Independent Market Report on Global and Indian Dental Labs and Branded Products

Frost & Sullivan 26.12.2024

ABBREVIATIONS

Abbreviation	Full Form			
' 000	Thousand			
3D	Three Dimension			
AiMED	Association of Indian Medical Device Industry			
ASEAN	Association of Southeast Asian Nations			
B2B2C	Business to Business to Consumer			
BER	Business Environment Rankings			
BITs	Bilateral Investment Treaties			
Bn	Billion			
CAD	Computer-aided Design			
CAGR	Compound Annual Growth Rate			
САМ	Computer-aided Manufacturing			
СВСТ	Cone Beam Computed Tomography			
CDSCO	Central Drugs Standard Control Organization			
CHE	Current Healthcare Expenditure			
СҮ	Calendar Year			
D&C Act	Drugs & Cosmetics Act			
D2C	Direct to Consumer			
DCI	Dental Council of India			
DSO	Dental Services or Support Organization			
ECC	Early Childhood Carriers			
E-SDF	E-Silver Diamine Fluoride			
FDA	Food and Drug Administration			
FDI	Foreign Direct Investment			
FICCI	The Federation of Indian Chambers of Commerce & Industry			
FY	Fiscal Year			
G7	Group of Seven (Canada, France, Germany, Italy, Japan, the UK, and US)			
GDP	Gross Domestic Product			
GP	General Practitioner			
GVA	Gross Value Added			
IDA	Indian Dental Association			
IMF	International Monetary Fund			
INR	Indian Rupee			
IPR	Intellectual Property Rights			
IRDAI	Insurance Regulatory and Development Authority of India			
ISO	International Organization for Standardization			
KFF	Kaiser Family Foundation			
MDR	Medical Devices Rules			
Mn	Million			
MoHFW	Ministry of Health and Family Welfare			

MSME	micro, small, and medium-sized enterprise			
NADL	The National Association of Dental Laboratories			
NHS	National Health Service			
NMP	National Master Plan			
OECD	Organization for Economic Co-operation and Development			
ООР	Out-of-Pocket			
PET	Polyethylene terephthalate			
PETG	Polyethylene terephthalate glycol			
PETG	Polyethylene Terephthalate Glycol			
PFCE	Private Final Consumption Expenditure			
PFM	Porcelain Fused to Metal			
PLI	Production-Linked Incentive			
PM	Prime Minister			
PM-JAY	Pradhan Mantri Jan Arogya Yojana			
PU	Polyurethane			
R&D	Research and Development			
STEM	Science, Technology, Engineering, and Mathematics			
TPU	Thermoplastic polyurethane			
UK	United Kingdom			
US	United States			
US\$	US Dollar			
WHO	World Health Organization			

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1. MACROECONOMICS OVERVIEW

1.1. GLOBAL GDP GROWTH

The Global GDP growth is showing signs of rebound following the Covid-19 pandemic; with short-term sluggishness attributed to geopolitical and financial challenges expected to give way to stronger long-term growth.

1.1.1 WORLD, ADVANCED ECONOMIES, EMERGING MARKETS, AND DEVELOPING ECONOMIES

Emerging economies¹ will be the beacon of growth, outpacing GDP growth in advanced economies¹.

The confluence of pandemic-induced shutdowns, compounded by supply chain intricacies and the Russia-Ukraine conflict, has resulted in significant disruptions in energy and food markets, sparking a substantial inflationary surge and exacerbating a cost-of-living crisis. In response, many nations have adopted stricter monetary policies, which, while moderating GDP growth, are still propelling it forward.

Notably, there is a forecasted global GDP growth rate of 4.9% from 2024 to 2028, surpassing the historical average of 4.1% from 2018 to 2023. This anticipated rise is buoyed by Emerging Markets and Developing Economies, which are expected to achieve a CAGR of 6.1% during this period. Several factors contribute to this robust 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.

Conversely, Advanced Economies are anticipated to record a comparatively more modest CAGR of 4.0%. Nevertheless, this marks an improvement from past figures, driven by positive employment prospects in the United States and rising consumption trends in Europe. This optimistic long-term economic outlook is poised to stimulate global investments and bolster demand in vital sectors, such as healthcare.

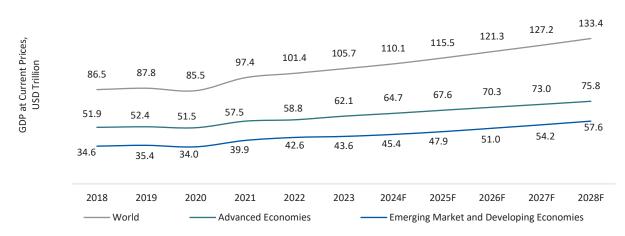


Exhibit 1.1: GDP at Current Prices, Global, 2018-2028F

Source: World Economic Outlook-October 2024, Frost & Sullivan

¹ https://www.imf.org/en/Publications/WEO/weo-database/2024/April/groups-and-aggregates

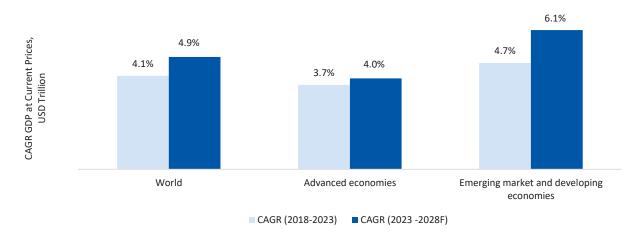


Exhibit 1.2: CAGR GDP at Current Prices, Global, 2018-2028F

Source: World Economic Outlook-October 2024, Frost & Sullivan

1.1.2. G7 COUNTRIES AND KEY EMERGING MARKET COUNTRIES

The GDP growth is shifting from advanced economies of G7² to emerging economies like Asia, particularly India.

Apart from Sub-Saharan Africa and the ASEAN 5, India and China are emerging as two of the largest and swiftest-growing economies. Notably, India's growth rate between 2018 and 2023 was higher than China (5.7% vs. 5.0%) and India's projected GDP growth between 2024 and 2028 is nearly 1.7 times that of China's (10.3% vs. 5.9%).

