Independent Market Research (IMR) on Cardiovascular Devices Market

Frost & Sullivan

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DISCLAIMER

The market research process for this study has been undertaken through secondary/desk research and primary research, which involves discussing the market status with subject matter experts.

The research methodology used is a mix of secondary and primary research, where the quantitative market information was sourced from secondary data sources, primary research, and trusted portals. The information is subject to fluctuations due to possible business and market changes. Frost & Sullivan's estimates and assumptions are based on varying levels of quantitative and qualitative analyses, including industry journals, company reports, and information in the public domain.

The data has been collated from publicly available sources such as industry reports, annual reports, company filings, and the Ministry of Corporate Affairs (MCA) database. Forecasts, estimates, predictions, and other forward-looking statements contained in this report are inherently uncertain because of changes in factors underlying their assumptions, events, or combinations of circumstances that cannot be reasonably foreseen. Actual results and future events could differ materially from forecasts, estimates, predictions, or such statements. All financial and operational details for SMT are for continuing operations and are provided by the company.

Frost & Sullivan has prepared this study independently and objectively and has taken adequate care to ensure its accuracy and completeness. We believe that this study presents an accurate and fair view of the Cardiovascular Devices market in selected geographies within the limitations of, among others, secondary statistics and primary research, varying scenarios created due to the macro-economic and demand factors, and it does not purport to be exhaustive. Our research has been conducted with an "overall industry" perspective, and it may not necessarily reflect the performance of individual companies in the industry. Frost & Sullivan shall not be liable for any loss suffered because of reliance on the information contained in this study. This study should also not be considered a recommendation to buy or not to buy the shares of any company or companies as mentioned in it or otherwise.

Abbreviation	Full Form
3D	Three-Dimensional
AB-PMJAY	Ayushman Bharat Pradhan Mantri Jan Arogya Yojana
AdvaMed	Advanced Medical Technology Association
AFib	Atrial Fibrillation
AI	Artificial Intelligence
AIMEd	Association of Indian Medical Device Industry
ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency)
APAC	Asia-Pacific
ASC	Ambulatory Surgery Center
ASCs	Ambulatory Surgical Centres
ASD	Atrial Septal Defect
ASEAN	Association of Southeast Asian Nations
BMS	Bare Metal Stents
Bn	Billion
CABG	Coronary Artery Bypass Grafting
CAD	Coronary Artery Disease
CAGR	Compound Annual Growth Rate
Cath	Catheterization
CDSCO	Central Drugs Standard Control Organization
CE	Conformité Européenne
CER	Comparative Effectiveness Research
CGHS	Central Government Health Scheme
CHE	Current Health Expenditure
CMS	Centers for Medicare & Medicaid Services
CoEs	Centers of Excellence
CT	Computed Tomography
CTO	Chronic Total Occlusion
CVD	Cardiovascular Disease
CY	Calendar Year
DALYs	Disability-Adjusted Life Years
DCBs	Drug-Coated Balloon Catheters
DES	Drug-Eluting Stents
DRG	Diagnosis Related Groups
DVT	Deep Vein Thrombosis
ECG	Electrocardiogram
ESIS	Employees' State Insurance Scheme
EU	European Union
EUDAMED	European Database on Medical Devices
F	Forecasted

FDA	Food and Drug Administration
FDI	Foreign direct Investment
FFS	Fee-for-Service
FICCI	Federation of Indian Chambers of Commerce and Industry
FY	Financial Year
G7	Group of Seven
GAVI	Global Alliance for Vaccines and Immunization
GDP	Gross Domestic Product
GHTF	Global Harmonisation Task Force
GMP	Good Manufacturing Practices
HCPs	Healthcare Professionals
IBEF	Indian Brand Equity Foundation
ICDs	Implantable Cardioverter-Defibrillators
IHME	Institute for Health Metrics and Evaluation
IP	Intellectual Property
IRDAI	Insurance Regulatory and Development Authority of India
IVD	In Vitro Diagnostic
IVL	Intravascular Lithotripsy
IVU	Intravascular Ultrasound
KKR	Kohlberg Kravis Roberts & Co.
LAA	Left Atrial Appendage
LAAC	Left Atrial Appendage Closure
LATAM	Latin America
LCoGS	Lancet Commission on Global Surgery
LMICs	Lower-Middle-Income Countries
M&A	Mergers and Acquisitions
MDD	Medical Device Directive
MDR	Medical Device Regulation
MEA	Middle East and Africa
MedTech	Medical Technology
Mn	Million
MNC	Multinational Corporation
MoHFW	Ministry of Health and Family Welfare
MRI	Magnetic Resonance Imaging
MS	Mitral Stenosis
MSME	Micro, Small and Medium Enterprises
NCD	Non-Communicable Disease
NHI	National Health Insurance
NIPER	National Institutes of Pharmaceutical Education & Research
NMP	National Master Plan

NMPA	National Medical Products Administration
NPPA	National Pharmaceutical Pricing Authority
OCT	Optical Coherence Tomography
OOP	Out-of-Pocket
PAD	Peripheral Artery Disease
PCI	Percutaneous Coronary Intervention
PET	Polyethylene Terephthalate
PFO	Patent Foramen Ovale
PLI	Production-Linked Incentive
PMA	Premarket Approval
PMDA	Pharmaceuticals and Medical Devices Agency
PM-JAY	Pradhan Mantri Jan Arogya Yojana
PRIP	Pharmaceutical and Medical Devices Industry Promotion
PTA	Percutaneous Transluminal Angioplasty
PTCA	Percutaneous Transluminal Coronary Angioplasty
PVIs	Peripheral vascular interventions
PVL	Paravalvular Leak
R&D	Research and Development
RPM	Remote Patient Monitoring
SFA	Superficial Femoral Artery
SHD	Structural Heart Disease
SSN	Servizio Sanitario Nazionale
ST	Stent thrombosis
SUS	Sistema Único de Saúde
TAVI	Transcatheter Aortic Valve Implantation
TAVR	Transcatheter Aortic Valve Replacement
TDB	Technology Development Board
TMVR	Transcatheter Mitral Valve Repair
TTVR	Transcatheter Tricuspid Valve Repair
UCMPMD	Uniform Code for Marketing Practices in Medical Devices
UHC	Universal Healthcare Coverage
UK	United Kingdom
UNICEF	United Nations Children's Fund
US	United States
USD	United States Dollar
WHO	World Health Organisation

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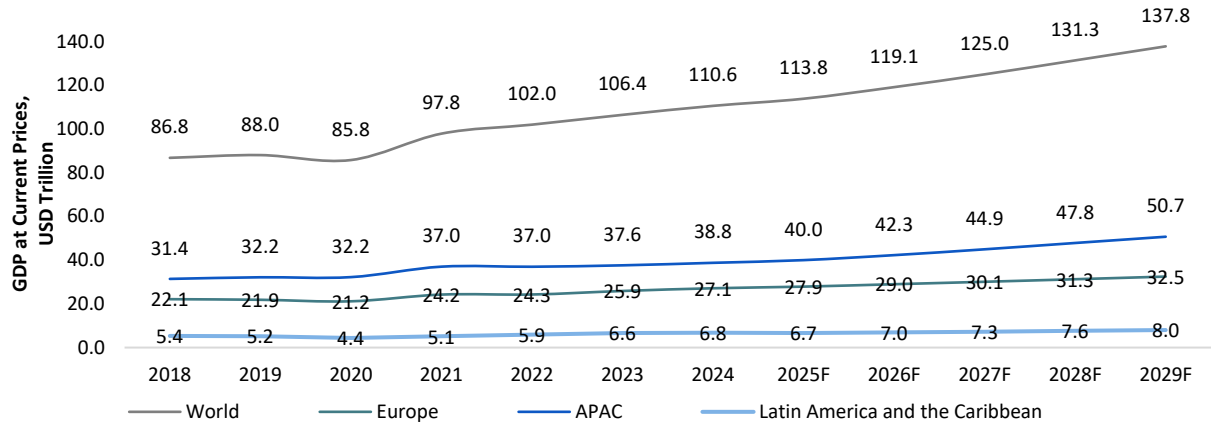
1. GLOBAL AND INDIAN MACROECONOMIC OVERVIEW

1.1. GLOBAL GDP OUTLOOK

The global GDP is estimated to grow from USD 110.6 trillion in 2024 to USD 137.8 trillion in 2029. Notably, there is a forecasted global GDP growth rate of 4.5% from 2024 to 2029, surpassing the historical average of 4.1% from 2018 to 2024 due to factors such as easing inflationary pressures and less restrictive monetary policies, and an increase in household income, private consumption and private investments.

Exhibit 1.1: GDP at Current Prices, Global, 2018-2029F



Source: World Economic Outlook-April 2025, Frost & Sullivan

The year-on-year global GDP growth is projected at 4.7% in 2025-26 and at 4.9% in 2026-27.

1.2. GLOBAL GDP GROWTH

Global GDP growth has rebounded following the Covid-19 pandemic and continues to steadily grow. Global growth is expected to remain stable yet underwhelming, with short-term sluggishness attributed to geopolitical and financial challenges expected to give way to stronger long-term growth.

1.2.1. WORLD, ADVANCED ECONOMIES, EMERGING MARKETS, AND DEVELOPING ECONOMIES[1]

While APAC's emerging economies will be the beacon of growth, with a growing contribution to global economic growth, there is notable growth in Europe, and Latin America and the Caribbean regions.

The confluence of supply chain disruptions caused due to geopolitical scenarios such as the Russia- Ukraine and Israel- Palestine conflict has resulted in significant disruptions in energy and food markets, sparking a substantial inflationary surge and exacerbating a cost-of-living crisis. Moreover, trade wars through tariff hikes by the US and other countries could have a multifaceted economic impact, with the World Bank identifying several key consequences, including increased risks to global growth, inflation concerns, and disruptions in

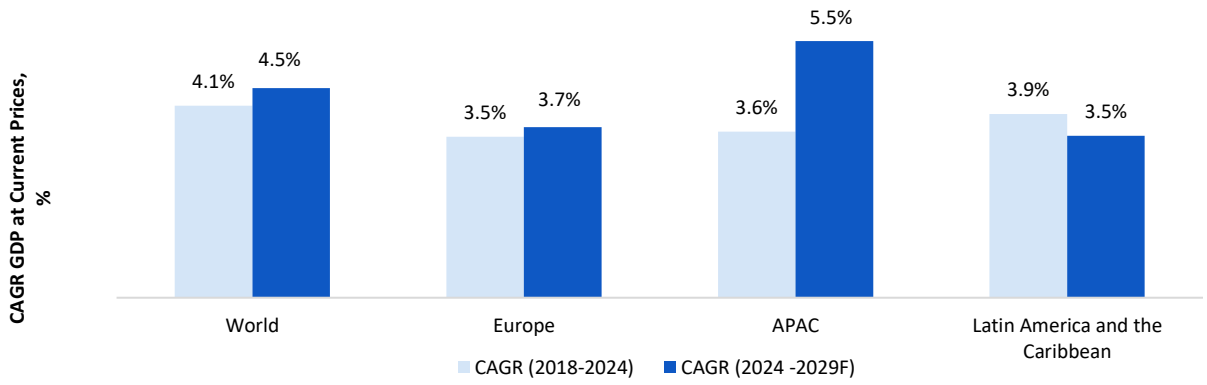
[1] Advanced Economies include Euro Area, Major Advanced Economies (G7), Other Advanced Economies (Advanced Economies excluding G7 and Euro Area), European Union, ASEAN-5;
Emerging Market and Developing Economies include Emerging and Developing Asia, Emerging and Developing Europe, Latin America and the Caribbean, Middle East and Central Asia and Sub-Saharan Africa

trade and investment networks. However, it is expected to impact only selected geographies such as China, certain south-east Asian countries and Europe. In response, many nations have adopted stricter monetary policies, which, while moderating GDP growth, are still propelling it forward. This anticipated rise is buoyed by APAC, with its emerging markets and developing economies, which are expected to achieve a CAGR of 5.5% from 2024 to 2029. Several factors contribute to this GDP growth, including increased private consumption, elevated corporate expenditures, favorable demographics, strengthened balance sheets, improved macroeconomic stability reducing the need for policymakers to tighten monetary policies, and structural policy reforms.

Europe is anticipated to record a comparatively more modest CAGR of 3.7% between 2024 and 2029. Nevertheless, this marks an improvement from past figures, driven by positive employment prospects and rising consumption trends in Europe. The region's economy is recovering, benefiting from a strong crises' response. This optimistic long-term economic outlook is poised to stimulate global investments and bolster demand in vital sectors, such as healthcare.

The Latin America and the Caribbean region show a negative downward trend, with CAGR declining from 3.9% (2020–2024) to 3.5% (2024–2029F). However, the positive GDP growth in the region is largely driven by strong performance in key economies like Brazil and Mexico, indicating stronger economic development across the region.

Exhibit 1.2: CAGR GDP at Current Prices, Global, 2018-2029F



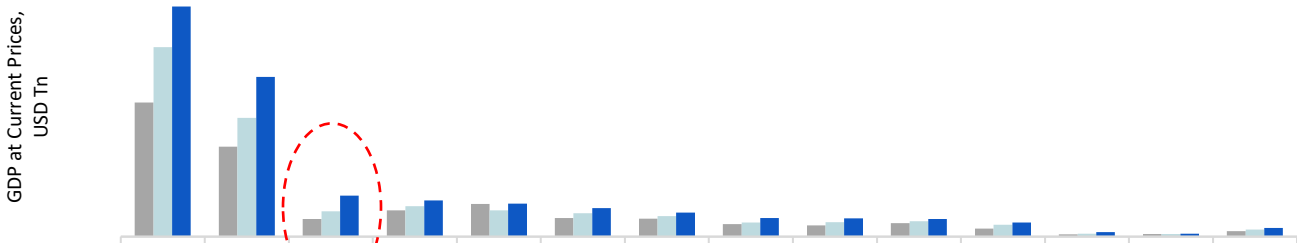
Source: World Economic Outlook-April 2025, Frost & Sullivan

1.2.2. G7 Countries and Key Emerging Market Countries

While Europe is growing at 3.7% on a large base, emerging economies like Asia are expected to play a larger part in global growth in the future.

Apart from Sub-Saharan Africa and the ASEAN 5[2], India and China are emerging as two of the largest and swiftest-growing economies. Notably, India's growth rate between CY2018 and CY2024 was higher than most of the major economies except Mexico and India's projected GDP growth between 2024 and 2029 is nearly 1.7 times of China, 2.6 times of the US, 3.0 times of Germany, 2.5 times of UK, 3.6 times of Italy and 3.1 times of France. In contrast, the G7 nations[3], characterized by mature economies, concentrated markets, and ageing populations, confront limited growth prospects. These economies are deeply affected by global banking uncertainties, ongoing conflicts (Israel-Palestine and Russia-Ukraine), tariff hikes across countries and tighter monetary policies, emphasizing the dynamic shift toward rapidly growing emerging and developing Asian economies. Moreover, the impact on tariff hikes across countries and the US-China trade war could exacerbate trade tensions, lower investment, reduce market efficiency, distort trade flows, and again disrupt supply chains. Growth could suffer in both the near and medium term, but at varying degrees across economies.

Exhibit 1.3: GDP at Current Prices, Select Countries, 2018-2029F



	USA	China	India	Germany	Japan	UK	France	Brazil	Canada	Italy	Mexico	Philippines	South Africa	Saudi Arabia
2018	20.7	13.8	2.7	4.1	5.0	2.9	2.8	1.9	1.7	2.1	1.3	0.3	0.4	0.8
2024	29.2	18.3	3.9	4.7	4.1	3.6	3.2	2.2	2.2	2.4	1.8	0.5	0.4	1.1
2029F	35.5	24.6	6.3	5.6	5.1	4.4	3.7	2.9	2.8	2.7	2.2	0.7	0.5	1.3

Source: World Economic Outlook-April 2025, Frost & Sullivan

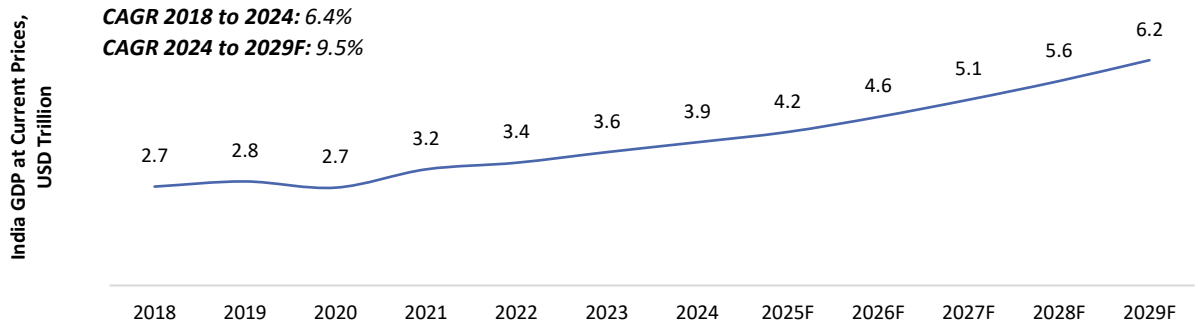
India's resilience amid the pandemic, coupled with emerging geopolitical trends such as the "China plus one" strategy, thrusts it into the spotlight. Meanwhile, China contends with challenges stemming from a vulnerable property sector, geopolitical uncertainties, an increase in import tariffs by the US and waning export momentum, projecting a growth rate of 5.5% from 2024 to 2029. India's GDP at current prices reached USD 3.9 trillion in 2024 and is anticipated to climb to USD 6.3 trillion by 2029, maintaining a strong CAGR of 9.5% from 2024 to 2029. As a result, India is poised to ascend as the world's third-largest economy by 2027, surpassing Japan and Germany, with a GDP surpassing USD 5 trillion. India aims to achieve developed economy status by 2047. This growth surge is fueled by escalating domestic demand,

[2] Association of Southeast Asian Nations (ASEAN): Indonesia, Malaysia, the Philippines, Singapore, and Thailand.

[3] The G7, or Group of Seven, is an informal forum of seven major industrial democracies: the United States, Canada, France, Germany, Italy, Japan, and the United Kingdom, which focuses on global economic and political issues.

substantial government and private global investments, reinforced global ties and reforms centered around Atmanirbhar Bharat[4], and a flourishing micro, small, and medium-sized enterprise (MSME) sector.

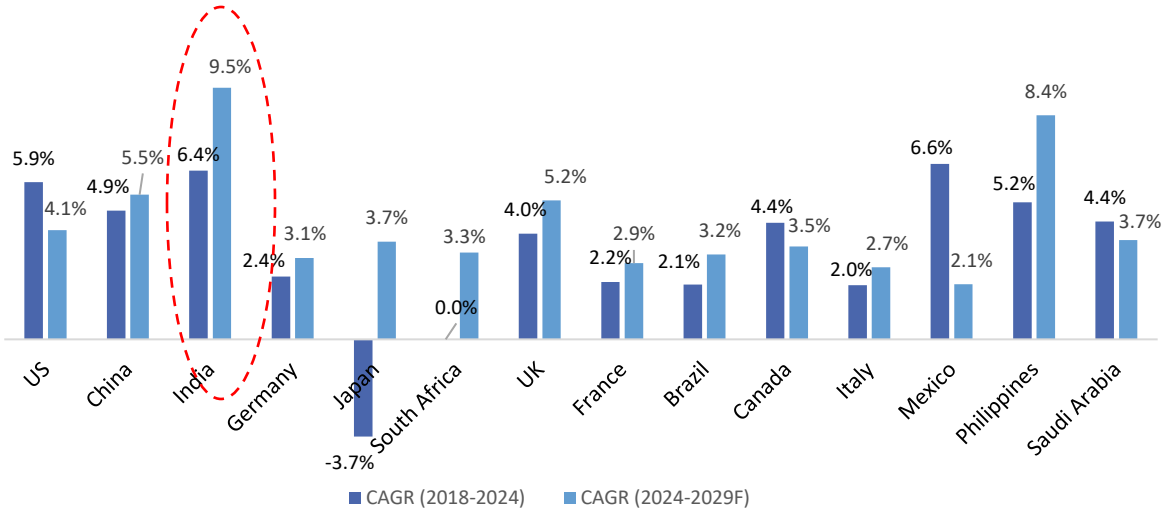
Exhibit 1.4: GDP at Current Prices, India, 2018-2029F



Source: World Economic Outlook-April 2025, Frost & Sullivan

Economies such as Brazil, Mexico, the Philippines, and South Africa are also on track for robust growth. Their strengths lie in a resilient agriculture sector, burgeoning consumption trends, significant presence in nickel mining, and secure manganese supply, respectively. Although several of these economies match the growth pace of India and China, their smaller size and population make them less attractive for substantial investments.

Exhibit 1.5: CAGR of GDP at Current Prices, Select Countries, 2018-2029F



Source: World Economic Outlook-April 2025, Frost & Sullivan

[4] Atmanirbhar Bharat, or "Self-reliant India," is a vision and initiative introduced by the Indian government. It aims to make India a self-reliant and economically strong nation. This concept emphasizes the importance of reducing dependence on imports and promoting domestic production and manufacturing.

1.2. GLOBAL INFLATION TRENDS

The global annual inflation (based on average consumer prices) stood at 5.76% in 2024, down from its peak of 8.62% in 2022, and it is expected to decline to 3.23% in 2029. While there has been a gradual decline, inflation rates still vary significantly across regions. Europe and Central Asia have been key drivers of overall inflation due to their higher weightage in the global average and substantial swings in inflation rates. Central banks worldwide have been implementing monetary policy adjustments to combat inflation. By raising interest rates, they aim to reduce consumer and business spending, thereby easing inflationary pressures. However, the effectiveness of these measures can vary, and there is a risk of causing economic slowdowns if they are not carefully managed. Global headline inflation is expected to continue declining gradually, though it may remain above pre-pandemic levels for some time. The pace of disinflation is likely to vary across regions, with developed economies potentially seeing faster progress in reducing inflation compared to emerging markets.

Table 1.2: Global Inflation Trend, 2019 – 2029F

Year	World	Advanced Economies	Emerging economies and developing nations
2019	3.50%	1.40%	5.10%
2022	8.62%	7.31%	9.58%
2024	5.76%	2.61%	7.93%
2026F	3.63%	2.02%	4.67%
2029F	3.23%	2.03%	3.96%

Source: World Economic Outlook, Frost & Sullivan

1.3. GLOBAL CURRENT HEALTHCARE EXPENDITURE

Government policies, economic conditions, healthcare reforms, and personal awareness have increased healthcare spending.

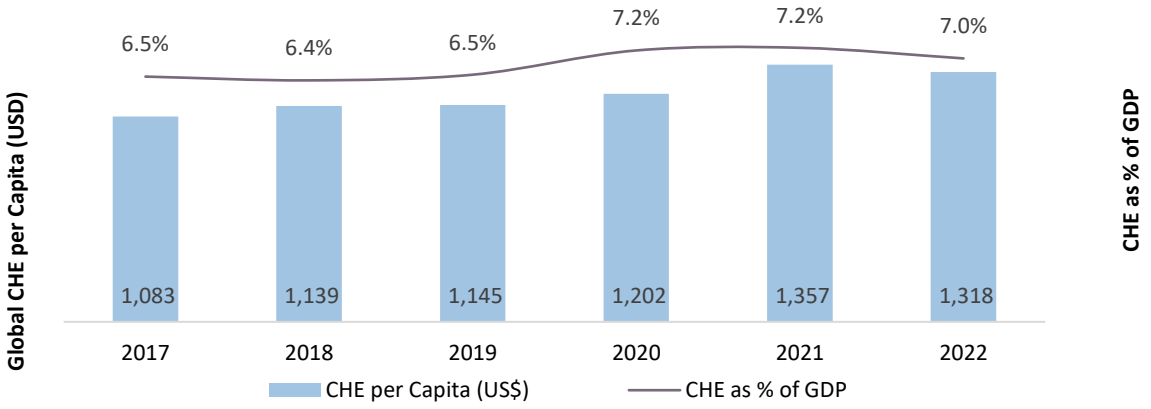
The global Current Healthcare Expenditure (CHE)[5] per capita and CHE as a percentage of GDP are on an upward trajectory with rising economies, increased accessibility and affordability, advances in medical technology, growing prevalence of chronic diseases, ageing population, post-pandemic behavioural changes, and heightened focus on wellness and self-medication. Based on the latest available data from WHO, from 2017 to 2022, the CHE per Capita increased at a CAGR of 4.0% and the CHE as a percentage of GDP increased from 6.5% to 7.0% in 2022.

[5] CHE refers to the total amount spent on healthcare goods and services within a specific period, typically a year. It's a measure of how much resources are allocated to healthcare relative to other sectors of the economy.

A country's total CHE is contributed by various financing sources such as Government sources, Household out-of-pocket payments, Voluntary healthcare payment schemes, and other financing schemes.

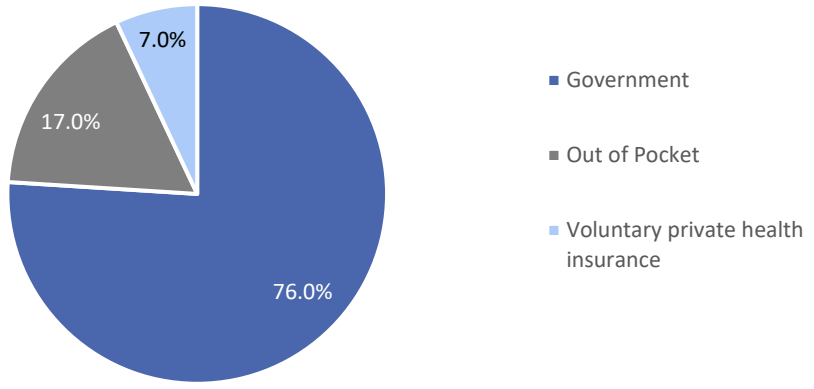
Exhibit 1.9: Global Current Healthcare Expenditure (CHE) : 2017 - 2022

CHE per Capita CAGR (2017-2022) = 4.0%



Source: WHO, Frost & Sullivan

Exhibit 1.10: Current Healthcare Expenditure contribution by sources, 2022



Source: WHO, Frost & Sullivan

1.3.1. GROWTH DRIVERS FOR RISING HEALTHCARE EXPENDITURE

Healthcare expenditures have been growing consistently and considerably for the last five decades by around 4 per cent since 1970. The major drivers for rising healthcare expenditures are increased access to healthcare, prevalence of chronic diseases, precision medicine & next generation diagnostics.

Increased access to healthcare: The WHO launched the UHC (Universal Healthcare Coverage) more than three decades ago with the program focusing on ensuring essential healthcare services are available to all citizens without creating a financial hardship. The success of the program has translated into more governments' increased investment in their healthcare infrastructure and favorable policy reforms to increase coverage that have led to better quality and accessibility to healthcare services to its citizens. Access to vaccines and generics, particularly in the low-to-mid income countries, have also risen owing to

programs from global bodies such as GAVI, Vaccine Alliance, UNICEF etc. Technological advancements have also played their part in improved access, particularly post pandemic, as the global population came close to telemedicine, and mobile health services. There is also increasing use or development of AI and automation that can help decrease the lead time of diagnosis by automating diagnostic workflows.

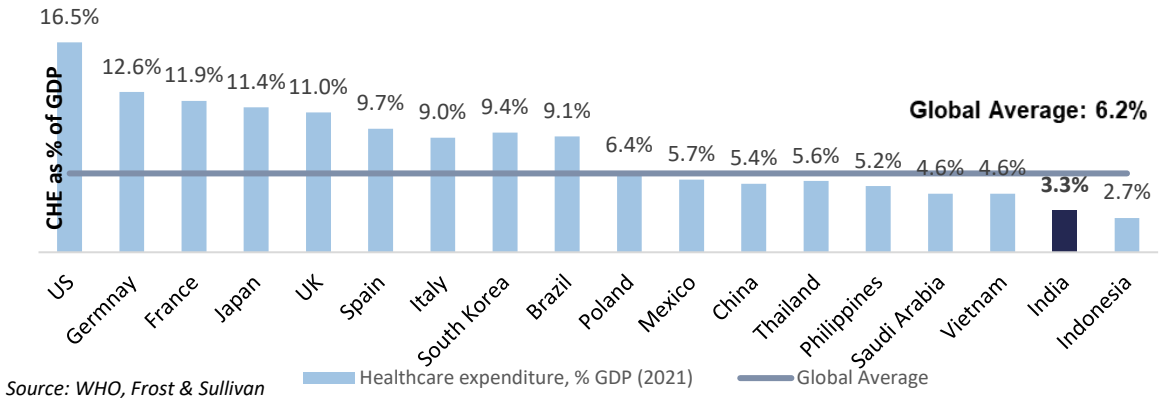
Prevalence of chronic diseases: Chronic diseases are expected to cost an estimated USD 47 trillion by 2030 and will be the leading cause of death worldwide according to WHO. The burden of chronic diseases such as diabetes, heart disease, cancer and respiratory diseases is increasing across the globe. The primary factors contributing to the increased burden are ageing population, increased life expectancy, urbanization, imbalanced diets, poor air quality and lifestyle changes. The impact of chronic disease has always been significant among the population aged 60 and older, with better healthcare access and increased life expectancy, the chronic disease populace set to expand significantly. The number of people aged 60 and above is set to rise from 1.1 billion in 2023 to 2.1 billion by 2050, with a majority of the population located in the low-and-middle-income countries.

Pharmaceutical and Medical Device Innovations: While pharmaceutical and medical device innovation significantly benefits healthcare, these advancements can also contribute to escalating costs. The process of developing a new medical device is expensive, time-consuming, and requires substantial investment in research, development, and regulatory approvals. The rising prices of new drugs and devices, coupled with increased utilization of advanced technologies, are driving up overall healthcare expenses. However, the benefits of these innovations, such as improved patient outcomes and extended lifespans, often outweigh the costs. Due to the R&D intensive nature of the industry, these costs are often passed on to the payers and/or patients, leading to an increase in healthcare expenditure. Advances in medical device areas such as robotic surgery, implants and advanced imaging systems, whilst successful in improving patient outcomes, carry a significant cost factor.

1.3.2. CURRENT HEALTHCARE EXPENDITURE ACROSS SELECT COUNTRIES

In the developed economies, many countries have high Current Health Expenditure (CHE) as % of the country's GDP. For example, the United States, with its well-developed need-based healthcare approach, has the highest CHE as a percentage of GDP of the country, 16.5%, followed closely by Germany, France and Japan at 13.0%, 11.9% and 11.4%, respectively. Most of the advanced or developed economies have a high proportion of CHE to GDP due to higher government spending in these economies in addition to advancement in medical and device innovation, which also stems from these regions. The emerging economies, particularly in the low-and-middle-income countries, receive external aid to supplement their low government spending on healthcare. The majority of the emerging and developing economies in Asia, such as India, China, the Philippines, Vietnam, Indonesia, and Thailand have a low CHE compared to the advanced economies of North America and Europe. However, a key element across the globe in terms of healthcare expenditure is the investment in strengthening the resilience of healthcare services post the COVID-19 pandemic. The global average of CHE as a percentage of GDP is 6.2%.

