasma glucose, high body-mass index, high levels of low-density lipoprotein (LDL), cholesterol and diabetes
- Environmental factors such as ambient air pollution
- Genetic inherited mutations in genes that regulate cholesterol and lipid metabolism

Industry Challenges

While the market is growing, medical device original equipment manufacturers (OEMs) face three pressing challenges:

Regulatory Complexity
The cardiology sector demands devices that meet high standards of safety, accuracy and reliability as patient lives often depend directly on their performance. This means OEMs must invest significant time and resources into rigorous testing, clinical trials and approvals from regulatory bodies. As regulations evolve, staying compliant while maintaining a competitive edge remains a persistent challenge.

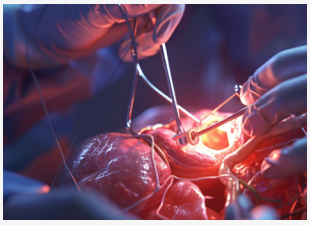
Technological Pace
Rapid technological advancement, with innovations such as AI-enhanced diagnostics, miniaturized devices and telehealth integrations, means OEMs must continuously adapt to stay relevant. The increased complexity of medical devices with added features and functions while maintaining small sizes is driving innovative manufacturing solutions. Balancing cutting-edge features with cost-effectiveness, usability and durability is a delicate task, especially when speed-to-market is critical.

Supply Chain Resilience
The production of cardiology devices often relies on specialized components, some of which may be subject to global shortages or geopolitical risks. OEMs must establish resilient supply chains while ensuring quality and consistency in manufacturing.

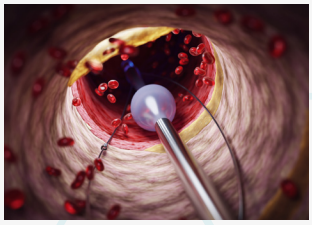
Technological Advancements in Cardiology

Over the past 25 years, treatment of heart and vascular diseases has evolved significantly in four key areas: revascularization for coronary artery disease, aortic valve replacement, repair of aortic aneurysms and electrophysiology and pacing. These once invasive treatments are improving patient outcomes thanks to transcatheter-based procedures that often utilize bioresorbable and drug-eluting therapies.

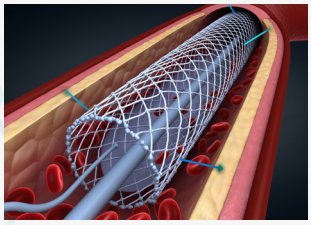
Evolution of Treatments of Coronary Artery Disease



Open Heart Surgery CABG — 1960s

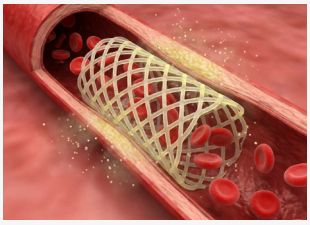


Balloon Angioplasty — 1970s



Bare Stents — 1990s

Drug-Eluting Stents — 2002



Bioresorbable Drug-Eluting Scaffolds — 2013 and beyond

Catheter-based Innovations

Catheter-based innovations consistently rely on shared principles in design architecture, material selection, construction techniques and manufacturing processes - regardless of the therapeutic modality they support.

Electrophysiology (EP) Ablation

EP catheter ablation is rapidly becoming a gold standard in precision treatment for arrhythmias. Innovations like pulsed field ablation (PFA) offer safer and more effective alternatives to traditional thermal ablation techniques. Real-time lesion assessment, another game-changing development, allows clinicians to monitor treatment efficacy during procedures for better outcomes. Sophisticated mapping systems and advanced ablation devices make arrhythmia treatment more efficient and accessible. As these technologies evolve, they are expected to reduce patient recovery times, lower complication rates and improve overall quality of care.