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, and waning export momentum, projecting a growth rate of 5.9% from 2024 to 2028. India's GDP at current prices reached US\$ 3.6 trillion in 2023 and is anticipated to climb to US\$ 5.7 trillion by 2028, maintaining a strong CAGR of 9.9% from 2024 to 2028.

As a result, India is poised to ascend as the world's third-largest economy by 2028, surpassing Japan and Germany, with a GDP surpassing US\$ 5 trillion. India aims to achieve developed economy status by 2047, underpinned by a strong growth projection of 9.9% between 2024 and 2028. This growth surge is fueled by escalating domestic demand, substantial government, and private global investments, reinforced global ties and reforms centered around Atmanirbhar Bharat, and a flourishing micro, small, and medium-sized enterprise (MSME) sector.

² https://www.imf.org/en/Publications/WEO/weo-database/2023/April/groups-and-aggregates

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.

In contrast, the G7 nations, characterized by mature economies, concentrated markets, and aging populations, confront limited growth prospects. These economies are deeply affected by global banking uncertainties, ongoing conflicts (Israel-Palestine and Russia-Ukraine), and tighter monetary policies, emphasizing the dynamic shift toward rapidly growing Emerging and Developing Asian economies.

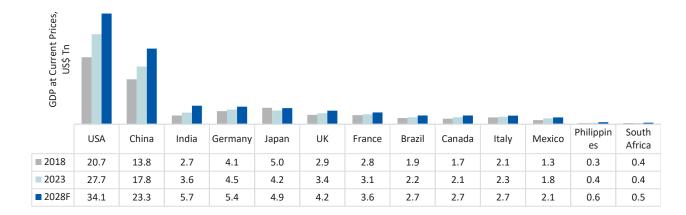


Exhibit 1.3: GDP at Current Prices, Select Countries, 2018-2028F

Source: World Economic Outlook-October 2024, Frost & Sullivan



Exhibit 1.4: CAGR of GDP at Current Prices, Select Countries, 2018-2028F

Source: World Economic Outlook-October 2024, Frost & Sullivan

5.7 5.2 4.7 4.3 India GDP at Current Prices, 3.9 3.6 3.4 3.2 2.8 2.7 2.7 US\$ Trillion 2018 2019 2020 2021 2022 2023 2024F 2026F 2027F 2028F 2025F

Exhibit 1.5: GDP at Current Prices, India, 2018-2028F

Source: World Economic Outlook-April 2024, Frost & Sullivan

Table 1.1: Growth Rates for India GDP at Current Prices				
CAGR (FY18 – FY23) CAGR (FY23 – FY28F)				
India	5.7%	9.9%		

Source: World Economic Outlook-October 2024, Frost & Sullivan

1.2. **GDP PER CAPITA**

The GDP growth is also outpacing the population growth, leading to higher GDP per capita worldwide, but the growth remains more pronounced in emerging economies.

GDP per capita serves as a key indicator of economic prosperity, providing insight into the average income per person. As per data from the International Monetary Fund (IMF), global GDP per capita has shown significant growth, rising from US\$ 10.92 thousand in 2017 to US\$ 13.36 thousand in 2023, indicating a CAGR of 3.4%.

In 2023, among the G7 nations, the United States led with the highest GDP per capita at current prices, reaching US\$ 82,715, closely followed by Canada, Germany, and the United Kingdom. However, despite their strong purchasing power, these advanced economies have reached a saturation point, with GDP per capita growth plateauing, typically remaining in the range of 2-5%. A modest recovery is expected, with growth projected to range between 3-6% from 2024 to 2028.

In contrast, emerging market economies are poised for robust and sustained growth. Among these economies, China and Mexico had the highest GDP per capita at current prices in 2023, standing at US\$ 12,597 and US\$ 13,641, respectively. However, India stands out with the most impressive projected CAGR of 9.0% between 2023 and 2028, indicating significant potential for rapid expansion in the near future.



Exhibit 1.7: GDP per capita at Current Prices, Select Countries, 2018-2028F

Source: World Economic Outlook-April 2024, Frost & Sullivan

Table 1.2: CAGR for GDP per Capita (at Current Price)					
Country	CAGR (2018-2023)	CAGR: (2023-2028F)			
USA	5.5%	3.8%			
China	5.0%	5.7%			
India	4.8%	9.0%			
Germany	1.8%	3.5%			
Japan	-3.2%	3.8%			
United Kingdom	2.8%	4.0%			
France	1.5%	3.1%			

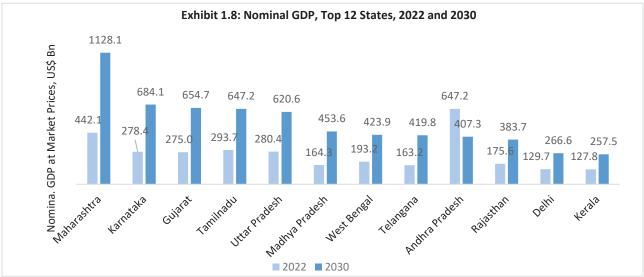
Brazil	2.0%	4.2%
Canada	2.2%	3.0%
Italy	2.2%	3.4%
Mexico	6.5%	2.3%
Philippines	3.6%	7.1%
South Africa	-2.6%	2.4%

Source: World Economic Outlook-April 2024, Frost & Sullivan

1.2.1. GDP of top states in India

India is witnessing increased commercial activity in many states and some big states will grow their GDP significantly by 2030.

Top 5 states in India (Maharashtra, Karnataka, Gujarat, Tamil Nadu, and Uttar Pradesh) will account for 56.0%, and the top 12 states to account for 96% of the country's GDP in 2030. Tamil Nadu, Uttar Pradesh, Karnataka, and Gujarat will become half-a-trillion-dollar economies by 2030, and Telangana, Madhya Pradesh, Maharashtra, Karnataka and Gujarat are expected to register the biggest jumps in contribution to the national GDP with growth rates of above 11%.