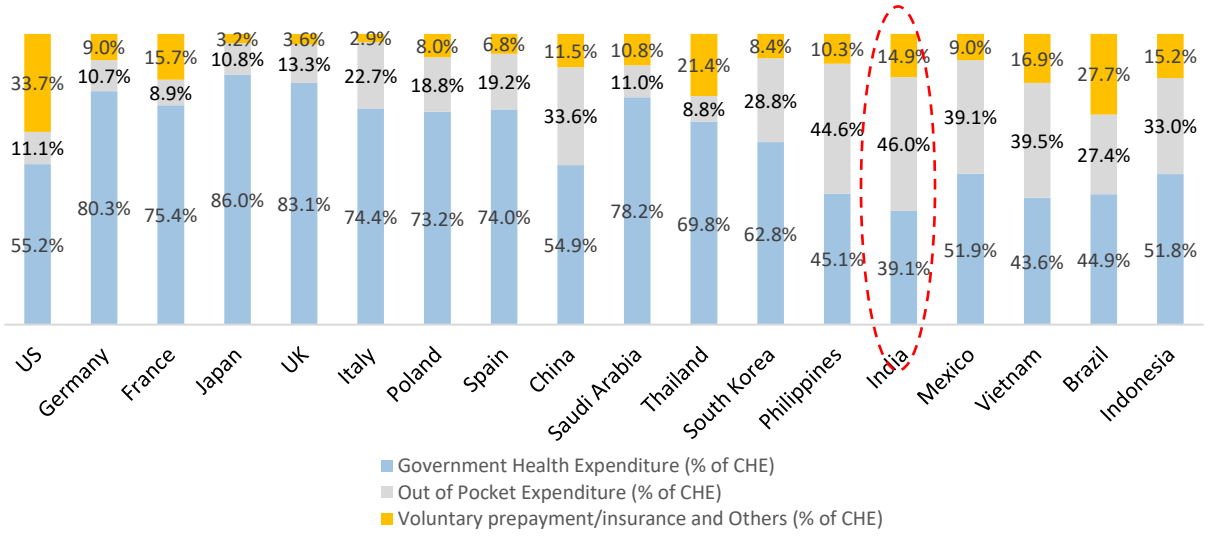
Exhibit 1.11: Current Healthcare Expenditure as % GDP, select Countries: 2022



Source: WHO, Frost & Sullivan

While the government expenditure accounts for a larger share (more than 50%) in most the country's total CHE in most of the major economies like the US, Australia, France, Japan, UK, China and Saudi Arabia, it is very low in India, contributing only 39%. Moreover, while the high adoption of private health insurance helps in closing the gap in government funding and reducing the burden of out-of-pocket expenditure in countries such as the US and the Philippines, the share of out-of-pocket expenditure is as high as 46.0% in India.

Exhibit 1.12: Current Healthcare Expenditure by sources (%), select Countries: 2022



Source: WHO, Frost & Sullivan

In emerging economies such as India, Brazil, the Philippines and Vietnam, the share of government expenditure is increasing to decrease the burden on out-of-pocket expenditure. Moreover, the adoption of private insurance is increasing in these countries, improving the affordability to medical care and decreasing the catastrophic healthcare expenditure for patients. In India, the share of government funding in CHE has increased from about 31% in 2017 to about 39% in 2022. In Brazil, the share of government funding in CHE has increased from about 41% in 2017 to about 45% in 2022. In the

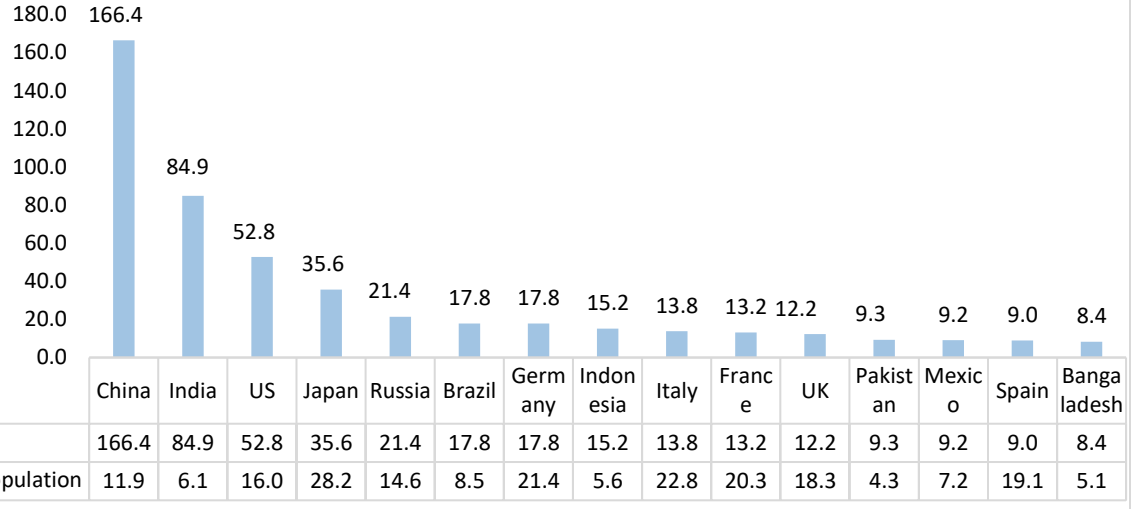
Philippines, the share of government funding in CHE has increased from about 30% in 2017 to about 45% in 2022.

2. DEMOGRAPHIC AND DISEASE BURDEN, GLOBAL AND INDIA

2.1. GLOBAL AGEING POPULATION

Globally, people are living longer. Most people nowadays can anticipate living well into their sixties and beyond. Both the number and percentage of older people in the population are rising in every nation. One in six individuals will be 65 years of age or older by 2030. At this point, there will be 1.4 Bn people over the age of 65, up from 1 Bn in 2020. The number of individuals in the world who are 65 years of age or older is expected to double to 2.1 Bn by 2050. It is anticipated that between 2020 and 2050, the number of people 80 years of age or older will triple, reaching 426 Mn. The proportion of the world's population over 65 years will nearly double from 12% in 2015 to 22% in 2050.[6] China, India, the US, Japan, and Russia are the top 5 countries with the highest population of older adults.[7]

Exhibit 2.1: Top 15 countries with highest population of older adults, 2023



	China	India	US	Japan	Russia	Brazil	Germany	Indonesia	Italy	France	UK	Pakistan	Mexico	Spain	Bangladesh
65+ (in Mn)	166.4	84.9	52.8	35.6	21.4	17.8	17.8	15.2	13.8	13.2	12.2	9.3	9.2	9.0	8.4
% of Total Population	11.9	6.1	16.0	28.2	14.6	8.5	21.4	5.6	22.8	20.3	18.3	4.3	7.2	19.1	5.1

2.2. RISING NON-COMMUNICABLE DISEASES BURDEN

The total global disease burden from non-communicable diseases (NCDs), measured in DALYs (Disability-Adjusted Life Years)[8] per year has increased from 1,150 in 1990 to 1,700 in 2021. The top 5 NCDs as per

[6] WHO, Ageing and Health
[7] Population Reference Bureau, United Nations Population Division, World Population Prospects 2019
[8] DALYs are used to measure total burden of disease - both from years of life lost and years lived with a disability. One DALY equals one lost year of healthy life.

DALYs are Cardiovascular disease, Cancer, Mental disorder, Musculoskeletal disorders, and Diabetes and Kidney disease. NCDs are the number one cause of death and disability worldwide and disproportionally affect people in low and middle-income countries (LMICs) across Europe, Asia and Latin America regions, where three out of four cases occur. Noncommunicable diseases (NCDs), including heart disease, stroke, cancer, diabetes and chronic lung disease, are collectively responsible for 74% of all deaths worldwide. More than three-quarters of all NCD deaths, and 86% of the 17 million people who died prematurely, or before reaching 70 years of age, occurred in low- and middle-income countries as of 2021.

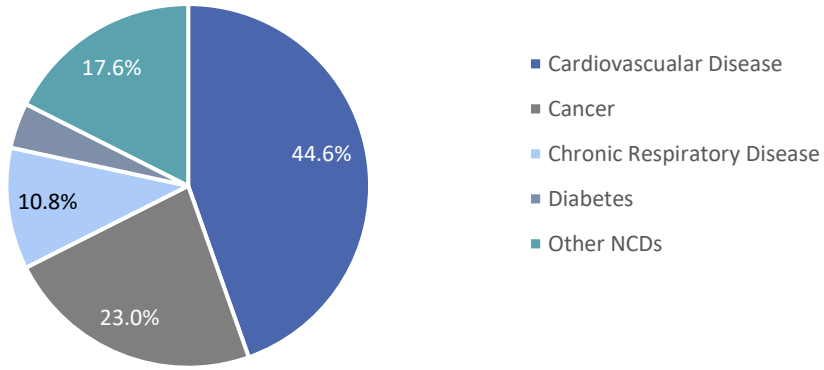
NCDs account for a majority of deaths in most Asian countries. In the South-East Asia Region alone, they are responsible for an estimated 8.5 million deaths annually, representing a significant proportion of all deaths. This burden is also reflected in the high number of disability-adjusted life years (DALYs) lost due to these conditions. A concerning feature of the NCD burden in Asia is the high rate of premature deaths (before the age of 70). This is particularly evident in low- and middle-income countries within the region, where a larger proportion of NCD-related deaths occur in younger individuals compared to high-income nations. Factors such as rapid urbanization, globalization, changing lifestyle and aging populations are contributing to the increasing prevalence of NCDs across Asia.

Moreover, in regions such as Europe, NCDs, including cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes, are the leading causes of death and disability in the European Region. They account for a staggering 86% of all deaths and 77% of the disease burden. With an aging population in Europe, the prevalence of NCDs is expected to rise. The annual number of new NCD cases is projected to increase by 16% by 2050, and deaths are expected to increase by 50% from 2023 levels.

The burden of NCDs for most of the major economies is increasing due to factors such as change in lifestyle and dietary habits and increasing detection of metabolic disorders. The NCD burden in India has increased by more than 50% from 1990 to 2021 (158.5 million DALYs in 1990 to 289.5 DALYs in 2021). While the burden of most NCDs such as Cardiovascular, Neurological, Cancer, and Musculoskeletal diseases have nearly doubled from 1990 to 2021, the burden of Diabetes and Kidney disease has more than tripled in that period. Cardiovascular diseases accounted for most NCD deaths, or at least 18 million deaths in 2021, followed by cancers (10 million), chronic respiratory diseases (4 million), and diabetes (over 2 million including kidney disease deaths caused by diabetes).[9] The number of people living with diabetes alone rose from 200 million in 1990 to 830 million in 2022 and 14% of adults aged 18 years and older were living with diabetes, an increase from 7% in 1990, as per WHO. Prevalence has been rising more rapidly in low- and middle-income countries than in high-income countries. Diabetes causes blindness, kidney failure, heart attacks, stroke and lower limb amputation. Further, Hypertension (high blood pressure) affects over 1.3 billion adults globally, which is about 1 in 4 adults. It is estimated that approximately 220 million people in India were living with hypertension as of 2022, and in 2030, this is expected to reach 1.7 billion.

[9] WHO

Exhibit 2.2: Share of NCDs in mortality, Global, 2021



Source: WHO, Frost & Sullivan

Table 2.1: Burden of NCDs as per DALY, Select countries, 1990 and 2021		
Country	**1990 (DALY, in million)**	**2021 (DALY, in million)**
India	**158.0**	**289.5**
US	83.1	125.3
Germany	25.2	25.0
UK	17.7	17.4
Italy	15.9	16.6
France	14.5	16.1
Spain	9.8	11.5
Canada	6.2	9.0
South Africa	6.1	11.9
Australia	4.0	5.7
Saudi Arabia	2.7	6.7

Source: Secondary sources, IHME, Frost & Sullivan

2.2.1. DIABETES AND HYPERTENSION DISEASE BURDEN

Globally, 14% of adults aged 18 years and older were living with diabetes in 2021, an increase from 7% in 1990, as per WHO. Prevalence has been rising more rapidly in low- and middle-income countries than in high-income countries. The number of people living with diabetes alone rose from 200 million in 1990 to 830 million in 2022[10], with India accounting for approximately 101 million people with diabetes, 15% of the global diabetes burden. Projections indicate that by 2030, the diabetes population could rise to 1.4 billion globally and 134 million in India. The prevalence of diabetes varies across different regions of India, with urban areas having a higher prevalence (14.6%) compared to rural areas (5.2%). Additionally, the prevalence of prediabetes is also significant, indicating a large number of individuals who may develop type 2 diabetes in the near future.

[10] WHO Factsheet

Further, Hypertension (high blood pressure) affects over 1.3 billion adults globally, which is about 1 in 4 adults, and in 2030, this is expected to reach 1.7 billion. Hypertension affects over 220 million people in India as of 2022, making it one of the largest at-risk populations worldwide. Globally, Diabetes and hypertension have been recognized to be the two top drivers of the NCD burden.

Table 2.2: Hypertensive Cardiac Disease and Diabetes burden, Select regions, 2021

	Hypertensive Cardiac Disease			Diabetes (Type 2)		
Country	**2021 (DALY, in Mn)**	**Deaths (Mn)**	**Deaths (%)**	**2021 (DALY, in Mn)**	**Deaths (Mn)**	**Deaths (%)**
Global	**25.46**	**1.3**	**1.96%**	75.34	1.60	2.37%
North America	1.40	0.07	1.87%	5.17	0.07	2.03%
Western Europe	1.30	0.10	2.36%	3.82	0.09	1.96%
Central and Eastern Europe, and Central Asia	1.73	0.10	1.69%	4.12	0.09	1.48%
Latin America and Caribbean	1.30	0.07	1.37%	8.79	0.21	4.34%
North Africa and Middle East	2.85	0.14	3.41%	6.30	0.11	2.80%
South Asia	**4.12**	**0.19**	**1.33%**	**16.85**	**0.41**	**2.77%**
India	**3.16**	**0.15**	**1.27%**	**13.01**	**0.32**	**2.73%**

Source: IHME, Frost & Sullivan

2.2.2. GROWING BURDEN OF UNDIAGNOSED NCD POPULATION

The growing global burden of undiagnosed kidney disease, diabetes, and hypertension, all major non-communicable diseases (NCDs), is a significant public health concern, particularly in low and middle-income countries, where these diseases are increasingly prevalent and often lead to premature deaths. A substantial portion of individuals with these NCDs remain undiagnosed, particularly in low- and middle-income countries (LMICs). Approximately 50% of all individuals with diabetes are unaware of their condition, with 239.7 million people globally undiagnosed in 2021. Similarly, Hypertension is often underdiagnosed, especially in low- and middle-income countries and in India, high blood pressure is the most important risk factor for disease burden and mortality. Emerging economies such as India and China face substantial challenges in the early detection and management of NCDs, especially in rural areas with limited healthcare access.

2.2.3. GROWING BURDEN OF CARDIOVASCULAR DISEASES

Cardiovascular Disease (CVD) accounts for one-third of all global deaths, and about 80% of CVD deaths take place in low- and middle-income countries where raised blood pressure happens to be amongst the most important risk factors for CVDs. Of the 20.5 million CVD-related deaths globally in 2021, approximately 80% occurred in low- and middle-income countries. The prevalence of CVDs in India surpasses the global average by a significant margin. For instance, India's age-standardized death rate

for CVDs (282 deaths per 100,000, with a range of 264–293) exceeds the global figure (233 deaths per 100,000, with a range of 229–236).[11] India faces a heavy CVD burden. CVD accounts for 28% of all deaths in India, and in 2021, the country had 10.8 million CVD incident cases and 2.9 million deaths, representing 16.2% and 14.9% of the global CVD incident cases and deaths, respectively.

2.2.4. DRIVERS OF CARDIOVASCULAR DISEASES

Cardiovascular diseases (CVDs) are a leading cause of morbidity and mortality globally, influenced by a complex interplay of various risk factors.

Lifestyle Factors

Lifestyle choices significantly contribute to the prevalence of CVDs. Key lifestyle factors include:

- **Diet:** Poor dietary habits, characterized by high intake of saturated fats, trans fats, and sugars, can lead to obesity and hypertension, both of which are major risk factors for CVDs. A diet low in fruits and vegetables further exacerbates these risks.
- **Physical Inactivity:** Sedentary behavior is prevalent among populations such as truck drivers, leading to increased obesity rates and associated cardiovascular risks.
- **Smoking and Alcohol Use:** Tobacco use is a well-established risk factor for CVDs, contributing to the development of atherosclerosis. Excessive alcohol consumption can also lead to hypertension and other cardiovascular complications.

Physiological Factors

Several physiological conditions are closely linked to the development of CVDs:

- **Hypertension:** High blood pressure is a significant risk factor, responsible for approximately 50% of all deaths related to heart disease and stroke.
- **Obesity and Metabolic Syndrome:** Obesity is associated with various metabolic disorders, including diabetes and dyslipidemia, which increase the risk of CVDs. The prevalence of obesity among truck drivers is notably high, with studies indicating that 83.4% of long-haul truck drivers are overweight or obese.
- **Diabetes:** Diabetes mellitus is a significant risk factor for cardiovascular complications, as it can lead to increased blood sugar levels and subsequent damage to blood vessels .

Age and Gender

Age is a non-modifiable risk factor, with the incidence of CVDs increasing significantly in individuals over 55 years. Men are generally at a higher risk than women, although the risk for women increases post-menopause.

Genetic and Environmental Factors

[11] Secondary sources

Genetic predisposition plays a role in an individual's susceptibility to CVDs. Additionally, environmental factors such as air pollution and socioeconomic status can influence cardiovascular health. For instance, individuals living in areas with high pollution levels are at an increased risk of developing heart disease

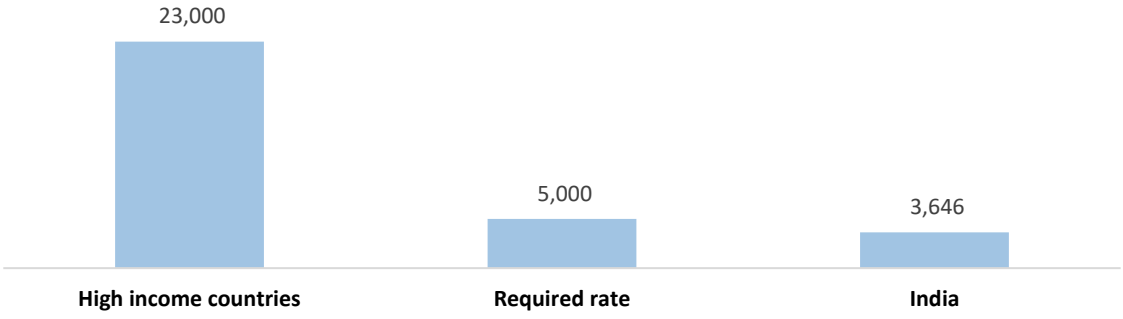
Psychosocial Factors

Stress, depression, and social isolation have been identified as contributing factors to cardiovascular health. Chronic stress can lead to unhealthy coping mechanisms, such as poor diet and smoking, further increasing the risk of CVDs.

2.3. SURGICAL VOLUME TREND

The Lancet Commission on Global Surgery (LCoGS) set the benchmark of 5,000 procedures per 100,000 population annually to meet surgical needs adequately. 11% of the global burden of disease requires surgical care or anaesthesia management or both. Some studies have estimated this burden to be as high as 30%. Most LMICs have surgical volumes below the LCoGS benchmark of 5,000 procedures per 100,000 population, with an average of 877 surgeries. Surgical volume is one of the indicators mentioned by LCoGS, which captures a country's met surgical need, with a benchmark of 5,000 procedures per 100,000 population annually in 2030. Many countries, especially low- and middle-income countries (LMICs), are facing a high burden of communicable diseases and an increasing burden of non-communicable and surgical diseases like cancers and road traffic injuries. Some countries report that less than 10% of the total surgical need are being met.[12] In India, studies estimate that around 3,646 surgeries are needed annually per 100,000 population to meet the surgical needs (significantly lower than the global benchmark), while the number of surgeries in high-income countries is estimated to be around 23,000 per 100,000 population. India conducts over 30 million surgeries annually, with approximately 82 per cent of procedures performed in small and medium hospitals. Out of the total healthcare spend, around 70% is on in-patient care, and more than 70% of the inpatient care spending is led by surgeries.[13]

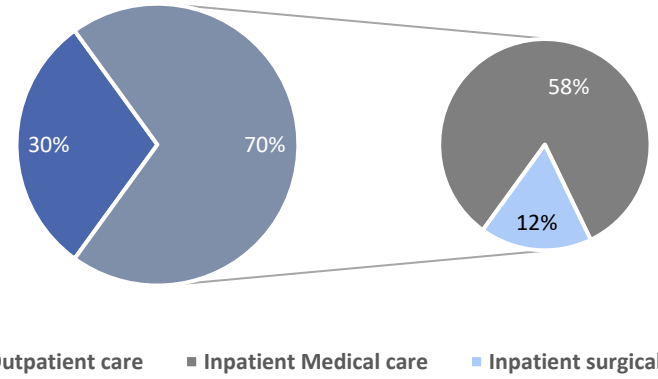
Exhibit 2.3: Surgeries per 100,000 population, 2024



Source: Lancet, Frost & Sullivan

[12] Secondary sources
[13] Secondary sources

Exhibit 2.4: Share of Outpatient and Inpatient Medical and Inpatient surgical care, India, 2024



Source: Frost & Sullivan

2.4. OVERVIEW OF INDIAN HEALTHCARE SERVICE PROVIDER INFRASTRUCTURE

India is one of the largest healthcare delivery systems globally. The country currently has 1.3 million doctors, with 90,000 doctors graduating annually from 595 medical colleges. India currently has 4.8 hospitals per 100,000 population. In the last decade, the country invested in building infrastructure, while in this decade, the country is focused on utilizing the infrastructure optimally to address access and affordability issues, continuing to invest in infrastructure optimally. According to the government of India, India has 0.7 government beds per 1,000 people, and the bed capacity in government hospitals across India has consistently grown from 470,000 lakh beds in 2005 to 860,688 beds in 2023.[14]

India has seen a notable rise in medical schools and graduate seats in response to the increasing need for healthcare professionals. The number of medical colleges has nearly tripled in the last two decades. The significant increase in medical colleges reflects a concerted effort to address India's growing demand for healthcare professionals. The number of registered allopathic doctors experienced substantial growth, increasing from 0.6 million in 2005 to 1.3 million in 2022.[14]

While India's healthcare infrastructure is large and growing in terms of absolute numbers, there is a significant disparity between the number of available beds and the number of beds necessary as per WHO standards. The data reveals that India has around 1.6 beds (government and private hospital beds) per 1,000 people, which is only about half of the recommended beds by WHO (3.0 beds per 1000). China, despite being one of the most populous countries in the world, scores well on the hospital bed density with 5.0 beds per 1,000 population. As per the estimates, the Indian hospital market poses significant opportunities to increase hospital beds by at least 30% to ensure fair access to healthcare facilities for all individuals. This would indicate that an additional 2.2 million beds[15] would be needed in the country's hospital sector over the next 15 years.

[14] Secondary Sources
[15] NITI Aayog report 'Investment Opportunities in India's Healthcare Sector', 2021

Table 2.3. Comparison of beds and physician density in select countries				
Country	**Beds/1000 people**	**Gap as per WHO bed requirement/1000 people**	**Physicians/1000 people**	**Gap as per WHO Physician requirement/1000 people**
India	**1.6**	**1.4**	**0.7**	**1.8**
US	2.7	0.3	3.6	-1.1
China	5.0	-2.0	2.5	0
Saudi Arabia	2.1	0.9	3.1	-0.6
France	6.0	-3.0	3.3	-0.8
United Kingdom	2.4	-0.6	3.2	-0.7
Germany	7.8	-4.8	4.5	-2.0
Vietnam	2.5	0.5	0.8	1.7
Thailand	2.3	0.7	0.9	1.6
South Korea	12.8	-9.8	2.5	0
Brazil	2.5	0.5	2.1	0.4
Mexico	1.0	2.0	2.6	-0.1
Poland	6.1	-3.1	3.4	-0.9
Italy	3.2	-0.2	4.2	-1.7
Spain	2.9	0.1	4.5	-2.0

Source: Based on the latest available data (2021) from WHO, Frost & Sullivan

India's healthcare market remains significantly underpenetrated, creating a critical gap in accessible medical infrastructure. This systemic shortfall presented a strategic opportunity for private healthcare operators to address unmet demand. Over time, private healthcare infrastructure—particularly specialized tertiary care facilities—has emerged as the cornerstone of India's healthcare ecosystem. The sector has since evolved into a multi-billion-dollar industry, redefining care delivery standards while establishing itself as a dominant economic and clinical force within the national healthcare landscape.

Globally, the WHO projects a shortfall of approximately 10 million healthcare workers by 2030, with low- and -middle-income countries being most affected. This shortage is exacerbated by an aging global population, an increasing burden of chronic diseases, and the lingering effects of the COVID-19 pandemic. While high-income countries such as the US, UK, Germany, France, and Australia generally have higher ratios of both doctors and nurses per capita, reflecting stronger healthcare infrastructure and investment, India, despite having large absolute numbers of healthcare professionals, shows lower per capita figures due to its massive population.

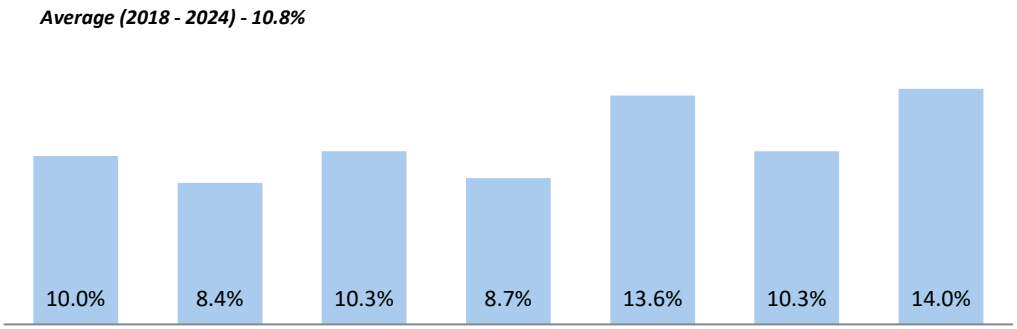
2.5. HEALTHCARE INFLATION AND INSURANCE ADOPTION IN INDIA

While annual retail inflation was at 5.2% in December 2024, the medical inflation is at 14.0%.[16] Over the past six years, healthcare inflation in India has outpaced general inflation rates, averaging 10.8%. The

[16] Secondary sources

high medical inflation is due to higher demand for healthcare services due to demand factors such as rising chronic diseases, increased affordability and increasing adoption of health insurance, and supply factors such as increase in equipment, labour, and raw material costs.

Exhibit 2.5: Healthcare Inflation in India, CY2018-2024



Source: Frost & Sullivan

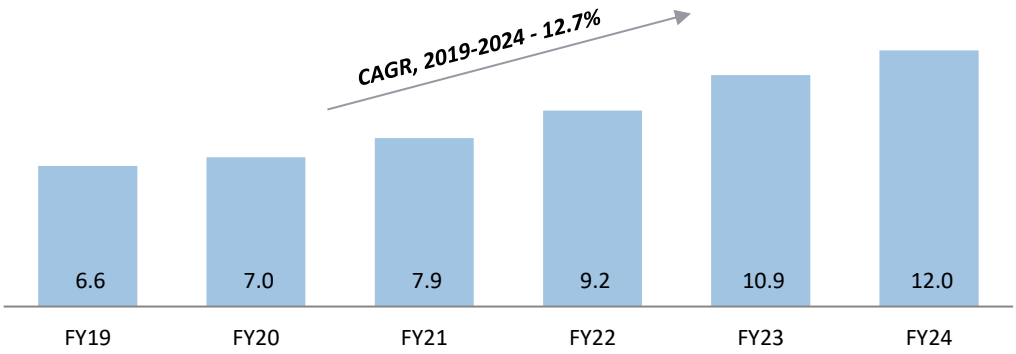
India is witnesing rising insurance adoption and increasing healthcare coverage from the Government.

India is witnessing increasing healthcare financing from the government. A pivotal government initiative, the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), provides comprehensive hospitalization coverage to approximately 70 crore individuaels, or the lower 50.0% of the population. Only about 37% of the total population (514 million people) are covered by health insurance schemes, leaving a significant portion uninsured.[17] Government expenditure as a percentage of healthcare expenditure in India has grown from 33.0% in 2017 to 39.1% in 2022. While India's Out-of-Pocket (OOP) healthcare spending has decreased from 55.1% in 2017 to at 46.0% in 2022 due to higher insurance penetration, it is notably high. Furthermore, this OOP burden surpasses that of Asian peers, who typically rely on OOP for approximately 30.0-35.0% of healthcare expenses, significantly exceeding the World Health Organization's recommended range of 15.0-20.0%[18].

The adoption of private health insurance is increasing in India, where the gross premium underwritten has increased from USD 6.6 billion in FY 2019 to USD 12.0 billion in 2024 at a high CAGR of 12.7%. Factors such as increased awareness of health insurance products, prevention of catastrophic health expenditure by households, increase in medical costs, increased acceptance of health insurance by hospitals and increase in household income are key drivers for the adoption of health insurance.

[17] Secondary sources
[18] WHO Report

Exhibit 2.6: Health insurance premium collection (USD Bn), FY2019-2024

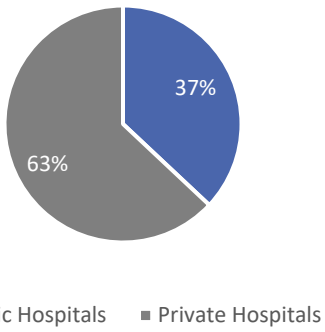


Source:IBEF, Frost & Sullivan

2.5.1. DOMINANCE OF PRIVATE SERVICE PROVIDERS

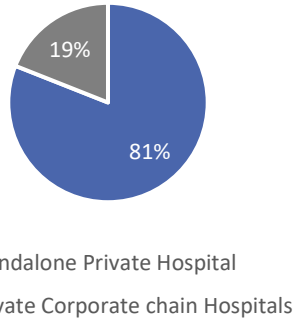
According to industry estimates, India has more than 73,000 hospitals, of which private hospitals account for about 63%, while the remaining are government hospitals. The private sector plays a dominant role in India's healthcare delivery system. In 2023, the private sector had approximately 1,185,242 beds compared to the public sector's 860,688 beds.[19] Within private hospitals, the majority of them are standalone private hospitals (81%) which are small and medium-sized hospitals, mainly offering secondary/higher-secondary care. Large hospital chains with facilities across multiple states and cities account for about 19% of the market.

Exhibit 2.7A: Share of Public and Private Hospitals in India, 2024



Source: Frost &

Exhibit 2.7B: Share of type of Private Hospitals in India, 2024



Source: Frost & Sullivan

Majority of the hospitals are clustered in 7 states i.e., Uttar Pradesh, Karnataka, Telangana, Kerala, Maharashtra, Tamil Nadu, and West Bengal. India's healthcare sector has witnessed remarkable transformation in recent years, with the private sector playing an increasingly prominent role. While hospitals have traditionally dominated healthcare delivery, a robust private ecosystem is now driving

[19] National Health Profile (2023); Medical Dialogues

growth in non-hospital healthcare settings. This shift represents a fundamental change in how healthcare is accessed and delivered across the country.

The private healthcare sector in India has expanded significantly, accounting for approximately 70-80% of all healthcare expenditures. This growth has been fueled by several factors including:

- Urbanization and rising middle-class populations with greater disposable incomes
- Increased awareness of health and wellness
- Government policies encouraging private sector participation
- Medical tourism generating approximately USD 5 to 6 billion annually

2.5.2. GROWING DEMAND FOR HOSPITAL AND CATH LAB INFRASTRUCTURE IN INDIA

The number of hospitals in India has been steadily increasing, particularly in the private sector, driven by factors like growing demand for healthcare services, increased disposable income, and advancements in medical technology. While the total number of hospitals has risen, the private sector has experienced a more substantial surge, outpacing the growth in public hospitals. The healthcare infrastructure in India has expanded significantly, with the number of hospitals increasing from approximately 43,500 in 2019 to more than 70,000 by 2024. India remains a preferred medical tourism destination because of the availability of high-end clinical procedures at a much cheaper rate compared to most countries.

