

# India's Orthopaedic and Cardiac Implant Sector Poised to Touch \$5 Billion by FY28

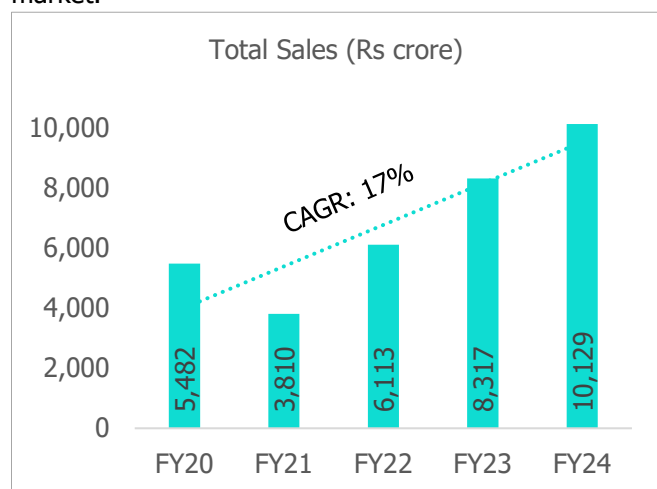
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## Synopsis

- India's orthopaedic and cardiac implant sector<sup>1</sup>, including exports, which stood at ~\$2.4 to \$2.7 billion in FY24, is expected to reach ~\$4.5 to \$5.0 billion by FY28, driven by strong domestic demand and gradually growing export presence.
- India's medical implant exports have grown at a CAGR of 25% in the past six years ended FY24. Major export destinations include Europe and various semi-developed countries; however, the United States of America (US), which is the largest market for implants, remains largely untapped.
- Sector growth is led by increasing per capita income, greater healthcare awareness, an ageing population, expanding healthcare infrastructure, and broadening insurance coverage. Home-grown manufacturers have grown at a faster pace than the dominant foreign MNCs in recent years, aided by their price competitiveness and a gradual build-up of an efficacy and safety track record. The bright prospects for domestic implant manufacturing have also attracted interest from large pharmaceutical companies, with Zydus Lifesciences Limited and Alkem Laboratories Limited having already announced investments in the manufacturing and distribution of implants.
- Ongoing trade and tariff uncertainty, imposition of price caps, regulatory scrutiny, and patent litigations are expected to be key monitorables for the medical implant sector.

## Orthopaedic and Cardiac Implant market

The global orthopaedic and cardiac implant market is valued at over ~\$70 billion, while India's share stood at ~\$2.3 to \$2.5 billion in FY24. Key products include coronary stents and scaffolds, heart valves, transcatheter aortic valve replacement (TAVR) devices, joint replacement implants (for knees, hips, and shoulders), spinal implants, trauma fixation devices, and other medical devices. During the four years ended FY24, the revenue of a sample set of entities engaged in the manufacturing or marketing of implants (comprising a mix of foreign MNCs and domestic entities, which accounted for around 90% of the market size) grew at a CAGR of 17%, signalling a rapidly growing market.



