



INDIAN MEDICAL DEVICES SECTOR ANALYSIS

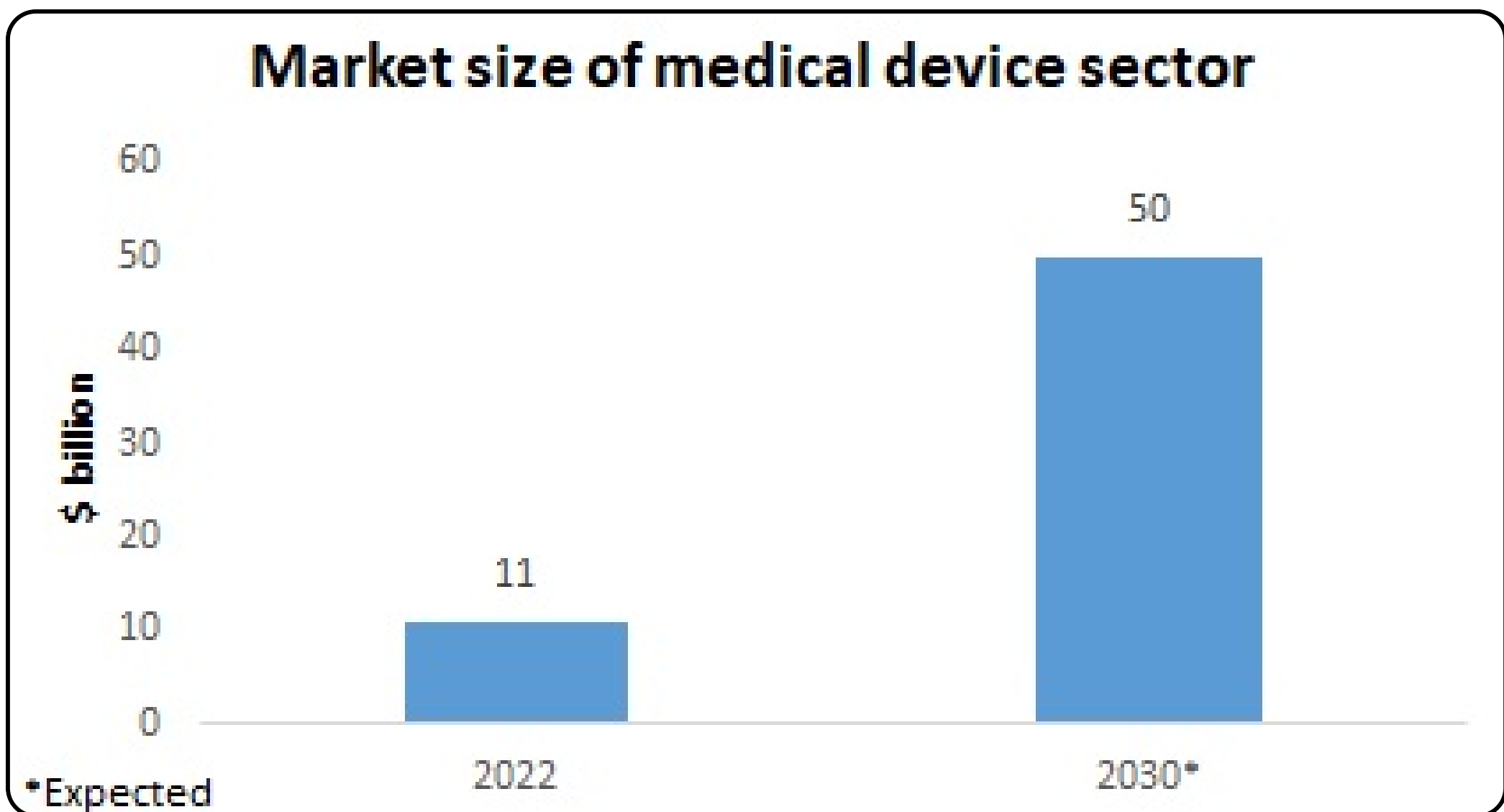
April- 2024



The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector, particularly for the prevention, diagnosis, treatment and management of all medical conditions and disabilities. It forms an important pillar in the healthcare delivery system along with healthcare providers, pharmaceuticals and healthcare insurance industry, thereby helping achieve the key objectives of the National Health Policy (NHP), 2017. A wide range of medical devices, from consumables to implantable medical devices, are produced in India. The majority of medical devices manufactured in India are disposables like catheters, perfusion sets, extension lines, cannulas, feeding tubes, needles, and syringes, as well as implants like cardiac stents, drug-eluting stents, intraocular lenses, and orthopaedic implants. However, there is still a huge gap in the current demand and supply of medical devices in India, as India has an overall 70-80 per cent import dependency on medical devices. At present, many medical device manufacturers (domestic and international) are chasing this massive under penetration of medical devices in India as a significant growth opportunity.