The private sector has been instrumental in expanding healthcare infrastructure, particularly in areas where public healthcare institutions face challenges. While it is estimated that a total of 24,000 new beds will be added by private hospitals in the next 3 to 5 years, India requires 100,000 additional beds in the next 5-7 years just to meet its healthcare demand on the back of increasing non-communicable diseases such as diabetes, cardiac disorders, and cancer.

Similarly, the Cath lab infrastructure is rapidly growing in India. While India had about 650 Cath labs in 2015, it has grown to more than 2,500 in 2023, and about 200 to 250 new Cath labs are being set up each year. However, to meet the demand for cardiac and other minimally invasive procedures, India needs more than 7,500 Cath labs.

3. OVERVIEW OF THE GLOBAL MEDICAL DEVICE ECOSYSTEM

Medical devices, defined broadly, refers to instruments, apparatus, machines, implants, or similar articles used to diagnose, cure, mitigate, treat, or prevent disease, without being absorbed or metabolized by the body.[20]. It encompasses various products, including surgical instruments, diagnostic tools, and other capital equipment used across healthcare settings such as homes, clinics, hospitals, and laboratories. The industry produces an enormous variety of products, ranging from common medical supplies such as surgical gloves and syringes to advanced imaging equipment and implantable devices like cardiac

[20] Secondary sources

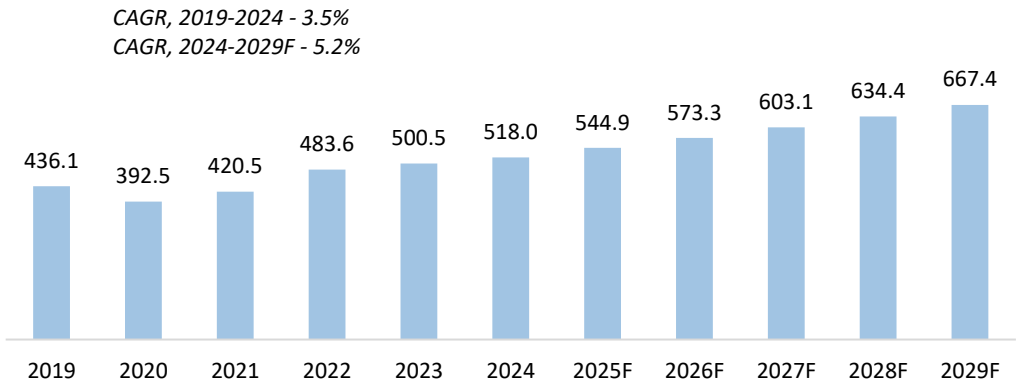
defibrillators and artificial joints. Currently, there are approximately 2.0 million types of medical devices available in the global market, categorized into over 7,000 generic device groups.[21]

3.1. GLOBAL MEDICAL DEVICE MARKET SIZE AND FORECAST

The medical device industry is poised for sustained growth of 5.2%, underpinned by continuous innovation, regulatory evolution, and shifting demographic trends.

The global medical device industry has undergone significant transformation over the past decade, driven by rapid advancements in technology, rampant deal-making, and value chain compression. In 2024, the industry was valued at approximately USD 518.0 billion, having grown at a CAGR of 3.5% from 2019 to 2024. With continued innovation, increased adoption of digital health solutions and artificial intelligence-driven diagnostics, increasing healthcare expenditures, improving infrastructure, and rising demand for early disease detection and personalized treatment, the market is forecasted to reach USD 667.4 billion by 2029, reflecting a projected CAGR of 5.2% during the 2024–2029 period.

Exhibit 3.1: Global Medical Device Market (USD Bn), 2019-2029F



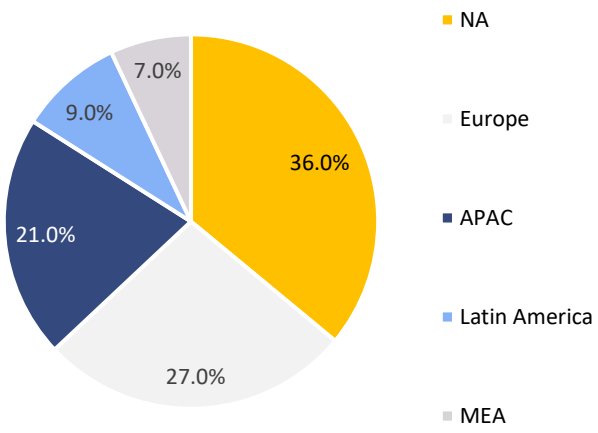
Source: Frost & Sullivan

[21] WHO: Medical Devices

3.2. MEDICAL DEVICE MARKET REVENUE SPLIT BY REGION

Among the regions, North America holds the highest revenue share in medical devices, with ~36.0% share. The region continues to benefit from well-established healthcare infrastructure, robust R&D investments, and favourable reimbursement policies, valuing the market at about USD 186.0 billion in 2024. Following North America, Europe region holds the second largest revenue, with ~27.0% share. Bolstered by regulatory harmonization under the MDR and strong adoption of innovative diagnostic and treatment modalities, the market is valued at about USD 140.0 billion. Asia-Pacific (APAC) regions hold the third largest share in the medical device market, with a share of 21.0% and valued at about USD 109 billion in 2024. Latin America medical device market has a share of about 9.0% and is valued at about USD 47 billion in 2024. The Middle East and Africa (MEA) medical device market has a share of about 7.0% and is valued at USD 36 billion in 2024.

Exhibit 3.2: Global Medical Device market, share by region, 2024

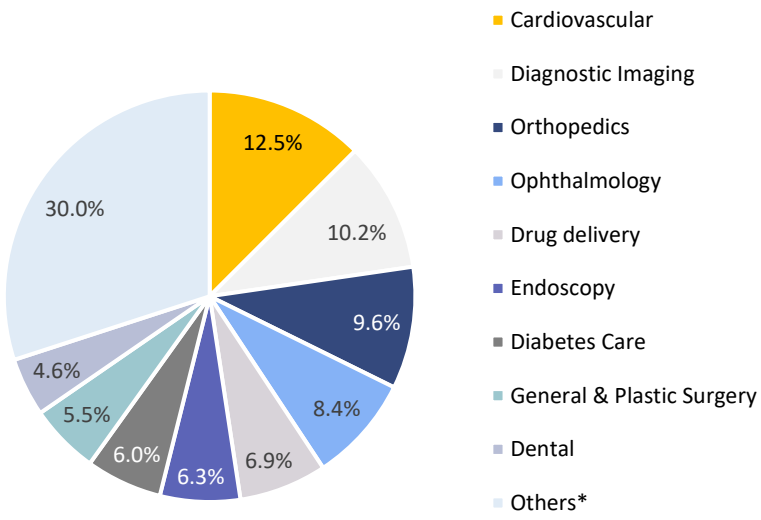


Source: Frost & Sullivan

3.3. MEDICAL DEVICE MARKET REVENUE SPLIT BY SEGMENTS

Among the medical device product segments, Cardiovascular devices account for the highest market share (12.5%), followed by other segments such as Diagnostic imaging (10.2%), Orthopedics (9.6%), Ophthalmology (8.4%), Drug delivery devices (6.9%) and Endoscopy devices (6.3%). The Cardiovascular devices market is estimated to grow at a CAGR of about 7.8% between 2024 and 2029. The increasing prevalence of cardiovascular diseases has boosted the use of medical devices in hospitals and clinics worldwide. Cardiovascular diseases like coronary artery disease, hypertension, heart failure, and arrhythmias are increasing globally and contribute to a major share in mortality worldwide

Exhibit 3.3: Global Medical Device market, share by segments, 2024



**Others include IVD devices, Neurovascualr devices, ENT, Uology and Dialysis devices*

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3.4. MEDICAL DEVICE REGULATORY ENVIRONMENT

Medical device companies benefit from a diversified product portfolio spanning different risk classes, enabling them to navigate regulatory challenges while optimizing market access and revenue streams. Strategic alignment with evolving global regulations is paramount to sustaining competitiveness in the dynamic medical device industry.

- Given the diversity of Medical device products, regulatory agencies worldwide classify them based on risk levels to ensure safety and efficacy. However, classification frameworks and approval processes vary significantly across regions, influencing market access, innovation timelines, and compliance costs for Medical device companies.

- The classification of medical devices has evolved as regulatory agencies recognized the need for structured, risk-based oversight. In one of the most stringent markets, in the United States, the Food and Drug Administration (FDA) formalized its classification system with the 1976 Medical Device Amendments, introducing three classes based on risk levels.[22]. Europe initially operated under the Medical Device Directive (MDD) before transitioning to the more stringent Medical Device Regulation (MDR), which follows a four-tier classification system. Japan's Pharmaceuticals and Medical Devices Agency (PMDA) adopted a similar four-class framework.

- India's regulatory landscape was historically fragmented, with limited oversight, until the introduction of the Medical Device Rules in 2017 under the Central Drugs Standard Control Organization (CDSCO),

[22] FDA: PMA Approvals

which established a structured classification system aligned with global best practices. Other emerging markets such as Turkey (MDR) and China (NMPA), while initially having less stringent regulatory frameworks, have progressively aligned with international standards to enhance compliance and global market access.

- While developed markets prioritize safety through rigorous regulatory oversight, emerging markets seek to balance safety with expedited approval pathways. As a result, India's evolving regulatory framework aligns with international best practices yet retains distinct approval mechanisms that shape market entry strategies.

- Medical device classification and approval processes present inherent complexities, particularly for high-risk devices. Medical devices, diagnostics, and capital equipment are categorized into different classes based on their potential risk to patients. Low-risk devices include items such as surgical gloves and blood pressure monitors, whereas high-risk devices encompass implantable pacemakers, artificial heart valves, and advanced imaging systems.

The classification frameworks of major regulatory agencies are structured as follows:

Table 3.1: Select Regulatory agencies and classification of Medical Device

Country	Classification	Definition by Class	Approval Pathways
USA (FDA)	Class I, II, III	Low, moderate, and high risk	Class I: General controls; Class II: 510(k) submission[23]; Class III: Premarket Approval (PMA)
European Union (MDR)	Class I, IIa, IIb, III	Low to highest risk	CE marking via notified bodies, clinical evidence required for higher classes
Japan (PMDA)	Class I, II, III, IV	Low to highest risk	Local clinical trials for high-risk devices
China (NMPA)	Class I, II, III	Low to high-risk	Local clinical trials are required for Class II and III unless prior approvals exist in major markets. For devices that pose high risks to human health, NMPA approval is particularly stringent, and local trials are more likely to be mandated
India (CDSCO)	Class A, B, C, D	Low to highest risk	Class A: Self-certification; Class B: Notified body certification; Class C & D: CDSCO approval with clinical data for novel devices

Source: Frost & Sullivan

- Low-risk devices, such as surgical instruments, thermometers, and basic diagnostic tools, often undergo simplified approval pathways. In the US, many Class I devices are exempt from premarket notification, requiring only adherence to general controls for quality and labeling compliance. Similarly, in India, Class A devices require self-certification, while Class B devices undergo third-party certification. However, as risk levels escalate, regulatory complexity increases substantially.

- Class III devices (FDA and European MDR classification) and Class C and D devices (Indian classification), are typically intended to support or sustain human life, are implanted in the body, and

[23] Under the 510(k) pathway, a medical device manufacturer submits a premarket notification to the FDA, demonstrating that the device is "substantially equivalent" to a device that has already been cleared by the FDA and is in commercial distribution.

present a potential high risk if they fail. Examples include heart valves, implantable pacemakers, and certain types of surgical mesh. Due to this, regulatory authorities impose the most stringent requirements on these products. The process to bring a Class III device (and Class C/D medical device) to market typically involves extensive pre-clinical and clinical testing, comprehensive regulatory submissions and strict manufacturing controls. These requirements create significant financial, technical, and operational barriers to entry, and new entrants must invest heavily in R&D, regulatory expertise, and compliance infrastructure. In developed markets, approval pathways for Class III devices include the FDA's Premarket Approval (PMA) process, which entails comprehensive clinical trials and stringent safety benchmarks, the European MDR's requirement for robust clinical evidence, and Japan's PMDA mandate for local clinical trials. Conversely, emerging markets such as India and China offer expedited approvals for devices already recognized by regulators in the US and EU.

- Regulatory complexity significantly influences market strategies for MedTech companies, necessitating a well-defined approach to navigating diverse approval pathways. Companies must develop comprehensive regulatory strategies that account for region-specific compliance requirements, separate clinical trial mandates, and evolving regulatory frameworks. Diversification across different classes of devices mitigates regulatory risks and revenue fluctuations.

- Companies with devices in Class III category benefit from high barriers to entry due to stringent regulations and high investments required for clinical trials and building brand reputation. MedTech companies need to carefully assess each region's regulatory landscape, weighing the benefits of expedited approvals in emerging markets against the predictability and stringent safety requirements in developed markets to get strong market access. Cost and resource allocation are crucial, as high-risk devices necessitate substantial R&D investments, specialized regulatory expertise, and extended approval timelines.

Challenges in regulatory compliance, manufacturing, and market access differ by risk classification, influencing the ability of companies to scale operations efficiently:

Table 3.2: Risk-based classification of Medical Devices and Regulatory challenges

Class	Regulatory Challenges	Example	Manufacturing Challenges	Market Access Challenges
Low-risk (Class I/A)	Varied exemptions and compliance requirements across regions	Bandages, Stethoscopes, Thermometers	Standardized processes but competitive cost pressures	Rapid market entry but price sensitivity
Moderate-risk (Class II/B)	Special controls and variable premarket requirements	Blood pressure monitors, Hearing Aids, Surgical gloves	Higher quality assurance costs and design controls	Greater differentiation is needed for competitive positioning
High-risk (Class III/C)	Extensive clinical data requirements, prolonged approval timelines	X-Ray Machines, Defibrillators, Hemodialysis machines,	Complex manufacturing processes, stringent validation needs	Higher market entry barriers, reimbursement complexities

		Cardiac Monitor		
Highest-risk (Class IV/D)	Rigorous regulatory scrutiny, mandatory clinical trials, post-market surveillance	Cardiac pacemakers, Heart Valves, Orthopedic Implants, Stents	Advanced R&D investments, sophisticated manufacturing infrastructure	Comparatively limited market size by volume, high cost of commercialization

Source: Frost & Sullivan

3.5. MARKET DYNAMICS IN THE GLOBAL MEDICAL DEVICE INDUSTRY

3.5.1. INCREASE IN BURDEN OF CHRONIC NON-COMMUNICABLE DISEASES (NCD)

The global prevalence of chronic NCDs continues to escalate, driving demand for advanced medical technologies. NCDs already account for more than half of the global burden of disease and account for 1.73 billion Disability Adjusted Life Years (DALY)[24]. The main types of NCDs include cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes. These diseases are often associated with older age groups but also affect younger individuals, with 17 million NCD deaths occurring before the age of 70 in 2021.

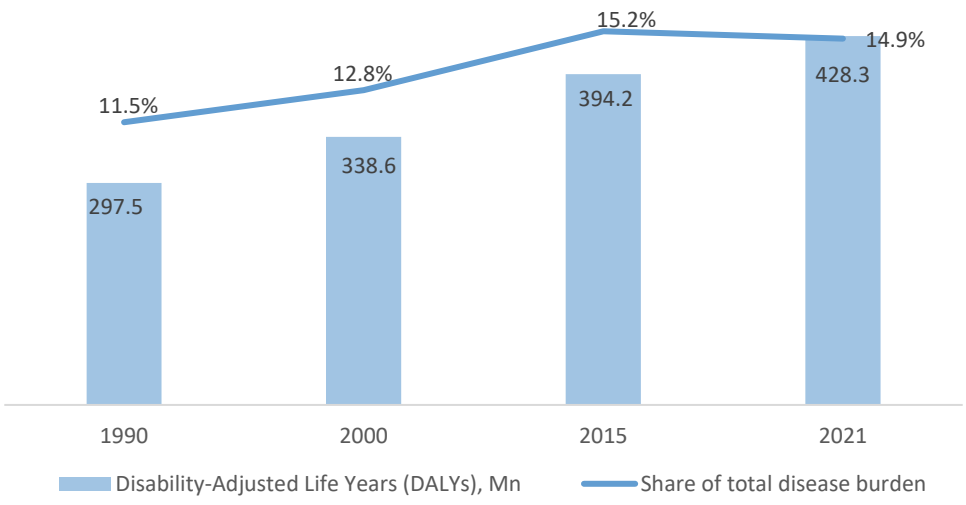
Cardiovascular diseases (CVDs) represent the leading cause of mortality worldwide, accounting for nearly 20.5 million deaths annually in 2021, which translates to approximately 32% of total global deaths. The annual Cardiovascular disease mortality is expected to increase to 22.2 million by 2030 and 35.6 million in 2050.

The burden of CVD continues to rise due to an aging population and increased prevalence of risk factors such as hypertension, diabetes, obesity, smoking, and sedentary lifestyles. It is estimated that over a billion people globally live with some form of cardiovascular disease, ranging from coronary artery disease and heart failure to arrhythmias and valvular disorders. The impact of cardiovascular diseases is not only measured in terms of mortality but also the quality of life lost and the economic burden on healthcare systems. CVDs contributed to nearly 430 million disability-adjusted life years (DALYs) lost annually in 2021, which has increased from about 298 million in 1990, and the share of CVD of the total disease burden has increased from 11.5% in 1990 to 14.9% in 2021.[25]

[24] A Disability-Adjusted Life Year (DALY) is a measure of the overall disease burden, expressed as the number of years of healthy life lost due to premature death, disability, or ill-health. It combines years of life lost due to premature mortality (YLLs) with years of life lived with a disability (YLDs). One DALY represents the loss of one year of full health.

[25] Secondary sources

Exhibit 3.4: Cardiovascular Disease Burden, 1990 to 2021



Source: IHME, Global Burden of Disease study, Frost & Sullivan

3.5.2. INCREASE IN NUMBER OF CLINICIANS AVAILABLE TO TREAT CARDIAC CONDITIONS

The increase in the number of clinicians available to treat cardiac conditions is a significant trend in the global healthcare landscape. This growth is driven by several factors, including advancements in medical education, the expansion of telehealth services, and the increasing demand for specialized care due to rising rates of cardiovascular diseases. Many countries are investing in expanding their medical education systems to produce more healthcare professionals. For example, in 2024, the WHO reported that 189 countries (97%) provided stock data for more than five occupations, and 137 countries (71%) reported data for more than 10 occupations, indicating a broader and more specialized healthcare workforce. This expansion includes training more cardiologists and other specialists focused on cardiovascular health. India has the highest number of cardiac surgeons.

India has about 800 cardiac surgeons (table 3.2), and among the South Asian countries, India has the highest number of cardiac surgeons, primarily due to its large population. Between 2017 and 2022, there has been a 20% to 30% increase in the number of cardiac surgeons across South Asia, thanks to a consistent output of new professionals in the field. Most cardiac surgeons in this region are trained locally, as India, Pakistan, Bangladesh, Sri Lanka, and Nepal have established their own education and training systems for cardiovascular and thoracic surgeons. Globally, specialized education and training in cardiothoracic surgery began in the 1960s, with India being the pioneer in the South Asia region for initiating these specialized programs.[26]

[26] Secondary sources

3.5.3. EXPANSION OF REIMBURSEMENT AND INSURANCE COVERAGE

- The expansion of insurance coverage for cardiac procedures and day-surgery cases is a multifaceted trend, driven by advancements in medical technology, evolving healthcare policies, and a growing emphasis on cost-effectiveness. While most developed and emerging economies have coverage for cardiovascular procedures either under public reimbursement programmes, it is covered under most of the voluntary private health insurance schemes.

- In 2019, the Centers for Medicare & Medicaid Services (CMS) of the US began transitioning reimbursement for certain cardiovascular procedures, including Percutaneous Coronary Intervention (PCI), to the ambulatory surgery center (ASC) setting. This shift aims to lower the cost of care and create greater cost savings for patients by moving procedures to lower-cost environments. In 2020, the CMS added 17 new cardiac procedures to the list of ambulatory surgery center (ASC)--approved procedures, including angioplasty procedures. This change is expected to move more PCI and angiography procedures into ASCs, reducing costs and increasing accessibility. Private insurance companies in the U.S. also cover PCI procedures, though specific coverage details vary by plan. The shift toward value-based care has influenced reimbursement, linking it to the effectiveness of the device and patient outcomes. Further, the CMS proposed payment rate increases for ambulatory surgical centers (ASCs) conducting cardiovascular procedures that meet quality reporting requirements. For 2025, CMS has proposed a 2.6% increase in payment rates for ASCs. This is expected to encourage more cardiac procedures to be performed in outpatient settings, which are typically lower cost compared to inpatient settings.

- European markets such as Germany, Poland, Spain, and Italy are notable for their stringent regulatory environments, complex tendering processes, and high demand for clinically validated, innovative products. Germany, known for its stringent regulatory environment and group purchasing organization-driven procurement, operates under a Diagnosis Related Groups (DRG) system for hospital procedures. Germany’s medical device market is highly regulated market that demands implantable medical devices (e.g., DES, TAVI) to meet strict clinical validation and reimbursement standards. The country’s high entry barriers such as the need for robust clinical data, “zero backorder” supply capabilities, and competitive pricing make it accessible only to mature, globally capable players. Catheters used in surgery or diagnostic settings are reimbursed as part of the overall DRG payment. This system helps to ensure that cardiac procedures are covered under public insurance, making them more accessible to patients.

- Reimbursement in France is handled by Assurance Maladie, the French social security system. Catheters are reimbursed as part of procedural costs, with special provisions for home care patients using urinary catheters. Strict pricing regulations apply to ensure that only cost-effective products are reimbursed.

- Italy's public healthcare system, the Servizio Sanitario Nazionale (SSN) covers most cardiac procedures which are reimbursed under the Fee-for-Service (FFS) model. Healthcare providers charge for each service or procedure, and the SSN reimburses them based on predefined fee schedules. Patients receive cardiac procedure services at public hospitals or SSN-designated private

hospitals. The hospital bills the SSN directly based on the procedure and applicable reimbursement standards. Patients pay the co-payment portion at the time of service. The SSN sets reimbursement limits for medical devices used in cardiac procedures. If the actual cost of a device exceeds the reimbursement limit, patients must cover the excess out-of-pocket. For example, drug-eluting stents used in coronary angioplasty have a reimbursement cap set by the SSN. Stents priced above this cap require patients to pay the difference.

- Brazil's healthcare system is a three-tiered model comprising the public healthcare system (Sistema Único de Saúde, or SUS), private healthcare, and supplementary health services. SUS reimburses healthcare providers through a combination of capitation payments and fee-for-service (FFS) based on service volumes. SUS covers a wide range of cardiac procedures, such as coronary angiography, coronary angioplasty, and coronary artery bypass grafting (CABG). However, due to resource constraints and long waiting times, patients may face delays in accessing these procedures. SUS typically reimburses healthcare providers using FFS or DRG (Diagnosis-Related Groups) payment systems. In FFS, providers charge for each service or procedure, and SUS reimburses based on predefined fee schedules. Under DRG, patients are categorized by diagnoses and procedures, with a fixed reimbursement amount per case. As the largest healthcare market in LATAM region, Brazil is expanding public coverage under SUS. There is growing demand for cost-effective, clinically proven implantable solutions like DES and TAVI, especially in public and hybrid private-public hospital settings. Reimbursement processes are evolving, making early presence critical.

- South Korea implements a public and single-payer healthcare system based on fee-for-service payments. The National Health Insurance (NHI) covers most medical services, including cardiac procedures. FFS is the most common reimbursement method for cardiac procedures in South Korea. Healthcare providers charge for each service or procedure, and the NHI reimburses them based on predefined fee schedules. For example, for coronary angiography and percutaneous coronary intervention (PCI), fees are charged separately for the procedure, medical devices, and medications, with the NHI reimbursing a certain percentage of these costs. The Health Insurance Review & Assessment Service (HIRA) sets reimbursement limits for medical devices used in cardiac procedures. If the actual cost of a device exceeds the reimbursement limit, patients must cover the difference out of pocket. For instance, for drug-eluting stents used in PCI, HIRA specifies a reimbursement limit. Stents priced above this limit require patients to pay the excess cost. Additionally, some advanced or imported medical devices may not be fully reimbursed or may have relatively low reimbursement rates.

- In India, there is increased insurance coverage for cardiac procedures and day-surgery cases in India, including specialized heart insurance plans and broader coverage in general health insurance policies. These plans often cover hospitalization expenses, pre- and post-hospitalization costs, and even preventive check-ups. Critical illness insurance policies offer lump-sum payments for heart-related ailments. Cardiac treatment related insurance claims in India have doubled over the past five years. In the financial year 2023-2024, heart-related claims constituted 18-20% of total health insurance claims, up from 9-12% in 2019-2020.[27] Moreover, the Indian government’s PMJAY scheme

[27] Secondary sources

provides coverage for a wide range of cardiac procedures. This includes procedures like Coronary Artery Bypass Grafting (CABG), Percutaneous Transluminal Coronary Angioplasty (PTCA), and valve replacements. The scheme aims to provide cashless and paperless treatment for these procedures in empaneled hospitals.

- Vietnam is a fast-developing market in the APAC region which is investing aggressively in universal health coverage. Public hospitals are increasingly adopting advanced interventions like DES and TAVI, supported by government co-financing and foreign aid. Market access is driven by affordability, local partnerships, and early regulatory engagement.

Advancements in less invasive techniques, such as percutaneous coronary interventions (PCIs), transcatheter aortic valve implantation (TAVIs), and other catheter-based procedures have made day-surgery a viable option for many cardiac procedures, leading insurance companies to recognize their cost-effectiveness and patient benefits. Healthcare systems across nations are increasingly focused on shifting procedures from inpatient to outpatient settings to reduce costs and insurance companies are aligning their coverage policies with this trend, encouraging the use of day-surgery facilities and outpatient clinics.

3.5.4. REGULATORY TRENDS DRIVING ADOPTION OF CARDIOVASCULAR PROCEDURES

3.5.4.1. EU MDR TRANSITION FROM MDD

Europe initially operated under the Medical Device Directive (MDD) before transitioning to the more stringent Medical Device Regulation (MDR)

- **Stricter Approval Process**: The EU MDR introduces a more rigorous approval process for medical devices, including those used in cardiac procedures. This includes enhanced clinical evidence requirements, particularly for high-risk devices. Manufacturers must now provide more comprehensive data to demonstrate the safety and effectiveness of their products.
- **Extended Scope**: The MDR extends the scope of regulation to include a broader range of products, such as software and certain aesthetic devices, which were not previously covered under the MDD. This ensures that all devices used in cardiac procedures, from diagnostic tools to implantable devices, are subject to the same high standards.
- **Post-Market Surveillance**: The MDR places a greater emphasis on post-market surveillance, requiring manufacturers to continuously monitor the performance of their devices once they are on the market. This helps to identify and address any issues that may arise in real-world use, ensuring patient safety over the long term.
- **Transparency and Traceability**: The new regulation enhances transparency by requiring manufacturers to provide more detailed information about their devices, including their design, manufacturing processes, and clinical data. This information is made available through the

European Database on Medical Devices (EUDAMED), improving traceability and allowing for better oversight by regulatory authorities and healthcare providers.

- **Clinical Evidence Requirements**: The MDR raises the bar for clinical evidence, necessitating more robust studies and data to support the approval of devices. For cardiac procedures, this means that devices must be backed by stronger evidence of their effectiveness and safety, leading to better outcomes for patients.
- **Notified Bodies**: The role of Notified Bodies has been strengthened under the MDR. These organizations are now required to conduct more thorough assessments of devices, particularly for high-risk products. This ensures that only devices that meet the highest standards are certified and allowed in the market. A notified body is an organisation designated by an EU Member State (or other countries under specific agreements) to assess the conformity of certain products.

3.5.4.2. US FDA REGULATIONS

- **Premarket Approval (PMA) Process**: High-risk Class III devices, including implantable cardioverter-defibrillators (ICDs), pacemakers, coronary stents, and artificial heart valves, are reviewed via the PMA process. This process is generally regarded as the most rigorous medical device regulatory review process in the world. The applicant must provide valid scientific evidence to demonstrate the device's safety and effectiveness for its intended use(s). The FDA will then review the data submitted by the applicant, which may include clinical trial results, nonclinical testing data, and manufacturing information. It typically takes several years for a medical device to complete the PMA process and receive FDA approval.

- **Post-Market Surveillance**: The FDA has recently pushed for improved post-market surveillance of high-risk medical devices. While post-market device evaluation is important, studies show that physicians are quick to adopt new device technologies once they gain FDA approval.
- **Comparative Effectiveness Research**: There is a clear need for good comparative effectiveness data for new technologies, but there are particular issues with designing comparative clinical trials and interpreting CER assessments in the context of new medical devices.

3.5.4.3. GLOBAL HARMONIZATION

- **Global Regulatory Harmonization**: There is a growing push for global regulatory harmonization to streamline the approval process for medical devices. This includes initiatives to align regulatory requirements across different jurisdictions, such as the US, EU, and Japan, to facilitate faster access to innovative devices.

- **Joint Approval Processes**: Some strategies include considering a pilot program for joint approval processes of selected devices in partnership with other regions, such as the US Food and Drug Administration (FDA), to ensure timely access to innovative devices.

The regulatory trends driving the adoption of cardiac procedures are focused on enhancing patient safety, improving device performance, and ensuring timely access to innovative technologies. These trends are expected to continue as regulatory bodies adapt to the evolving landscape of medical device innovation. The stricter regulatory requirements under the MDR and FDA regulations lead to higher quality and safer medical devices, which is crucial for cardiac procedures where patient safety is paramount. While the MDR imposes stricter regulations, it also encourages innovation by setting higher standards that push manufacturers to develop safer and more effective devices. The transition to MDR may initially slow down the approval process as manufacturers adapt to the new requirements. However, in the long term, it is expected to streamline market access by creating a more uniform and transparent regulatory environment.

In countries such as China and India, the price caps introduced on stents are driving efforts to make these devices more affordable and accessible. The price caps have changed the market dynamics, with improved availability of affordable stents increasing their usage by about 40% and driving the demand for domestic products. The National Pharmaceutical Pricing Authority (NPPA) in India has imposed price caps on cardiac stents in 2017, reducing their prices by up to 85%. The ceiling price for bare metal stents was set at Rs 7,260, currently revised to 10,510 and for drug-eluting stents at Rs 29,600, currently revised to 38,267. This has made stents more affordable for patients, potentially increasing the adoption of procedures like angioplasty. China has implemented a national procurement policy to reduce the prices of medical devices, including cardiac stents. This policy has led to significant price reductions, with coronary stents now available at around 700 yuan, down from about 13,000 yuan. This move aims to make these life-saving devices more affordable and accessible to a broader population.

3.6. COMPARISON OF CARDIAC SURGEONS ACROSS GEOGRAPHIES

It is estimated that 1 to 1.5 million cardiac surgical procedures take place each year, and the average total cardiac surgical volume was 123.2 per 100,000 population per year. There is a huge demand for cardiac surgeons, especially in low and middle-income countries. The density of cardiac surgeons varies significantly across countries and regions, with high-income countries having a much higher density compared to low- and middle-income countries. Developed nations in North America and Western Europe tend to have a higher concentration of cardiac surgeons. Many developing countries, particularly in sub-Saharan Africa and parts of Asia, face significant shortages. This disparity contributes to unequal access to cardiac surgical care globally. This huge supply gap has raised awareness for the need of training and educational programs for cardiac surgeons in low and middle-income countries, which in turn is expected to drive the number of cardiac procedures and sale of required medical devices accordingly.