Transcatheter Aortic Valve Replacement (TAVR)

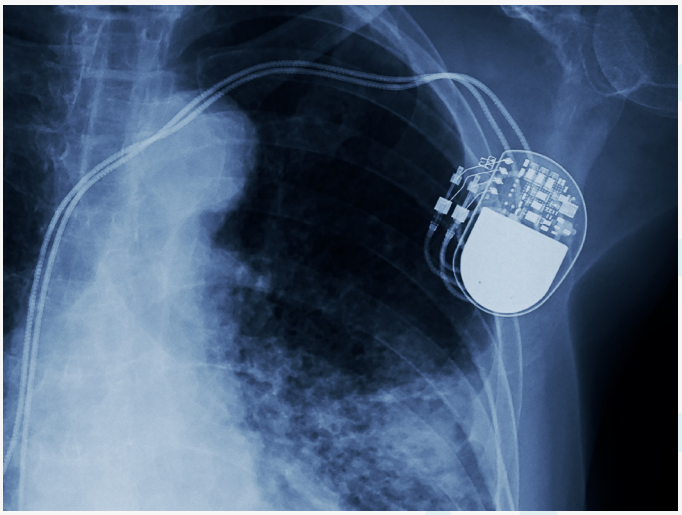
TAVR has revolutionized valve replacement, offering a minimally invasive solution for patients with aortic stenosis who might otherwise face significant risks with open-heart surgery. Innovations like cerebral embolic protection devices are reducing the risk of stroke during procedures, further enhancing patient outcomes. Additionally, advancements in valve durability and delivery systems are expanding the procedure's applicability to younger and lower-risk patients.

Vascular Grafts

Vascular grafts have seen significant advancements, particularly in minimally invasive aneurysm repair techniques. One medical device OEM in this area has a stent graft system known for its ease of deployment and flexibility, allowing for tailored solutions in treating abdominal aortic aneurysms. Another has a stent graft system designed to address thoracic aneurysms with

precision and reliability, offering enhanced conformability and durability. These innovations enable surgeons to perform complex procedures with greater accuracy while minimizing patient recovery times and complication risks.

Together, these advancements in EP ablation, TAVR, TMVR and vascular grafts are transforming the landscape of cardiovascular care, improving patient outcomes and setting the stage for the next generation of medical technologies.



Technical Considerations for Catheter-based Devices

The successful development of catheter-based cardiology devices relies on precise engineering as they are typically deployed intravenously. These devices must be extremely small, atraumatic to avoid vascular damage and highly reliable for safe and effective outcomes.

Functional Requirements:

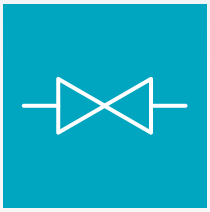
- **Low crossing force:** Ensures minimal resistance during device passage to reduce trauma and workflow disruption
- **Durable hemostasis:** Maintains vascular integrity under high pressure and during complex procedures
- **Multi-diameter compatibility:** Supports a range of catheter sizes from small diagnostic wires at 12 French gauge (Fr) to large therapeutic devices at 26 Fr

Design Inputs:

- Material selection
- Geometry transitions (rigid/flexible)
- Smooth articulation
- Durometer selection
- Insertion forces and angles
- Leak rates and size constraints
- ID/OD size requirements of catheter system

Features to Address Hemostasis:

To replicate or support the body's natural process to control bleeding during procedures like cardiac catheterization, angiography and stent placement, devices exhibit the following features:



Geometry

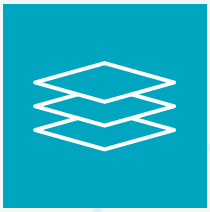
Single valve or seal stack assembly including the design intent to address valve prolapse concerns.

Slit design

X-slit, Y-slit, cross-slit and other custom geometries allow controlled opening while maintaining a seal.

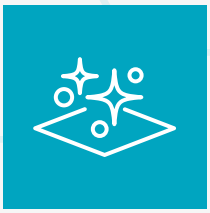
Tapered/conical profiles

Aid in guiding devices and reducing insertion force and fluid backflow through the device.



Multi-layer seals

Dual or triple-layer membranes provide mechanical integrity in complex assemblies and enhances design optimization and minimizes envelope size.



Coatings/surface modifications

Enable a valve seal to recover its original shape and sealing integrity after being deformed and aid in uninterrupted device articulation throughout the workflow of a procedure.