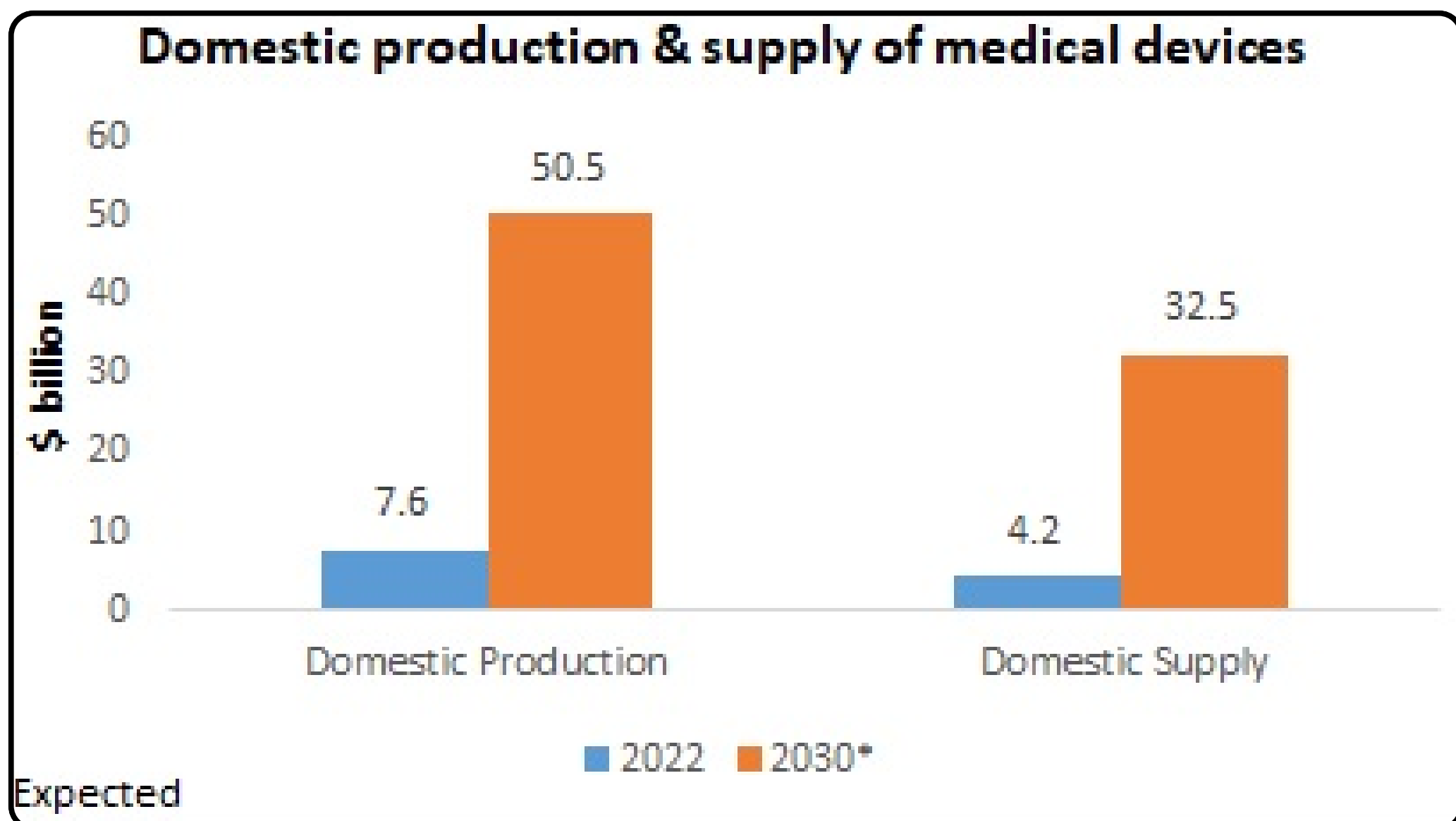
India is the 4th largest Asian medical devices market after Japan, China, and South Korea, and among the top 20 medical devices markets globally. The Indian medical devices sector's contribution has become even more prominent as India supported the domestic and global battle against COVID-19 pandemic through the large scale production of medical devices & diagnostic kits, such as Ventilators, Rapid Antigen Test kits, Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) kits, Infrared (IR) Thermometers, Personal Protective Equipment (PPE) Kits & N-95 masks.

The medical devices are a multi-disciplinary sector, with the following broad classification: (a) Electronic equipment (b) Implants; (c) Consumables and Disposables (d) Surgical instruments and (e) In-Vitro Diagnostic (IVD) Reagents. Several segments in the medical device sector are highly capital intensive, with long gestation period, require continuous induction of new technologies, continuous training of healthcare professionals to adapt to new technologies, and involve rapid innovation. The market size of the medical devices sector in India is estimated to be \$11 billion as of 2022 and its share in the global medical device market is estimated to be 1.5 per cent. It is projected to reach \$50 billion by 2030.



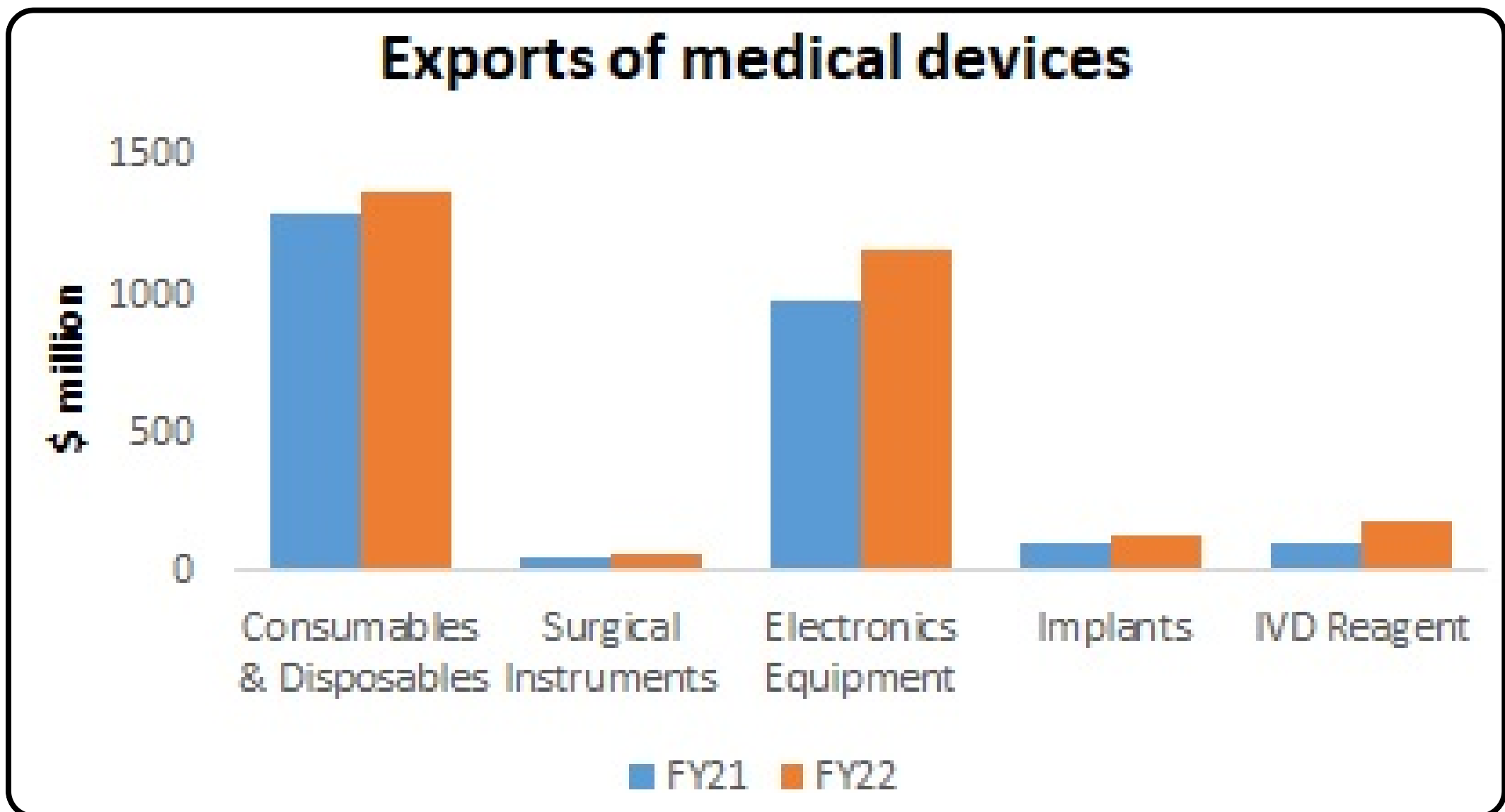
PRODUCTION AND SUPPLY OF HEALTH AND MEDICAL DEVICE SECTOR

In 2022, the PLI Scheme for pharmaceuticals worth Rs 18,420 crore (\$2.24 billion) was launched. This scheme aims to enhance India's manufacturing capabilities by increasing investment and production in the pharmaceutical and medical devices sectors and contribute to the availability of a wider range of affordable medicines for consumers. The domestic production of health and medical device sector is at around \$7.6 billion in 2022 and is likely to expand to \$50.5 billion by 2030. On the other hand, supply of health and medical device sector is around \$4.2 billion and is expected to grow to \$32.5 billion by 2030. Recently, the government approved investment of Rs 6000 crore to 74 industries in the pharmaceutical and medical device manufacturing sectors under the production linked incentive (PLI) scheme. The government has taken a holistic approach and begun the process for the development of a cost-effective, sustainable and affordable process for 16 APIs (active pharmaceutical ingredient) and two KSMs (key starting material).