Countries such as the US, Brazil, Germany, South Korea, and Italy have more than a thousand cardiac surgeons, with the US having as high as 3,946[28]. As per the density of cardiac surgeons per million population, South Korea has the highest (22.1) followed by Italy (17.3), Germany (13.3) and the US (11.6). India has only about 800 cardiac surgeons, and the number is woefully short of the demand. The density of cardiac surgeons in India is very low (0.6 per million population).

[28] As per latest available data from various secondary sources and estimates.

Table 3.3: Cardiac Surgeons density across select countries, 2023		
Country	**Cardiac surgeons**	**Estimated Cardiac surgeon per million**
US	3,946	11.6
Brazil	2,560	10.4
Germany	1,113	13.3
South Korea	1,139	22.1
Italy	1,033	17.3
Spain	363	7.6
France	350	5.3
UK	250	3.7
India	**800**	**0.6**

Source: Secondary sources, Frost & Sullivan estimate

3.7. IMPORTANCE OF CATHETERIZATION (CATH) LABS

Cath Labs, or catheterization laboratories, are specialized facilities equipped with advanced imaging systems and interventional devices for diagnosing and treating heart-related conditions. Cath labs are crucial for diagnosing and treating a wide range of cardiovascular conditions. Their importance stems from their ability to provide minimally invasive procedures that offer significant benefits to patient.

Cath labs play a crucial role in Cardiovascular therapy due to the following reasons:

- **Diagnostic and Treatment Capabilities**: Cath Labs are primarily used for diagnosing and treating cardiovascular diseases, such as coronary artery disease and structural heart defects. They enable minimally invasive procedures like angioplasty, stenting, and pacemaker implantation.
- **Minimally Invasive Procedures**: Cath Labs use minimally invasive techniques, which reduce recovery times and improve patient outcomes. These procedures are often preferred over traditional open-heart surgeries due to their lower risk and shorter recovery periods.
- **Advanced Imaging Technology**: Cath Labs are equipped with state-of-the-art imaging systems, such as 3D and 4D imaging, rotational angiography, Intravascular Ultrasound (IVUS) and Optical Coherence Tomography (OCT). These technologies allow for precise visualization of the heart's internal structures, enhancing diagnostic accuracy and procedural efficiency.
- **Support for Complex Surgeries**: Cath Labs are essential for performing complex cardiac interventions, including transcatheter aortic valve implantation (TAVI), MitraClip repairs, and left atrial appendage (LAA) occlusions. These procedures are becoming increasingly common as the population ages and the prevalence of cardiovascular diseases rises.
- **Training and Education**: Cath Labs also serve as training grounds for medical professionals, enabling them to develop and refine their skills in interventional cardiology. This helps to ensure a continuous supply of skilled healthcare providers capable of delivering high-quality care.

Emerging Trends in Cath Labs

The field of Cath Labs is rapidly evolving, driven by technological advancements and changing healthcare needs. Some key emerging trends include:

- **Hybrid Cath Labs**: These labs combine the benefits of traditional Cath Labs with advanced imaging capabilities, enabling comprehensive cardiac care in a single setting. They allow for faster recovery times, reduced hospital stays, and improved patient outcomes.
- **Robotic-Assisted Interventions**: Robotic systems are revolutionizing Cath Lab procedures by offering enhanced precision, control, and efficiency. They reduce radiation exposure for healthcare professionals and improve patient outcomes by allowing for more accurate and delicate maneuvers during complex procedures.
- **Integration of AI and Machine Learning**: Artificial intelligence and machine learning algorithms are being integrated into Cath Lab procedures to improve diagnostic accuracy and procedural efficiency. These technologies enable real-time decision-making and enhance the ability to predict and respond to potential complications.
- **Virtual and Augmented Reality**: Virtual and augmented reality technologies are gaining traction in Cath Labs for enhanced procedural planning and training. They provide immersive experiences that help physicians better visualize and understand complex cardiac conditions.
- **Mobile Cath Labs**: Mobile Cath Labs are becoming more prevalent, especially in regions with limited access to advanced cardiac care. These labs enhance accessibility and cost-efficiency, making advanced cardiac procedures available to a broader population

Recent advancements in procedures and emerging technologies are significantly transforming treatment processes in Cath labs. Diagnostic angiogram and angioplasty procedures are increasingly replacing traditional surgery, allowing many patients to be discharged on the same day as their treatment. In India, hospital-based Cath labs dominate the market, capturing over 95 percent of the revenue share. This trend can be attributed to the growing number of corporate hospital-based Cath labs, favorable reimbursement policies, and access to high-quality care and equipment in these settings.

Freestanding Cath labs are also experiencing notable growth due to their lower service costs and more efficient treatment processes. During the Covid-19 pandemic, many patients opted for independent labs to reduce the risk of infection associated with hospital-based settings, which faced challenges due to the pandemic's impact. Additionally, patients favor independent Cath labs because they do not require an overnight admission post-surgery, allowing for quicker recovery.

Ambulatory Catheterization centers offer enhanced personalized patient care, which is often difficult to achieve in hospital environments. Furthermore, automated Cath labs are increasingly sought after, as they help reduce the workload for cardiologists. With the introduction of artificial intelligence-enabled diagnostic imaging platforms, interventional cardiology systems can now guide non-invasive cardiovascular procedures with improved precision and versatility.

The number of Cath labs and their density per million population varies widely across countries. While India has a higher number of Cath labs, the density per million population is only 1.8. Similarly, while US

has 2,000 Cath labs, the density is lower (5.9 per million) compared to countries such as Germany (11.8 per million), Italy (7.3 per million) and South Korea (7.2 per million), which have higher Cath lab density.

Table 3.4: Cath Lab density across select countries, 2023

Country	Cath Labs	Cath Lab per million
US	2,000	5.9
Brazil	1,100	5.2
Germany	990	11.8
South Korea	375	7.2
Italy	436	7.3
Spain	265	4.7
France	330	5.0
UK	323	4.7
India	**2,500**	**1.8**

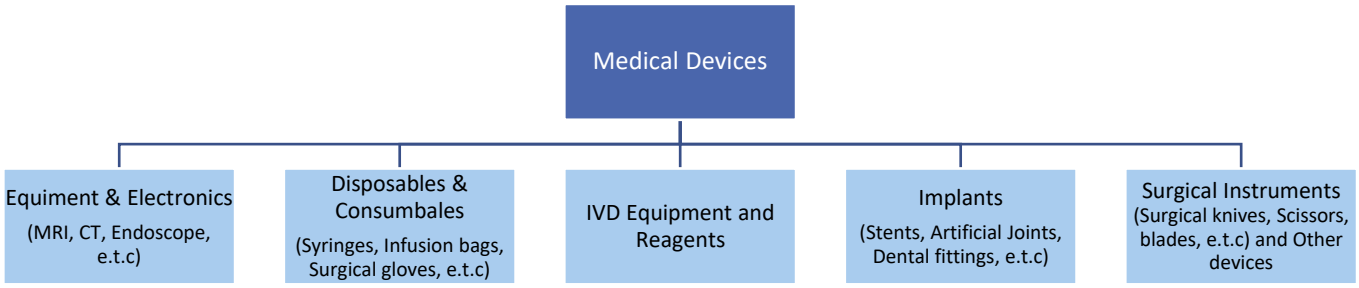
Source: European society of cardiology, Frost & Sullivan estimate

4. OVERVIEW OF THE INDIAN MEDICAL DEVICE ECOSYSTEM

Major segments of the Indian Medical device industry include Equipment and Electronics, Disposables and Consumables, IVD equipment and Reagents, Implants, Surgical Instruments and other devices. India is counted among the top 20 global medical device markets in terms of value. The Indian Medical Device market[29] is the fastest growing segment in the Indian healthcare market, and it is estimated to reach USD 60.2 Bn by 2030 at a growth rate of 20.4% from its estimated value of USD 16.4 Bn in 2023.[30] The Indian Medical device market is estimated to contribute 1.65% of the global medical device market as of 2023, and India aims to reach 10-12% in global market share within 25 years. Export of medical devices from India increased from USD 2.3 Bn in 2020 to USD 3.4 Bn in 2023 at a CAGR of 14.0%, and it is projected to reach USD 18.0 Bn in 2030 at a CAGR of 27% between 2023 and 2030.[31] The major export countries for Indian Medical devices are the US, Germany, China, Singapore, France, Türkiye, Brazil, The Netherlands, Iran, and Belgium. India exported most medical devices to the US (USD 668.9 Mn) in 2023, followed by export to Germany (USD176.2 Mn), China (USD145.6 Mn), and the Netherlands (USD 106.5 Mn).[32]

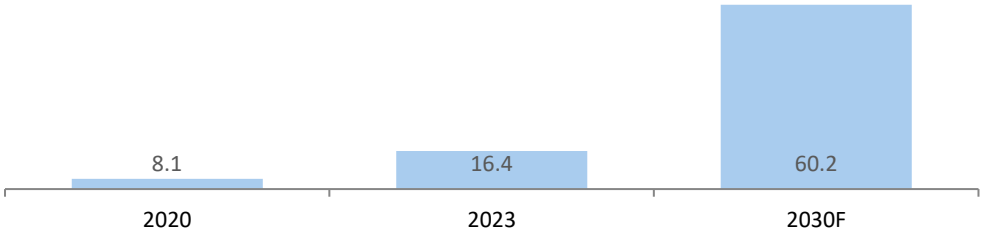
[29] Includes domestic consumption and exports
[30] Foundation of MSME Clusters, Global Trade Research Initiative, Indian Brand Equity Foundation
[31] IBEF
[32] AiMED, Secondanry sources

Exhibit 4.1: Key Segments of the Indian Medical Device Industry



Source: Foundation of MSME Clusters, Frost & Sullivan

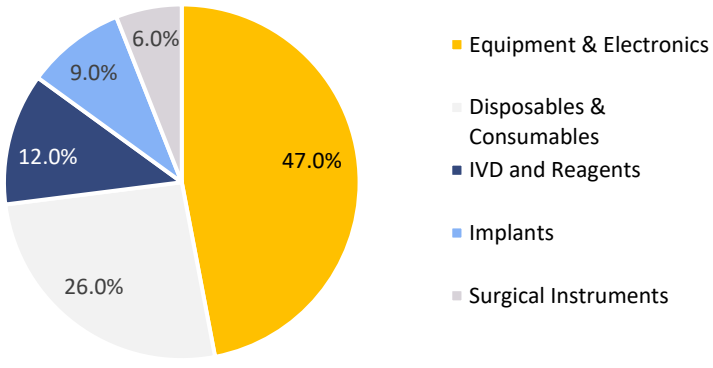
Exhibit 3.6: Indian Medical Device Market* (USD Bn), 2020-2030F
CAGR 2023 - 2030F: 20.4%



**Included exports; Source: IBEF, Foundation of MSME Clusters, Frost & Sullivan*

Among the segments of the Indian Medical Device market, Equipment and Electronics has a major revenue share of the total market (47%), followed by Disposables and Consumables (26%), IVD and Reagents (12%), Implants (9%), and Surgical Instruments (6%).

Exhibit 3.7: Share of mdical device segments, 2023



Source: Frost & Sullivan

Table 4.1: Market Size of Indian Medical Device Segments (USD Bn)			
Segment	**Market Size 2023**	**Estimated Market Size 2030F**	**Forecast CAGR (2023-2030)**
Equipment & Electronics	7.7	24.2	17.8%
Disposables & Consumables	4.3	17.1	21.8%
IVD and Reagents	2.0	8.5	23.0%
Implants	1.5	5.4	20.4%
Surgical Instruments	1.0	5.0	25.4%
Total	**16.4**	**60.2**	**20.4%**

**Total may vary due to rounding error; Source: Foundation of MSME Clusters, Frost & Sullivan*

The Indian Medical Device market is transitioning from being import-dependent with increase in domestic production and an increasing share of exports. Medical Device exports from India is expected to grow from USD 3.4 Bn in 2023 to USD 18.0 Bn in 2030. Increasingly, the domestic manufacturers are gaining market share and are meeting the demands of both domestic and international markets with their innovative products. As per statement by Indian Brand Equity Foundation (IBEF), India has achieved a significant milestone in the medical goods sector by transitioning to a net exporter of medical consumables and disposables in 2022-23.[33]

Table 4.2. Indian Medical Device market, Export trend (2023-2030F)		
Year	**2023**	**2030F**
Indian Medical Device Market (Domestic Consumption) (USD Bn)	13.0	42.2
Indian Medical Device Exports (USD Bn)	3.4	18.0
Total Indian Medical Device Industry including exports	**16.4**	**60.2**

Source: IBEF, Foundation of MSME Clusters, Global Trade Research Initiative, Frost & Sullivan

Indian Medical device companies have established a strong foothold in the domestic as well as international market due to their ability to deliver quality medical products, various government-led initiatives aimed at fostering growth, including the PLI Scheme and Medical Devices Parks Scheme[34], and availability of skilled talent and labor-cost advantage over global competitors. Indigenous players have achieved recognition by not only promoting the domestic production of high- end medical devices but also by exporting to the world in huge quantities. Domestic medical device manufacturers have established themselves in branded products, creating a unique brand positioning and demand/brand pull from physicians and patients.

[33] IBEF

[34] The Indian government's "Promotion of Medical Devices Parks" scheme was introduced to foster domestic manufacturing of medical devices by providing financial assistance for creating common infrastructure facilities in selected states, with a total outlay of Rs. 400 crore and a tenure from FY 2020-21 to FY 2024-25.

4.1. INDIAN MEDICAL DEVICE REGULATION

The Indian government has introduced multiple initiatives and enacted various regulations to support the development of the Medical Device sector. Under the Drugs & Cosmetics Act 1940, the Indian government regulates medical devices (i.e., tools, implants, software, and other items meant for human or animal medical use) as "drugs." The Draft Drugs and Cosmetics (Amendment) Bill, 2015, aimed to modernize the Drugs and Cosmetics Act, 1940, by introducing provisions for clinical trials and regulating medical devices while also revising Good Manufacturing Practices (GMP) for drugs and medical devices. In July 2023 , the Ministry of Health and Family Welfare (MoHFW) released a draft of the New Drugs, Medical Devices, and Cosmetics bill, aiming to replace the existing Drugs and Cosmetics Act, 1940, with the goal of modernizing regulations and ensuring quality, safety, and efficacy of drugs, medical devices, and cosmetics. In 2017, the MoHFW notified Medical Devices Rules, 2017 and the new Rules have been framed in conformity with Global Harmonisation Task Force (GHTF) framework and to conform to best international practices. Under the new rules, Medical Devices are classified as per GHTF practice, based on associated risks, into Class A (low risk), Class B (low to moderate risk), Class C (moderate to high risk) and Class D (high risk). The manufacturers of medical devices will be required to meet risk proportionate regulatory requirements that have been specified in the rules and are based on best international practices. The Indian Certification for Medical equipment Plus (2021) program by the Quality Council of India[35] and the Association of Indian Medical Device Industry (AIMEd)[36] aims to assist government agencies in identifying fake goods and forged certifications while also confirming the efficacy, safety, and benefits of medical equipment. The Indian government issued a notification in January 2022 mandating that all manufacturers of medical devices register their products with the Central Drugs Standard Control Organization (CDSCO), India's national regulatory body for cosmetics, pharmaceuticals and medical devices, to comply with the ISO 13485 certification requirement. The purpose of this criterion is to guarantee the safe manufacture and management of medical devices. In 2017, India's National Pharmaceutical Pricing Authority (NPPA) capped the price of coronary stents, aiming to reduce the cost of heart procedures and to boost domestic production. In September 2022, the Indian government announced to set up a separate Export Promotion Council (EPC) for Medical Devices to boost exports of medical devices by help exporters in promoting their products in international markets through various promotional activities including organising and participating in international trade fairs, buyer-seller meets, in line with the foreign trade policy of India.

National Medical Device Policy was introduced by the Indian government in May 2023. Its objectives include providing affordable, high-quality medical devices to all people, increasing domestic manufacturing capacity, improving product quality and global competitiveness, improving clinical outcomes through early diagnosis and accurate treatment, encouraging a healthier lifestyle through the widespread use of devices, encouraging innovation in the industry, and building robust local manufacturing capabilities and resilient supply chains. To support the sector's growth and development, the strategy also seeks to simplify regulations and enable infrastructure, R&D, and innovation.

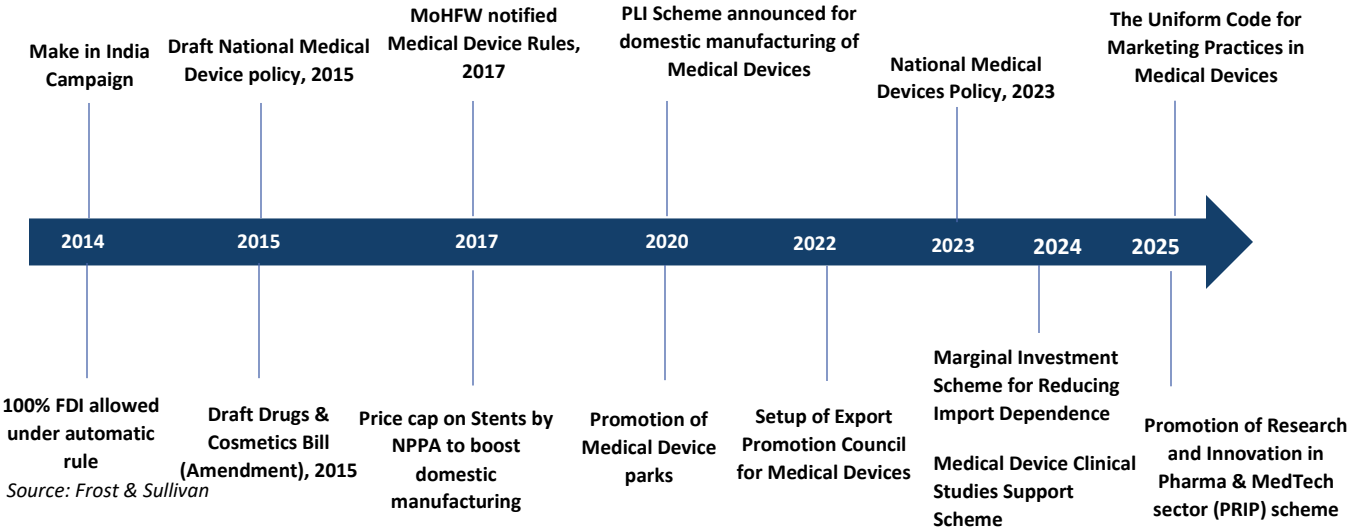
[35] Quality Council of India (QCI) was set up in 1997 jointly by the Government of India and the Indian Industry represented by the three premier industry associations i.e. Associated Chambers of Commerce and Industry of India (ASSOCHAM), Confederation of Indian Industry (CII) and Federation of Indian Chambers of Commerce and Industry (FICCI), to establish and operate national accreditation structure and promote quality through National Quality Campaign.

[36] An Umbrella Association of Indian Manufacturers of Medical Devices covering all types of Medical Devices including Consumables, Disposables, Equipments, Instruments, Electronics, Diagnostics and Implants

In 2023, Promotion of Research and Innovation in Pharma MedTech sector (PRIP) scheme was launched by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, with the goal of transforming India into a global powerhouse for R&D in the Pharma MedTech sector. The scheme has a total financial outlay of INR 5,000 crores, which includes INR 700 crores to establish Centers of Excellence (CoEs) at seven National Institutes of Pharmaceutical Education & Research (NIPERs), and INR 4,250 crores to accelerate investments in the R&D ecosystem within the sector.

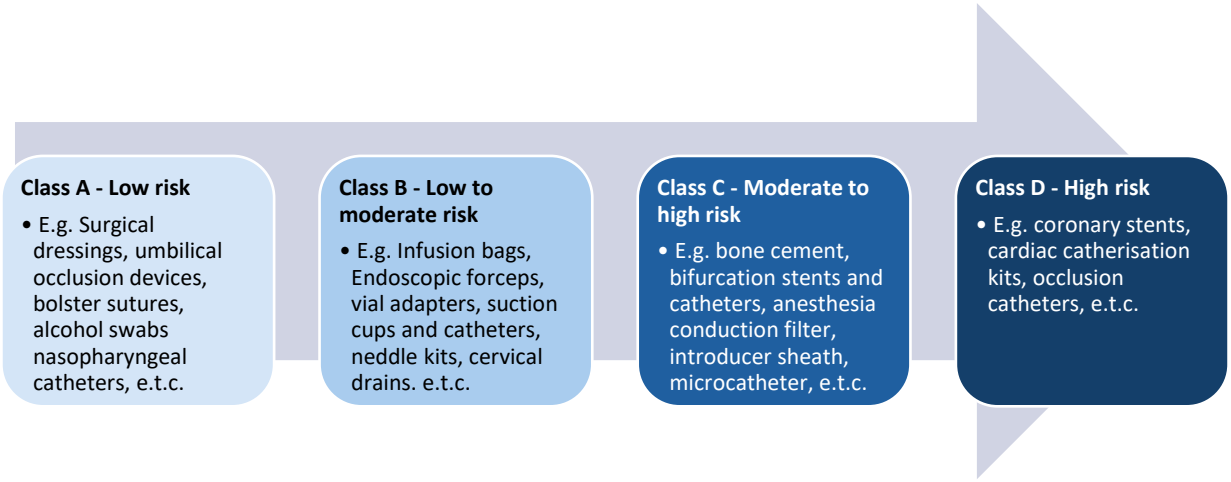
The Uniform Code for Marketing Practices in Medical Devices (UCMPMD) India, released in 2024, aims to regulate the ethical marketing of medical devices in India. This code sets guidelines for promotion, conduct, and interactions between medical device companies and healthcare professionals (HCPs). It prohibits certain practices like offering gifts and monetary grants, while allowing for permitted activities like training and research.

Exhibit 4.2: Timeline of Policies to Boost Medical Device Industry



Source: Frost & Sullivan

Exhibit 4.3: Classification of Medical Devices in India



Source: IBEF, Frost & Sullivan

Medical devices are categorized into one of four classes under the MDR – based on increasing risk from Class A to Class D. Class A devices are low-risk devices such as surgical dressings, umbilical occlusion devices, bolster sutures, alcohol swabs, and nasopharyngeal catheters. Class B devices are low to moderate risk devices such as infusion packs, endoscopic forceps, vial adapters, suction cups and catheters, Sengstaken- Blakemore tube, feeding tubes, and gastrointestinal tubes. Class C devices are moderate to high-risk devices such as anesthesia conduction filter, introducer sheath, microcatheter, imaging catheter colonic stents, and pancreatic instruments. Class D devices are high risk devices such as coronary stents, cardiac catheterization kits, cardiovascular, intravascular diagnostic catheters, and occlusion catheters.

4.2. GOVERNMENT REFORMS FOR MANUFACTURING SECTOR

From economic to structural reforms, several of the Indian government's initiatives have bolstered investment and streamlined growth across several sectors, most notably pharmaceutical and medical device manufacturing.

- **Development of "Make in India" Programs for Pharmaceuticals and Medical Devices with PLI Scheme:** Under current administration, the Indian government has implemented several favorable policies to promote manufacturing such as Production-Linked Incentive (PLI) scheme, PM Gati Shakti- National Master Plan (NMP), and industrial development schemes in states with industrial backwardness. The reforms have been targeted towards increasing the impact of the manufacturing sector on the country's GDP as a part of the government's bold vision. The Production Linked Incentive (PLI) scheme provides financial incentives worth approximately INR 3,420.0 crore[37] to

[37] Ministry of Chemicals and Fertilizers: Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices to promote Indigenous manufacturing of medical devices

encourage the production of high-value medical devices, reducing import dependency and enabling global-scale manufacturing. Additionally, new Medical Device Parks, with a total financial outlay of INR 400.0 crore[38], in Himachal Pradesh, Uttar Pradesh, Madhya Pradesh, and Tamil Nadu are offering plug-and-play infrastructure to accelerate domestic production for international markets.

The recently introduced National Medical Devices Policy fosters collaboration across industry and academia, creating a robust MedTech ecosystem aligned with global market needs. Meanwhile, the R&D Policy for Pharmaceuticals & Medical Devices is enhancing interdisciplinary research, supporting startups, and strengthening India's position as an innovation hub for medical technology.

- **Foreign direct Investment (FDI) policy:** There has been a keen focus by the Indian government in terms of implementation of favorable FDI policy reforms for pharmaceutical and medical device companies. The central government in 2017 established the Medical Devices Rule to clearly differentiate between pharmaceutical and medical device companies to streamline regulatory environment and promote investments. Further, the Union cabinet approved the amendment to FDI% for greenfield pharmaceutical projects allowing up to 100.0% FDI through automatic route and 74.0% FDI through automatic route for Brownfield pharmaceuticals projects without the requirement of government approval[39].

  Foreign direct investment (FDI) in MedTech sector has increased over the years, reflecting global confidence in Indian manufacturers. India has become an attractive destination for FDI in recent years, influenced by several factors which have boosted FDI. India ranked 40th in the World Competitive Index 2024, from the 43rd rank in 2021. India was also named as the 48th most innovative country among the top 50 countries, securing the 40th position out of 132 economies in the Global Innovation Index 2023. These factors have boosted FDI investments in India. Cumulative FDI inflows until June 2024 (April 2000 to June 2024) stood at USD 35.4 billion in the Healthcare industry and USD 3.3 billion in the MedTech industry. With FDI inflows increasing, companies have been able to enhance production capabilities and invest in cutting-edge technology.

  Private equity firms are also actively investing in Indian MedTech startups and established players, facilitating their expansion into international markets. Additionally, strategic M&A activities are enabling Indian firms to acquire global expertise, expand their geographic reach, and strengthen their product portfolios in high-demand therapeutic areas. Indian medical device firms have garnered considerable attention from PE companies due to their capabilities to offer high-quality products at low cost, competing with global MNCs. For example, in 2024, Warburg Pincus invested around USD 300.0 million in Appasamy Associates, a leading Indian ophthalmic equipment manufacturer, to support its expansion and innovation efforts. Similarly, in 2024, global investment firm KKR announced the acquisition of Indian medical devices maker Healthium Medtech from UK-based Apax Partners, valuing the company at approximately USD 839.0 million. Since 2017, there have been about 59 PE transactions in MedTech, with deals increasing by 3.3 times compared to pre-COVID-19 levels. Moreover, the share of medical devices to the total healthcare deal value has doubled from 6% between 2017 and 2020 to 11% between 2021 and mid-2024.

[38] Ministry of Chemicals and Fertilizers: Medical Device Parks

[39] IBEF

- **Emergence of public insurance coverage and integration of public and private healthcare delivery sectors:** The awareness of the impact of healthcare on the country's growth is clearly reflected through IRDAI's (Insurance Regulatory and Development Authority of India) 2047 vision of insuring every citizen with life and health insurance cover by bringing together the public and private sector players. The imminent roll-out of the BIMA SUGAM, a revolutionary digital platform, which will serve as a one-stop shop for regulated buying, selling insurance, policy reviews and claims settlements to ensure clarity on coverage and claims for insurer and healthcare delivery sector. Another example of strengthening the public insurance coverage is the government's Pradhan Mantri Jan Arogya Yojana (PM-JAY) scheme which is focused on shifting the country's healthcare delivery model from a fragmented approach towards a need-based service. Central government's Ayushman Bharat scheme (PMJAY) covers a wide range of diseases including cardiac conditions (e.g., stents, balloon angioplasty), cancer, neurosurgery, kidney transplants, burns, and congenital disorders. About 70 crore beneficiaries are covered under the PMJAY scheme. The increased insurance coverage and integration of public and private healthcare delivery sectors is set to create a greater demand for indigenously manufactured pharmaceuticals and medical devices.

4.2.1. SHIFT FROM MNC TO INDIGENOUS COMPANIES, FOLLOWING THE PATH OF PHARMACEUTICAL INDUSTRY

Indian MedTech ecosystem is observing a similar trend to the pharmaceutical industry, which has seen a shift from reliance on multinational corporations (MNCs) to the rise of domestic companies, especially in the area of generic drug manufacturing, due to an innovative ecosystem, cost arbitrage and supportive government policies. Moreover, India's pharmaceutical industry not only satisfies its domestic needs but also plays a significant role in the global market by exporting a substantial portion of its production. India is a leading supplier of generic medicines and vaccines, contributing significantly to global drug security. Similarly, Indigenous Medtech companies can often offer competitive pricing compared to MNCs, making their devices more accessible to a wider range of patients and healthcare providers.

India's Medtech industry has significantly fewer players compared to its pharmaceutical sector due to its nascent stage, higher technological barriers, skills requirement and more complex regulatory environment. In comparison to pharmaceuticals, the Medtech regulatory environment is more complex. Unlike pharma, Medtech is Intellectual Property (IP) led and requires higher upfront R&D and testing, especially in the case of implants, which require significant clinical evidence. Medical devices span a wide range of categories, from simple syringes to complex imaging equipment, each with different regulatory requirements. Indian MedTech industry has very few scaled companies, such as PolyMed, SMT and Healthium and the market opportunity is attractive for the scaled players to grow significantly. Despite the growth of India's Medtech industry, it remains heavily reliant on imports. However, under the impetus of government policies and the technology investments and innovations of domestic companies, import substitution is progressing.

4.3. COMPETITIVE ADVANTAGE OF INDIAN MEDTECH COMPANIES

India's Medtech sector is poised for significant export growth, driven by multiple competitive advantages while maintaining high quality threshold for global market. Below are key aspects:

Table 4.3. Comparison of Indian Pharma and Medical Device ecosystem and initiatives		
	Pharmaceutical	**MedTech**
Cost Advantage	30-35% lower costs than US/EU	~30% lower mfg. and R&D costs, Indian government has set up 20+ MedTech clusters aimed at cost reduction.
Upgrading Quality & Exports	International acceptance, improved post Schedule M in 1988	Launched Medical Device Regulation (MDR) (2017) and National Medical Device Policy (2023)
Policy Impact	Government taking several steps to improve quality and practices, expected to benefit large companies	Government launching Medtech schemes like PLI, PRIP, TDB grants, Marginal Investment Scheme for Reducing Import Dependence, Medical Device Clinical Studies Support Scheme, support for Medtech Parks etc.
Competitive intensity	High (Large number of public listed Pharma companies)	Low (Very less public listed MedTech companies)
Barriers to entry	Moderate to Low	High
Risk of genericization	High	Low
Technical expertise and Technology upgradation	Moderate	High

Source: Frost & Sullivan

Manufacturing Cost Advantage

- **Low Labor Costs**: India has a large pool of skilled and semi-skilled labor available at relatively lower wages compared to developed countries and some other emerging economies. This helps in reducing the overall production costs of medical devices. In the manufacturing sector, India has one of the lowest manufacturing labor costs where average hourly labor costs are significantly lower than those in the US and Europe. In 2024, while India's average hourly wage is less than USD 2, it is between USD 32 and 34 in the UK, USD 28 and 30 in the US, USD 36 and 42 in Europe, and USD 5 and 6 in China. These differences make India a cost-competitive location for manufacturing operations.
- **Affordable Raw Materials**: The country has access to a wide range of raw materials at competitive prices. For instance, in the orthopedics segment, cheap titanium is available for manufacturing screws and plates. Additionally, other essential materials required for producing various medical devices are also relatively inexpensive, contributing to lower manufacturing costs.
- **Economies of Scale**: With the growing domestic market and increasing demand for medical devices, Indian manufacturers can achieve economies of scale. This allows them to produce goods at a lower per-unit cost, making their products more price-competitive in the global market.