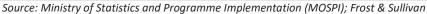


Table 1.3: Projected Growth rate of Top 12 states by GDP (2020 – 2030)				
Maharashtra	12.4%			
Karnataka	11.9%			
Gujarat	11.5%			
Tamil Nadu	10.4%			
Uttar Pradesh	10.4%			
Madhya Pradesh	13.5%			
West Bengal	10.3%			
Telangana	12.5%			
Andhra Pradesh	-5.6%			
Rajasthan	10.3%			
Delhi	9.4%			
Kerala	9.2%			

Source: Ministry of Statistics and Programme Implementation (MOSPI); Frost & Sullivan

1.3. INDIA'S PRIVATE FINAL CONSUMPTION EXPENDITURE (PFCE)

Increasing confidence in financial growth and stability in the country is also reflected in increasing PFCE, with a notable rise in expenditure on education and health.

Private Final Consumption Expenditure (PFCE), representing the expenditures made by households and individuals on goods and services, excluding government spending and net exports, constitutes the largest share of India's Gross Domestic Product (GDP). PFCE to GDP ratio at current prices during 2021-22 and 2022-23 are estimated at 61.0% and 60.9% respectively. Furthermore, the PFCE has grown drastically from FY12 to FY22 at a CAGR of 307.7%. This surge in PFCE is a testament to the escalating demand for services, driven by growing confidence in the economy and personal financial stability.

Among the various components of PFCE, including housing, water, food, non-alcoholic beverages, electricity, gas, other fuels, and transportation, the most notable growth between FY 2017 and FY 2022 was observed in communication, education, and health. Health, in particular, saw a noteworthy increase, accounting for 5.2% of the total PFCE in FY 2022, up from 4.5% in FY 2017.

Health PFCE encompasses expenditures related to a wide range of healthcare services, such as doctor's fees, hospital charges, medications, medical tests, and health insurance premiums, along with other healthcare-related expenses. This statistic serves as an indicator of the overall affordability and accessibility of healthcare within the nation.

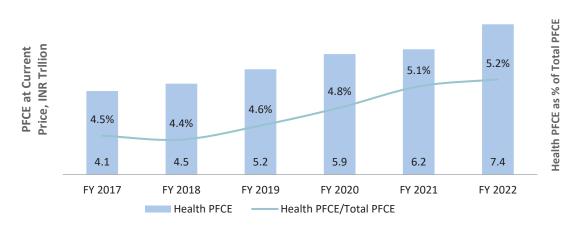


Exhibit 1.9: India's PFCE on Health at Current Price: FY 2012 - FY 2022

Source: Ministry of Statistics & Programme Implementation, Frost & Sullivan

Table 1.4: Growth Rates for India's PFCE on Health at Current Price				
CAGR (FY17 – FY22)				
Health PFCE	12.5%			
Total PFCE	9.3%			

Source: Ministry of Statistics & Programme Implementation, Frost & Sullivan

1.4. GROWTH DRIVERS FOR INDIA'S GDP

India's unique demographic dividend and commendatory reforms are accelerating economic growth in the country.

1.4.1. DEMOGRAPHIC ADVANTAGE

India not only holds the distinction of being the world's most populous nation but also possesses a uniquely expanding working-age demographic, which stands in sharp contrast to many regions facing aging and shrinking working populations. As of 2022, a substantial 49.8% of India's population belonged to the working age group of 25 to 64 years, showing an increase from 47.8% in 2017, and this percentage is projected to further rise to 51.7% by 2027. India's youthful population presents a significant competitive advantage in terms of labor force availability. Moreover, the country's large pool of graduates, particularly in Science, Technology, Engineering, and Mathematics (STEM) fields, proficient in English, distinguishes India from other nations. This advantage proves especially beneficial in skill-intensive industries such as medical device research and development (R&D) and manufacturing. Additionally, the rapid urbanization and rising income levels of the working population will stimulate demand for goods and services, further propelling growth.

1.4.2. GOVERNMENT REFORMS FOR MANUFACTURING SECTOR

Historically, manufacturing has contributed 16-17% to the country's GDP. With a focus on boosting manufacturing across sectors including automotive, engineering, chemicals, pharmaceuticals, medical devices, and consumer durables through initiatives like the Production-Linked Incentive (PLI) scheme, PM Gati Shakti- National Master Plan (NMP), and industrial development schemes in states with industrial backwardness, the manufacturing sector is expected to represent 25% of GDP by 2025. These reforms are anticipated to concurrently enhance India's Business Environment Rankings (BER), particularly in infrastructure improvement, from the 14th position in the 2018-2022 period to the 10th position in the 2023-2027 period, positioning India ahead of the Philippines, Indonesia, and Vietnam.

1.4.3. Positive Government Reforms

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

1.4.3.1. FDI POLICY

India has been steadily enhancing its Foreign Direct Investment (FDI) policies to foster a more favorable investment environment through simplified procedures, sectoral reforms, digital initiatives, Intellectual Property Rights (IPR) Protection, Bilateral Investment Treaties (BITs), and attractive incentives. The Government's 100% FDI approval for Medical Device industry under the automatic route for both brownfield and greenfield setups (introduced in 2015) is expected to boost the industry. From April 2000 to September 2023, FDI inflow in the medical and surgical appliances sector stood at US\$ 3.22 Bn. Strong FDI inflows also reflect confidence among global players on the Indian medical devices market.³

1.4.3.2. EMERGENCE OF PUBLIC INSURANCE COVERAGE AND INTEGRATION OF PUBLIC AND PRIVATE HEALTHCARE DELIVERY SECTORS

The Government of India is working towards addressing the demand and supply gap across the healthcare sector in insurance, manufacturing, and healthcare delivery services through the expansion of public insurance coverage and integration of public and private healthcare delivery sector (Increased government interventions with PM-JAY coverage, access, and upgradations)

1.4.3.3. PRADHAN MANTRI JAN AROGYA YOJANA (PM-JAY)

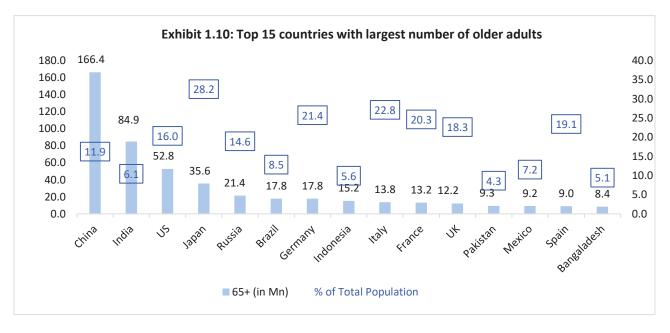
PM-JAY scheme under Ayushman Bharat, launched in 2018, is the world's largest health insurance, providing access to 12 crore families with INR 5 Lakh health cover per family to avail healthcare services in secondary and tertiary care hospitals (in both public and private sector). There are ~70 crore beneficiaries under the scheme. By 2047, IRDAI aims to achieve "Insurance for All", and PM-JAY is an integral part of that program. IRDAI's efforts to drive insurance penetration is likely to help India move to the top 5 countries in the global insurance market in terms of revenues by 2047.