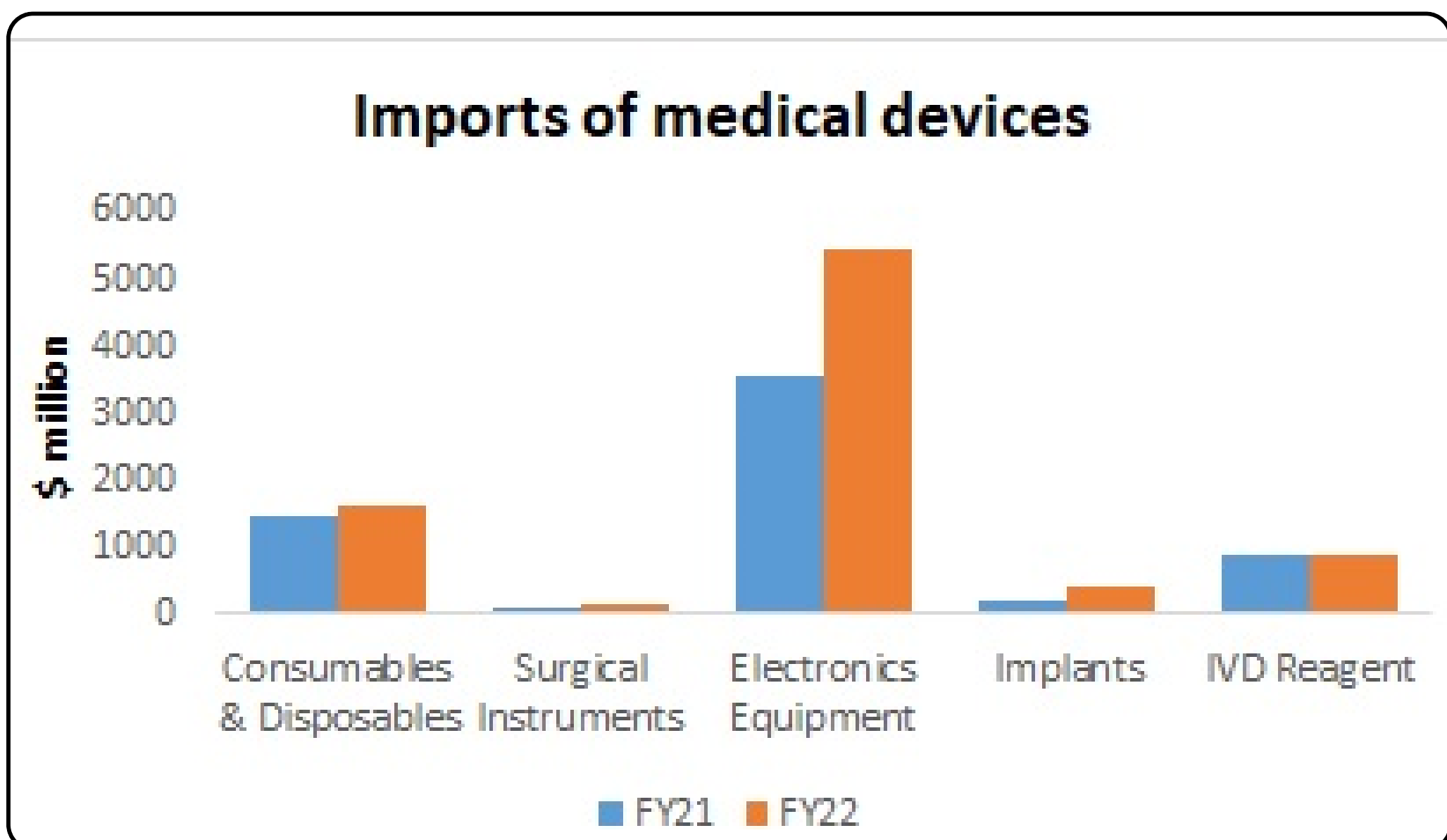
EXPORTS OF MEDICAL DEVICES

The country's total exports of medical devices increased by 15.44 per cent to \$2923 million in the FY22 over \$2532 million FY21. Category-Wise export of Consumables & Disposables increased by 6.82 per cent from \$1290 million in FY21 to \$1378 million in FY22. Electronics Equipment export rose 18.07 per cent to \$1163 million in reporting period over \$985 million in the corresponding period of previous year. Moreover, Surgical Instruments (\$71 million), Implants (\$135 million) and IVD Reagent (\$176 million) exports jumped 31.48 per cent, 36.36 per cent and 69.23 per cent in FY22, respectively, over the FY21. Moreover, major export destinations with 40.15 per cent share in total export are USA (\$631.48 million), China (\$146.94 million), Germany (\$127.29 million), France (\$89.36 million), Singapore (\$82.73 million) and UAE (\$79.01).