Access to R&D and Innovation Ecosystem

- **Government Support**: The Indian government has launched several initiatives to promote R&D in the Medtech sector. For example, the Production-Linked Incentive Scheme for medical devices offers financial incentives for incremental sales, encouraging companies to invest in research and development. Additionally, the government has set up dedicated Medtech research parks and innovation hubs, providing infrastructure and support for startups and established players to conduct cutting-edge research. The Scheme for Promotion of Research and Innovation in Pharma MedTech sector (PRIP) was launched by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India in August, 2023, with the goal of transforming India into a global powerhouse for R&D in the Pharma MedTech sector. The scheme has a total financial outlay of INR 5,000 crores, which includes INR 700 crores to establish Centers of Excellence (CoEs) at seven National Institutes of Pharmaceutical Education & Research (NIPERs), and INR 4,250 crores to accelerate investments in the R&D ecosystem within the sector. India's TDB (Technology Development Board) provides financial assistance to Indian industries and organizations to support the development and commercialization of indigenous technology and the adaptation of imported technology for domestic applications. TDB offers various funding schemes, including grants, equity investments, and loans, to foster innovation and technological advancement. Indian Government's Marginal Investment Scheme for Reducing Import Dependence was launched in November 2024, to promote domestic production of key components, raw materials and accessories used in manufacturing of medical devices, including in-vitro diagnostic devices, in order to reduce dependence of Indian medical device manufacturers on imported key components and raw materials and increase the depth of our value chains. Further, the Government launched Medical Device Clinical Studies Support Scheme to assist both established companies and start-ups in conducting clinical studies by providing financial incentives for conductive animal studies and human clinical trials.
- **Collaborations with Global Players**: Indian Medtech companies have been collaborating with global giants to leverage their expertise and resources for R&D. For instance, Siemens Healthineers has established an R&D center in Bangalore, which focuses on developing products for emerging markets. Such collaborations not only bring in advanced technologies and know-how but also provide Indian companies with access to global markets.
- **Large Patient Pools for Clinical Trials**: India's vast and diverse population offers a unique advantage for conducting clinical trials. The large patient pools enable faster recruitment and more comprehensive data collection, which is crucial for the development and validation of new medical devices. This accelerates the innovation cycle and reduces the time-to-market for new products, giving Indian Medtech players a competitive edge in the global arena.
- **Lower cost of R&D in India**: India offers a lower cost environment for R&D in the pharmaceutical and medical device sectors compared to developed nations. This is due to factors like lower land and labor costs, as well as competitive resource costs. The cost of R&D in India is significantly lower than in developed countries, potentially being one-fifth the cost.

Growing Export Market

- **Increasing Global Recognition**: Indian Medtech companies have been gaining recognition for their high-quality and cost-effective products. India's medical device export is expected to grow from USD 3.4 billion in 2023 to USD 18.0 billion in 2030. India's key export destinations are the US, Europe, and Southeast Asia.
- **Diversified Product Portfolio**: Indian Medtech players have demonstrated their capabilities across various segments, including Cardiovascular devices, In-Vitro Diagnostics (IVD), imaging, and general consumables. Companies like SMT, a market leader in minimally invasive cardiovascular devices, have seen strong export growth, particularly in the European market. This diversified product portfolio allows Indian companies to cater to a wide range of global market needs.
- **Emerging Market Opportunities**: As the global healthcare landscape evolves, emerging markets in Southeast Asia, Africa, Eastern Europe, and South America are presenting significant opportunities for Indian Medtech players. These regions are in need of high-quality medical devices at affordable prices, which aligns perfectly with India's competitive advantage. Indian companies can leverage their cost-effective manufacturing capabilities and innovative products to capture a larger share of these emerging markets.

With the right government policies, regulatory support, and continuous investment in R&D and manufacturing infrastructure, India's Medtech sector has the potential to become a global powerhouse. By leveraging its multiple competitive advantages, Indian Medtech players can not only meet the growing domestic demand but also establish themselves as key suppliers of medical technologies worldwide, providing affordable and high-quality healthcare solutions to the global population.

While Pharma and MedTech Benefit from similar macroeconomic tailwinds such as cost advantage and favourable government policies to promote manufacturing and investments, Medtech companies enjoy distinct advantages such as low competitive intensity, high barriers to entry and no risk of genericization.

5. OVERVIEW OF CARDIOVASCULAR DEVICES

5.1. GLOBAL CARDIOVASCULAR DEVICES MARKET OVERVIEW

The global Cardiovascular devices market includes all products used for coronary vascular and peripheral vascular procedures market ranging from implants and accessories used for treating vascular blocks, aortic diseases and all other vascular diseases conditions.

The global Cardiovascular devices market can be segmented into Vascular Interventional Devices (comprising of coronary, peripheral and neurovascular interventions) and Structural Heart Devices.

- Coronary vascular intervention devices deals with the diagnosis and treatment of blocked or narrowed arteries supplying blood to heart using minimally invasive, catheter-based procedures and specialized imaging techniques. Coronary interventions are performed largely by interventional cardiologists who have expertise in using devices such as catheters, stents, balloons, guiding tools etc. Peripheral vascular interventions deals primarily with peripheral

circulatory condition in which narrowed blood vessels reduce blood flow to the limbs and all arteries outside coronary artery. Neurovascular intervention refers to minimally invasive, image-guided procedures used to diagnose and treat conditions affecting the blood vessels of the brain and spinal cord. These procedures, often performed by interventional neurologists or neurointerventionalists, utilize catheters and other specialized devices to address issues like aneurysms, arteriovenous malformations (AVMs), strokes, and carotid artery stenosis.

- Structural heart devices deal with diseases or abnormalities in the tissues, walls and valves of the heart.

Exhibit 5.1: Product Segmentation of Cardiovascular Devices Market

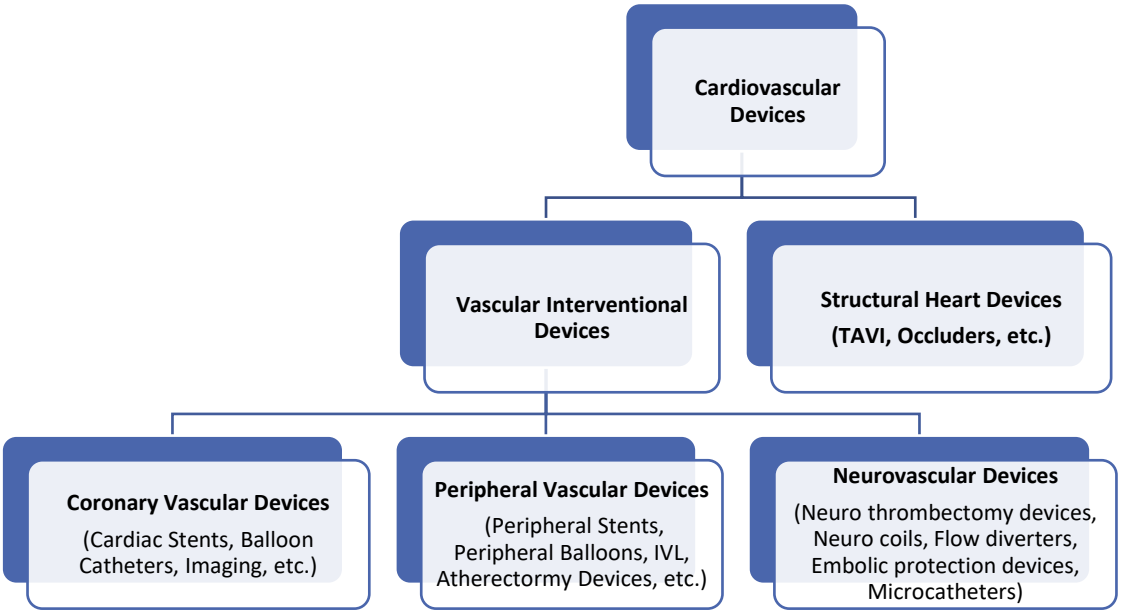
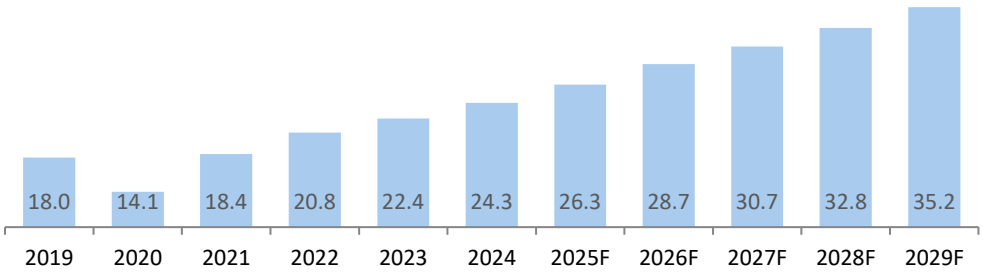


Exhibit 5.2: Global Cardiovascualar Device Market (USD Bn), 2019-2029F
CAGR 2024 - 2029F: 7.8%



Source: Frost & Sullivan
Note: The market size is related to the scope of coverage which consists of vascular interventional devices and structural heart devices

- The global Cardiovascular devices market has witnessed consistent growth over the past decade, driven by increasing prevalence of cardiovascular disease (CVD) and peripheral vascular disease, technological advancements, and rising healthcare expenditure. In 2024, the market is valued at approximately USD 24.3 billion, with a 6.2% CAGR over the past five years. The growth trajectory is expected to continue, with projections indicating the market will reach USD 35.2 billion by 2029, growing at a 7.8% CAGR between 2024 and 2029. This expansion is fueled by rising demand for minimally invasive procedures and improved patient access to advanced treatment, especially in structural heart conditions.

5.1.1. MARKET DYNAMICS FOR CARDIOVASCULAR DEVICES

- The cardiovascular device industry is at the forefront of innovation, continuously advancing toward safer, more effective, and less invasive solutions that not only extend life expectancy but also enhance the quality of life for millions of patients worldwide. A 2022 survey by the European Society of Cardiology found that over 80% of patients preferred minimally invasive cardiovascular surgeries when medically suitable. Patients value the smaller incisions, reduced pain, faster recovery, and better cosmetic outcomes offered by minimally invasive procedure. As we move forward, the interplay between medical technology, regulatory advancements, and healthcare delivery models will shape the future trajectory of cardiovascular disease management across the globe. Cardiovascular diseases (CVDs) represent the leading cause of mortality worldwide, accounting for nearly 18 million deaths annually, which translates to approximately 32% of total global deaths[40]. The burden of CVD continues to rise due to an aging population, and increased prevalence of risk factors such as hypertension, diabetes, obesity, smoking, and sedentary lifestyles. It is estimated that over a billion people globally live with some form of cardiovascular disease, ranging from coronary artery disease and heart failure to arrhythmias and valvular disorders. The impact of cardiovascular diseases is not only measured in terms of mortality but also the quality of life lost and the economic burden on

[40] WHO: Cardiovascular Diseases

healthcare systems. CVDs contribute to nearly 400 million disability-adjusted life years (DALYs) lost annually.[41]

- Medical devices have fundamentally transformed the landscape of cardiovascular disease management, improving survival rates, reducing hospitalizations, and enhancing patients' quality of life. From the early development of pacemakers and mechanical heart valves to today's cutting-edge transcatheter therapies, the cardiovascular device market has seen a remarkable evolution. In the hospital setting, cardiovascular devices are critical in acute care, from percutaneous coronary interventions (PCI) with stents and balloons to complex surgical procedures involving artificial heart implants and ventricular assist devices (VADs). Advanced imaging modalities such as Intravascular Ultrasound (IVUS), Optical Coherence Tomography (OCT), and angiography have significantly improved early detection and treatment planning, leading to better outcomes and reduced complications. In ambulatory and outpatient settings, the availability of minimally invasive solutions such as catheter-based ablation for arrhythmias, implantable cardiac monitors, and wearable ECG devices has enabled early diagnosis, remote monitoring, and timely interventions, reducing the need for prolonged hospital stays and emergency admissions. In home-care settings, technological advancements have paved the way for remote patient monitoring (RPM) solutions that allow continuous tracking of vital parameters, including heart rate, blood pressure, and arrhythmias. Wearable medical technology such as smartwatches with ECG functionality is playing an increasing role in the early detection of atrial fibrillation (AFib) and other cardiovascular anomalies, enabling timely medical interventions.

- The increasing integration of digital health tools, artificial intelligence, and machine learning in cardiovascular care is further optimizing diagnosis, treatment personalization, and disease management. AI-powered ECG interpretation, automated risk stratification models, and telehealth consultations are improving patient engagement and accessibility to specialized care, particularly in underserved regions. The increasing advancements in next-generation biomaterials, minimally invasive interventions, and hemodynamic monitoring technologies are further optimizing cardiovascular diagnosis, treatment personalization, and disease management. Innovative drug-eluting stents, polymer-coated drug-eluting balloons, and transcatheter valve replacement systems are enhancing procedural outcomes and reducing long-term complications. Innovations such as real-time blood flow sensors, next-gen pacemakers with energy-harvesting capabilities, and catheter-based hemodynamic monitoring are improving early disease detection and post-surgical recovery, particularly for high-risk patients. Furthermore, regulatory frameworks and reimbursement policies are evolving to support the adoption of advanced cardiovascular devices. Governments and healthcare agencies are investing in early screening programs, value-based healthcare models, and reimbursement structures that encourage the use of innovative devices to prevent disease progression and reduce long-term healthcare costs.

Underpenetration and growth adoption of minimally invasive procedures in Emerging economies

[41] Secondary sources

The interventional cardiology market underwent a big transformation in the last decade with a substantial rise in number of Percutaneous Coronary Intervention (PCI) procedures. However, there is a wide disparity in the adoption of PCI procedure across countries. European market for vascular intervention and structural heart devices is characterized by its large size, high regulatory standards, and significant growth potential through 2030. While the number of PCI procedures is estimated to be ranging around 3,000 to 6,000 procedures per million in most of the high-income developed economies such as in Europe in North America, it is less than 1,500 procedures per million in the emerging economies such as China and India, highlighting a significantly lower utilization and under penetration in emerging geographies. Moreover, the number of Cath labs in emerging economies is low compared to the rising incidence of vascular diseases. Due to factors such as increased access to treatment, affordability and growing adoption of health insurance, the number of vascular device procedures such as PCI is rapidly growing in emerging Asian economies such as India, China, Vietnam and Thailand which is driving the overall market growth. Moreover, the implementation of price cap on stents in markets such as China and India, has accelerated the cardiovascular procedure volumes and were beneficial for domestic players as opposed to MNCs due the former's ability to manufacture low-cost, high quality devices. Further, the growing capability of indigenous companies in India and China to meet the demand for affordable and high quality vascular products in emerging markets as well as regulated high-income markets is expected to propel the market further. Other markets also present significant growth opportunities, with large and expanding addressable markets in countries such as Brazil, Thailand, South Korea, Mexico, and South Africa.

5.2. GLOBAL VASCULAR INTERVENTIONAL DEVICES MARKET OVERVIEW

5.2.1. GROWTH TRENDS OF MINIMALLY INVASIVE SURGERY (MIS) VERSUS TRADITIONAL PROCEDURES IN INTERVENTIONAL CARDIOLOGY

The overall trend in interventional cardiology is a growing preference for MIS whenever clinically appropriate. MIS has witnessed a rapid evolution in the past two decades, driven by technological advancements and improved surgical techniques. MIS is gaining popularity among both physicians and patients due to its potential benefits, including reduced surgical trauma, decreased postoperative pain, shorter hospital stays, faster recovery, lower infection risk, quicker return to routine activities, and improved cosmetic outcomes. Innovations in areas like video-assisted thoracoscopic surgery, robotic technology, advanced imaging (real-time 3D echocardiography, intraoperative navigation), and specialized instruments are fueling the growth of MIS.

Initially focused on valve surgery and Coronary Artery Bypass Grafting (CABG), minimally invasive techniques are now being applied to a wider range of cardiac conditions, including congenital heart defects, Atrial Septal Defect (ASD) repair, and excision of left atrial tumors. Transcatheter techniques are also expanding rapidly for valve and coronary pathologies.

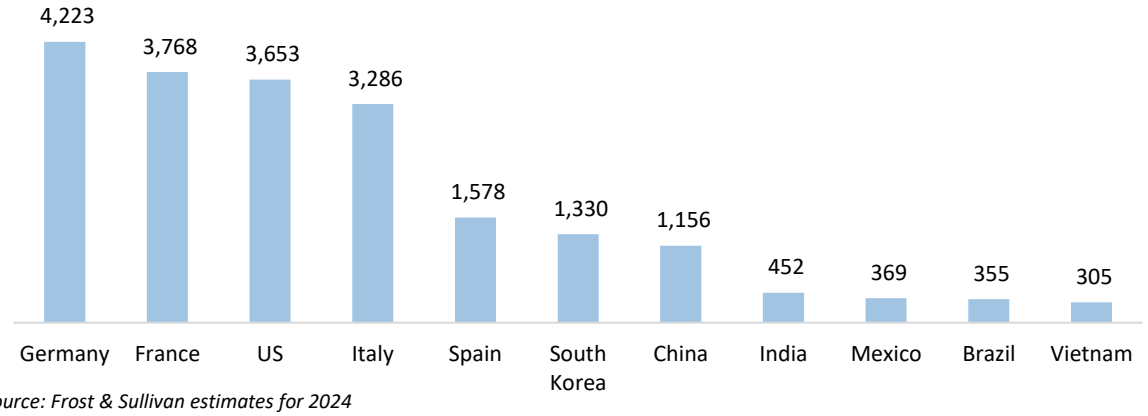
5.2.2. TRENDS IN PCI PROCEDURES

The vascular intervention market underwent the biggest transformation in the last decade with a substantial rise in the number of PCI procedures. PCI procedure volumes are experiencing a positive growth trend globally, driven by advancements in medical technology, increased focus on complex cases, and policy changes. This growth is expected to continue as healthcare systems adapt to meet the

growing demand for minimally invasive cardiac procedures. The number of PCI procedures in the US has increased from about 0.95 million in 2018 to more than 1.20 million in 2024. Similarly, there is an increasing trend in other countries. Large increase and growth in PCI procedure volumes is seen in emerging markets such as China and India, which have large populations and increasing adoption of minimally invasive procedures. For instance, in China, it has increased from 0.9 million in 2018 to more than 1.6 million in 2024.

While the average number of PCI procedures per million population is more than 3,000 in countries such as the US, Germany, France and Italy, it is less than 500 in countries such as India, Vietnam, Brazil and Mexico, and is less than 1,500 in countries such as China and South Korea. This highlights a significantly lower utilization and under-penetration in emerging geographies. Lower PCI utilization is further evident in countries like India and China where the number of Cath labs is low compared to the rising incidence of vascular diseases. Globally, the shift CABG to PCI (a non-surgical procedure that uses a catheter) in the last decade was driven by growth in emerging markets, which had low penetration. The three main drivers for the adoption were; 1) reduction in average duration for hospitalization 2) better suitability of non-invasive procedures for old age patients who are at high risk and generally have co-morbidities; 3) reduction in the price of the stents, in the cost of procedures, increased coverage of these procedures from governments in countries like Thailand, China and India etc.

Exhibit 5.3: PCI Proceure per million population in select countries, 2024



Source: Frost & Sullivan estimates for 2024

Focus on Complex PCI Cases

- **Complex PCI Patients**: There is a growing focus on complex PCI cases, such as those involving chronic total occlusions (CTOs) and left main coronary artery disease. This shift is driven by advancements in medical technology and the need to address unmet clinical needs.
- **Specialized Devices**: The development of specialized devices, such as hemostasis valves and extension guide catheters, allows complex cases to be treated through minimally invasive procedures rather than traditional CABG surgeries.

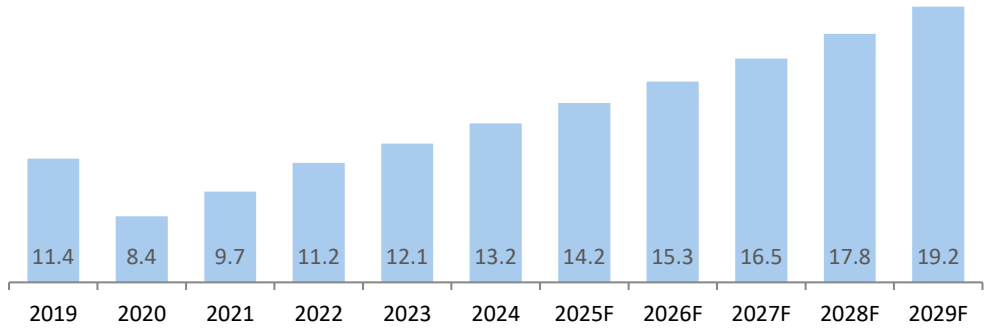
Impact of Technology and Policy Changes

- **Technological Advancements**: New technologies, such as IVUS and OCT, provide more detailed visual assessments of coronary arteries, enhancing diagnostic accuracy and procedural efficiency.
- **Policy and Reimbursement Changes**: The reimbursement and insurance coverage for day care PCI procedures are increasing globally, driven by policy changes and the shift toward value-based care. This trend is expected to continue as healthcare systems adapt to meet the growing demand for minimally invasive cardiac procedures and improve patient access to care.
- **Volume-Outcome Relationship:**
  - **High-Volume Hospitals**: Studies have shown that high-volume hospitals achieve better outcomes than low-volume hospitals. This relationship persists even with recent changes in PCI practices and perioperative management.
  - **Operator Volume**: Operator volume also plays a significant role in patient outcomes. High-volume operators (those performing more than 100 PCIs per year) tend to have better outcomes compared to low-volume operators.

5.2.3. VASCULAR INTERVENTIONAL DEVICES MARKET FORECAST

Vascular intervention refers to minimally invasive procedures used to diagnose or treat diseases of the blood vessels. Vascular interventional devices, constituting 54.0% of the vascular devices market in 2024, encompass devices such as stents, catheters, angioplasty devices, atherectomy devices and renal denervation devices balloons used in minimally invasive procedures to treat coronary and peripheral artery disease. This segment, valued at USD 13.2 billion in 2024, is projected to reach USD 19.2 billion by 2029, growing at a CAGR of 7.8%, driven by the rising prevalence of cardiovascular diseases (CVDs), increasing adoption of PCI, and technological advancements in drug-eluting stents. Advances in DES, bioresorbable scaffolds, and robotic-assisted interventions are enhancing procedural success rates and expanding treatment options for complex lesions. The growing geriatric population, coupled with higher risk factors such as diabetes, hypertension, and obesity, is fueling demand for percutaneous coronary interventions (PCI) over traditional open-heart surgeries. Additionally, expanding catheterization lab infrastructure in emerging markets, along with favorable reimbursement policies and increasing physician

Exhibit 5.4: Global Vascular Interventional Device Market (USD Bn), 2019-2029F
CAGR 2024 - 2029F: 7.8%



Source: Frost & Sullivan

training programs, is boosting procedural volumes. The integration of artificial intelligence (AI) and intravascular imaging technologies is further optimizing patient outcomes, reinforcing sustained growth in this segment.

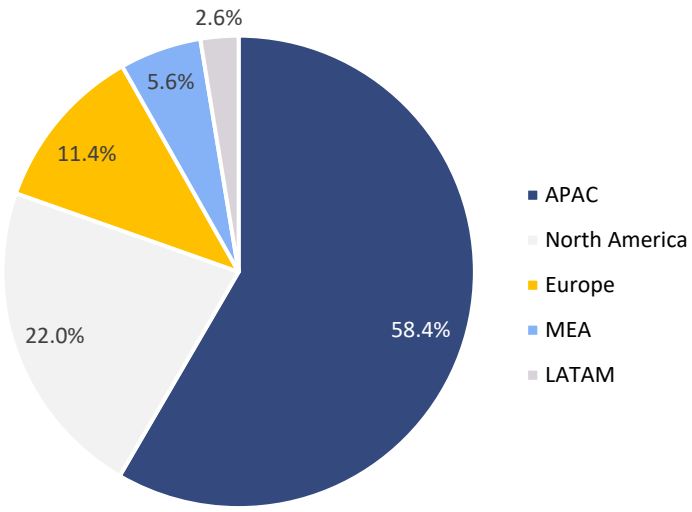
5.2.4. VASCULAR INTERVENTIONAL DEVICES BY KEY REGIONS

The vascular device market exhibits regional variations in terms of market size, growth rate, and product adoption, influenced by factors such as disease burden, healthcare infrastructure, regulatory environment, and reimbursement policies. While North America and Europe remain the largest markets due to advanced healthcare systems and widespread adoption of minimally invasive procedures, Asia-Pacific (APAC)—particularly India and China—is experiencing the fastest growth, driven by increasing healthcare access and rising CVD prevalence.

- The APAC region holds the largest revenue share of the global vascular interventional device market with about 58% share, and the region is experiencing the fastest growth globally, projected to have a CAGR of 10.0% from 2024 to 2029. The market in the region is valued at USD 7,702.5 million in 2024 and is estimated to reach USD 12,381.3 million in 2029. India, China and Japan are currently leading this market. Meanwhile, Southeast Asia—comprising countries like Indonesia, Vietnam, Thailand, Malaysia, and the Philippines—is undergoing rapid expansion due to improvements in healthcare infrastructure.
- Governments in China and India are focusing on boosting domestic production to reduce reliance on imports. China's "Made in China 2025" initiative and India's National Medical Devices Policy 2023, along with the "Make in India" initiative, aim to strengthen local industries. Additionally, other emerging markets in the region such as Thailand, Vietnam, and Indonesia are attracting investments due to their growing middle-class populations and government efforts to expand healthcare access. Moreover, countries such as India, Thailand and Malaysia are becoming regional hubs for cardiovascular procedures, attracting international patients.

- North America is the second largest market for the global vascular interventional device market with 22% revenue share, valued at USD 2,911.5 million in 2024, and estimated to reach USD 3,755.8 million in 2029 at a CAGR of 5.2%. The United States dominates the region, accounting for a major share of the North American market, driven by a high prevalence of CVDs, well-established healthcare infrastructure, and rapid adoption of next-generation cardiovascular technologies. CVDs remain the leading cause of death in North America, accounting for over 931,578 (in 2024) deaths annually in the US alone[42]. Major players such as Medtronic, Abbott, and Boston Scientific drive innovation and commercialization in the region, supported by a high insurance penetration due to favorable reimbursement trends from CMS and private insurance providers.

Exhibit 5.5: Share of Vascular Interventional Device market by regions, 2024



Source: Frost & Sullivan

- Europe represents the third-largest market for vascular interventional devices, with about 11.4% revenue share. The market in the region is valued at USD 1,498.2 million in 2024 and it is expected to reach USD 1,749.3 in 2029, growing at a CAGR of 3.1%. The region benefits from universal healthcare systems, strong regulatory frameworks, and the presence of leading cardiovascular device manufacturers. Germany, France, and the UK account for the largest market shares, while Eastern European countries are showing higher growth rates due to increasing healthcare investments. Europe has one of the oldest populations globally, increasing the incidence of heart disease and demand for minimally invasive interventions. European healthcare systems prioritize cost-effective solutions, leading to higher demand for drug-coated balloons and alternative therapies that reduce the need for repeat procedures.

[42] CDC: Heart Disease Facts

- The Middle East and Africa (MEA) vascular interventional devices market is valued at USD 736.9 million in 2024 and is expected to reach a value of USD 771.7 million in 2029, growing at a CAGR of 0.9%. The countries such as Saudi Arabia and United Arab Emirates have favourable reimbursement policies for cardiovascular treatments, and the governments are committed to healthcare sector development, introducing policies and funding to support the growth of the cardiovascular device market.
- The Latin America vascular interventional device market is valued at USD 344.9 million in 2024 and is estimated to reach USD 550.7 million in 2029, growing at a CAGR of 9.8%. The growth in the region is driven by major economies such as Brazil and Mexico. In recent years, Brazil and Mexico have been increasing healthcare investments and upgrading healthcare facilities. For example, Brazil has launched initiatives such as the "More Doctors" program to expand primary healthcare coverage and improve cardiac care infrastructure. Brazil has the largest population in Latin America, with a high incidence of cardiovascular diseases. The growing number of patients creates substantial demand for cardiovascular devices. The Brazilian and Mexican governments have introduced a series of policies and initiatives to promote the development of the cardiovascular device market. For example, Brazil's National Health Surveillance Agency (ANVISA) has streamlined the approval process for medical devices, shortening the time required for product registration and accelerating market entry. In Mexico, the government has implemented healthcare reforms aimed at improving healthcare service quality and accessibility, increasing funding for cardiovascular disease treatment, and encouraging the adoption of advanced medical technologies.

Table 5.1: Vascular Interventional Devices Market, Market Size and Growth by region, 2024 and 2029F

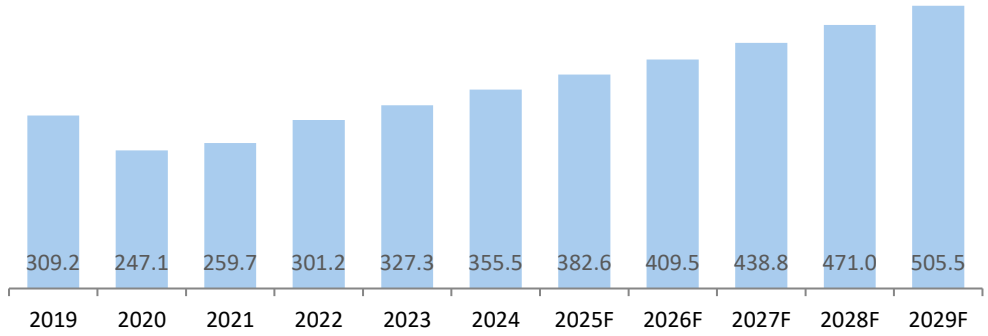
Region	Market Size (USD Mn)		Growth (2024-2029F)
	2024	2029F	
APAC	7,702.5	12,381.3	10.0%
North America	2,911.5	3,755.8	5.2%
Europe	1,498.2	1,749.3	3.1%
MEA	736.9	771.7	0.9%
LATAM	344.9	550.7	9.8%

Source: Frost & Sullivan

5.2.5. INDIAN VASCULAR INTERVENTIONAL DEVICES MARKET FORECAST

Indian vascular Interventional Device market is valued at USD 355.5 million in 2024 and it projected to grow to USD 505.5 million in 2029 at a CAGR of 7.3%, driven by factors such as the growing prevalence of coronary heart disease, increase in ageing population, rising disposable incomes and growing health insurance coverage, growing penetration of cardiologists and cath labs healthcare facilities, focus on early diagnostics, greater government support and expenditure and presence of domestic players, , offering low-cost and high quality products.

Exhibit 5.6: Indian Vascular Interventional Device Market (USD Mn), 2019-2029F
CAGR 2024 - 2029F: 7.3%



Source: Frost & Sullivan

5.2.6. VASCULAR INTERVENTIONAL DEVICES BY KEY SEGMENTS

Vascular Interventional Devices are medical tools used to diagnose and treat vascular diseases, primarily involving the heart and blood vessels, through minimally invasive procedures. These devices, like stents and balloon catheters, are introduced into the body through small incisions, enabling procedures like angioplasty and stenting to open blocked arteries and restore blood flow.

- Vascular Interventions are classified into Coronary interventions and Peripheral Vascular Interventions (PVIs). Coronary interventions, specifically PCI, are minimally invasive procedures used to open blocked or narrowed coronary arteries, restoring blood flow to the heart. They are a non-surgical alternative to open-heart surgery, often used for conditions like coronary artery disease (CAD), heart attacks, and angina. PVIs are minimally invasive procedures used to treat conditions affecting blood vessels outside the heart, like peripheral artery disease (PAD) and deep vein thrombosis (DVT). These interventions use catheters to access and treat blood vessels in areas like the arms, legs, and lungs. Common techniques include balloon angioplasty, stenting, atherectomy, and thrombectomy.