³ Indian Brand Equity Federation

1.4.3.4. DEVELOPMENT OF "MAKE IN INDIA" PROGRAMS FOR PHARMACEUTICALS AND MEDICAL DEVICES WITH PLI SCHEME

In medical devices, India is the fourth largest in Asia and stands amongst the top 20 markets in the world. Majority of domestic manufacturers (65%) operate in the consumables segment and cater to local consumption with limited exports.

The Indian Government is taking supportive measures such as promoting indigenous manufacturing of high-tech medical devices, production-linked incentive schemes (PLIs) on medical devices and establishing new medical devices park to boost overall growth of India's domestic medical devices market. To reduce import dependency on capital equipment and high-end medical products, the Government of India has launched the 'Make in India' initiative, and as of March 2024, there were 26 approved applicants under PLI for medical devices, with a committed investment of INR 1,206 crore (US\$ 147 million). In 2019, the Government undertook to set up four medical device parks in Andhra Pradesh, Telangana, Tamil Nadu, and Kerala which will be equipped with the necessary infrastructure, reducing the manufacturing costs.



Source: Population Reference Bureau, United Nations Population Division, World Population Prospects 2019, Frost & Sullivan

1.5. 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 on the planet. One in six individuals on the planet will be 60 years of age or older by 2030. At this point, there will be 1.4 Bn people over the age of 60, up from 1 Bn in 2020. The number of individuals in the world who are 60 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

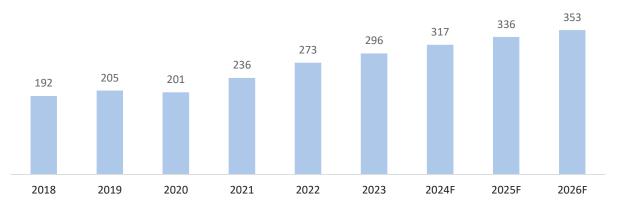
proportion of the world's population over 60 years will nearly double from 12% in 2015 to 22% in 2050.⁴ China, India, US, Japan, and Russia are the top 5 countries with largest number of older adults.⁵

1.6. GLOBAL DISPOSABLE INCOME

Household net adjusted disposable income is the amount of money that a household earns, or gains, each year after taxes and transfers. It represents the money available to a household for spending on goods or services. Household adjusted disposable income includes income from economic activity (wages and salaries; profits of self-employed business owners), property income (dividends, interests, and rents), social benefits in cash (retirement pensions, unemployment benefits, family allowances, basic income support, etc.), and social transfers in kind (goods and services such as health care, education, and housing, received either free of charge or at reduced prices). Across the OECD (Organization for Economic Co-operation and Development), the average household net adjusted disposable income per capita is US\$ 30,490 a year.⁶

1.6.1. DISPOSABLE INCOME IN INDIA

India's total disposable personal income increased to INR 296 Mn in 2023 from INR 192I Mn in 2018 growing at a CAGR of 9%.⁷ The total disposable personal income is estimated to reach INR 353 Mn in 2026.





Source: Ministry of Statistics & Programme Implementation, Frost & Sullivan

While India's Upper-middle and High-income class population is expected to have positive growth from 2021 to 2031 (5% and 12%), the Low-income and Lower-middle income population is expected to decline (-9% and --3%).

⁴ WHO, Ageing and Health

⁵ Population Reference Bureau, United Nations Population Division, World Population Prospects 2019

⁶ OECD BetterLifeIndex

⁷ Trading Economics, Ministry of Statistics & Programme Implementation

Table 1.5: Population growth across income segments, 2021-2030				
Income class	Income level at 2020-21 prices	Population (2021), Mn	Population (2031F), Mn	CAGR (2021-30F)
Low-income	< 1.25 Lakh	196	79	-9%
Lower-middle	1.25 – 5 Lakh	732	568	-3%
Upper-middle	5 – 30 Lakh	432	715	5%
High	>30 Lakh	56	169	12%

Source: People Research on India's Consumer Economy (PRICE), Frost & Sullivan

1.7. GLOBAL HEALTHCARE OUTLOOK (US, UK)

1.7.1 UNITED STATES

The Unites States spent about 16.6% of its GDP in health care in 2022. The spending grew 4.1% to reach US\$4.5 trillion in 2022, faster than the increase of 3.2 percent in 2021. The per capita healthcare spending in 2022 was US\$ 12,222, 2.9% increase from 2021, driven by strong growth in Medicaid and private health insurance spending.^{8,9} The share of insured population in the US is 92% in 2022 which is historical high, and Private health insurance enrollment increased by 2.9 Mn individuals and Medicaid enrollment increased by 6.1 Mn individuals in 2022 compared to 2021.⁹ US Healthcare spending Per Capita and as a percentage of GDP is far higher than other high-income countries. Other advanced economies spend US\$ 6,651 Per capita on Healthcare which is about half of what the U.S. spends.⁸ Health spending is projected to return to an annual growth rate of 4.8% between 2022 and 2031, as the consumption of health care services (utilization) rebounds and health sector prices grow due to inflation.¹⁰ Over the course of 2025–30, the average annual growth in national health expenditures is projected to exceed that of the overall economy, which is expected to result in a health share of the economy up to 19.6% by 2030.¹¹

As per American Dental Association, the National Dental Expenditure in the US increased from US\$ 152 Bn in 2016 to US\$ 165 Bn in 2022, and as per National Association of Dental Plans, the total dental insurance enrollment increased from 77% in 2016 to 88% in 2022.