IMPORTS OF MEDICAL DEVICES

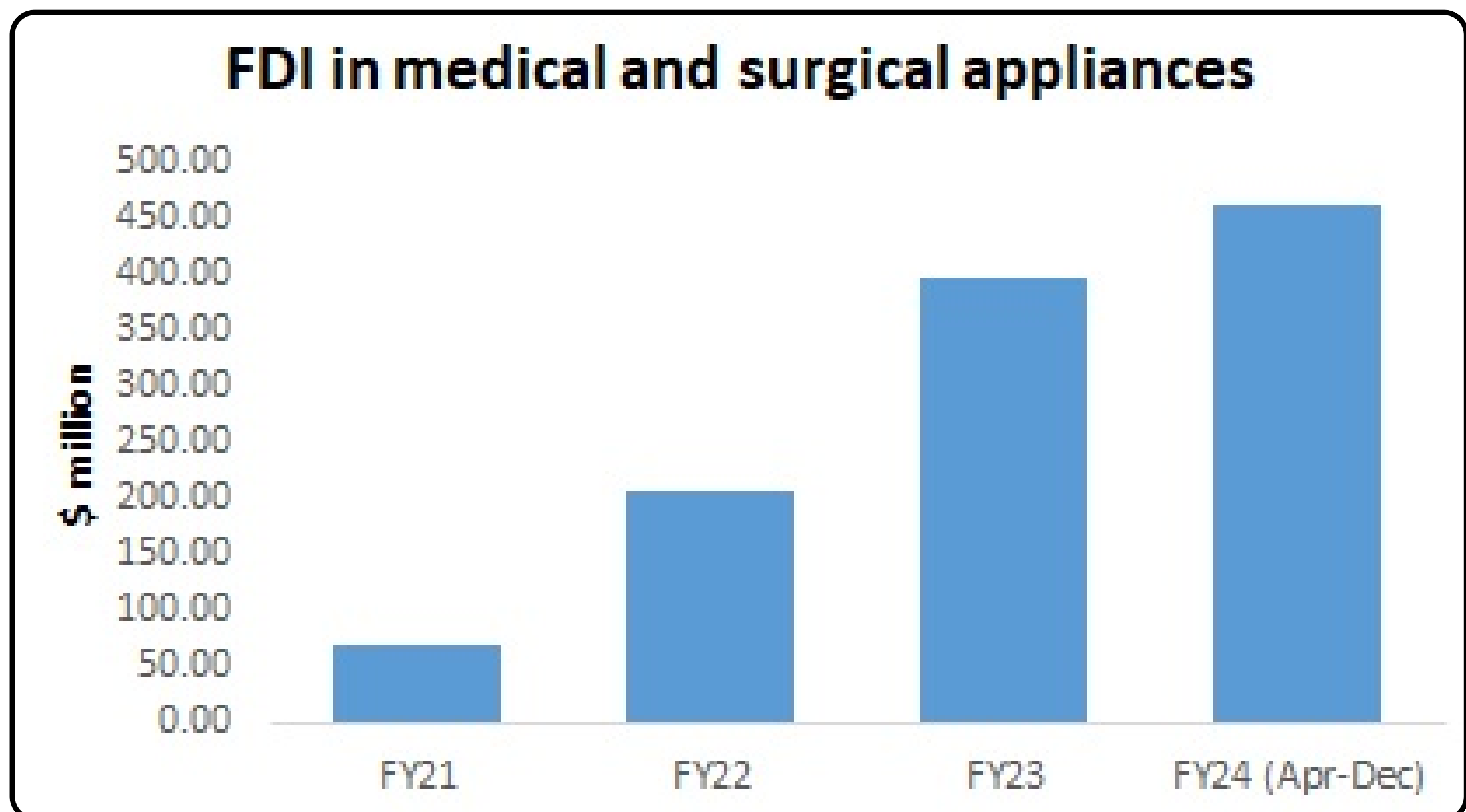
The country's dependence on medical devices shipped from abroad grew significantly between April 2021 to March 2022 (FY22) with imports jumping by 36.82 per cent to \$8540 million from \$6242 million in FY21. Category-Wise import of Consumables & Disposables rose 10.40 per cent from \$1471 million in FY21 to \$1624 million in FY22. Electronics Equipment import surged 52.45 per cent to \$5441 million in reporting period over \$3569 million in the corresponding period of previous year. Moreover, Surgical Instruments (\$169 million), Implants (\$423 million) and IVD Reagent (\$883 million) imports advanced 62.50 per cent, 87.17 per cent and 1.26 per cent in FY22, respectively, over the FY21. Moreover, major import destinations with 62.29 per cent share in total import are UAE (\$1657.67 million), USA (\$1464.73 million), China (\$782.35 million), Germany (\$729.21 million), Singapore (\$343.08 million) and France (\$341.99 million).