Table 5.2: Major Vascular Interventional Devices for Coronary and Peripheral interventional procedures

Category	Products	Description
Major Coronary	Cardiac Stents	Cardiac stents are small mesh tubes which are inserted into narrowed arteries to keep them open and maintain blood flow. Used in

interventional devices		percutaneous coronary interventions (PCI) for treating coronary artery disease (CAD). Types of stents include Bare Metal Stent, Drug-Eluting Stent and Bioabsorbable Stent
	Cardiac Balloons	Cardiac balloons are inflatable devices which are used to open narrowed or blocked arteries during angioplasty procedures, facilitating stent placement or restoring blood flow. Cardiac balloons used in angioplasty procedures include SC (Semi-Compliant), NC (Non-Compliant), HPNC (High-Pressure Non-Compliant), CTO (Chronic Total Occlusion), Coronary DCB, POT (Proximal Optimization Technique), and others. These balloons are classified by their wall compliance, pressure capabilities, and specialized designs for different clinical scenarios.
	Cardiac Accessories	Cardiac accessories include devices such as Guidewires, Diagnostic catheters, Sheaths and Introducers, Manifolds & Pressure Lines, Contrast Injector, Guiding Catheters, Microcatheters and Balloon Inflation Devices.
	Cardiac imaging (IVUS and OCT)	Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) are both invasive cardiac imaging techniques used to visualize coronary arteries. IVUS uses ultrasound waves, while OCT uses near-infrared light to visualize arteries.
	Intravascular Lithotripsy (IVL)	IVL is a technique that utilizes shockwaves to modify calcified plaque (Calcium deposit) in arteries, making it easier to treat with other interventional procedures and improving patient outcomes, especially in cases of severe calcification.
Peripheral interventional devices	Peripheral stents	Peripheral stents include Superficial Femoral Artery (SFA) and iliac arteries, are small, expandable tubes inserted into narrowed or blocked arteries to help improve blood flow. They are a common treatment for peripheral artery disease (PAD).
	Aortic Endografts (AAA/TAA)	Aortic endografts are stent graft systems used to treat aneurysms in the abdominal (AAA) or thoracic (TAA) aorta. These devices are delivered via catheter and deployed within the aneurysm to exclude the weakened aortic wall from circulation, reducing the risk of rupture. Endovascular aneurysm repair (EVAR for AAA) and thoracic endovascular aortic repair (TEVAR for TAA) are minimally invasive alternatives to open surgery.

	Peripheral Balloons	Peripheral balloon catheters are medical devices used during Percutaneous Transluminal Angioplasty (PTA) to widen narrowed arteries in the upper or lower limbs
	Atherectomy devices	Atherectomy devices are medical tools used in a procedure called atherectomy, which involves removing plaque buildup from arteries, thereby freeing the arteries from blockage
	Renal Denervation device	Renal denervation devices helps to reduce blood pressure by interrupting nerve signals in the kidneys. These devices typically use radiofrequency or ultrasound energy to target and disrupt the renal sympathetic nerves, which can contribute to high blood pressure.

Source: Frost & Sullivan

Vascular interventional devices, comprising coronary interventional devices and peripheral and neuro interventional devices, constitute a larger share of the overall cardiovascular devices market. Coronary devices interventional devices can be broadly sub divided into stents, cardiac catheters and cardiac accessories on the basis of device type. These devices are utilized in treating different types of issues pertaining to coronary arteries.

- **Cardiac Stents** are tiny tubes placed by specialists in an artery or duct for facilitating the flow of bodily fluids in the targeted body area. Cardiac stents are specifically designed for coronary artery where stents are inserted during coronary angioplasty supporting artery walls. This helps to keep the arteries open and improve blood flow to the heart. On a broad level, stents can be classified into three type i.e. bare metal stents (stent without a coating or covering), bioabsorbable stents (stents made of polylactic acid - a naturally dissolvable material) and drug eluting stents (stents coated with medication that is eluted to prevent the growth of scar tissue in artery linings). Within the last decade, research shows a decrease in the number of deaths related to CAD, possibly due to the growth of PCI procedures and early interventions. Cardiac Stents have a major share in vascular interventional devices (35%). The global market value for the product is about USD 4,560 million in 2024, and it is estimated to grow to USD 6,081.1 million in 2029 at a CAGR of 5.9%.

- **Cardiac catheters or PTCA catheters** are utilized for catheterization procedure which involves the insertion of a catheter into heart's chambers or vessels for treating or diagnosing certain cardiovascular conditions. Catheters are of various types depending on the type of functions performed. Within the branch of interventional cardiology, cardiac balloon catheters are primarily used for balloon angioplasty. This procedure is mainly targeted for opening narrow arteries in or near to patient's heart. The global PTCA catheter market is valued at USD 1,250.5 million in 2024. Owing to its critical usage in treating complex cardiovascular issues, the global PTCA catheters market is expected to grow at CAGR of 5.8% from 2024 to 2029 and reach USD 1,644.3 million by 2029. Growth in this market is primarily attributed to the rising prevalence of complex cardiovascular diseases and associated morbidities.

- **Coronary drug-coated balloon catheters (DCBs)** are interventional devices coated with anti-proliferative drugs (e.g., paclitaxel or sirolimus) on their surface. When inflated at the lesion site,

the drug is released and absorbed into the vessel wall, inhibiting the proliferation of vascular smooth muscle cells and endothelial cells, thereby preventing or reduce narrowing of the vessel again. The global Drug coated balloon catheter market is valued at USD 500.2 million in 2024 and it is expected to reach USD 708.2 million by 2029, growing at CAGR of 7.2%.

- **Cardiac accessories** include a range of other devices (such as inflation devices, guiding catheters, diagnostic catheter, Y-connectors, balloons, sheaths etc.) which are used in conjunction with other cardiovascular devices for diagnosis, monitoring or treatment procedures. The global cardiac accessories market is driven by growth in the volumes of procedures, and the market value for the product is expected to grow from USD 1,147.2 million in 2024 to USD 1,494.7 in 2029 at a CAGR of 5.4%.

- **Cardiac Imaging devices**, including Intravascular Ultrasound (IVUS) and Optical Coherence Tomography (OCT) are two important intravascular imaging technologies used in coronary vascular interventions. The Cardiac Imaging market for IVUS and OCT is valued at USD 740.0 million in 2024 and it is expected to reach USD 967.2 million in 2029, growing at a CAGR of 5.5%

- **Intravascular Lithotripsy (IVL)** is a minimally invasive procedure that uses sound waves to break down calcified plaque in blood vessels, particularly in the coronary arteries and peripheral vessels. IVL can help prepare the vessel for subsequent procedures like stent implantation, making it easier to deploy and potentially improving long-term outcomes. The global IVL device market is valued at USD 420. Million in 2024 and it is estimated to reach USD 622.9 million in 2029, growing at a CAGR of 8.2%.

- **SFA (Superficial Femoral Artery) and Iliac artery stents** are tiny, mesh-like tubes used to treat blockages in the superficial femoral artery and the iliac arteries. The combined SFA and Iliac peripheral stent global market is valued at USD 1,595.8 million in 2024 and is estimated to reach USD 2,366.7 million in 2029, growing at a CAGR of 8.2%

- **Peripheral drug-coated balloons (DCBs)** are used in endovascular procedures to treat peripheral artery disease (PAD) by dilating narrowed arteries and delivering a drug to the arterial wall to prevent restenosis (re-narrowing). The global market for the product is valued at USD 1,201.0 million in 2024 and is estimated to reach USD 1,951.6 by 2029, growing at a CAGR of 10.2%

- **Atherectomy devices** are used to remove plaque buildup in arteries, typically for treating PAD or coronary artery disease. The global market for the product is valued at USD 830.0 million in 2024 and is estimated to reach USD 1,180.5 by 2029, growing at a CAGR of 7.3%

- **Renal denervation** procedure involves inserting a catheter into the renal arteries (the blood vessels supplying the kidneys) through an incision in the groin (femoral artery). The catheter delivers either radiofrequency or ultrasound energy to the renal sympathetic nerves. The primary goal of renal denervation is to reduce blood pressure, particularly in patients with resistant hypertension (high

blood pressure not controlled by medications). The global market for the product is valued at USD 950.0 million in 2024 and is estimated to reach USD 2,191.9 by 2029, growing at a CAGR of 18.2%.

Table 5.3: Global Market revenue and forecast of major Vascular Interventional Devices, 2024 and 2029F			
Products	**Global Market Value (USD Mn)**		**Growth (2024-2029F)**
	2024	**2029F**	
Coronary Stents	**4,559.4**	**6,081.1**	**5.9%**
Peripheral Stents (SFA and Iliac Stents)	1,595.8	2,366.7	8.2%
Percutaneous Transluminal Coronary Angioplasty (PTCA) balloon catheter	1,250.5	1,644.3	5.6%
Peripheral Drug Coated Balloon	1,201.0	1,951.6	10.2%
Cardiac Accessories	1,147.2	1.494.7	5.4%
Renal Denervation device	950.0	2,191.9	18.2%
Atherectomy Devices	830.0	1,180.5	7.3%
Cardiac Imaging (IVUS and OCT)	740.0	967.2	5.5%
Coronary Drug Coated Balloon Catheter	500.2	708.2	7.2%
Intravascular Lithotripsy (IVL)	420.0	622.9	8.2%
Total Vascular Interventional Devices	13,194.10	19,209.10	7.8%

Source: Frost & Sullivan

5.2.7. OVERVIEW OF CORONARY STENT

Stents are crucial in treating coronary artery disease (CAD), a condition where plaque buildup narrows the arteries, leading to symptoms like chest pain (angina) and potentially heart attacks. Stents are typically delivered to the blocked artery during a minimally invasive procedure called percutaneous coronary intervention (PCI), also known as angioplasty with stenting. Coronary stents have evolved significantly since their introduction, primarily categorized based on their material and how they interact with the artery. The increasing global burden of cardiovascular diseases, fueled by an ageing population, continuous innovation in stent design, materials, and drug coatings, particularly with newer generation DES, increasing adoption of minimally invasive procedures and improving healthcare infrastructure and reimbursement are the major drivers for the market growth.

Bare Metal Stents (BMS) are the earliest type of stents, made of bare metal alloys (e.g., stainless steel, cobalt-chromium). While effective at providing structural support to keep the artery open, a significant

drawback was the high rate of restenosis, where the artery would re-narrow due to the overgrowth of scar tissue inside the stent. This necessitated repeat procedures for many patients.

Drug Eluting Stents (DES) are the current gold standard and dominating the market, DES are bare-metal stents coated with a polymer that slowly releases anti-proliferative drugs. These drugs inhibit cell growth and reduce the formation of scar tissue, thereby significantly lowering the risk of restenosis compared to BMS. They have dramatically improved long-term outcomes for patients. Drug-eluting stents continue to hold the largest market share among the stents, due to their proven efficacy and safety.

Table 5.4: Coronary Stent Market Size and Growth: India, EU and RoW; 2024 and 2029F

Region	Market Size (USD Mn)		Growth (2024-2029F)
	2024	2029F	
India	**249.2**	**342.3**	**9.6%**
EU	578.9	598.4	0.7%
RoW	3,731.3	5,140.4	6.6%
Total Coronary Stents	4,559.40	6,081.09	5.9%

Source: Frost & Sullivan

5.2.8. OVERVIEW OF DRUG-ELUTING STENTS (DES)

- DES are a significant innovation in the treatment of cardiovascular diseases. They dominate the stent market, driven by multiple factors such as favorable reimbursement policies, technological advancements and a decrease in restenosis compared to BMS. DES integrate stent placement with drug therapy, offering a minimally invasive approach that reduces vessel trauma, shortens recovery times, and lowers complication risks. Polymer-based coatings dominate the global drug-eluting stent market due to their ability to improve stent performance. Polymers act as drug carriers, regulating drug release rates and enabling localized delivery to the arterial wall. Controlled release prevents restenosis and extends the duration of effective treatment.

- Stent thrombosis (ST) is considered to be a fatal complication of the angioplasty interventions and this largely arises early after implantation and can persist for years with stents. With increasing age, the risk of co-morbidities like diabetes mellitus, renal failure, congestive heart failure, and use in arterial bifurcations, long lesions, or overlap increases the risk of ST by approximately 0.6–1% annually.

- The industry underwent a transformation in the last decade moving away from CABG to PCI procedures and also from bare metal stents to drug eluting stents. Currently at least 90% of the stenting procedures around the world use only drug-eluting stents. It is important to note that at least 1.2-1.6 stents are used per procedure in normal circumstances, thus driving the growth of drug-eluting stents further. The initial growth in volume of PCI procedures was driven by conversion

from CABG to PCI, followed by the reimbursement coverage for PCI across most established economies. But later, post 2017, even the emerging economies such as India, China, Brazil and Vietnam witnessed a surge in volume of procedures, despite poor reimbursement, as there was a reduction in pricing of the quality products made available from both multinational and emerging companies, increasing the affordability for the population paying out-of-pocket.

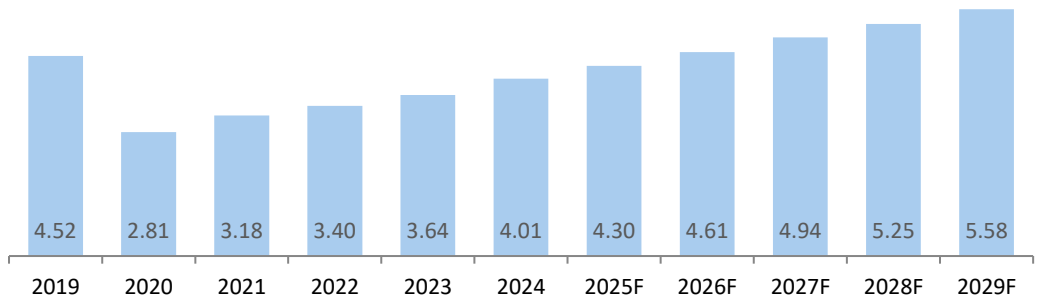
Table 5.5: BMS and DES Market Size and Growth: India, EU and RoW; 2024 and 2029F			
Region	**Market Size (USD Mn)**		**Growth (2024-2029F)**
	2024	**2029F**	
Drug Eluting Stents (DES)			
India	**186.9**	**287.2**	**9.0%**
EU	459.7	489.6	1.3%
RoW	3,360.7	4,805.7	7.4%
Total	4,007.3	5,582.5	6.9%
Bare Metal Stents (BMS)			
India	62.3	55.1	-2.4%
EU	119.2	108.8	-1.8%
RoW	370.6	334.7	-2.0%
Total	552.1	498.6	-2.0%

Source: Frost & Sullivan

5.2.8.1. DES MARKET REVENUE FORECASTS GLOBALLY

The global drug-eluting stent market is expected to reach USD 5.58 billion in 2029 from USD 4.01 billion in 2024 at a CAGR of 6.9%. The growth in the DES market is driven by both an increasing demand for minimally invasive cardiovascular procedures and improved adoption of DES due to accessibility, affordability and quality outcomes.

Exhibit 5.7: Global DES Market (USD Bn), 2019-2029F
CAGR 2024 - 2029F: 6.9%



Source: Frost & Sullivan

5.2.8.2. DES MARKET FORECAST ACROSS REGIONS AND UTILIZATION TREND

The DES market is witnessing growth across all regions, mainly due growing prevalence of cardiovascular diseases, increased reimbursements and insurance coverage and preference for minimally invasive procedures which are driving growth in procedure volumes.

Table 5.6: DES, Market Size and Growth by key regions, 2024 and 2029F

Region	Market Size (USD Mn)		Growth (2024-2029F)
	2024	2029F	
APAC	2,291.2	3,623.3	9.6%
North America	954.3	1,122.5	3.3%
Europe	457.7	489.6	1.3%
LATAM	106.6	158.1	8.2%

Source: Frost & Sullivan

- The DES market in North America is expected to grow from USD 954.3 million in 2024 to USD 1,122.5 million in 2029, at a CAGR of 3.3%. In the North America market, the US holds the highest share of DES volume with 1.72 million devices sold in 2024, and this is expected to increase to 2.2 million

devices in 2029 at a CAGR of 5.2%. The market is driven by a high prevalence of coronary artery disease (4.6%, 3,605 cases per 100,000 people), which is primarily treated by stents/catheters. The transformation of the market from CABG to coronary angioplasty happened in the early 2000s. The conversion from bare metal stents to drug-eluting stents happened between the years 2005 to 2010. Thus, the market is highly stabilized and driven by an increase in the volume of procedures conducted, rather than conversion from alternative therapies. Due to the maturity of the market, the companies drove differential innovation to their core products to drive more sales. Despite PCI being a minimally invasive procedure, it was largely conducted in a hospital setting before 2020. In 2019, the Centers for Medicare & Medicaid Services (CMS) approved 6 types of angioplasty procedures to be reimbursed in ambulatory surgical centres (ASCs). CMS policies have significantly driven the shift of PCI procedures from inpatient to outpatient settings, particularly to ASCs. This trend aligns with the U.S. healthcare system's focus on cost reduction and quality improvement. CMS payments for PCI procedures in ASCs are lower than those for hospital inpatient settings, potentially up to 37% less. Similarly, commercial payers have introduced policies to reward outpatient PCI while strongly discouraging inpatient procedures. This incentivizes hospitals and physicians to perform PCI in outpatient settings, reducing costs for both healthcare providers and patients.

- The DES market in Europe is valued at 457.7 million in 2024 and is expected to reach 489.6 million in 2029, at a CAGR of 1.3%. European countries (mainly in Western Europe) have been the second-largest contributor for the vascular interventional devices market revenue for the longest period in the last decade. Currently, the market has undergone a series of transformation; hence, there is low revenue contribution despite a stable increase in volume of procedures. The five major Western European countries (Germany, France, Spain, Italy and UK) account for about 75% of the total European procedure volume. While the pricing of DES in these countries declined due to government reimbursement pressure, with variations across countries, the prices are stable now.

- The DES sales volume in most of the Western European countries, such as Germany, France, Italy and Spain, is expected to witness a growth of about 2.0% to 4.0% from 2024 to 2029. For instance, the DES volume in Germany is expected to increase from 0.45 million in 2024 to 0.52 million in 2029. Similarly, in France, the DES volume is expected to increase from 0.36 million in 2024 to 0.42 million in 2029.

Table 5.7: DES sales volume for select countries, in thousands, 2024 and 2029F			
Region	**DES Volume (in thousands)**		**Growth (2024-2029F)**
	2024	**2029F**	
US	1,722.1	2218.5	5.2%
China	2,115.0	3,344.5	9.6%
Germany	455.5	522.90	2.8%
France	360.8	418.1	3.0%
Italy	270.5	316.5	3.2%
Spain	106.8	120.2	2.4%
India	819.0	1,392.6	11.2%
Brazil	153.0	235.5	9.0%
Mexico	41.4	63.7	9.0%
Vietnam	36.6	55.8	8.8%

Source: Frost & Sullivan

- The majority of European countries have healthcare insurance policies covering vascular interventional treatments. Drug-eluting stents are reimbursed in the Western European economies under the public system. In recent years, the use of intravascular ultrasound (IVUS) and optical coherence tomography (OCT) in PCI procedures has gradually increased in Europe to achieve improved treatment outcomes. Similarly, the proportion of elective PCI procedures with same-day discharge is gradually increasing.

- The APAC region has a dominant share in the DES market with an estimated value of USD 2,291.2 million in 2024, and it is expected to grow to USD 3,623.3 million in 2029, grown at a CAGR of 9.6%. The Asia Pacific region, driven by countries like China and India is expected to witness strong growth in the angioplasty devices segment. India is expected to witness a high growth of 11.2% in DES sales volume, from about 0.82 million in 2024 to about 1.4 million in 2029, due to rapidly increasing angioplasty procedure volumes (from 0.81 million to about 1.1 million). China witnessed a transformation in the last 10 years where the volume of procedures increased from 0.2 million in 2009 to almost 1.6 million in 2024, and there is an annual increase of more than 150,000 procedures. The DES sales volumes in China is expected to increase from 2.11 million in 2024 to 3.44 million in 2029. Before 2015, with more than 80% of the market driven by multinational companies, price of stent was very high and DES was considered unaffordable for a large cohort of the population. This led to the entry of domestic manufacturers in the late 2010s. Approximately 10 key domestic manufacturers developed drug-eluting stents and other cardiovascular intervention products to support the

domestic demand, and provided their products at competitive prices. The pricing trends of the domestic manufacturers were significantly lower than that of the multinational providers. The new centralized procurement approach for medical institutions initiated in China has changed the dynamics of the market further. In 2020, coronary stents were introduced under the centralized procurement scheme and involved the participation of around 5 global companies and >5 domestic companies. This demonstrated how potential volumes can support price reduction of between 40-50% from originally listed prices. As price reduction ensured volume sales, the companies also benefited from the process. The price reduction is likely to increase the adoption of PCI procedures and estimates reveal that by 2029, China is estimated to have 1,800 procedures conducted per million population.

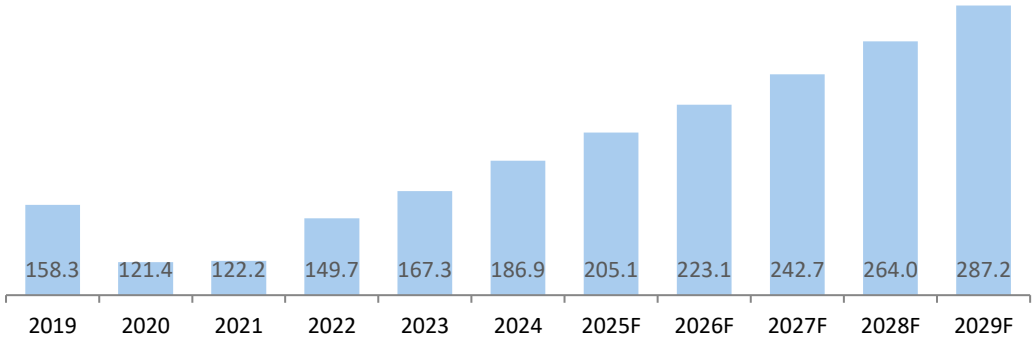
- The Latin American DES market is valued at USD 106.6 million in 2024 and is estimated to reach USD 158.1 million in 2029, growing at a CAGR of 8.2%. Brazil and Mexico are large markets in the region, having a combined revenue share of more than 65% in the region. Brazil's Unified Health System (SUS) provides reimbursement for PCI procedures, including drug-eluting stents. However, reimbursement levels are relatively low and primarily cover basic healthcare needs. Private insurance also plays a significant role in reimbursement. Most private health insurance plans in Brazil cover PCI procedures, but the reimbursement amounts vary by insurance provider and policy. In recent years, the number of PCI procedures in Latin America has been steadily increasing. The number of PCI procedures in Brazil grew at a CAGR of 8.0%, from about 75,266 in 2018 to about 117,700 in 2024. Mexico also saw a CAGR of about 7.0% during the same period, increasing from 30,000 in 2018 to over 44,000 in 2024. The DES sales volumes in Brazil is estimated to reach from about 153,000 in 2024 to over 235,000 in 2029, and in Mexico, it is expected to increase from about 58,000 in 2024 to about 89,000 in 2029. Factors driving this growth include rising awareness of cardiovascular diseases, advancements in medical technology, and improved healthcare infrastructure. In Brazil, the proportion of elective PCI procedures performed in outpatient settings is gradually rising. In 2023, 35% of elective PCI procedures were completed on an outpatient basis, up from 20% in 2020.

5.2.8.3. INDIAN DES MARKET REVENUE FORECAST

The Indian DES market is valued at USD 186.9 million in 2024 and it is estimated to reach USD 287.2 million by 2029, growing at a CAGR of 9.0%. Increasing cardiovascular disease prevalence, increasing affordability due to government reimbursements and insurance coverage and higher adoption of DES compared to BMS are the major drivers of market growth. In India, the National Pharmaceutical Pricing Authority (NPPA) imposed price caps on cardiac stents in 2017, reducing their prices by up to 85%. The ceiling price for BMS was set at Rs 7,260, currently revised to 10,510 and for DES at Rs 29,600, currently revised to 38,267. This has made stents more affordable for patients, potentially increasing the adoption of procedures like angioplasty. According to data from the NPPA, the use of DES has increased by about 40% since the price cap was introduced. Moreover, the introduction of price cap were beneficial for domestic players as opposed to MNCs due the former’s ability to manufacture low-cost quality devices. India is estimated to have the highest growth in DES sales volume in the forecast period (2024 to 2029), growing

at a CAGR of 11.2%. The DES volumes is expected to increase from 0.82 million in 2024 to 1.4 million in 2029.

Exhibit 5.8: Indian DES Market (USD Mn), 2019-2029F
CAGR 2024 - 2029F: 9.0%



Source: Frost & Sullivan

5.2.8.4. COMPARATIVE PROFILE OF MAJOR DES PRODUCTS

Table 5.8: Major companies and their DES stent profile					
Manufacturer	**DES Stent**	**Key DES Stent**	**Drug**	**Polymer**	**Stent Platform**
Sahajanand Medical Technologies	Supraflex Cruz, Supraflex, Tetriflex	Supraflex Cruz	Sirolimus	Bioabsorbable Polymer	Cobalt Chromium
Abbott Vascular	Xience Expedition, Xience Prime, Xience V, Xience Sierra, Xience Alpine, Xience Skypoint	Xience Skypoint	Everolimus	Non-bioabsorbable Fluoropolymer	Cobalt Chromium
Medtronic	Resolute Onyx, Onyx Frontier, Resolute Integrity	Resolute Onyx	Zotarolimus	BioLinx	Shell: Cobalt alloy, Core: Platinum Iridium
Boston Scientific	Synergy, Promus Premier, Promus Elite, Promus Element	Synergy	Everolimus	Bioabsorbable Polymer	Platinum Chromium
		Promus Element Plus	Everolimus	Fluoropolymer	Cobalt Chromium
Teleflex*	Orsiro	Orsiro	Sirolimus	Bioabsorbable Polymer	Cobalt Chromium
Biosensors	BioFreedom Ultra, BioFreedom, BioMatrix NeoFlex, BioMatrix Alpha	BioFreedom Ultra	Biolimus-A9	-	Cobalt Chromium
Terumo	Ultimaster Tansei	Ultimaster™ Tansei™	Sirolimus	Bioabsorbable Polymer	Cobalt Chromium
Lepu Medical	Nano, NeoVas, GuReater CoCr, Partner	Nano	Sirolimus	Bioabsorbable Polymer	Cobalt Chromium
		GuReater CoCr	Sirolimus	Bioabsorbable Polymer	Cobalt Chromium
SinoMed	HT Supreme BuMA	HT Supreme	Sirolimus	Bioabsorbable Polymer	Cobalt Chromium
		BuMA	Sirolimus	Bioabsorbable Polymer	Stainless Steel
Integris Health	Yukon Choice PC Elite Yukon Choice PC, Ultima PC, ISAR Summit	Yukon Choice PC	Sirolimus	Bioabsorbable Polymer	Stainless Steel
		Ultima PC	Sirolimus	Bioabsorbable Polymer	Cobalt Chromium

*Biotronik's vascular intervention business was acquired by Teleflex in July, 2025

Abbott Vascular, Boston Scientific, Medtronic, Teleflex, Biosensors and Terumo are prominent global multinational players in the DES stent market with greater than 90% market share. However, with growing demand, there is a push toward developing technologically advanced products with features like better drug delivery kinetics, improved healing, and better trackability and pushability. This market evolution provides market expansion opportunities for other companies in India and China, such as SMT and Lepu Medical, which have a presence in select geographic regions currently and which have developed advanced products that are lower cost and have high quality compared to established products.

5.3. OVERVIEW OF GLOBAL STRUCTURAL HEART DEVICES MARKET

5.3.1. STRUCTURAL HEART DISEASE BURDEN

- Structural Heart Disease (SHD) is a problem involving tissues or valves of the heart. SHDs encompasses a range of conditions affecting the heart's normal structure and function. These conditions can be present at birth (congenital) such as septal defects or develop later in life (non-congenital or acquired) such as stenosis (narrowing of valves) owing to wear and tear from aging and deterioration due to infections as well. All SHDs involve a defect or disorder in the structure of the heart tissue or valves or its functioning. Common symptoms of SHD involve strokes, shortness of breath, high blood pressure, leg cramps, and kidney dysfunction.

- Valve defects involve stenosis (narrowing) such as aortic or mitral valve stenosis or regurgitation (leakage) which can impair blood flow. Stenosis occurs when the valve leaflets thicken or stiffen, restricting blood flow. Regurgitation happens when the valve leaflets don't close properly, causing blood to leak backward. Wall defects, like atrial or ventricular septal defects, create abnormal pathways due to hole in the wall between the atria or ventricle, allowing blood to flow between the left and right chamber within the heart. SHD represent a significant portion of the global cardiovascular disease burden. SHDs, including conditions like rheumatic heart disease and congenital heart disease, contribute substantially to the burden of cardiovascular diseases. Despite advancements in surgical therapy, including transcatheter therapies, SHD is often underdiagnosed and detected late; it is also undertreated and receives relatively little attention from the general public and policymakers. Inequalities exist in access to timely diagnosis and treatment between regions, leading to health care disparities related to SHD. Addressing these gaps in disparities will require intensified efforts directed at prevention, early detection, and materially enhanced disease management strategies. As the global population ages, the prevalence of degenerative structural heart conditions, such as aortic stenosis and mitral valve disease, is expected to rise. Rheumatic heart disease, for instance, is more prevalent in low- and middle-income countries and is often associated with poverty and inadequate access to healthcare. Rheumatic heart disease is the most common cause of valvular heart disease in low- and middle-income countries.

- Aortic-valve stenosis is an increasingly important cause of cardiovascular disease, particularly among older adults, with an overall global prevalence of 2.8% among adults older than 75 years of age. In India, the prevalence of moderate or severe aortic stenosis in patients more than 75 years old is 3.0%, and it is 3.4% in Europe and the USA. Research suggests that an ageing population, in addition to birth defects, can be a key driver for increasing structural heart disease. In fact, in the USA alone,

approximately 1 in every 1,859 babies is born with an atrial septal defect. By 2050, it is expected that around 1.5 billion people (age 65+) in the world will have some kind of heart disease, with 50% having undiagnosed valvular disease. Such growth highlights the need for timely diagnosis and effective treatment of patients suffering from different types of structural heart diseases.

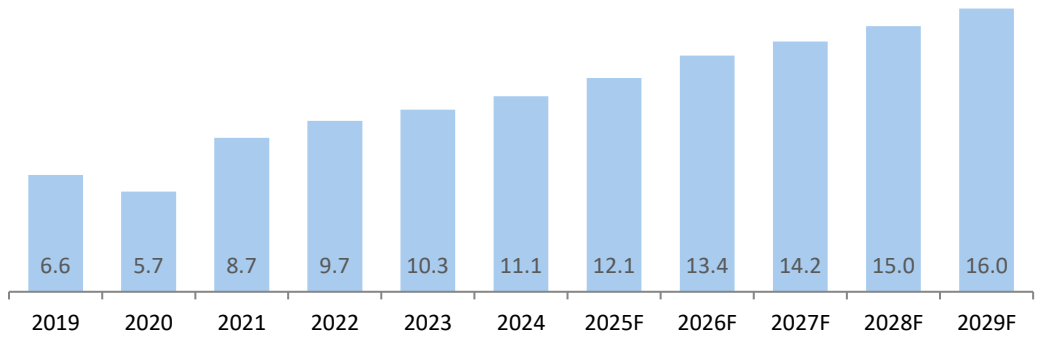
- Aortic stenosis is a progressive disease in which the rate of change of the aortic-valve area is estimated to be 0.1 cm^2 annually, although there is wide variability among patients. In the absence of therapies to prevent or slow progression toward severe aortic stenosis, which remains a major unmet clinical need, timely aortic-valve replacement represents the main treatment option.