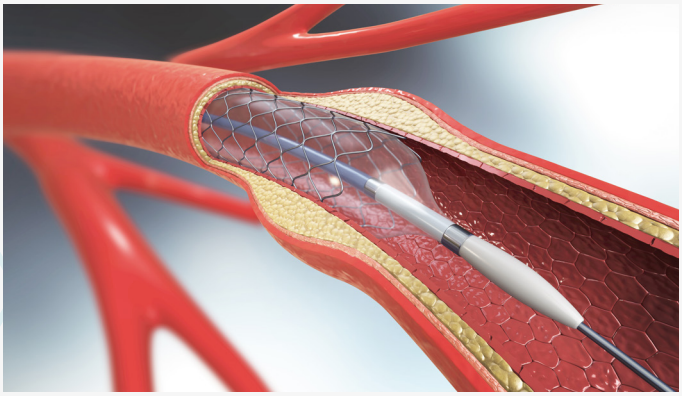
Material Considerations:

Unlocking the full potential of materials science is one of the most efficient ways of elevating product and finished device performance and value while creating product differentiation. Critical material considerations for cardiology devices are:

- **Elastomeric properties:** Biocompatible elastomers that can deform and recover repeatedly without losing integrity and have the appropriate durometer for the intended use case.
- **Fatigue resistance:** Materials must withstand repeated insertions and withdrawals without tearing or permanent deformation.
- **Low coefficient of friction (COF):** Materials need to exhibit smooth movement, low wear and greater control during use. This is achieved through formulation, coatings and surface modification techniques or secondary processes.
- **Sterilization stability:** Material must remain stable after ethylene oxide (EtO) or gamma sterilization without becoming brittle or sticky. Material stability is also a critical consideration when assembling components with automated systems.
- **Resealing:** Elastomers are prone to reseal after slitting. This is mitigated through formulation and processing.

When these characteristics are understood steps can be taken to prevent undesired outcomes, such as adjustments within the material formulation or to component design, tailored manufacturing steps or the addition of secondary processes.

Manufacturing Techniques:



- **Tooling:** Precision alignment is critical to avoid parting line shifts that affect wall thickness and performance.
- **Molding:** Process controls ensure high-quality with repeatable outcomes throughout the product life cycle.
- **Slitting:** Special features such as slitting for valves require precision of location and or depth control for the proper function of the component, especially when resealing is a critical to function feature.
- **Inspection:** Leverage sophisticated automation inspection systems for visual attribute features. Automated systems are equipped to 100 percent inspect products resulting in higher quality, reliability and consistency.

Artificial Intelligence (AI) in Cardiology

AI is reshaping cardiology through its ability analyze large amounts of data and help physicians make more accurate diagnoses and treatment plans for patients. This includes using algorithms to interpret imaging tests such as CT scans, MRIs and ultrasounds, as well as analyzing patient data to identify patterns and predict potential heart conditions.

AI is also being used to develop more personalized treatments for patients based on their individual risk factors and genetic makeup. This can help doctors create targeted treatment plans that are tailored to each patient's specific needs.

The use of AI in cardiology also extends beyond diagnostic capabilities. It is being utilized in remote patient monitoring systems, where devices such as wearable sensors and monitors collect real-time data on a patient's heart rate, blood pressure and other vital signs. This information is then analyzed by AI algorithms to detect any abnormalities or changes that could indicate a potential cardiac issue.

Moreover, AI is playing a crucial role in helping doctors make more accurate and timely decisions during emergency situations. For example, when a patient presents with chest pain in the emergency room, AI algorithms can quickly analyze their symptoms and medical history to determine the best course of action.

Finally, with vast amounts of data generated from various sources such as electronic health records, clinical trials and medical literature, AI can help identify patterns and trends that would be nearly impossible for a human to detect. This can lead to the development of new treatments and medications, as well as a better understanding of diseases and their causes.

Key Therapy Areas in Cardiology

The evolution of cardiology has led to the development of several key therapy areas, each encompassing a diverse array of products crucial to modern cardiovascular care:

- Monitoring and mapping: Devices that provide detailed diagnostics of the heart's electrical activity and structure
- Cardiac diagnostic catheters: Tools used to diagnose and assess various heart conditions
- Interventional cardiology devices: Includes balloons, stents and other devices used in procedures like angioplasty
- Cardiac rhythm management: Pacemakers and defibrillators that regulate heart rhythm
- Implantable cardiac leads: Wires that connect implantable devices to the heart muscle
- Structural heart segments: Devices used to repair or replace heart valves and other structural components

Collaborating with Reliable Partners

To keep pace with technological advancements and these key therapy areas, medical device engineers need CDM partners that deeply understand the intricacies of their projects. OEMs should look for CDMs that provide diverse capabilities, end-to-end solutions, in-house materials and have a commitment to collaboration.