⁸ Peterson – KFF Health System Tracker (January 2024)

⁹ Center for Medicare and Medicaid Services, National Health Expenditures 2022 Highlights

¹⁰ Kaiser Family Foundation (KFF), How Much is Health Spending Expected to Grow? (October 2023)

¹¹ Health Affairs, National Health Spending Projected to Hit \$6.8 Trillion by 2030 (March 2022)

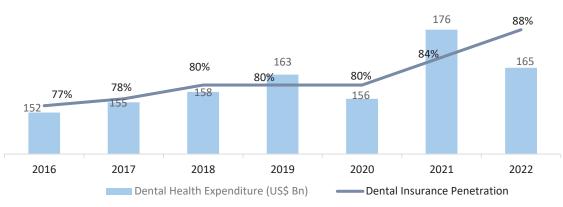


Exhibit 1.12: US Dental Health Expenditure (US\$ Bn) and Dental Indusrance Penetration, 2016-2022

Source: American Dental Association, Frost & Sullivan

1.7.2 UNITED KINGDOM

The United Kingdom spends about 11.3% of its GDP on Healthcare. The Per Capita spend on healthcare is US\$ 4,986.¹² UK healthcare expenditure was around US\$350 billion in 2022, an increase of 0.7% from 2021.¹³ In the UK, the share of public funding for health is high and it has remained relatively unchanged at around 80% of total health spending for over the last two decades. Through Government funded National Health Service (NHS), UK citizens enjoy high levels of protection against the financial consequences of ill health and minimal out-of-pocket payments.

¹² OECD Health at a Glance 2023 Country Note (UK)

¹³ Office for National Statistics (UK)

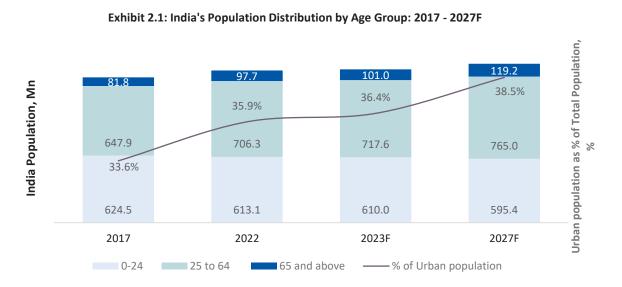
2. INDIAN HEALTHCARE LANDSCAPE

2.1. INCREASED HEALTHCARE EXPENDITURE

Healthcare has been an underpenetrated segment historically but with rising levels of disposable income in comparison to peers and heightened post-pandemic awareness of superior health management, focus on healthcare is growing, leading to increased discretionary spending on the segment.

2.1.1. RISING HEALTHCARE EXPENDITURE DUE TO AGING POPULATION AND HEALTHCARE NEEDS The share of senior citizens will increase to about 21% by 2030, creating demand for specialized healthcare services, including dental care services.

In India, the proportion of the old has been rising quickly in recent years, and this trend is probably going to continue in the decades to come. It is anticipated that the proportion of the population over 65 will rise from 10.5 percent in 2022 to 20.8 percent in 2050. The elderly will make up more than 36% of the nation's population by the end of the century.¹⁴ With an aging population and increased life expectancy, the need for health care specialized services such as nutritional services, chronic health services, dental services, and home care services is expected to have a larger role. The aging of the population increases the prevalence of acute and chronic illnesses and drives healthcare consumption, including dentistry.



Source: World Bank, Frost & Sullivan

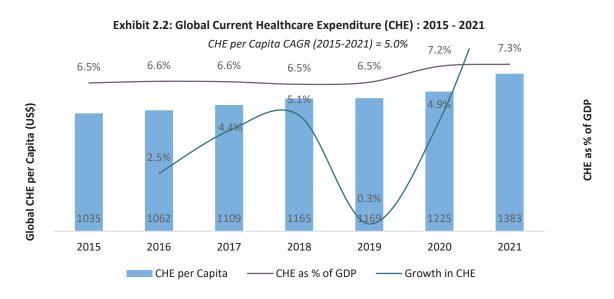
¹⁴ UNFPA, India Ageing Report

2.1.2. GLOBAL CURRENT HEALTHCARE EXPENDITURE

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

Current healthcare expenditure (CHE) as a percentage of GDP is on an upward trajectory with rising economies, increased accessibility and affordability, advances in medical technology, growing prevalence of chronic diseases, aging population, post-pandemic behavioral changes, and heightened focus on wellness and self-medication. In the five years between 2015 and 2021 CHE per Capita increased at a CAGR of 6.0%, reaching 7.3% of GDP in 2021, up from 6.5% in 2015. Globally, nearly 63.4% of healthcare expenditure is shouldered by domestic general government sources, with 36.4% coming from domestic private sources. External sources contribute a minimal 0.24% to global healthcare spending.

Furthermore, in 2020, 16.4% of healthcare expenditure was paid out-of-pocket, reflecting significant financial burden borne by individuals and households.



Source: WHO, Frost & Sullivan

2.1.3. CURRENT HEALTHCARE EXPENDITURE IN INDIA COMPARED TO OTHER KEY COUNTRIES

India's healthcare spending is increasing but remains lower than its peers. It heavily relies on Out-of-Pocket payments, emphasizing the need for affordable alternatives, such as affordable healthcare services.

India's CHE as a percentage of GDP is a mere 3.3%, which is very low compared to developing and other Asian peers, implying huge scope for affordable healthcare products and services. Compared to global economies, healthcare expenditure has been historically low in India because of high dependence on Out-of-Pocket (OOP) expenditure and the under-penetration of healthcare and ancillary services. However, as private insurance coverage increases, government insurance schemes such as Ayushman Bharat widen and strengthen the overall healthcare expenditure, which is expected to increase further. The early signs of the impact of ongoing changes are already evident from declining dependence on OOP. India's Current Healthcare Expenditure (CHE) per Capita has increased from US\$ 57 in 2014 to US\$ 74 US\$ in 2021 at a CAGR of 3.9%.