POSITIVES FOR THE SECTOR

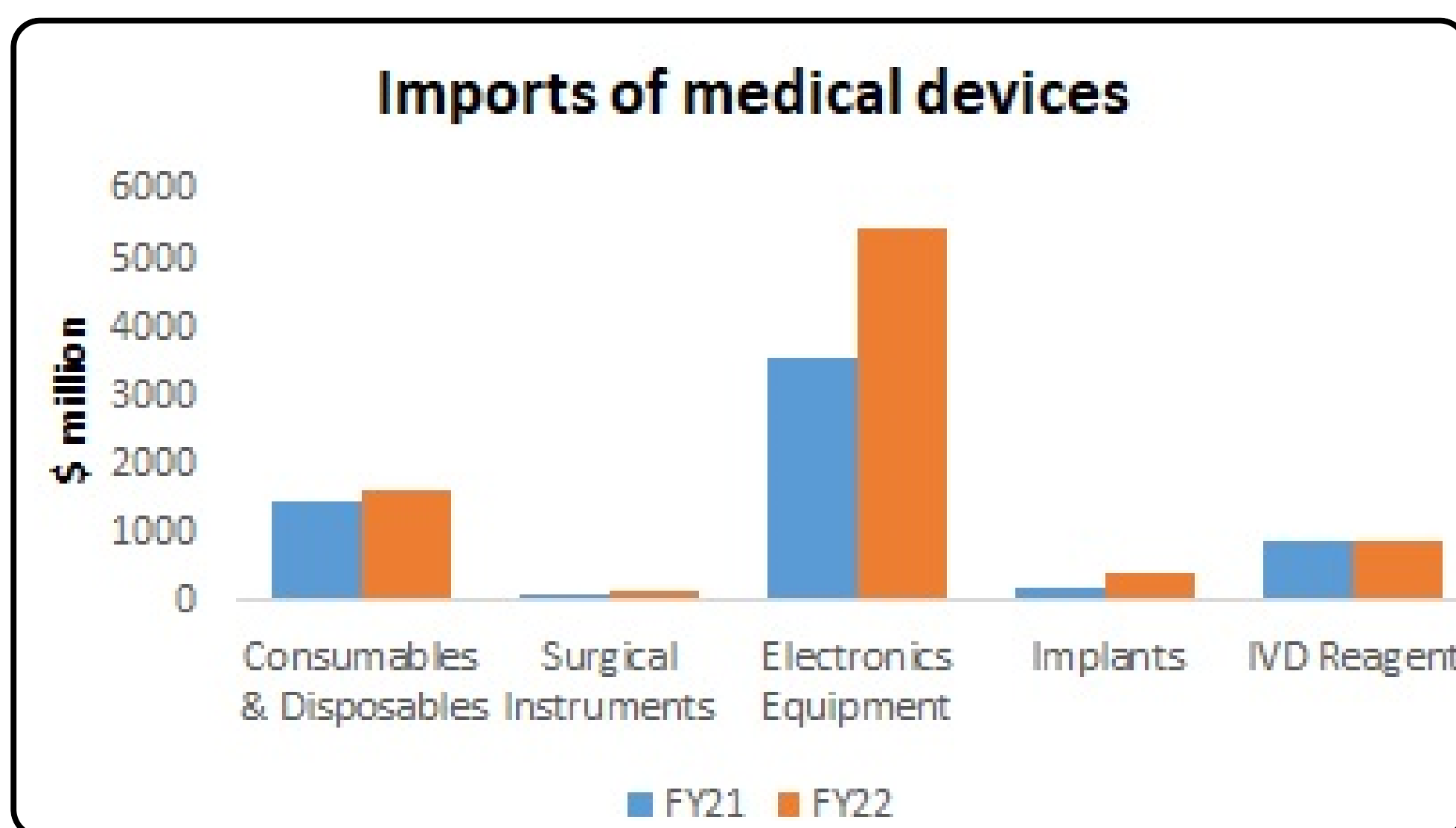
- **SURGE IN FDI IN MEDICAL AND SURGICAL APPLIANCES:**

The foreign direct investment (FDI) up to 100 per cent under the automatic route is permitted for the manufacturing of medical devices. India has witnessed a record-breaking surge of \$464 million in foreign investments in medical and surgical appliances during April to December period of fiscal year 2023-24 (FY24), which represents leading research-based medical technology companies with a large footprint in manufacturing and training in the country. This also shows the high potential of this sector and global investors' recognition of the same. The government's focus on increasing the ease of doing business in the country, the creation of a globally harmonized regulatory for the medical device sector. Notably, this surge also indicates a shift in global dynamics, with Western nations, including Japan, increasingly favoring India as their preferred destination for friend-shoring activities. In FY23, FDI in medical and surgical appliances surged 90.92 per cent to \$397.20 million from \$ 208.05 million in FY22.



- **EXPECTED FALL IN IMPORT DEPENDENCE:**

The medical devices sector has huge potential to expand from current \$11 billion to \$50 billion by 2030. This is likely to help to cut India's import dependence from current 64.6 per cent to 35 per cent and increase export from current 3.4 billion to 18 billion by 2030. This shift could generate over 1.5 million jobs in medical device manufacturing and healthcare services like hospitals and labs. The growth will come from rapid expansion of India's health sector which is projected to grow from \$200 billion annually to \$600 billion by 2030, as more Indians opt for formal healthcare services. This surge will drive the demand for medical devices. Expanding global trade in Medical devices from current \$450 billion to \$800 billion by 2030 will also help.



- **DIGITAL HEALTH TECHNOLOGIES IN INDIA TO TRANSFORM SECTOR:**

The digital health market in India is rapidly expanding, with the country emerging as a significant player in this sector globally. The growth of India's digital health technologies is being driven by factors such as an increase in chronic diseases, improved accessibility to healthcare services, and a proliferation of mobile devices. India's population of over 1.428 billion people faces a range of health challenges, and the country's healthcare system grapples with issues such as low public spending, inadequate infrastructure, a shortage of skilled workers, and unequal access to quality care. The COVID-19 pandemic has accelerated the adoption of digital health technologies, as people seek remote and contactless healthcare services amid lockdowns and social distance measures. Some of the key emerging digital health technologies in India include:

1. SELF-MONITORING HEALTHCARE DEVICES:

Self-monitoring healthcare devices are wearable or portable devices that allow users to measure and track their own health parameters such as blood pressure, glucose level, heart rate, oxygen saturation, etc. Self-monitoring healthcare devices empower users to take charge of their own health, prevent or manage chronic diseases, and improve their well-being. Self-tracking healthcare devices can also provide valuable data for healthcare providers and researchers.

2. POINT-OF-CARE TESTING (POCT):

POCT is gaining prominence in the diagnostics sector due to its ability to improve access to diagnostics, particularly in remote or resource-limited settings, and its potential for early detection and management of diseases such as infectious diseases, diabetes, and cardiovascular conditions.

3. USE OF AI IN MEDICAL DEVICES:

Artificial Intelligence (AI) is reshaping the medical device sector in India, bringing about transformative changes in healthcare. By harnessing AI algorithms, doctors can leverage vast amounts of patient data to make accurate diagnoses and informed treatment decisions. These algorithms have the ability to uncover hidden patterns and trends that may not be readily apparent, providing valuable insights beyond what the human eye can perceive. Additionally, AI plays a vital role in developing personalised treatment plans tailored to individual patients.

MEDICAL DEVICE PARKS

In a bold move that would make India 'Aatmanirbhar', the Government has taken a key initiative to support the medical devices industry to reach its potential in the coming years identifying the industry is as a sunrise sector with great potential for diversification and employment generation. Recognizing the need for higher levels of investments for the creation of proper infrastructure in the sector, the Department of Pharmaceuticals has notified the Scheme for "Promotion of Medical Device Parks" with the objectives of easy access to standard testing and infrastructure facilities through creation of world class common infrastructure facilities for increased competitiveness will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market; and reaping the benefits arising due to optimization of resources and economies of scale.

The Medical Devices Parks to be developed under the scheme was supposed to provide common infrastructure facilities at one place thereby creating a robust ecosystem for the medical device manufacturing in the country and also reducing the manufacturing cost significantly. The total financial outlay of the scheme was Rs 400 crore and the tenure of the scheme is from FY 2020-2021 to FY 2024-2025. The financial assistance to a selected Medical Device Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States, financial assistance would be 90% of the project cost. Maximum assistance under the scheme for one Medical Device Park would be limited to Rs 100 crore.

On March 02, 2024, the government has inaugurated 27 Bulk Drug Park projects, 13 Manufacturing Plants for Medical Devices under the PLI Scheme. The bulk drug plants inaugurated are located across various states including Maharashtra, Gujarat, Karnataka, Telangana, Andhra Pradesh, Punjab, Haryana and Rajasthan. The PLI-I scheme of the Union government identified 48 critical bulk drugs for manufacturing locally. The success of this inaugural scheme led the government to launch the Rs 15,000 crore PLI-II scheme which envisaged to increase cost competitiveness for medicines and medical products in the international market.

Under the scheme, financial incentive is given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under four Target Segments of the scheme i.e. (1) Cancer care equipment, (2) Imaging Devices, (3) Critical care devices, and (4) Body implants. Total 26 applicants have been approved for 138 products under the scheme. Investment of around Rs 875 crore have already been grounded towards capacity creation under the scheme. The inauguration of the above 13 Greenfield plants will be a big step towards achieving self-reliance in manufacturing of wide range of medical devices. With a wide base of scientists, bio-medical engineers, and a growing innovation ecosystem in the country, the India MedTech sector is poised to grow rapidly. Indian manufacturers are continuously innovating. Indigenous development of cancer care equipment, such as Linear Accelerator for radiotherapy and evolved coronary stents, under the PLI scheme, are illustrious example of the same.

GOVERNMENT INITIATIVES

For the medical devices sector in India, the Government has undertaken various steps by easing many rules and regulations, focusing on ease of doing business, technological advancements and simplifying investment mechanisms etc.