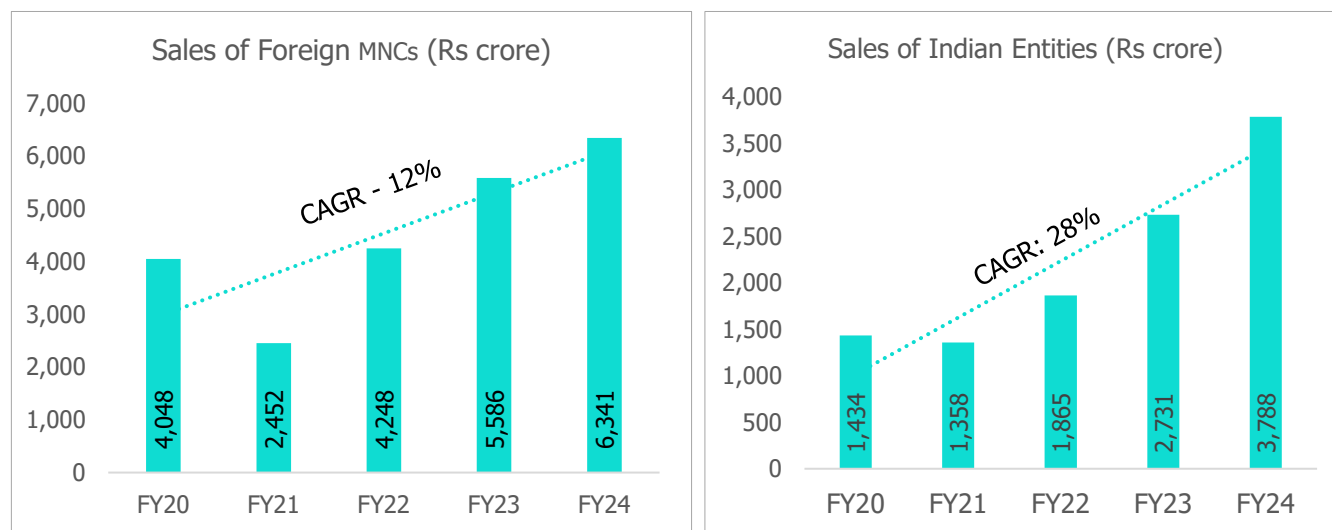
The segment is dominated by the presence of foreign MNCs, which largely import the implants and sell them in India. The implant business requires strong technological capabilities, a proven track record of safety and efficacy, a broad marketing and distribution network, and a robust post-sales support system. Foreign MNCs, with their long-standing track record of safety and effectiveness worldwide, have built trust among medical practitioners, which has led to their dominance in the Indian market. However, over the past few years, Indian manufacturers have not only challenged foreign MNCs in the domestic market but are also gradually venturing into the export market.

Source: Compiled by CareEdge Ratings; The sales are at the enterprise level. The study represents sample entities accounting for around 90% of the market size.

<sup>1</sup> Sector size is estimated at end-user level.

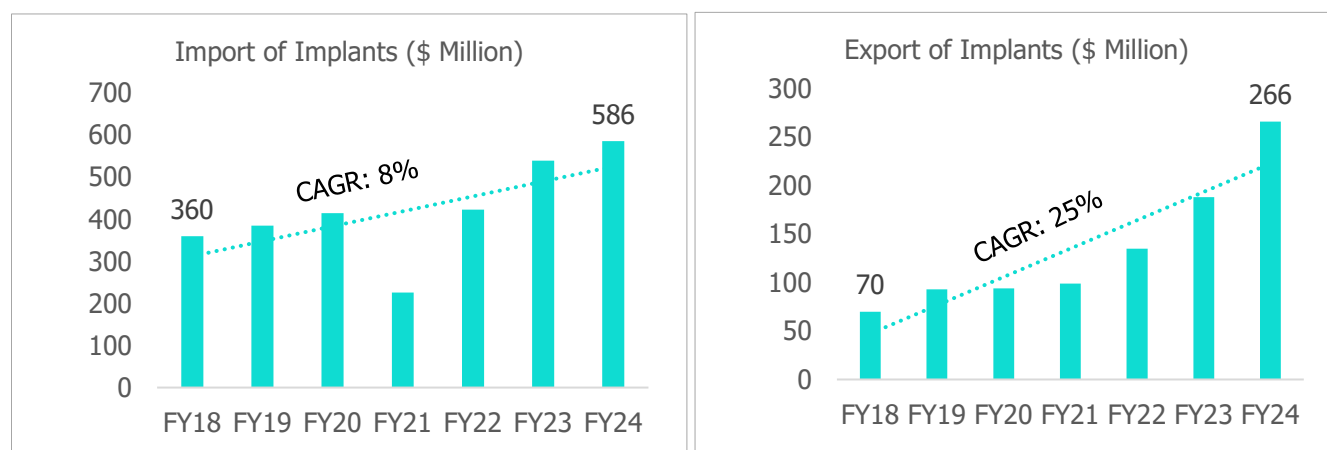
### Homegrown companies are gaining share and expanding in the export market

Foreign MNCs had a dominant market share of more than 90% in value terms in India's orthopaedic and cardiac implant market during the pre-COVID period. However, India is gradually reducing its dependence on imports. Sales of homegrown implant manufacturers have grown at a compound annual growth rate (CAGR) of 28% (including a CAGR of 37% for exports) during the four years ended FY24, outpacing the sales CAGR of 12% for foreign multinational corporations (MNCs) during the same period. The sales volume growth of domestic entities was even higher, driven by their competitive pricing and increased participation in government-sponsored insurance schemes.