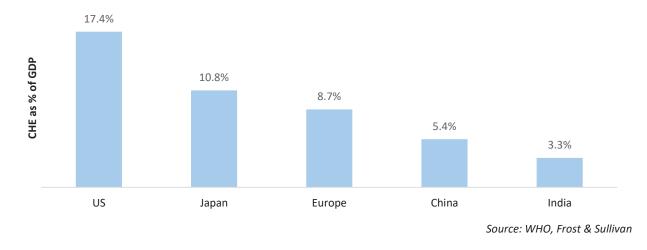


Exhibit 2.3: Current Healthcare Expenditure as % GDP by Country: 2020

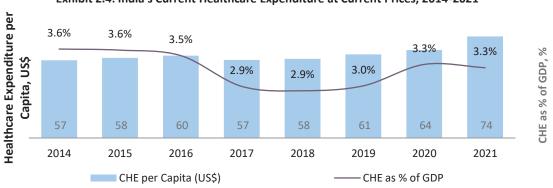


Exhibit 2.4: India's Current Healthcare Expenditure at Current Prices, 2014-2021

Source: WHO, Frost & Sullivan

2.1.4. CURRENT HEALTHCARE EXPENDITURE IN INDIA BY SOURCE OF FUNDING

India is witnesing rising insurance adoption and increasing healthcare coverage from the government. However, high out-of-pocket expenditure continues to impose a financial burden on individuals.

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 individuals, or the lower 50% of the population. Social and private voluntary health insurance covers 20% of the population, accounting for 25 crore individuals¹⁵.

¹⁵ Niti Aayog

Government expenditure as a percentage of healthcare expenditure in India has grown from 25.6% in 2015 to 36.6% in 2020. However, India's Out-of-Pocket (OOP) healthcare spending, at 50.6% in 2020, is notably high compared to other healthcare funding schemes within the nation. Furthermore, this OOP burden surpasses that of Asian peers, who typically rely on OOP for approximately 30-35% of healthcare expenses, significantly exceeding the World Health Organization's recommended range of 15-20%¹⁶. Encouragingly, India's OOP expenditure has been declining, reducing from 64.7% in 2015 to 50.6% in 2020, and private insurance adoption is slowly increasing.

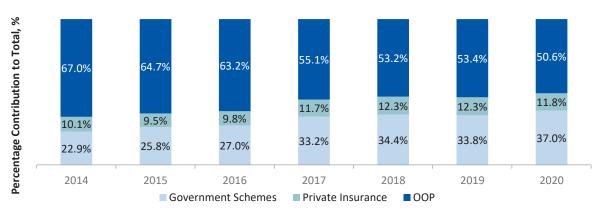


Exhibit 2.5: India's CHE by Financing Scheme: 2014-2020

Source: World Bank, Frost & Sullivan

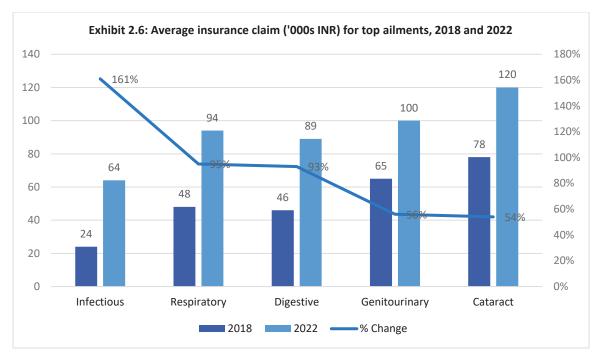
2.1.5. HEALTHCARE INFLATION IN INDIA

While annual retail inflation was at 5.69% in December 2023¹⁷, the medical inflation is at 14.0%.¹⁸ The rising 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.

¹⁶ WHO Report

¹⁷ Pib, Ministry of Statistics & Programme Implementation

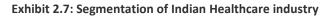
¹⁸ Health Report of Corporate India 2023, Plum

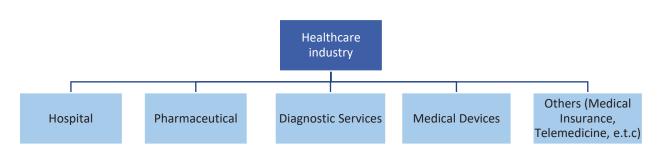


Source: Policybazaar, Frost & Sullivan

2.2. SEGMENTATION OF INDIAN HEALTHCARE INDUSTRY.

Indian Healthcare industry is segmented into Hospitals, Pharmaceuticals, Diagnostics, Medical equipment supplies, medical insurance, and Telemedicine. The estimated market size of the Indian Healthcare industry is US\$ 352 Bn in 2022, and it is estimated to grow at CAGR of 22.0%.¹⁹ The industry is expanding due to the country's rapid economic growth, middle-class income gains, and health insurance carriers' expanded market penetration. Furthermore, there has been a nationwide surge in government healthcare spending due to shifting demographics and a move from chronic to lifestyle disorders. The Indian Healthcare Market is expected to reach US\$ 636 Bn by 2025.





Source: IBEF, Frost & Sullivan

¹⁹ NiTi Aayog and Frost & Sullivan analysis

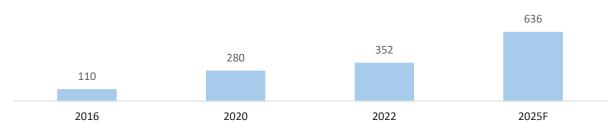


Exhibit 2.8: Indian Healthcare Market (US\$ Bn), 2016 - 2025F CAGR: 22%

The Indian Healthcare market is dominated by Hospital segment with about 74% share (US\$ 260.4 Bn, 2022), followed by Pharmaceutical with about 11.6% Share (US\$ 40.9 Bn, 2022), Medical Devices with about 4.4% share (US\$ 15.4 Bn, 2022), and Diagnostics with about 2.6% share (US\$ 9 Bn, 2022).²⁰ Among the Healthcare segments, the Medical Device segment is expected to grow fast between 2022 and 2030 with a CAGR of about 20.4%, followed by Hospitals (18.2%), Diagnostics (13.0%) and Pharmaceuticals (12.2%).²⁰