- **INTRODUCTION OF NATIONAL MEDICAL DEVICES POLICY, 2023:**

The policy is expected to facilitate an orderly growth of the medical device sector to meet the public health objectives of access, affordability, quality and innovation. This sector is expected to realize its full potential, with the strategies - building an enabling ecosystem for manufacturing along with a focus on innovation, creating a robust and streamlined regulatory framework, providing support in training and capacity building programs and promoting higher education to foster talent and skilled resources in line with the sector requirements. Encouraging domestic investments and production of medical devices complements the Government's 'Atmanirbhar Bharat' and 'Make in India' programs.

- **INDIA ALLOCATES RS 5,000 CRORE TO PROPEL RESEARCH AND INNOVATION:**

In a move towards advancing research and innovation in the pharmaceutical and medical technology (Pharma-MedTech) sector, the Ministry of Finance announced the "Promotion of Research and Innovation in Pharma-MedTech" (PRIP) initiative. This long-term scheme aims to fortify pharmaceutical infrastructure and propel research across six transformative areas. The announcement showcased the government's commitment to fostering advancements in the healthcare industry. The second component of PRIP is dedicated to promoting research in the pharmaceutical sector across six moon-shot areas. The areas of focus include new chemical entities, complex generics (including biosimilars), medical devices, stem cell therapy, orphan drugs, and anti-microbial resistance.

- **PLI SCHEME FOR MEDICAL DEVICES:**

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RECENT DEVELOPMENTS

- **INDIA, US TO INCREASE ENGAGEMENT TO ADDRESS ISSUES IN MEDICAL DEVICES TRADE:**

India and the US have agreed to increase engagement to resolve various issues that could negatively impact the trade in the medical devices sector. The issue came up for discussion during the 14th Trade Policy Forum (TPF) meeting in January 2024. It was co-chaired by US Trade Representative Katherine Tai and Commerce and Industry Minister Piyush Goyal. According to a joint statement, both ministers acknowledged the need to ensure patient access to affordable medical devices, including through the Trade Margin Rationalization (TMR) approach. They also emphasised the importance of enhancing engagement to address measures that could negatively impact the ongoing trade in the sector, such as standards and pricing issues for medical devices, including for cardiac stents and knee implants. The two sides also noted that this engagement would facilitate access to cutting-edge medical technology for patients.

- **INDIAN AND RUSSIAN MEDICAL DEVICE MAKERS COLLABORATE TO BOOST BILATERAL TRADE:**

A forum representing Indian medical device makers has joined hands with a Russian trade organisation to promote bilateral trade in the segment. The Association of Indian Medical Device Industry (AIMED) and the Centre for the Development of Russia Strategic Partnership (DRISP) signed a Memorandum of Understanding (MoU), even as authorities in the two countries project an overall \$30 billion mutual trade by 2025. The collaboration would help promote trade and investment, besides bolstering development and the exchange of technology. According to St Petersburg International Economic Forum (SPIEF), India-Russia trade hit a record \$39.8 billion in 2022-23.

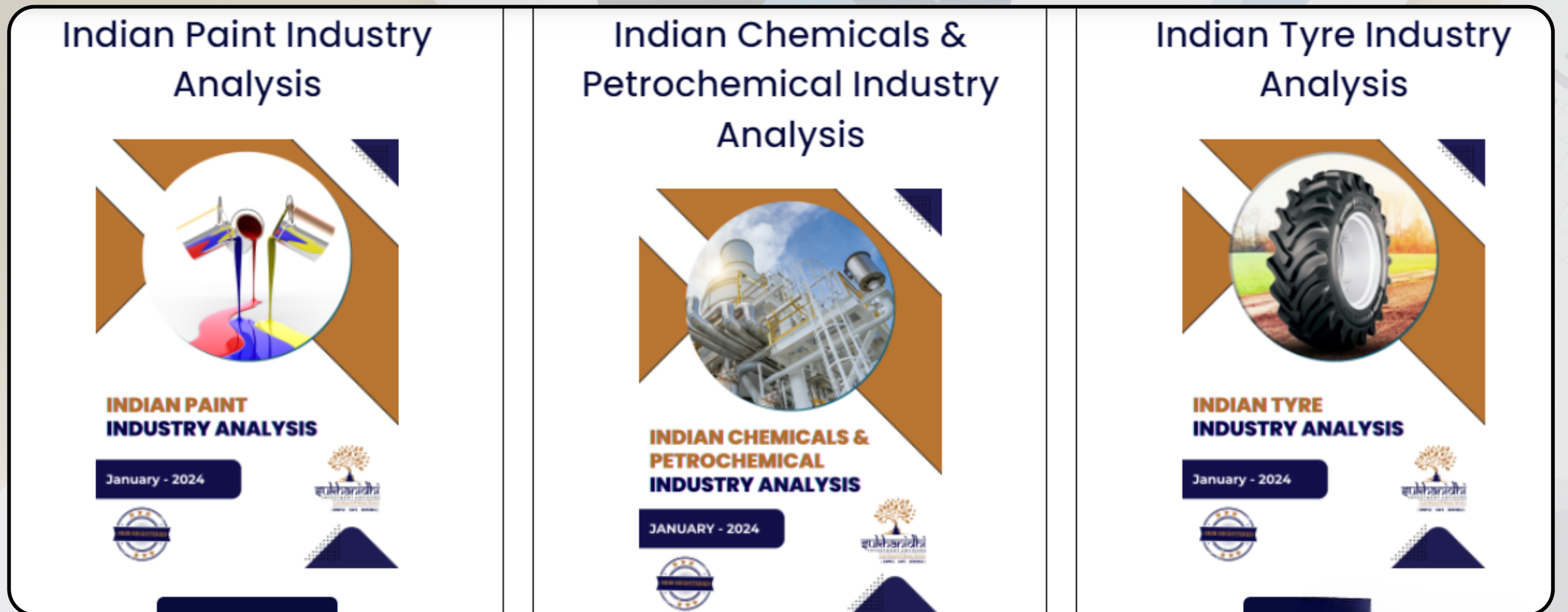
- **INDIA LAUNCHES A SINGLE-WINDOW PORTAL FOR MEDICAL DEVICES MANAGEMENT:**

In a move to streamline the import, clinical investigations, and testing of medical devices, the Centre has launched the National Single Window System (NSWS). The NSWS has been established as a genuine single-window system, which acts as a one-stop shop for all the approvals required by the investor and facilitates ease of doing business. The NSWS portal, distinct from the existing SUGAM and cdscomonline portals, has been developed by Tata Consultancy Services (TCS). It facilitates applications for the certificate of registration and licences to manufacture or import medical devices for various purposes, including clinical investigations, tests, evaluations, demonstrations, and training.

