

# **Endomyocardial Biopsy Devices Market Size and Forecast (2021 - 2034), Global and Regional Share, Trend, and Growth Opportunity Analysis Report Coverage: By Product Type (Biopsy Forceps and Catheters, Guidance Systems and Accessories), Guidance Technique (Fluoroscopy-guided EMB, Echocardiography-guided EMB, and Hybrid Techniques), Application (Transplant Rejection Monitoring, Myocarditis Diagnosis, Cardiomyopathy Evaluation, and Other Cardiac Pathologies), End User (Cardiac centers and hospitals, Diagnostic, and Research Institutes, and Academic Institutions), and Geography (North America, Europe, Asia Pacific, Middle East and Africa, and South and Central America)**

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## **Abstracts**

According to our new research study on “Endomyocardial Biopsy Devices Market Forecast to 2034 –Global Analysis – by Product Type, Guidance Technique, Application, End User, and Geography,” the market is anticipated to grow from US\$ 352.25 million in 2025 to US\$ 500.01 million by 2034, with a CAGR of 4.0% during 2026–2034. The endomyocardial biopsy devices market growth is attributed to the rising volume of heart transplant procedures, the rising prevalence of cardiovascular diseases (CVDs), and technological advancements in biopsy forceps and catheter design.

Endomyocardial biopsy (EMB) devices are used to obtain cardiac tissue samples, primarily for diagnosing myocarditis, cardiomyopathies, transplant rejection, and other cardiac pathologies. Key products include biopsy forceps, flexible catheters, and disposable or reusable designs, used with guidance systems like fluoroscopy, echocardiography, or emerging robotic navigation for precision. Accessories such as introducer sheaths, guidewires, and localization tools support the procedure. The primary end users are cardiac centers, hospitals, diagnostic and research institutes, and academic institutions. EMB is critical in cardiology for accurate diagnosis, treatment planning, and post-transplant monitoring, reflecting a niche yet essential segment of the cardiac biopsy devices market.

The endomyocardial biopsy devices market in North America is segmented into the US, Canada, and Mexico. Innovation in advanced cardiac delivery systems, regulatory support, and ongoing regulatory engagement are driving the endomyocardial biopsy devices market in North America. An example of this momentum is evident with recent developments from BioCardia, Inc., including the acceptance of a pre-submission package by the US Food and Drug Administration (FDA) for their Helix™ Transendocardial Delivery Catheter. This acceptance is indicative of how, through ongoing regulatory engagement with governmental agencies, streamlined regulatory pathways and early interaction with agencies, the development of endomyocardial biopsy devices is being accelerated. On March 17th, 2026, BioCardia announced that the FDA granted the pre-submission package for the Helix system after they had preliminary discussions with both the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The collaboration of CDRH & CBER represents the continued convergence between innovations in devices and biologics, especially in biopsy-guided therapies, and CDRH will lead the review in cooperation/consultation with CBER with the support of the CardiAMP Cell Therapy Breakthrough Designation. The use of healthcare programs such as breakthrough designations and the use of pre-submission consultation programs provides more certainty for manufacturers to invest in the development of minimally invasive biopsy devices that both diagnose and deliver targeted therapies directly to myocardial tissue, expediting the process of bringing new devices to market and facilitating the acceptance of endomyocardial biopsy devices throughout North America.

The combination of diagnostic and therapeutic capabilities into single catheter-based systems is expanding, including the fact that the Helix system has both intramyocardial delivery capabilities and diagnostic capabilities. The increasing incidence of

cardiovascular disease in North America (along with the interest in precision medicine) has led clinicians to seek out tools that will allow accurate tissue sampling and delivery of targeted therapies to the targeted areas of the heart. In addition, catheter design, imaging guidance, and the ability to treat with cell-based therapies like CardiAMP depend upon being able to access the heart with precise accuracy; therefore, hospitals and research institutions are more frequently making use of these technologies to provide better care for patients while minimizing the risks associated with traditional surgical interventions. The development of regulatory processes, convergence of technologies, and growing demand within the clinical community for improved patient access to therapies are positioning North America as a leader in the development of endomyocardial biopsy devices.

The US Food and Drug Administration, International Society for Heart & Lung Transplantation, European Society of Cardiology are among the primary and secondary sources referred to while preparing the endomyocardial biopsy devices market report.

### **Reason to buy**

Saves and reduces time required for identifying the market growth, size, leading players, and segments in the global Endomyocardial Biopsy Devices market.

Highlights key business priorities to assist companies in realigning their business strategies

Emphasizes key findings and recommendations that uncover emerging industry trends in the global Endomyocardial Biopsy Devices market, enabling stakeholders across the value chain to craft effective long-term strategies

Develop/modify business expansion plans by analyzing substantial growth prospects in mature and emerging markets

Scrutinizes in-depth global Endomyocardial Biopsy Devices market trends, along with factors driving the market, as well as those hindering it

Enhances the decision-making process by understanding the strategies that underpin commercial interest with respect to client products, segmentation, pricing, and distribution

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