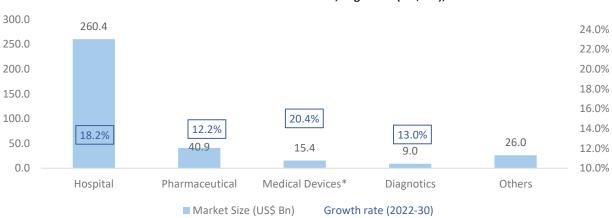


Exhibit 2.9: Indian Healthcare Market, Segments (US\$ Bn), 2022

Note: Medical Device market includes exports. Source: IBEF, Frost & Sullivan

2.3. INDIAN MEDICAL DEVICE INDUSTRY

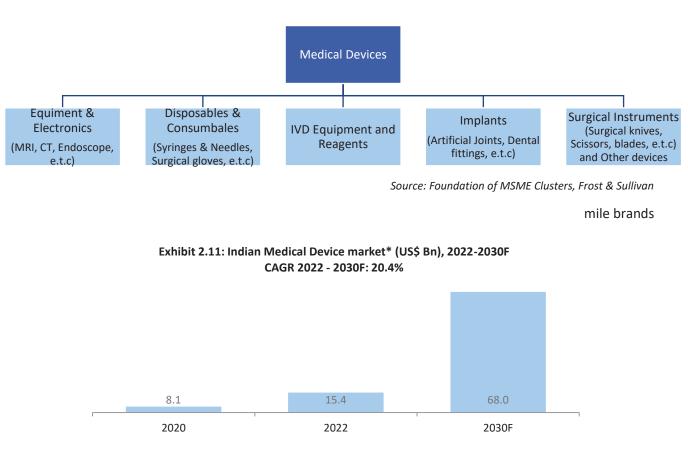
Major segments of the Indian Medical device industry include Equipment and Electronics, Disposables and Consumables, IVD equipment and Reagents, Implants, Surgical Instruments and other devices. India is counted among the top 20 global medical devices market. The Indian Medical Device market²¹ is estimated to reach US\$ 50.0 Bn by 2030 at a growth rate of 20.4% from its estimated value of US\$ 15.4

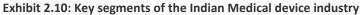
Source: IBEF, Frost & Sullivan

²⁰ India Briefing, IBEF, NiTi Aayog, Invest India

²¹ Includes domestic consumption and exports

Bn in 2022.²² It is estimated to contribute 1.65% of the global medical device market. Export of medical devices from India increased from US\$ 2.29 Bn in 2020 to US\$ 3.40 Bn in 2022. The Indian medical device exports are projected to reach US\$ 18 Bn in 2030.²³ 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 (\$668.9 Mn) in 2023, followed by export to Germany (\$176.2 Mn), China (\$145.6 Mn), and the Netherlands (\$106.5 Mn).²⁴





*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%).

²² Foundation of MSME Clusters, Global Trade Research Initiative, Indian Brand Equity Foundation

²³ IBEF

²⁴ AiMED, Business Standard

Table 2.1: Market Size of Indian Medical Device Segments (US\$ Bn)				
Segment	Market Size 2022	Share (2022)	Estimated Market Size 2030F	Forecast CAGR (2022-30)
Equipment & Electronics	7.3	47.0%	27.4	18.0%
Disposables & Consumables	4.0	26.0%	19.4	21.8%
IVD and Reagents	1.8	12.0%	9.4	23.0%
Implants	1.4	9.0%	6.1	20.2%
Surgical Instruments	0.9	6.0%	5.6	25.7%
Total	15.4		68.0	20.4%

Source: Foundation of MSME Clusters, Frost & Sullivan

The Indian Medical Device market is transitioning from being import dependent with increase in domestic production and increasing share of exports. The Medical Device exports from India is expected to grow from US\$ 3.4 Bn in 2022 to US\$ 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 2022-23.²⁵

Source. Toundation of Wishie Clasters, Global Trade Research Initiative, Trost & Suniva						
Table 2.2. Indian Medical Device market, Export trend (2022-2030F)						
Year	2022	2030F				
Indian Medical Device Market (Domestic Consumption) (US\$ Bn)	12.0	50.0				
Indian Medical Device Exports (US\$ Bn)	3.4	18.0				
Total Indian Medical Device Industry including exports	15.4	68.0				

Source: 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, 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.

²⁵ https://www.ibef.org/news/india-reverses-old-trend-in-medical-consumables-business-is-now-a-net-exporter

2.4. INDIAN MEDICAL DEVICE REGULATION

Under the 1940 Drugs & Cosmetics Act (D&C Act), the Indian government controls medical devices (i.e., tools, implants, software, and other items meant for human or animal medical use) as "drugs." To improve the safety, efficacy, and conformity of medicines, medical devices, and cosmetics sold in India with international standards, the Ministry of Health and Family Welfare (MoHFW) released the New Drugs, Medical Devices, and Cosmetics bill in July 2022, replacing the D&C Act. The Indian Certification for Medical equipment Plus (2021) program is a new initiative by Quality Council of India and the Association of Indian Medical Device Industry which 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 to comply with the ISO 13485 certification requirement. The purpose of this criterion is to guarantee the safe manufacture and management of in vitro diagnostic goods and medical devices. The National Medical Device Policy was introduced by the Indian government in May 2023. Its objectives include providing affordable, highquality 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.