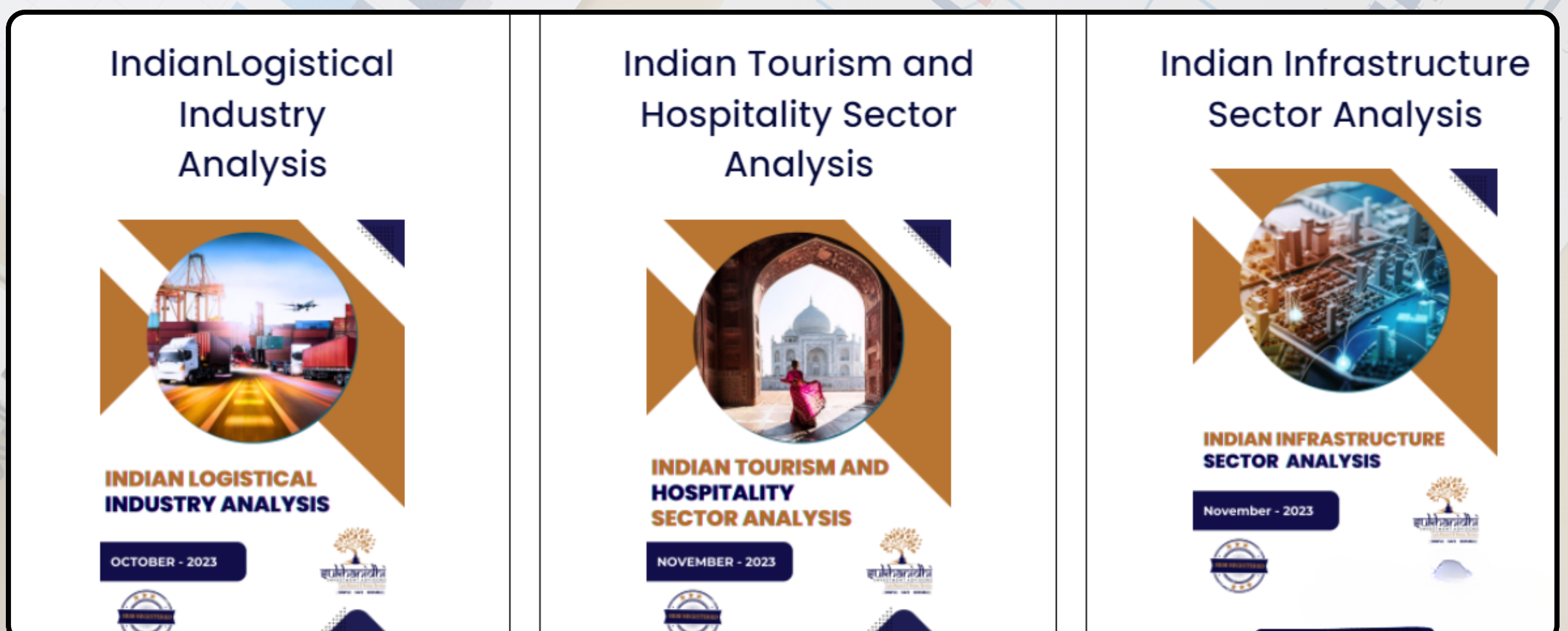
OUTLOOK

The Indian medical devices sector is on a growth track and has an enormous potential to become self-reliant and to contribute towards the goal of universal health care. The outlook of the sector is hopeful in the coming time with the help of the government policies, the adoption of digital technologies and artificial intelligence (AI). India has become a Centre for pioneering innovations. The government has played a role in driving initiatives to boost the sector. These include introducing the New Medical Devices Policy 2023 and establishing the Export Promotion Council for Medical Devices. Additionally, two schemes - Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) and Assistance for Medical Devices Clusters for Common Facilities (AMD-CF). PRIP focuses on creating Centre of Excellence within existing biotechnology, research and healthcare institutions to strengthen research infrastructure in priority areas such as precision medicines, new chemical and biological entities, medical devices and solutions for resistance. AMD-CF aims to create shared infrastructure facilities in clusters dedicated to devices and enhance testing capabilities for these devices. These initiatives aim to address innovation challenges and promote technology exchange.

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A LITTLE ABOUT OURSELVES



Why We Started?

After speaking with hundreds of investors, we discovered that while most investors recognise the importance of investing in equities, many lack the time, knowledge, or necessary resources to evaluate stocks or construct a long-term equity portfolio. As a result, people risk their savings on a companies based only on the recommendations of relatives, friends, brokers, or any business channel, and end up losing their hard-earned money.

And after such instances, we realised the need for professional advice and decided to start the first equity research and investment advisory firm in Hubballi-Dharwad to assist individual investors across India with the sole purpose of offering unbiased, high-quality, fundamental, and affordable equity investment advice to create serious wealth over long-term.

Who We Are?

We are the first equity research and investment advisory firm based in North Karnataka and have 12 + years of experience in equity research and advising High Net worth Individuals (HNI's), Ultra High Net worth Individuals (UHNI's) and NRI's across India and the globe.

What We Do?

We help individual investors in generating inflation-adjusted, risk-adjusted, and tax-efficient returns and create sustainable wealth over the long term by recommending a high-quality direct equity (shares) portfolio.

What We Don't Do?

- Momentum trading
- Debt investments
- Derivatives (Futures & Options)
- Technical analysis
- Timing the market
- Over-diversifying
- Hedging
- Nonsense

What We Expect From Investors?