Source: Compiled by CareEdge Ratings.

To boost domestic manufacturing of medical devices, including implants, the Government of India announced a production-linked incentive (PLI) scheme with an outlay of Rs 3,420 crore. Six domestic manufacturers have been approved under the Production Linked Incentive (PLI) scheme. India's export growth rate for implants has significantly outpaced the implant imports during the last 5-6 years.



Source: Ministry of Chemicals and Fertilizer- Department of Pharmaceuticals – Annual Report 2024

### Price caps limit margins, albeit increasing affordability and driving volume growth

Since February 2017, the National Pharmaceutical Pricing Authority (NPPA) has implemented price caps on various types of stents and joint replacement products. The prices are, however, reviewed annually and revised based on movements in the Wholesale Price Index (WPI) if warranted.

The prices of knee implants are capped at approximately ~Rs 32,000 to ~ Rs 83,000, depending on the type and material used. Drug-eluting stents are capped at ~Rs 38,000, while bare metal stents have a ceiling price of ~Rs 10,500. Price caps adversely affected the foreign MNCs' high-margin products, forcing them to discontinue some of their premium products from the Indian market. However, it significantly improved affordability, especially for implants manufactured by domestic companies, thereby enabling them to expand their market share. Schemes like Ayushman Bharat further improved the affordability and expanded the market. The price caps have also enabled domestic players to gain market share, giving them a competitive edge over MNCs. Domestic manufacturers are successfully meeting the stringent quality standards required for the manufacturing of orthopaedic and cardiac implants, with several manufacturing facilities having been approved by domestic and many reputed foreign regulators.

### **Demand tailwinds in the domestic market and huge export potential**

According to the United Nations' projections, India's population in the 45 years and above age group is expected to grow by ~2.3% to 2.4% per annum between 2020 and 2050, compared to an overall population growth rate of ~0.6% to 0.7%. Increasing per capita income and affordability, rising healthcare awareness, an ageing population, expansion in healthcare infrastructure, and increasing insurance penetration are expected to drive the domestic demand for implants in the long term.

Although Indian companies have successfully penetrated several developed and semi-developed markets, they account for a very low share of the global implant market due to their relatively shorter track record of safety and efficacy. Penetrating the USA, the largest market for implants, remains key to long-term export growth potential. However, access to the USA market is challenging, as it requires extensive US-compliant clinical trials for large samples, which is a costly and time-consuming process. Additionally, the US market is fiercely competitive, with the presence of multiple large entities, and requires relationships with hospital procurement chains or GPOS (Group Purchasing Organisations), a local presence, and post-sale support.

### **CareEdge Ratings' View**

Foreign MNCs, with their long track record of safety and efficacy, have built trust among medical practitioners, which has led to their dominance in the Indian market. However, Indian implant manufacturers are making rapid strides in the domestic market and are gradually expanding their presence in the export market. With the entry of several new players, competition in the domestic market for commoditised and entry-level products has intensified in the last few years, resulting in some pricing pressure. The anticipated entry of large pharmaceutical companies into this segment is likely to intensify competition further. With only 7.5% customs duty on the import of most coronary and orthopaedic implant products, any potential trade deal with the US resulting in tariff reduction is not likely to materially change the market dynamics for domestic manufacturers. However, material changes in non-tariff barriers, such as the relaxation of price caps, can significantly alter the competitive landscape for domestic manufacturers compared to MNCs.

"India's medical implant sector is on a robust growth trajectory, driven by strong domestic demand and growing exports. India's implant sector, including exports, is expected to reach ~\$4.5 to \$5.0 billion by FY28, registering an impressive CAGR of around 15-16%. Additionally, with supportive government policies and a growing healthcare infrastructure, the implant market is advancing towards 'Atmanirbharta,' said Krunal Modi, Director at CareEdge Ratings.

Continuous innovation, leading to new product development and launches, is key to maintaining growth and profitability. Although the price caps have enhanced affordability and expanded the market size, restrictive price caps for a prolonged period may limit the R&D spending in this segment," stated Akshay Morbiya, Assistant Director at CareEdge Ratings.

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