- Mitral stenosis (MS) is a form of valvular heart disease characterized by the narrowing of the mitral valve orifice. The most common cause of mitral stenosis is rheumatic fever, though the stenosis typically does not become clinically relevant until several decades later. Uncommon causes of mitral stenosis are calcification of the mitral valve leaflets and congenital heart disease. While the prevalence of rheumatic disease in developed countries is declining, with an estimated incidence of 1 in 100,000, it is higher in developing nations. For instance, in Africa, the prevalence of rheumatic disease is 35 cases per 100,000.

5.3.2. MARKET REVENUE FORECASTS FOR STRUCTURAL HEART DEVICES

- The global structural heart devices market is expected to reach USD 16.0 billion in 2029 from USD 11.1 billion in 2024 at a CAGR of 7.7%. The growth in the market is driven by both an increasing demand for minimally invasive cardiovascular procedures and improved adoption of TAVI and other products due to accessibility, affordability and quality outcomes. The global structural heart device market has been witnessing growth, driven by growing awareness, increased healthcare expenditure and technological development. Advancements in the structural heart segment have replaced the open heart surgical procedures with minimally invasive procedures like TAVI and TMVI, further driving growth within the segment.

Exhibit 5.9: Global Structural Heart Device Market (USD Bn), 2019-2029F
CAGR 2024 - 2029F: 7.7%



Source: Frost & Sullivan

- The global structural heart devices market can be segmented into TAVI, TMVI, Occlusion devices, Left Atrial Appendage (LAA) closure device and other devices. These devices are mainly used in the treatment of aortic stenosis (TAVI and TMVI), septal defects (occlusion devices) and LAA defects. TAVI has the major share of the structural heart device market, with about 58% in 2024. The global TAVI market is valued at about USD 6.4 billion in 2024 and it is estimated to grow to about USD 8.8 billion in 2029 at a CAGR of 6.5%. Structural heart devices not only command premium pricing due to their advanced technology and clinical value but also benefit from growing demand in both domestic and international markets.

Table 5.9: Structural Heart Devices Market Size and Growth: India, EU and RoW; 2019, 2024 and 2029F

Region	Market Size (USD Mn)		
	2024	2029F	Growth (2024-2029F)
India	39.7	121.5	25.1%
EU	3,426.9	4,944.1	7.6%
RoW	7,595.1	10,963.0	7.6%
Total Structural Heart	11,061.7	16,028.6	**7.7%**

Source: Frost & Sullivan

- TAVI has evolved into a mature and established treatment for aortic valve stenosis over the past decade. With advancement in technology such as balloon-expandable and self-expandable valves, there has been an iterative improvement in the TAVI valve and delivery systems. Moreover, the latest generations of these devices have enhanced hemodynamic performance, improved sealing, reduced profiles, and minimized complications such as paravalvular regurgitation and stroke. Many researchers and cardiologists have shown varied advantages of TAVR procedure over a traditional surgical aortic valve replacement (SAVR). TAVI procedures have become increasingly standardized, with operators gaining extensive experience. The introduction of minimalistic approaches, such as routine use of conscious sedation and single arterial access, has streamlined the procedure, reduced complications, and improved outcomes comparable to or even superior to SAVR. A wealth of clinical data has demonstrated the efficacy and safety of TAVI. Recent studies have also indicated that TAVI is effective and safe in low-risk patients, leading the European Society of Cardiology (ESC) guidelines to recommend TAVI as the primary therapeutic strategy for patients aged 75 and older. Initially, TAVI was primarily used for inoperable or high-risk surgical patients. However, with technological advancements and accumulating clinical evidence, its indications have gradually expanded to intermediate-risk and low-risk patients.

- Occluders are medical devices used to close abnormal openings or holes in the heart, such as Atrial Septal Defects (ASD), and Patent Foramen Ovale (PFO), and excludes Left Atrial Appendage (LAA) Occluder used for closing the LAA, a small pouch in the heart where blood clots can form and travel to the brain. Occluder devices play a critical role in the treatment of congenital and acquired heart

defects, such as atrial septal defects and patent foramen ovale, and represent a significant growth opportunity, particularly in developing countries where the prevalence of such conditions and the need for minimally invasive therapies are rising. An ASD occluder is a medical device used to close atrial septal defects (ASD) in the heart. These defects are holes in the heart's wall between the two atria. ASD occluders are typically used in a minimally invasive procedure where a catheter is inserted into a blood vessel and guided to the heart. Fenestrated occluders have a small hole in the device, allowing for some blood flow between the atria even after the ASD is closed. This can be beneficial in situations where rapid closure of the ASD might lead to increased pressure in the left atrium, potentially causing pulmonary congestion or heart failure. A VSD occluder is a medical device used to close a ventricular septal defect (VSD), a hole in the wall between the heart's ventricles, without open-heart surgery. These devices are delivered through a catheter and placed in the VSD, where they expand to seal the hole. A PFO occluder is a medical device used to close a patent foramen ovale (PFO), a small opening in the heart that can cause blood clots to travel to the brain and potentially lead to stroke. These devices are typically made of a mesh material and are designed to be inserted through a catheter into the heart and deployed to close the PFO. PFO closure can significantly reduce the risk of recurrent ischemic stroke in patients with a PFO-associated stroke. A PDA occluder is a medical device used to close a patent ductus arteriosus (PDA), a congenital heart defect where a blood vessel between the aorta and pulmonary artery remains open after birth. These devices are typically delivered via catheter, a thin, flexible tube inserted into a blood vessel, and are designed to expand and seal the PDA. PDA occluders offer comparable success rates to surgery and can be used in a wider range of patients, including those with complex PDA anatomy.

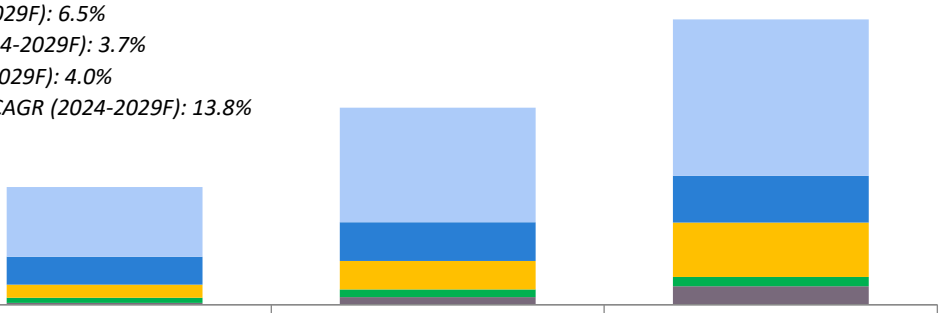
- Occluder technology has undergone significant advancements in recent years. Early occluders were relatively simple in design and functionality. For example, the first-generation Amplatzer ASD Occluder was a simple double-disc device. Modern occluders feature more complex structures and enhanced performance. For instance, the latest generation of Amplatzer Amulet occluders incorporate improvements in conformability, retrievability, and sealing, reducing procedural complications and improving success rates. As occluder technology continues to advance and clinical evidence grows, its adoption is expected to further expand globally, benefiting more patients. Occluders have about 20% revenue share in the SHD market. The global Occluder market is valued at about USD 2.2 billion in 2024 of and it is estimated to reach about USD 2.6 billion in 2029 at a CAGR of 3.7%. Its growing adoption is driven by expanding indications, increasing procedural volumes, and favorable reimbursement policies. The demand for occluders is expected to increase globally, with especially strong growth prospects in emerging markets due to expanding healthcare infrastructure, greater awareness, and increasing access to advanced cardiac care.

- LAA devices are used in the treatment of defects pertaining to LAA, which is a small, ear-shaped sac in the muscle wall of the left atrium (i.e. top left chamber of the heart). In case of normal heart functioning, the heart contracts with each heartbeat, and the blood in the left atrium and LAA is squeezed out of the left atrium into the left ventricle (i.e. bottom left chamber of the heart). However, when a person suffers from atrial fibrillation, the electrical impulses that control the heartbeat do not travel in an orderly fashion through the heart. Fast and chaotic impulses do not

give the atria time to contract and/or effectively squeeze blood into the ventricles. As a result of this blood starts collecting in LAA which can lead to clot formation in the LAA and atria. When these blood clots are pumped out of the heart, they cause stroke. LAA devices has a revenue share of about 15% in the SHD market. Growing prevalence of such cases along with major technological advancements from device manufacturers have triggered the growth in LAA device segment which is expected to reach USD 3.0 billion by 2029 from USD 1.6 billion in 2024, growing at CAGR of 13.8%.

Exhibit 5.10: Global Structural Heart Device Market by product segments (USD Bn), 2019-2029F

TAVI CAGR (2024-2029F): 6.5%
Occluder CAGR (2024-2029F): 3.7%
TMVI CAGR (2024-2029F): 4.0%
LAA closure device CAGR (2024-2029F): 13.8%



	2019	2024	2029F
Total	6.61	11.06	16.03
TAVI	3.92	6.42	8.79
Occluder	1.56	2.19	2.62
LAA closure	0.73	1.60	3.06
TMVI	0.30	0.43	0.52
Others	0.10	0.43	1.04

Source: Frost & Sullivan

Table 5.10: TAVI and Occluder Market Size and Growth: India, EU and RoW; 2024 and 2029F

Region	Market Size (USD Mn)		Growth (2024-2029F)
	2024	2029F	
Transcatheter Aortic Valve Implantation (TAVI)			
India	24.5	75.3	25.2%
EU	1,913.0	2,501.7	5.5%
RoW	4,485.9	6,210.6	6.7%
Total	6,423.4	8,787.6	**6.5%**
Occluder			
India	8.3	19.4	18.6%
EU	636.2	743.3	3.2%
RoW	1,540.8	1,859.3	3.8%

Total	**2,185.3**	**2,621.9**	3.7%

Source: Frost & Sullivan

5.3.3. MARKET REVENUE FORECASTS FOR STRUCTURAL HEART DEVICES BY REGION

North America accounted for the largest share in revenue (44%) in the structural heart devices market with a value of USD 4,830.8 million in 2024. Primarily driven by increasing prevalence of structural heart diseases, a large number of geriatric population having valvular heart diseases and increasing demand for minimally invasive procedures, has led to sustained growth in this region historically. However, due to established nature of the market resulting in tepid procedure volume growth coupled with pricing pressures resulting in declining reimbursement rates, the market is expected to grow at a low single-digit CAGR of 2.4% from 2024 to 2029. North America is followed by Europe, which is valued at USD 3,426.9 million in 2024, and it is estimated to grow at a CAGR of 7.6% between 2024 and 2029. Asia-Pacific (APAC) region, which is valued at USD 2,705.9 million in 2024, is expected to overtake the North American and European markets by value in 2029 due to high growth in the region. Countries in the emerging markets, like China and India, are experiencing rapidly expanding populations and an increasing prevalence of structural heart diseases. There has been a huge demand-supply gap in terms of treatment procedures required by the patients. Such factors, combined with the increasing purchasing power of the population and improving accessibility to technology and specialized valvular heart procedures, are expected to propel the market in the upcoming years. The Latin America (LATAM) market is valued at USD 50.2 million in 2024 and it is estimated to reach USD 83.7 million in 2029, growing at a CAGR of 10.7%. There is increasing adoption of structural heart devices in countries such as Brazil and Mexico due to increased accessibility and affordability, which is driving the market growth. The Middle East and Africa (MEA) market is valued at USD 47.9 million in 2029 and it is estimated to reach USD 63.7 million in 2029, growing at a CAGR of 5.8%.

Table 5.11: Structural Heart Devices Market, Market Size and Growth by region, 2024 and 2029F

Region	Market Size (USD Mn)		Growth (2024-2029F)
	2024	2029F	
North America	4,830.8	5,449.0	2.4%
Europe	3,426.9	4,944.1	7.6%
APAC	2,705.9	5,488.2	15.2%
LATAM	50.2	83.7	10.7%
MEA	47.9	63.7	5.8%

Source: Frost & Sullivan

5.3.4. INNOVATION AND EVOLUTION IN STRUCTURAL HEART THERAPY

- Structural heart interventions refer to minimally invasive procedures used to treat defects or abnormalities in the heart's structure. This involve procedures such as Transcatheter Aortic Valve

Repair (TAVI), Transcatheter Mitral Valve Repair (TMVR), Transcatheter Tricuspid Valve Repair (TTVR), Left Atrial Appendage Closure (LAAC) and others. TAVI and TMVR are more established and popular procedures among structural heart interventions. The structural heart devices market has witnessed remarkable innovation and evolution over the past few decades, transforming the treatment of various heart conditions. The structural heart devices market is dynamic, with ongoing research and development leading to innovative solutions that improve the quality of life for patients with heart disease. As technology advances and clinical evidence accumulates, transcatheter interventions are expected to play an even greater role in the management of structural heart conditions.

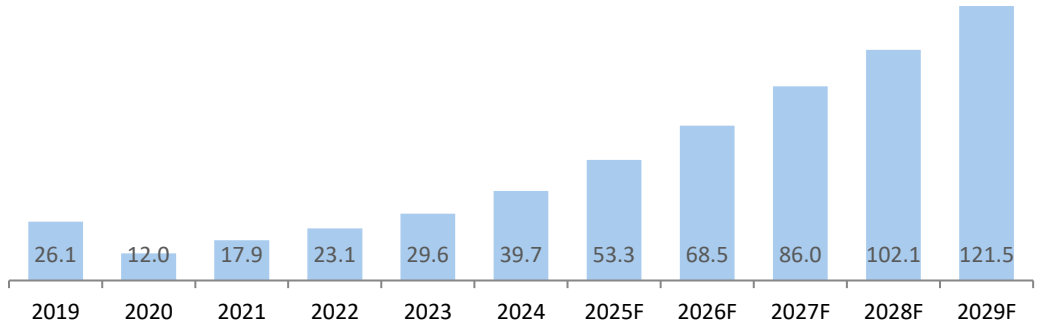
- TAVI is an advanced, minimally invasive therapy to treat severe aortic stenosis in high-risk, geriatric patients. Such patients cannot undergo normal cardiac surgery, and TAVI is considered to be the only viable alternative. The first successful TAVI procedure was performed in 2002. Early devices and techniques were primarily for patients deemed inoperable or at very high risk for traditional open-heart surgery. Factors such as valve design, delivery systems, and imaging guidance have improved the adoption and success of TAVI and TMVR procedures. Evolution from balloon-expandable valves to self-expanding and mechanically expandable valves offered improved precision, hemodynamics, and durability. The development of lower-profile delivery systems for easier access through smaller blood vessels reduced complications. Enhanced imaging techniques like 3D echocardiography and CT angiography have enabled better patient selection, valve sizing, and procedural guidance. The ability to reposition or retrieve the valve during the procedure has significantly improved safety and accuracy. TAVI is now widely used for patients across all risk categories, including those at low surgical risk.

- Occluder technology is evolving which includes advanced biodegradable occluders, hybrid occlusion tools, and precision delivery systems for improved the safety and efficacy of occluder devices, providing patients with more treatment options for congenital heart defects. However, major incumbents such as Abbott (which acquired AGA Medical in 2010) continue to sell the same generation of devices (Amplatzer) with minimal structural innovations over the last decade. Other players like Occlutech and LifeTech offer devices with slight delivery or material refinements, but no radical technology shift is evident across the market. Biodegradable occluders are still under clinical evaluation and not yet commercially available and hybrid occlusion tools (which combine multiple functionalities to address various heart defects simultaneously) are not a widely adopted or clearly defined product category in current practice.

5.3.5. INDIAN STRUCTURAL HEART DEVICES REVENUE FORECAST

The Indian structural heart device market is values at USD 39.7 million in 2024 and it is expected to reach USD 121.5 million in 2029, growing at a CAGR of about 25.1%. Increased awareness and adoption of treatment, coupled with increased affordability and availability of low-cost, high quality products from domestic companies has propelled the procedure volumes the country.

Exhibit 5.11: Indian Structural Heart Device Market (USD Mn), 2019-2029F
CAGR 2024 - 2029F: 25.1%

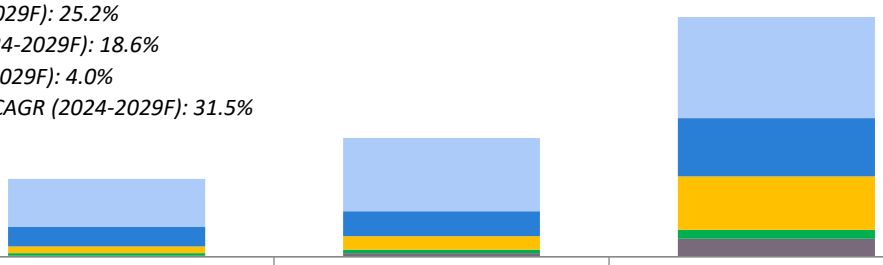


Source: Frost & Sullivan

Among the segments of the structural heart devices, TAVI has the highest revenue share in 2024, comprising of over 60% and with a revenue of USD 24.5 million. Occluders, with a revenue of USD 8.3 million in 2024, has a revenue share of about 21%. LAA closure devices, with a revenue of USD 4.5 million in 2024, has about 11% revenue share, and has the highest CAGR among structural heart devices (31.5%).

Exhibit 5.12: Indian Structural Heart Device Market by product segments (USD Mn), 2019-2029F

TAVI CAGR (2024-2029F): 25.2%
Occluder CAGR (2024-2029F): 18.6%
TMVI CAGR (2024-2029F): 4.0%
LAA closure device CAGR (2024-2029F): 31.5%



	2019	2024	2029F
Total	26.0	39.7	121.5
TAVI	16.0	24.5	75.3
Occluder	6.6	8.3	19.4
LAA closure	2.2	4.5	17.8
TMVI	0.9	1.2	3.0
Others	0.3	1.2	6.0

Source: Frost & Sullivan

5.3.6. TAVI PROCEDURE VOLUME TREND AND REVENUE FORECAST

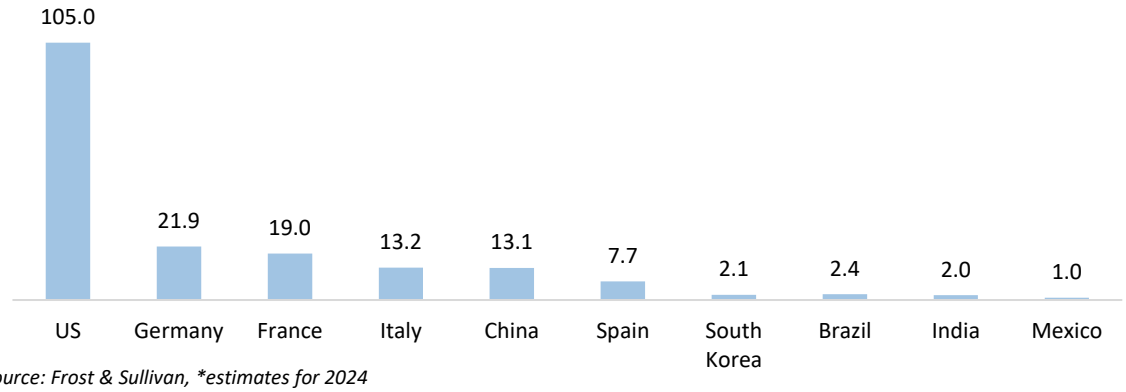
- There is accelerated growth in TAVI procedure volumes globally. In 2010, there were approximately 20,000 TAVI procedures performed worldwide which exceeded 100,000 by 2015 and now in 2024, more than 200,000 TAVI procedures are estimated to be conducted globally.

- In the U.S., TAVI procedures were approved by the FDA in 2011. In 2012, the procedure volume was approximately 11,000. By 2020, this number had reached more than 55,000. In 2024, the procedure volume in the U.S. exceeded 100,000. The US is estimated to have about 50% share in the global TAVI procedure volumes driven by the presence of developed healthcare infrastructure, increased adoption of TAVR devices, and technological advancements. The market is stable; the penetration has increased during the last decade as the market exploded with products to treat new complexities and broad adoption of the same by the US health system and FDA. The future growth would be driven by an increase in incidence. There is a likely expectation of price reduction and competitive intensity increases with the introduction of emerging companies from India, China, etc., penetrating the US market. This is likely to impact revenue growth potential marginally.

- In Europe, Germany leads in TAVI procedures, followed by France, Italy, the UK and Spain. While Germany performs about 22,000 annual TAVI procedures, France performs about 19,000 procedures. Italy performs about 13,000 procedures, and the UK and Spain perform fewer than 10,000 procedures. Europe accounts for the second-largest share in the global TAVI market and is expected to maintain this trend in the upcoming years. Growth will be driven by the rise in prevalence of severe aortic stenosis cases combined with the increase in the old age population, and high adoption rate of advanced transcatheter aortic valves. The market penetration is currently low across most countries, including the developed Western European countries. There is still scope for expansion of products for new applications, thus adding a cohort of new target patients. This growth from volume of procedures is likely to be impacted by pressure on pricing of the products from the reimbursement systems and competition from emerging companies, thus impacting overall revenue growth in the market.

- In the APAC region, TAVI procedure volumes are growing due to an increase in accessibility and adoption in countries such as China, India and South Korea. The market is currently under-penetrated and is likely to almost double in terms of penetration between 2024 and 2029. There is a lack of reimbursement, competitively priced alternatives and limited access to care, impacting the market adoption and growth currently. The TAVI procedure volume in China has grown from about 1,200 in 2018 to over 13,000 in 2024, and this is expected to more than double by 2029, reaching over 31,000 procedures. Similarly, the TAVI procedure volume has shown an accelerated growth and more than tripled from about 600 in 2018 to nearly 2,000 in 2024. The volumes are expected to reach more than 7,500 in India by 2029.

Exhibit 5.12: TAVI procedure volumes (in thousands), select countries, 2024*



*Source: Frost & Sullivan, *estimates for 2024*

- North America dominates the global TAVI market with about 42.0% revenue share, largely due to its well-established healthcare infrastructure and high adoption of TAVI procedures. The US market is particularly mature and sophisticated, with easy access to minimally invasive procedures and favorable reimbursement policies. However, growth in the TAVI market has shown signs of deceleration. TAVI was initially primarily used for high-risk or inoperable surgical patients. Over time, the market for TAVI in high-risk patient populations has become relatively saturated. Although indications have expanded to intermediate-risk and low-risk patients, the rate of adoption in these groups is slower than expected. The TAVI market in North America is valued at USD 2,696.6 million in 2024 and it is estimated to reach USD 2,757.2 million in 2029, growing at a CAGR of 0.4%.

- The TAVI market in Europe is valued at USD 1,913.0 million in 2024 and is expected to reach USD 2,501.7 million in 2029, growing at a CAGR of 5.5%. Increasing adoption of TAVI procedures and favourable reimbursement scenario in developed markets such as Germany, France, Spain and Italy is driving the market growth in the region.

- The TAVI market in the APAC region is valued at USD 1,751.6 million in 2024 and is expected to reach USD 3,436.3 million in 2029, growing at a CAGR of 14.4%. APAC region witnesses the highest growth in the TAVI market due to increasing prevalence of Aortic Stenosis, large population and increasing adoption of TAVI procedures in countries such as China and India.

- The TAVI market in the LATAM region is valued at USD 30.1 million in 2024 and is expected to reach USD 48.5 million in 2029, growing at a CAGR of 10.0%. The growth in the region is driven by major markets Brazil and Mexico, where there is increasing adoption of the TAVI procedures due to improved affordability and accessibility.

Table 5.12: TAVI Market, Market Size and Growth by region, 2024 and 2029F			
Region	**Market Size (USD Mn)**		**Growth (2024-2029F)**
	2024	**2029F**	
North America	2,696.6	2,757.2	0.4%
Europe	1,913.0	2,501.7	5.5%
APAC	1,751.6	3,436.3	14.4%
LATAM	30.1	48.5	10.0%
MEA	32.1	43.9	6.5%

Source: Frost & Sullivan

5.3.7. GROWTH DRIVERS FOR TAVI MARKET

- **Expansion of Indications**: Initially, TAVI was primarily used for high-risk or inoperable patients. However, as evidence of its safety and efficacy has accumulated, its indications have gradually expanded to include intermediate-risk and low-risk patients. Regulatory approvals and guideline recommendations have expanded the use of TAVI to include patients at intermediate and even low surgical risk. This has significantly increased the number of eligible patients worldwide. In 2019, the FDA approved TAVI for low-risk patients, significantly broadening the eligible patient population and driving market growth.
- **Aging Population:** The elderly are more susceptible to aortic valve diseases. With the global aging population, the number of elderly patients requiring TAVI is steadily increasing, providing a stable growth foundation for the TAVI market. Studies indicate a population prevalence of Aortic Stenosis of about 2.8% in people aged over 75 years.
- **Favorable Reimbursement Policies**: In recent years, reimbursement policies for TAVI procedures have improved in many countries. For instance, in the U.S., Medicare and Medicaid provide coverage for TAVI procedures. In Europe, countries such as Germany and the U.K. have also incorporated TAVI into their reimbursement frameworks. In Japan, TAVI procedures are covered under national health insurance. These policies have reduced the financial burden on patients, enhancing their access to TAVI treatments.
- **Rising Adoption of Minimally Invasive Procedures**: TAVI, as a minimally invasive procedure, offers advantages over traditional open-heart surgery, including shorter hospital stays, faster recovery times, and lower complication risks. These benefits align with the growing trend of minimally invasive treatments in the medical field and have contributed to the increasing adoption of TAVI.
- **Technological Advancements:** Continuous improvements in TAVI technology have enhanced its safety and efficacy. For example, the introduction of self-expanding valves has increased the success rate of TAVI procedures and improved patient outcomes. Additionally, advancements in imaging

technologies, such as 3D echocardiography and computed tomography, have enabled more precise TAVI planning and execution. These technological innovations have expanded the applicability of TAVI and boosted its adoption.

- **Increasing cases of Aortic Valve Stenosis**: Aortic valve stenosis is a common valvular heart disease. With the aging population, the incidence of aortic valve stenosis is rising. Approximately 1.5 million patients in the U.S. have severe aortic valve stenosis, with 50,000 new cases reported annually. In Europe, the number of patients with severe aortic valve stenosis exceeds 1 million. The growing patient population is driving the demand for TAVI procedures. Emerging economies such as India and China have witnessed a high number of structural heart cases. In India alone, more than 3% of people above 75 years of age suffer from aortic stenosis. Given the large population, a small percentage increase in these cases will add greater burden on stretched healthcare facilities.

5.3.8. REIMBURSEMENT TRENDS FOR TAVI

- In the U.S., Medicare and Medicaid provide reimbursement for TAVI procedures. A large majority of TAVR cases in the US are reimbursed through Medicare, and Medicare spending on the procedure has greatly increased as the number of cases has increased. Medicare pays for TAVR across all risk groups, with the cost of TAVR index hospitalization being USD 61,845 for low-risk surgical, USD 64,658 for intermediate risk, and USD 65,694 for high-risk.[43] Most private insurance plans in the U.S. also cover TAVI procedures, though reimbursement details vary by insurer. Generally, private insurance reimbursement rates are similar to or slightly higher than those of Medicare and Medicaid.

- Structural heart procedures are reimbursed by major state funded healthcare plans in different European countries. TAVI reimbursement policies in Europe are diverse, with reimbursement models including DRGs, add-on payments, and fee-for-service. Countries like Germany and France have relatively mature reimbursement systems with government's "statutory" health insurance paying for the cost of treatment, while others are still refining their frameworks. As TAVI technology advances and clinical evidence grows, reimbursement policies for TAVI procedures are expected to further improve, benefiting more patients. Similar to practices in the US, countries like France, UK, Germany, Belgium, etc. follow brand-specific reimbursement for medical devices which gets established for different companies. In Germany, TAVI is reimbursed through Diagnosis-Related Groups (DRGs). TAVI is already established as a standard procedure in Germany, and there is are no additional incentives to encourage its adoption. The reimbursement amount depends on factors such as hospital type and procedure complexity, and the reimbursement rate ranges from EUR 32,000 to EUR 36,000. France uses a combination of DRGs and add-on reimbursement for TAVI. Reimbursement amounts differ based on procedural access routes. For instance, transapical access TAVI has higher reimbursement than transfemoral access. The reimbursement rate ranges from EUR 27,000 to EUR 30,000 in France, and the add-on list allows for separate reimbursement of implantable devices, helping to cover part of the additional costs of TAVI. With growing evidence of

[43] Secondary sources

TAVI's efficacy and safety, European countries have gradually expanded reimbursement coverage for TAVI procedures. Initially limited to high-risk or inoperable patients, reimbursement now extends to intermediate-risk and low-risk patients in many countries. For example, in Germany and Switzerland, TAVI is covered for a broader range of patients. As TAVI technology advances and market demand grows, reimbursement amounts for TAVI procedures are gradually increasing. Governments and insurers recognize the value of TAVI in improving patient outcomes and reducing healthcare costs, leading to higher reimbursement rates to support healthcare providers.

- Reimbursement system in China varies from region to region. However, with the implementation of the New Rural Cooperative Medical System, almost all devices are covered by reimbursement for "in-hospital patients" in the country. Centralized procurement strategy of Chinese government reduces the original average prices making it cheaper for the patients to bear the cost of structural heart procedures. The TAVI procedures have not been covered for all applications across provinces, hence adoption is low.

- Japan provides reimbursement of TAVI procedures under the National Health Insurance (NHI). In October 2013, TAVI was approved for reimbursement under Japan's national health insurance system. The reimbursement amount is determined based on hospital fees and physician labor costs. According to the Japanese Association for Thoracic Surgery database, the number of TAVI procedures has been increasing annually. In 2023, Japan's TAVI procedure volume reached 10,000. Japan's clinical guidelines recommend TAVI for patients aged 80 and above. In October 2013, TAVI was approved for reimbursement under Japan's national health insurance system. The reimbursement amount is determined based on hospital fees and physician labor costs. According to the Japanese Association for Thoracic Surgery database, the number of TAVI procedures has been increasing annually, and it reached over 10,000 in 2023. Japan's clinical guidelines recommend TAVI for patients aged 80 and above.

- In India, Central Government Health Scheme (CGHS) includes TAVI in its reimbursable procedures, with specific reimbursement amounts allocated for the procedure and device. Also, Employees' State Insurance Scheme (ESIS) provides reimbursement for TAVI procedures. For instance, in the state of Haryana, ESIS covers TAVI under its health insurance program. While most private insurance plans in India cover TAVI procedures, the reimbursement details vary by insurer, with some plans offering full coverage and others providing partial reimbursement based on specific terms.

- In South Korea, TAVI was included in the national health insurance coverage in 2015, with the NHIS partially reimbursing the costs. Initially, coverage was restricted to high-risk and inoperable patients but has since expanded. Integration of TAVI into its national health insurance with increasing coverage, leading to a rise in the procedure's adoption. In May 2022, the insurance standards for TAVI were broadened, increasing coverage for patients over 80 regardless of risk and providing maximum coverage for high-risk patients.

- In recent years, Mexico and Brazil have been working to improve reimbursement policies for TAVI and structural heart procedures to enhance patient access to advanced medical technologies. However, challenges remain, including high procedure costs, limited medical resources, and economic constraints. Mexico's Instituto Mexicano del Seguro Social (IMSS) covers TAVI procedures. However, whether the procedure is performed depends on the hospital's budget and the recommendations of a specialized heart team. While public insurance systems like IMSS provide coverage, reimbursement may be subject to certain restrictions, such as hospital-level requirements and budget limitations. Additionally, the complexity of the procedure and the need for specialized medical teams may also impact reimbursement policies. In Brazil, TAVI procedures are covered by public and private insurance systems. The Brazilian Unified Health System (SUS) reimburses TAVI procedures under specific conditions. However, reimbursement amounts and specific policies may vary across regions.