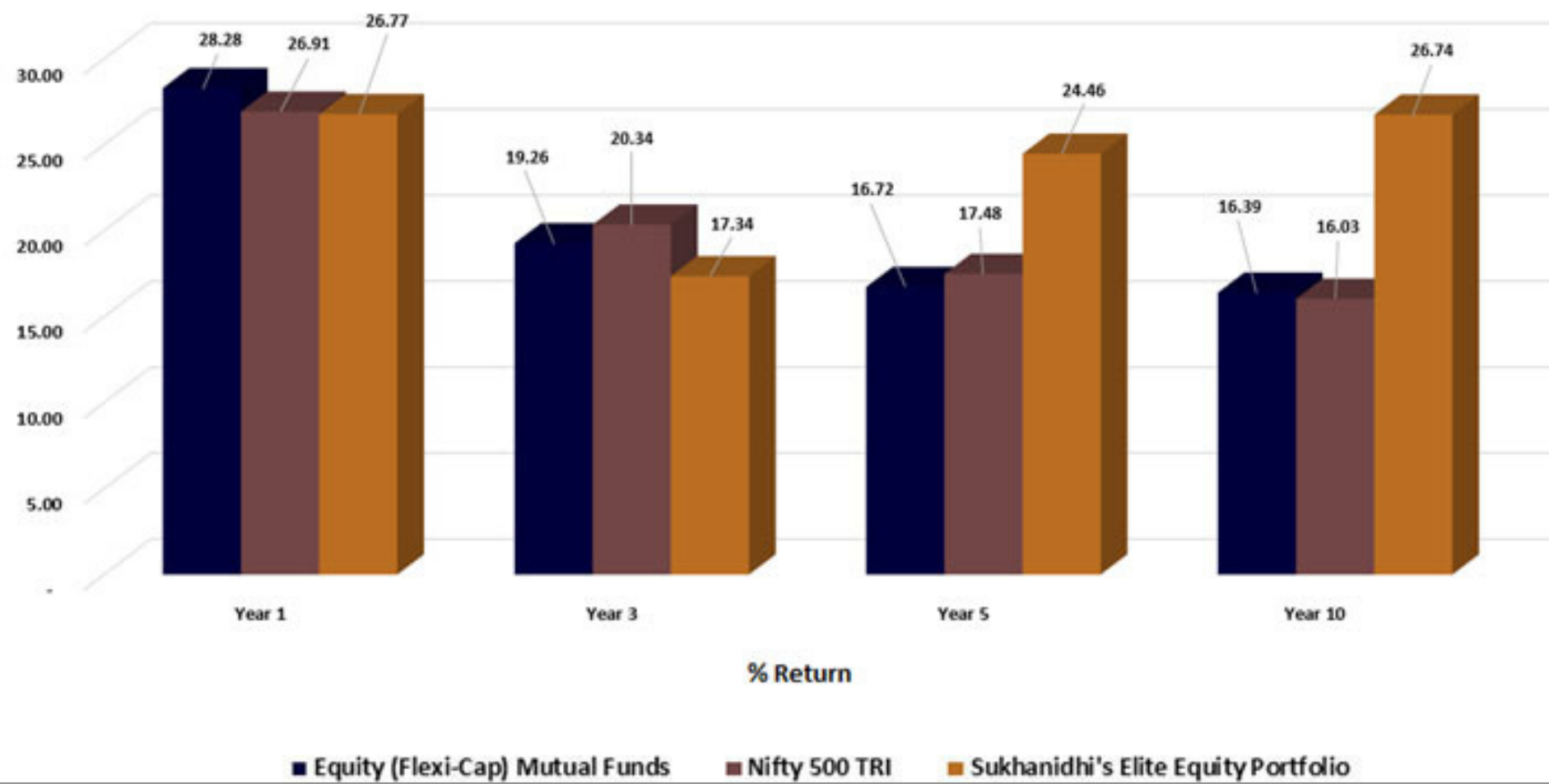
- A minimum commitment period of 5 years or more.

Why Sukhanidhi?

At Sukhanidhi, You Are Assured Of

- Excellence in our advisory services
- Objectivity and unbiased advice
- Credibility: we are SEBI-registered investment advisors
- Low cost: only fixed fees – no performance fees.
- Peace of mind: we uphold your trust with safeguarding your investments and offering our services at reasonable fees

Comparative performance analysis of Flexi-Cap Mutual funds vs Nifty 500 TRI vs Sukhanidhi's Portfolio



Here is why our portfolio is better than equity mutual fund and index fund

Maximize Returns & Reduce Your Expenses with Elite Equity Portfolio

Description	Flexi-cap MF		Nifty 500 (Index Fund)	Sukhanidhi's Portfolio
	Regular	Direct	Direct	Elite Equity
Lumpsum Investment (Rs)	50,00,000	50,00,000	50,00,000	50,00,000
Fees/Charges (in % Pa)	1.75%	1.00%	0.40%	1.00%
Fees/Charges (in Rs Pa)	87,500	50,000	20,000	50,000
5-Years CAGR Returns (in %)	16.72%	17.98%	17.48%	24.46%
Value of Investment at the end of 5th Year (in Rs)	1,08,31,694	1,14,29,098	1,11,88,959	1,49,32,035
Difference in Corpus	-41,00,340	-35,02,936	-37,43,075	-
Total Expenses / fees in last 5 years	-4,37,500	-2,50,000	-1,00,000	-2,50,000
Net Gains/Loss at the end of 5th year	-45,37,840	-37,52,936	-38,43,075	1,46,82,035

Source : Sukhanidhi Investment Advisors

Note: Our elite equity portfolio has generated a 26.74% CAGR (excluding dividend and bonus) in the last decade (10 years) as on 31st December 2023. Where in equity (Flexi-Cap) Mutual Funds 16.39% return and Nifty 500 Index has delivered a CAGR of 16.03% respectively. However, to be conservative, we are expecting around 15% CAGR(excluding dividend and bonus). There is no guarantee of returns and it is subject to prevailing market conditions.

What Our Client Say?



CA Aniruddha Phadnavis

Company Secretary & Compliance Officer,
VRL Logistics Ltd - Hubballi.

"Courteous, Sensible, Reliable, Effective"



Dr. Naveen H.C.

Prosthodontist Implantologist
Hubballi

Investing in equities has never been my cup of tea due to lack of knowledge and time constraint. It has been 4 years now that I have been associated with Mr. Vinayak Savanur. Since then, with his help, I have begun Investing in on equity shares portfolio for the next 20 years to take care of my after retirement expenses.

When I met him for the first time, he listened to each and every query of mine patiently and took me through the entire process they follow, from stock selection to portfolio construction in detail. Only then I found that Mr. Vinayak's way of approaching the stock market is very simple, safe, sensible. and I got convinced.

I would definitely recommend Sukhanidhi investment Advisors to anyone. Especially middle-aged practicing doctors like me. To utilize Mr. Vinayak Savanur's knowledge and expertise to plan their retirement well in advance and build a fool proof long-term equity portfolio.



Sanjot Shah

Director
Manickbag Automobiles Private Limited,
Hubballi

I have got experience from Sukhanidhi investments. The suggestions given by them are good and I am satisfied



CA Narasimhan Elangovan

Partner
KEN & Co., Chartered Accountants,
Bengaluru

Professional and well researched approach. Recommended for those who want to build wealth over long term! Great job Vinayak and team.



Satish Shenoy

General Manager
Samsung India Electronics pvt Ltd,
Mumbai.

A Good Methodology to filter best stocks to invest and easy to approach makes sukhanidhi team class apart; Thanks for your good service. Keep it up!!



Mamata Kulkarni

Texas, USA

Folks, its high time you get in touch with Sukhanidhi to fatten your wallets. Mr. Vinayak Savanur, a very knowledgeable financial advisor, patiently understands your concerns and accordingly guides you in reaching your financial goals. It has been a great pleasure to work with Mr. Savanur. The passion and dedication to his expertise was clear to see. We saw great results and we would strongly encourage others to work with Sukhanidhi! holding the investment for long periods, which is actually the prerequisite to get long term Compound returns from Equity investments. After coming in contact with SUKHANIDHI, after studying their methods in detail, I have now invested in their SUKHANIDHI ELITE EQUITY PORTFOLIO with a long term horizon of 5 to 15 yrs, with 3 different goals in sight, with the intention to withdraw the money as each life goal approaches during the future 15 yrs of my life.



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INVEST
₹ 10 LAKHS
(ONE TIME)
IN OUR
ELITE EQUITY
PORTFOLIO



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It's the best thing you can do to help others.



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