The most successful programs start with partnerships between med device OEMs and CDMs at the concept phase of a project. The benefits of early involvement include:

Enhanced part quality

Providing input on part design aspects, such as parting lines, draft angles, wall sections and weld joint design, help reduce potential defects in parts.

Shorter project timeline

Design for manufacturability (DfM) on the front-end means fewer rework iterations and design changes throughout process development.

Reduced cost to manufacture

Part design optimized for ease of manufacturing can lead to less potential scrap and streamlined production.

Case Story: LVAD Collaboration

A left ventricular assist device (LVAD) is a critical solution for patients awaiting heart transplants or living with near-zero natural heart function. Designated as FDA Class III devices, LVADs are implanted in the body for over 29 days and serve as a mechanical bridge sustaining life by pumping oxygenated blood from the left ventricle to the ascending aorta. They enable patients without a detectable pulse to live near-normal lives. LVADs are engineering marvels comprising hundreds of components, including batteries, electronics, software and intricate mechanical assemblies.

A medical device equipment manufacturer approached Trelleborg about producing a set of complex subassemblies and components for a LVAD. The customer was struggling to scale up manufacturing efficiently and effectively, despite having already specified most materials. They recognized Trelleborg's capacity to take on substantial, long-term projects using its robust quality management system. The device's complexity necessitated expertise in implantable metals, fabrics, polymers and overmolded electronics. Knowledge of these techniques was essential to designing critical aspects of the device pump, driveline, strain relief systems and fixation to the heart.

The Trelleborg team established trust through transparency regarding process parameters and intellectual property. The product development group provided early prototyping support and gave recommendations to improve the customer's own prototyping efficiencies. Tooling and process engineers offered advanced expertise in insert molding of metal components with silicones and demonstrated high process maturity for complex extrusion for a jacketed cable component. Additionally, quality engineers identified the most effective inspection methods to ensure customer specifications were met. Trelleborg was able to successfully launch the product line ahead of schedule providing the customer with a reliable and scalable manufacturing process for this life-sustaining device.

Outlook

The future of cardiology promises sustained growth, driven by continuous advancements in technology and innovative treatment approaches. Catheter-based interventions and implantable devices will remain at the forefront of this progress, enabling more precise, less invasive procedures that improve recovery times and overall patient outcomes.

A key area of focus is the development of smaller, more efficient devices, that enhance treatment precision while reducing the physical burden on patients. Additionally, the incorporation of bioresorbable materials, which allow devices to safely dissolve in the body after fulfilling their purpose, is minimizing long-term risks and complications. This approach prioritizes patient safety and comfort, while also addressing the need for sustainable medical solutions. As these innovations gain momentum, the field of cardiology is expected to see marked improvements in the prevention, diagnosis and treatment of heart conditions, ultimately transforming the standard of care for millions of patients worldwide.

Conclusion

The landscape of cardiovascular care is being reshaped by powerful trends in technology, patient care, and manufacturing. From AI-driven diagnostics to minimally invasive transcatheter therapies, innovation is creating unprecedented opportunities to improve patient lives. However, navigating the complexities of regulatory compliance, supply chain management, and rapid technological change requires deep expertise and strategic collaboration.

By partnering with a knowledgeable and experienced CDM like Trelleborg Medical Solutions, medical device OEMs can accelerate development, enhance product quality, and bring life-saving technologies to market faster. We empower medical device companies to turn ambitious concepts into reliable, scalable solutions.

Author

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Trelleborg Medical Solutions

Bonitati spearheads the growth and expansion of Trelleborg's medical device capabilities in the U.S., E.U. and APAC. He also oversees the business area's capabilities for the advancement of Active Pharmaceutical Ingredients (API) within combination products. Bonitati is responsible for evaluating financial performance, monitoring trends and analyzing market share, including target markets and product positioning.

With over 20 years of experience in the healthcare and medical industry, Bonitati has led technical and operations teams in new product development and commercial execution. He has successfully launched multiple Class II and III products in the cardiac rhythm management (CRM), neuroscience, and electrophysiology sectors.

1. Cardiovascular Devices Market Size & Share Report, 2030 (grandviewresearch.com)

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Trelleborg Medical Solutions develops, manufactures and supplies innovative engineered solutions for demanding medical, biotech and pharmaceutical applications in thermoplastics, silicone and other elastomers. We focus on meeting the most demanding needs of Healthcare & Medical customers with innovative solutions.

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