5.3.9. COMPARITIVE PROFILE OF MAJOR TAVI PRODUCTS

While leading companies such as Boston Scientific Corporation, Medtronic, Abbott Laboratories and Edwards Lifesciences Corporation hold significant market share in the structural heart market and drive industry trends, emerging companies such as SMT from India are competing with established players by developing innovative and cost-effective products addressing the needs of emerging and developed markets. Succeeding in the competitive TAVI market requires meeting stringent regulatory requirements and proven effectiveness in randomized control trials. Recently, in May 2025, Boston Scientific announced the discontinuation of sale of its CE-marked Acurate neo 2 and Acurate Prime transcatheter aortic valve systems.

The structural heart market is consolidating, with larger companies acquiring smaller ones to increase their market power. Acquisitions bring together companies with complementary research and development capabilities, fostering further innovation in the field. Acquisitions are a significant driving force in the structural heart market, shaping its competitive landscape and accelerating the development of new technologies. These companies focus on R&D innovation and product portfolio expansion to enhance competitiveness. For example, Edwards Lifesciences acquired JenaValve, JC Medical and Endotronix in 2024 to strengthen its product offerings for aortic regurgitation and heart failure treatment. CORCYM was formed in 2021 from the acquisition of LivaNova's heart valve business by Gyrus Capital. Indian company, SMT, acquired Vascular Concepts in 2020 to expand into structural heart portfolio.

Table 5.13: Major companies and their TAVI product profile			
Manufacturer	**Country**	**Name of TAVI**	**Description**
Edwards Lifesciences	US	SAPIEN 3 and SAPIEN 3 Ultra	These are balloon-expandable transcatheter heart valve systems. They utilize bovine pericardium tissue valves and a polyethylene terephthalate (PET) outer skirt. The SAPIEN platform is indicated for patients with symptomatic severe native calcific aortic stenosis or failing bioprosthetic aortic valves, and is also approved for valve-in-valve procedures.
		SAPIEN 3 Ultra RESILIA	This valve incorporates Edwards' RESILIA tissue technology, a bovine pericardial tissue treated with a novel preservation method designed to prevent calcium binding and enhance durability. It also allows for dry packaging.
Medtronic	US	CoreValve Evolut R Evolut PRO/PRO+	These are self-expanding transcatheter aortic valve systems featuring a supra-annular nitinol frame and a porcine pericardial tissue valve. The Evolut PRO and PRO+ models include a pericardial wrap for enhanced sealing. The Evolut systems are designed for a large effective orifice area and low gradients.
Abbott	US	Navitor	Navitor TAVI system is a minimally invasive treatment option for patients with severe aortic stenosis who are deemed to be at high or extreme risk for traditional open-heart surgery. The Navitor valve is a self-expanding transcatheter heart valve. A notable feature of the Navitor valve is its unique fabric cuff, known as the NaviSeal cuff.
SMT	India	Hydra THV	The Hydra THV is a self-expanding transcatheter aortic valve system. Key features include a recapturable and repositionable design for precise placement, a supra-annular valve position designed for superior hemodynamics with a larger effective orifice area and lower pressure gradient, and a bovine pericardium tissue valve. The stent frame is nitinol-based with a design that aims to maintain a circular configuration and provide secure fixation.
Meril Life Sciences	India	Myval	The Meril Myval Transcatheter Aortic Valve is made of Cobalt alloy frame and its tri-leaflet valve is constructed from bovine pericardium tissue, treated with Meril's proprietary anti-calcification technology for enhanced durability.

Source: Company website

6. INDUSTRY THREATS AND CHALLENGES FOR MEDICAL DEVICE COMPANIES

Continuous innovation and growth in the medical device sector are accompanied by a complex array of threats and challenges. These issues demand constant vigilance and strategic adaptation, influencing product development, market entry, patient safety, and financial viability. Key threats and challenges for medical device companies include:

Innovation Barriers: Developing new medical devices is a challenging endeavor. It's not only expensive and risky, but it also involves a lengthy process from the initial idea to getting the product on the

market. On top of that, there are significant regulatory hurdles to overcome. When high-profile products fail, it can result in legal problems for companies and even stricter regulations, which can stifle the development of new, innovative devices. Therefore, companies face the tough task of balancing the drive for innovation with the substantial risks and costs tied to research and development and entering the market.

Quality Management: Ensuring high product quality is paramount because product failures can result in expensive recalls, harm a company's reputation, and even endanger patients. Companies invest heavily in quality management systems (QMS) and post-market surveillance to comply with regulations and reduce these risks. The financial and operational fallout from poor quality and recalls can be catastrophic, potentially leading to business closure or bankruptcy.

Regulatory Complexity: Medical device companies face a complex and ever-changing global regulatory landscape. Strict regulations like the EU MDR in Europe and FDA requirements in the US demand careful navigation, with compliance becoming increasingly difficult due to frequently updated and market-specific rules. The push for international standard harmonization, seen in ISO 13485:2016, alongside evolving regulations such as the EU MDR and US FDA Quality System Regulation (QSR), adds to this complexity. This regulatory unpredictability, particularly in key markets like the US and EU, can lead to costly delays in product launches.

Economic Pressures and Pricing: The medical device companies could be impacted by inflation, escalating production costs, and stricter healthcare budgets. To successfully overcome the challenges, they must continually innovate and distinguish their products while maintaining competitive prices, all within a fiercely globally competitive market that includes aggressive lower-cost alternatives. Additionally, government-mandated price controls and large-scale procurement by healthcare providers severely restrict pricing power. With healthcare systems and insurers increasingly demanding cost-effectiveness, manufacturers are compelled to adopt value-based care and explore new pricing models, such as outcome-based or subscription services, which transfer more risk to them. The imperative is clear: develop cutting-edge technology that is both affordable and delivers demonstrable economic benefits.

Counterfeit and Substandard Products: Medical device innovation demands significant investment in research and development, making intellectual property (IP) crucial. Companies must aggressively protect their patents, trademarks, and trade secrets to prevent infringement and counterfeiting. These illicit activities not only dilute market share and damage reputation but also pose serious risks to patient safety. The spread of fake or substandard devices erodes trust in the industry, exposing legitimate companies to legal and reputational liabilities, and ultimately harming patients while undermining confidence in medical technologies.

Geopolitical and Trade Risks: Global economic decoupling, local manufacturing mandates, and regulatory isolationism—particularly between the US and China—pose risks to market access, supply chains, and intellectual property protection. Overreliance on specific suppliers or regions increases vulnerability to shocks. Excess or misaligned inventory from risk mitigation efforts can cause financial strain. Companies must adapt to shifting trade flows, sanctions, and local content requirements. To avoid impact on geopolitical risks, companies need to actively reconfigure their distribution and manufacturing strategies to enhance resilience and mitigate future disruptions. Some of the strategies

adopted to improve resilience and reduce lead times are diversification of sourcing and manufacturing footprint, enhanced supply chain visibility and digital transformation, and inventory management strategies.

7. COMPETITIVE BENCHMARKIGN OF COMPANIES IN THE VASCUALR DEVICES MARKET

The global vascular device market can be broadly divided into two sub segments; vascular devices and structural heart devices market. There are a few established companies with exclusive focus on the vascular industry who dominate various segments and a host of emerging companies which cater to specific sub-segments of the market, based on their expertise and areas of focus. The vascular devices market is consolidated, highly competitive and driven by innovation.

Role of Emerging Companies

The market had limited options to provide for competition until the early part of last decade. With change in reimbursement structure and increased pressure on pricing of products, the market has witnessed a change in the competitive landscape. There were many emerging companies that were earlier regionally focused, started expanding globally with FDA and CE approval of their products. These companies not only offered quality products, but also competitively priced products, thus driving the growth and success of these companies in newer geographies. Interestingly the market was driven by North America and Europe as they accounted for the largest revenue contribution globally. But between 2017 to 2019 with the reimbursement coverage for DES and pricing cap on procedure volumes in emerging geographies, the market witnessed a shift in volume sales contribution between geographies. There was an increase in volume sales in emerging economies and domestic participants in China and India were equally suited to penetrate the market and grow tremendously. Similarly, price reduction in Germany and other European countries also witnessed the successful penetration of the emerging companies, thereby increasing the competitive intensity in the countries. During the forecast period, we would see a bigger role of emerging companies globally in market penetration and growth.

7.1. PRODUCT PORTFOLIO OF MAJOR VASCULAR DEVICE COMPANIES

Below list represents few of the prominent global companies and their presence across different segments.

Table 7.1: Competitive Landscape: Comparison of Vascular Device product portfolio of select global and Indian companies

	Vascular Interventional Devices				Structural Heart Devices		
Company	**Drug Eluting Stent (DES)**	**Coronary Drug Coated Balloons (DCB)**	**PTCA Balloon**	**Peripheral DCB**	**Occluder**	**LAA Closure**	**Transcatheter Aortic Valve**
Major global companies							
Abbott	✓	X	✓	✓	✓	✓	✓
Teleflex	✓	✓	✓	✓	X	X	X
Biosensors	✓	✓	✓	✓	X	X	✓
Boston Scientific	✓	✓	✓	✓	X	✓	X
Edwards Life sciences	X	X	X	X	X	X	✓
Medtronic	✓	X	✓	✓	X	X	✓
Microport	✓	✓	✓	✓	X	X	✓
Lifetech Scientific	X	X	X	X	✓	✓	X
Terumo	✓	X	✓	X	X	X	X
Major Indian companies							
SMT	✓	✓*	✓	✓	✓	X	✓
Meril Lifesciences	✓	X	✓	✓	✓	X	✓
Integris Health	✓	✓	✓	X	X	X	X
Relisys Medical Devices	✓	X	✓	✓	X	X	✓
Polymed**	X	X	✓	X	X	X	X

Source: Company websites, Frost & Sullivan

** Under regulatory approval*

***Polymed is most focused on consumables*

Major participants have established themselves in specific segments of the market and are investing heavily in R&D to produce advanced and efficient versions of DES, TAVI and other cardiovascular devices. For example, Boston Scientific is the market leader in LAA occlusion device segment through its product Watchman. The company has sustained growth and maintained a product leadership position, by launching an advanced version of Watchman (i.e. Watchman Flex). These product advancements are designed to address gaps and cater to specific market requirements. North America and Europe are the key markets for majority of the cardiovascular devices companies, however emerging markets have gained attention from established participants who are competing with cost effective products offered from domestic companies. In addition to organic growth through R&D driven product development, participants (especially the established companies) are also targeting growth through inorganic route using mergers, acquisitions and increasing collaboration with prominent or niche participants in the segments.

Abbott Vascular, Boston Scientific, Medtronic, Teleflex, Biosensors and Terumo are prominent global participants in the DES stent market with greater than 90% market share. However, with growing demand, there is a push toward developing technologically advanced products. This market evolution provides an opening for other companies such as SMT, MicroPort Scientific, Terumo and Meril Life, which have a strong presence in fewer geographic regions currently, to expand globally.

Among the Indian companies, SMT has the largest product portfolio in the vascular device market. SMT is among a select few Class III players in India and globally to have a comprehensive portfolio of advanced cardiovascular implants, all of which are supported by a robust foundation of clinical evidence and strict regulatory compliance. Moreover, it is the first company in the world to receive CE certification for an in-house developed biodegradable polymer based paclitaxel-eluting stent (Infinnium) in December, 2005. SMT further innovated and introduced DES with proprietary LDZ link, which enhanced the deliverability of Supraflex Cruz, making it the most deliverable stent in its class. Deliverability implies high ‘ease of use’ for implanting physicians in deploying a stent into complex arteries and is considered an important parameter in the selection of a stent by physicians In 2019, SMT marked its direct presence in Europe through its subsidiary in Germany. SMT has a leading market share in the DES market in India, with a market share of about 25.0% in FY25, of the total DES sales volume in India. The company has become one of the fastest-growing vascular device companies in India (in terms of revenue), as of March 31, 2025.

SMT is considered to be one of the fast growing players and an upcoming market leader in select European markets. SMT is among the top 5 companies in terms of market share by sales volume of DES in Germany, Spain, Poland and Brazil, as of March 31, 2025. Additionally, SMT is among the top 5 companies in terms of market share by sales volume of Occluders in Thailand, South Korea and India as of March 31, 2025. The growth is driven by increased focus of the company in direct sales, reaching out to address the specialists' unmet needs in these geographies and better product performance. Company leverages from well-connected distributor network in many European countries like Italy and Netherlands.

7.2. CHANGING COMPETITIVE DYNAMICS IN THE GLOBAL VASCULAR DEVICE MARKET

Emerging markets primarily comprise developing economies like India, China, Egypt, Thailand, Saudi Arabia, etc. The medical devices industry in these countries has long been dominated by international companies, especially in the cardiovascular devices sector. Abbott Vascular, Boston Scientific and Medtronic have acquired the nomenclature of the major three in this space, catering to most of the patient needs through their long list of product offerings, which includes stents, catheters, TAVI[44], occlusion devices, LAA devices, accessories etc. The market domination of few participants in the vascular device market is attributed to high barriers to entry, due to strict requirements for testing and clinical evidence collection, relatively tougher regulatory approval process, requirement of significant scientific selling and KOL engagements to drive adoption and lack of access to latest technologies from most emerging companies. With medical devices being highly regulated products (with long gestation periods prior to commercialization) and the requirement for large-scale of operations for production efficiency, the sector has fewer participants succeeding. High investment requirement, long gestation period on ROI, minimal support from the government authorities and limited awareness about medical procedures have resulted in lesser domestic investments in emerging markets. However, now the cardiovascular device segment has been evolving as more and more domestic participants cater to regional requirements, product requirements and increase the affordability with price competitiveness.

The vascular device products are not only customized to regional requirements but also have unique and salient features meeting the demands of different patients. As these products are researched, prototyped, developed and manufactured in emerging geographies with exclusive focus on select application or feature, the operational efficiency is high. The manufacturing capabilities of these companies are robust and with reduced labor costs from emerging countries, the demand for these technological sophisticated and competitive products with the ability to reduce pricing by a range of 20-30% from the available products in the market are well received in emerging geographies. These products also play a role in the penetration of various procedures in the countries. These products are also leveraged in established countries like US, Europe, Japan as these products have the unique features to cater to niche unmet needs and provide financial flexibility for organizations, thus increase adoption.

The emerging companies like SMT, Meril, Lepu Medical, try to differentiate themselves and address the demand in domestic markets by focusing their products to address few or all potential complications during PCI procedures, including the complex PCI procedures.

The market participants conduct clinical studies regularly to highlight the sophistication in use of their products ranging from easy access, better long term safety, good post dilation expansion etc. These characteristics not only support marketability of the product, but also support utilizing for relevant outcomes expected by clinicians.

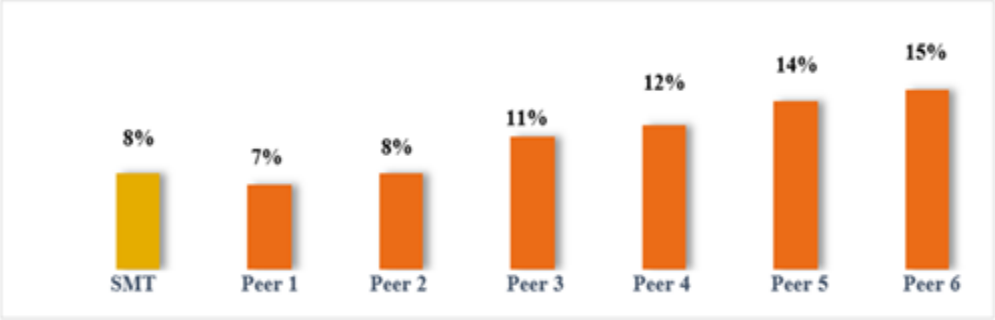
SMT is one of the few Indian medtech companies with results of key clinical trials on products published in top-tier journals such as The Lancet (impact factor 98.4) and NEJM (impact factor 96.2).[45,46] As per a

[44] Boston Scientific's TAVI and Occlusion devices are yet to receive approval in India
[45] Secondary sources
[46] Secondary sources

comparative investigation of coronary stent systems by Institut für Implantat Technologie und Biomaterialien e.V. conducted in 2021 and a device evaluation study published in Future Cardiology[47], SMT's Supraflex Cruz DES has been shown to offer better deliverability and clinical outcomes than DES of leading competitors. In this study, the mean track force required to push a DES through a test track was measured for SMT's Supraflex Cruz, Medtronic's Resolute Onyx, Boston Scientific's Synergy and Abbott's Xience Sierra. The lower the amount of force required, the better the deliverability. The mean track force of Supraflex Cruz was measured to be lowest with better deliverability compared to others.

SMT also has product portfolio covering the structural heart segment, which is high value and fast growing in emerging markets. SMT is one of the top 3 Occluder providers in India as of March 31, 2025. SMT's structural heart devices, Hydra (transcatheter aortic valve) and Cocoon (septal occluder) stand out among peers for their advanced features and safety profiles. For instance, The Genesis Study, published in the Catheterization and Cardiovascular Interventions journal, demonstrated the high efficacy of the Hydra valve in high-risk patients. In the Hydra CE study conducted in Europe and Asia Pacific, Hydra demonstrated a strong safety and efficacy profile on 157 patients enrolled in the study.[48] SMT's Cocoon Occluder has also been tested and validated as a best-in-class device when compared to its peers.[49,50]

Exhibit 7.1 Permanent Pacemaker Implantation (PPI) after 30 days of implant (Lower % is better)



Developed economies that are mature in terms of cardiovascular devices have witnessed the growing entry of these emerging companies offering additional choices of technologically advanced products, proven safety and efficacy standards at competitive pricing. Companies like SMT, have manufacturing bases in India and Thailand thus providing significant labor cost advantage and support competitive pricing to address affordability issues. Moreover, leading companies from emerging markets develop differentiated and innovative products with continuous investments in R&D. SMT has demonstrated a strong and consistent commitment to research and development, with its R&D ratio at par with global MNCs. Cost competitiveness (or affordability) is not only the key factor in emerging markets but is also becoming key decision criteria in developed markets owing to expensive treatment and scattered reimbursements for cardiovascular devices and procedures

[47] Secondary sources
[48] Secondary sources
[49] Secondary sources
[50] Secondary sources

Service is a key aspect that companies have adopted to develop new customers and differentiate themselves amongst the other emerging participants. This plays a significant importance in the route to market for emerging companies during their expansion globally. Such key factors have made SMT as one of the largest Indian manufacturers of vascular devices products globally, with a direct presence in 10 countries. SMT's products such as Supraflex Cruz (DES), Cocoon (occluders), and Hydra (TAVI) are widely accepted in international markets, supported by endorsements from leading key opinion leaders ("KOLs"), successful government tender wins, and acceptance by major European GPOs.

7.3. FINANCIAL ANALYSIS OF MAJOR INDIAN MEDICAL DEVICE COMPANIES

Table 7.2A: Comparison of KPIs of SMT with peers (As of and Financial year ended March 31, 2025)

Key Metrics	Unit	SMT	Micro Life Sciences Private Limited	Relisys Medical Devices Limited	Integris Health Private Limited	Laxmi Dental Limited	Poly Medicure Limited
Financial KPIs							
Revenue from operations [(1)]	₹ million	10,248.79	NA	NA	NA	2,391.07	16,698.32
EBITDA[(2)]	₹ million	1,280.21	NA	NA	NA	417.92	6,414.55
EBITDA margin [(3)]	%	12.49%	NA	NA	NA	17.48%	38.41%
Profit/(Loss)after tax ("**PAT**") [(4)]	₹ million	251.52	NA	NA	NA	253.75	3,385.57
PAT margin [(5)]	%	2.45%	NA	NA	NA	10.61%	20.27%
Net debt to EBITDA [(6)]	Times	0.91	NA	NA	NA	2.45	0.29
Return on equity [(7)]	(%)	3.68%	NA	NA	NA	25.32%	15.99%
Return on capital employed (%)[(8)]	(%)	10.37%	NA	NA	NA	14.19%	16.03%
Operational KPIs							
Gross Tangible Fixed Asset Turnover Ratio[(9)]	Times	3.49	NA	NA	NA	NA	NA
Net working capital days (overall) (based on days of revenue from operations) [(10)]	Number of days	144	NA	NA	NA	43	103
Revenue Split by Product categories[(11)]	%	VI devices: 65.86% SH devices: 15.35% Others: 18.79%	NA	NA	NA	Laboratory: 61.8% Aligner solutions: 32.3%	Infusion therapy: 63.28% Renal: 9.45% Others: 27.28%

Table 7.2A: Comparison of KPIs of SMT with peers (As of and Financial year ended March 31, 2025)							
Key Metrics	**Unit**	**SMT**	**Micro Life Sciences Private Limited**	**Relisys Medical Devices Limited**	**Integris Health Private Limited**	**Laxmi Dental Limited**	**Poly Medicure Limited**
						Others: 5.9%	
Revenue Split by Geography[12]	%	India: 31.28% Europe: 32.96% RoW: 35.76%	NA	NA	NA	India: 66.7% USA: 19.6% UK: 7.6% RoW: 6.1%	India: 30.36% Europe: 31.35% RoW: 37.50%
Presence in countries (Nos) [13]	Number	76	More than 100	NA	NA	More than 95	More than 125
Manufacturing Capacity (Product Wise)	Number	**VI devices** Stents: 840,000 Catheters: 960,000 **SH devices** TAVI devices:7,800 Occluders:42,000 **Others**:N.A.	NA	NA	NA	NA	**Others**:1,800,000,000
Product wise Capacity Utilization	%	**VI devices** Stents: 82.39% Catheters: 91.16% **SH devices** TAVI devices:14.44% Occluders:23.24% **Others**:N.A.	NA	NA	NA	NA	NA

Table 7.2B: Comparison of KPIs of SMT with peers (As of and Financial year ended March 31, 2024)							
Key Metrics	**Unit**	**SMT**	**Micro Life Sciences Private Limited**	**Relisys Medical Devices Limited**	**Integris Health Private Limited**	**Laxmi Dental Limited**	**Poly Medicure Limited**
Financial KPIs							
Revenue from operations [(1)]	₹ million	9,016.04	34956.5	1643.4	5622.28	1,935.55	13,757.96
EBITDA[(2)]	₹ million	1,100.47	6739.1	541.31	659.67	237.9	3,632.75
EBITDA margin [(3)]	%	12.21%	19.28%	32.94%	11.73%	12.29%	26.40%
Profit/(Loss) after tax ("**PAT**") [(4)]	₹ million	-73.54	3,328.40	363.02	-65.49	179.41	2,582.59
PAT margin [(5)]	%	-0.82%	9.52%	22.09%	-1.16%	9.27%	18.77%
Net debt to EBITDA [(6)]	Times	0.86	NA	NA	NA	2.45	0.29
Return on equity [(7)]	(%)	-2.34%	0.1473	0.1577	-0.0102	82.24%	17.57%
Return on capital employed (%)[(8)]	(%)	8.05%	14.93%	26.07%	13.76%	18..27%	22.23%
Operational KPIs							
Gross Tangible Fixed Asset Turnover Ratio[(9)]	Times	3.37	4.56	NA	5.68	4.32	1.21
Net working capital days (overall) (based on days of revenue from operations) [(10)]	Number of days	144	140	293	234	53	99
Revenue Split by Product categories[(11)]	%	VI devices: 68.57% SH devices: 12.26% Others: 19.17%	NA	NA	Finished goods: 60.97% Traded goods : 38.61% Royalty income: 0.42%	Laboratory: 64.4% Aligner solutions: 28.4% Others: 7.3%	Infusion therapy: 65.82% Renal: 7.23% Others: 26.96%
Revenue Split by Geography[(12)]	%	India: 34.80% Europe: 29.52% RoW: 35.68%	Domestic : 38.63% Export : 60.08%	Domestic : 84.88% Outside Export : 15.12%	Within India: 72.43% Outside India : 27.57%	India: 67.5% USA: 19.4% UK: 7.2% RoW: 5.9%	India: 31.36% Europe: 30.58% RoW: 37.45%

Table 7.2B: Comparison of KPIs of SMT with peers (As of and Financial year ended March 31, 2024)							
Key Metrics	**Unit**	**SMT**	**Micro Life Sciences Private Limited**	**Relisys Medical Devices Limited**	**Integris Health Private Limited**	**Laxmi Dental Limited**	**Poly Medicure Limited**
Presence in countries (Nos) [13]	Number	56	NA	NA	NA	NA	More than 125
Manufacturing Capacity (Product Wise)	Number	**VI devices** Stents: 780,000 Catheters: 960,000 **SH devices** TAVI devices:1,800 Occluders:30,000 **Others**:N.A.	NA	NA	NA	**Others**: 6,369,675	Others:1,200,000,000
Product wise Capacity Utilization	%	**VI devices** Stents: 85.10% Catheters: 94.53% **SH devices** TAVI devices:38.11% Occluders:50.24% **Others**:N.A.	NA	NA	NA	**Others**:43.71 %	NA

Table 7.2C: Comparison of KPIs of SMT with peers (As of and Financial year ended March 31, 2023)							
Key Metrics	**Unit**	**SMT**	**Micro Life Sciences Private Limited**	**Relisys Medical Devices Limited**	**Integris Health Private Limited**	**Laxmi Dental Limited**	**Poly Medicure Limited**
Financial KPIs							
Revenue from operations [1]	₹ million	7,955.49	23,582.90	1,576.25	4,695.51	1,616.30	11,152.30
EBITDA[2]	₹ million	1,107.73	4,560.50	553.39	483.06	89.64	2,692.38
EBITDA margin [3]	%	13.92%	19.34%	35.11%	10.29%	5.55%	24.14%
Profit/(Loss) after tax ("**PAT**") [4]	₹ million	119.34	5,048.80	361.22	197.12	-44.49	1,792.83
PAT margin [5]	%	1.50%	21.41%	22.92%	4.20%	-2.75%	16.08%
Net debt to EBITDA [6]	Times	0.58	2.58	0.44	3.02	3.61	0.57
Return on equity [7]	(%)	1.70%	54.03%	18.67%	3.25%	-20.45%	16.49%

Table 7.2C: Comparison of KPIs of SMT with peers (As of and Financial year ended March 31, 2023)							
Key Metrics	**Unit**	**SMT**	**Micro Life Sciences Private Limited**	**Relisys Medical Devices Limited**	**Integris Health Private Limited**	**Laxmi Dental Limited**	**Poly Medicure Limited**
Return on capital employed (%)[8]	(%)	10.54%	27.56%	30.35%	11.22%	0.37%	18.34%
Operational KPIs							
Gross Tangible Fixed Asset Turnover Ratio[9]	Times	4.35	4.78	NA	6.17	4.72	1.26
Net working capital days (overall) (based on days of revenue from operations) [10]	Number of days	142	129	227	223	52	104
Revenue Split by Product categories[11]	%	VI devices: 71.99% SH devices: 9.48% Others: 18.52%	NA	NA	Finished goods: 67.67% Traded goods : 31.69% Sale of services : 0.19% Royalty income: 0.44%	Laboratory: 66.2% Aligner solutions: 22.4% Others: 11.4%	NA
Revenue Split by Geography[12]	%	India: 36.39% Europe: 27.82% RoW: 35.78%	Domestic : 41.75% Export : 57.09%	Domestic: 83.38% Outside Export : 16.62%	Within India: 81.95% Outside Outside India : 18.05%	India: 68.5% USA: 18.6% UK: 7.3% RoW: 5.7%	NA
Presence in countries (Nos) [13]	Number	59	NA	NA	NA	NA	More than 125
Manufacturing Capacity (Product Wise)	Number	**VI devices** Stents: 792,000 Catheters: 840,000 **SH devices**	NA	NA	NA	**Others**: 5,699,625	Others:1,200,000,000

Table 7.2C: Comparison of KPIs of SMT with peers (As of and Financial year ended March 31, 2023)							
Key Metrics	**Unit**	**SMT**	**Micro Life Sciences Private Limited**	**Relisys Medical Devices Limited**	**Integris Health Private Limited**	**Laxmi Dental Limited**	**Poly Medicure Limited**
		TAVI devices:440 Occluders:12,996 **Others**:N.A.					
Product wise Capacity Utilization	%	**VI devices** Stents: 82.45% Catheters: 83.03% **SH devices** TAVI devices:24.44% Occluders:43.32 % **Others**:N.A.	NA	NA	NA	**Others**:38.96%	NA

Source:

a) *All the financial information for SMT is based on the Restated Consolidated Financial Information.*
b) *Annual report of the FY24 and FY23 are considered for extracting above details of the listed peer companies. (Laxmi Dental Limited and Poly Medicure Limited). FY25 information is considered from the financial statements as available on the website of the NSE.*
c) *Consolidated financial information, wherever applicable, has been considered hereabove*
d) *For Poly Medicure Limited, Calculation for Revenue spilt by Product categories & Revenue split by Geography is on standalone basis*
e) *For unlisted companies as mentioned above ((Micro Life Sciences Private Limited, Relisys Medical Devices Limited and Integris Health Private Limited) the financial information has been extracted from MCA*
f) *Prospectus of Laxmi Dental Limited is considered for extracting operational KPIs for Laxmi Dental Limited for the period FY23 and FY24*
g) *For Laxmi Dental Limited, Aligner products and Other aligner related products have been considered for calculating the manufacturing capacity*
h) *Operational KPIs for peers has been taken from reports, investors presentation as publicly available*

Notes:

(1) Revenue from Operations means Revenue from sale of products and other operating income.
(2) EBITDA is calculated as the sum of Profit/(loss) after tax, total tax expense, finance cost, and depreciation and amortization expense and exceptional items, minus other income.
(3) EBIDTA Margin is calculated as EBITDA divided by Revenue from operations.
(4) Profit/(Loss) after tax means the profit/(loss) for the year .
(5) PAT Margin is calculated as Profit/(loss) after tax divided by Revenue from operations
(6) Net Debt to EBITDA is calculated as Net Debt divided by EBITDA. Net Debt is defined as the sum of current borrowings and non-current borrowings, less cash and cash equivalents and DSRA deposits.
(7) Return on Equity attributable to owners of the Company, is calculated by dividing the Profit/(loss) for the year attributable to Owners of the Company by the Average of total equity attributable to owners of the Company.

The average is obtained by adding the Total Equity attributable to owners of the Company at the beginning and end of the year and dividing by two.

(8) Return on Capital Employed, also expressed as a percentage, is calculated by dividing EBIT by Capital employed. EBIT is the sum of profit/ (loss) after tax, total tax expense, finance costs, and exceptional Items. Capital employed is calculated as sum of total equity, total borrowings, total deferred tax liabilities, total lease liabilities minus goodwill, other intangible assets, intangible assets under development and right of use assets.

(9) Gross Tangible Fixed Asset Turnover Ratio is calculated by dividing Revenue from operations by the average of Property, Plant and Equipment (Cost), where the average is the sum of the property, plant and equipment cost at the beginning and end of the year divided by two.

(10) Net Working Capital Days is sum of Trade Receivable Days and Inventory Days as reduced by Trade Payable Days; where Trade Receivables Days or Debtors days are calculated as 365 divided by (Revenue from operations / Average trade receivables), Inventory Days is calculated as 365 divided by (Revenue from operations / Average inventory) and Trade Payable Days is calculated as 365 divided by (Revenue from operations / Average trade payables).

(11) Revenue Split by Product categories is the bifurcation of the total Revenue from Operations based on the products sold

(12) Revenue Split by Geography is the bifurcation of the total Revenue from Operations based on the location of the customers, however Revenue from Operations includes other operating revenue for which geographical split is not available

(13) Presence in Countries is the total number of countries from where revenue is generated based on the location of the customer at the end of the reporting period.