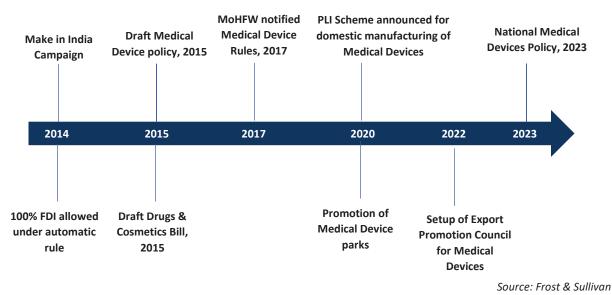
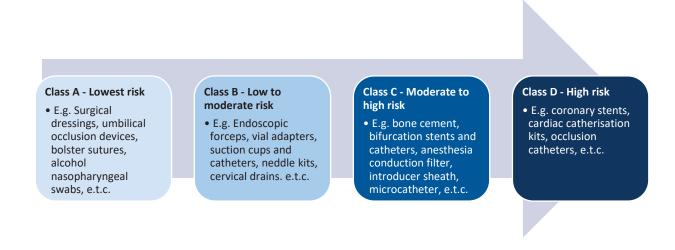


Exhibit 2.13: Timeline of policies to boost Medical Device industry

Exhibit 2.14: Classification of Medical devices in India



Source: IBEF, Frost & Sullivan

The Dental products are regulated under Medical Devices Rules (MDR), 2017, Medical Devices (Amendment) Rules, 2020, Drugs (Prices Control) Order, 2013 and Drugs and Cosmetics Act, 1940. MDR are issued under the Drugs and Cosmetics Act which came into effect January 1, 2018. Further, The Drugs and Cosmetics Act and MDR seek to regulate the import, manufacture, distribution and sale of all the Medical Device and ensure the availability of standard quality Medical Devices to the consumer. 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 of low-risk devices such as surgical dressings, umbilical occlusion devices, bolster sutures, alcohol swabs, and nasopharyngeal catheters. Class B devices are of low moderate risk such as endoscopic forceps, vial adapters, suction cups and catheters, Sengstaken- Blakemore tube, feeding tubes, and gastrointestinal tubes. Class C devices are of moderate high risk such as anesthesia conduction filter, introducer sheath, microcatheter, imaging catheter colonic stents, and pancreatic instruments. Class D devices are of high risk such as coronary stents, cardiac catheterization kits, cardiovascular, intravascular diagnostic catheters, and occlusion catheters. Dental products are classified under Class A, B and C category as per the risk. Most of the Dental Products fall under Class A and B category. As of October 2022, to manufacture, import, sell, or distribute dental products in India, a valid license from the Central Drugs Standard Control Organization (CDSCO) is mandatory. The Central Drugs Standard CDSCO is the licensing authority for Class C and Class D dental devices and the State Licensing Authority is the licensing authority for Class A and Class B dental devices in India.²⁶

²⁶ Drugs Controller General (India) DGHS, 2017 Notice, Indian Brand Equity Foundation

Table 2.3: Classification of Dental Products as per CDSCO ²⁷				
Type of Dental Product	Class			
Crowns and Bridges	В			
Implant	С			
Aligners	В			
Dentures	В			
Braces	В			

Source: CDSCO, Frost & Sullivan

Growing emphasis on compliance to quality standards and licensing requirements of dental products from the CDSCO to manufacture, import, sell, or distribute dental products is expected to drive the growth of large organized dental labs in India. Inability to meet quality standards and compliance burden would drive closure of unorganized and small dental labs.

2.5. DENTAL MARKET IN INDIA

India's dental care services market is estimated to be US\$ 3.4 Bn in 2023 and expected to grow at a rate of 12.6% to reach US\$ 7.8 Bn in 2030. The growth of the market is being driven by increasing prevalence of Oral Health disorders such as Dental Caries, Malocclusion and Periodontal diseases among the population, and greater demand for general and specialized dental care due to growing awareness.²⁸ While independent dental clinics run by individual practitioners make up most of the Indian dentistry market, there is growing number of dental chains in metropolitan and Tier I cities²⁹ due to improved affordability for dental care, increase in awareness and favorable financing environment to establish network clinics. The share of organized dental chains is expected to grow in the coming years. The Indian Dental Market is vast comprising of over 5,000 Dental Laboratories (entities manufacturing customized dental prosthesis such as crowns and bridges and supplying to dentists for treatment of patients) and 306 Dental Institutes.²⁶ Further, the Indian Dental Market is growing due to the expansion of dental tourism and government initiatives supporting it. Affordable dental care combined with the high caliber of skilled dentists and treatment in India draws tourists to the country for dental care. India can accelerate the growth momentum in dental tourism through the implementation of advanced technology to perform procedures like implant surgery, cosmetic dentistry, Orthodontics, and Paediatric dentistry while ensuring high quality standards in a cost-effective manner.

2.5.1. BURDEN OF ORAL HEALTH DISEASE

The Global prevalence of Oral Health diseases was 40 times higher than Cancer, 6.7 times higher than Cardio-vascular diseases and 3.6 times higher than Mental disorders in 2019. The need of dental care services is evident globally and in India.

As per WHO, "Oral Health is the state of the mouth, teeth and orofacial structures that enables individuals to perform essential functions, such as eating, breathing, and speaking, and encompasses psychosocial dimensions, such as self-confidence, well-being, and the ability to socialize and work without pain, discomfort, and embarrassment. Oral health varies over the life course from early life to

²⁷ https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Dental10oct.pdf

²⁸ International Dental Lab Expo & Conference

²⁹ Classification of Tiers as per Ministry of Finance (Government of India) HRA classification of X – Tier 1 (Population of 50 Lakh and above), Y – Tier 2 (Population of 5 to 50 Lakh) and Z – Tier 3 (Population below 5 Lakh) – Notification No. 2/5/17-E II(B), 7th July 2017

old age, is integral to general health and supports individuals in participating in society and achieving their potential."³⁰ While oral disorders are sometimes not acknowledged as such in the public domain, it is significant public health concern for nations globally. Almost 3.5 Bn people worldwide were afflicted by these diseases in 2019, and three out of every four of them reside in middle-income nations.¹⁹

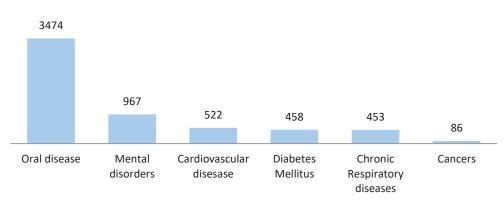


Exhibit 2.15: Global case number for select Non-communicable dieases (Mn), 2019

Across the World Bank regions (country income groups), the average prevalence of oral health disease is high (45%). In comparison to the population growth of roughly 45% between 1990 and 2019, the estimated case numbers of oral disorders increased by more than 1 Bn between 1990 and 2019, representing a 50% rise.¹⁹

Table 2.4: Percentage change in estimated prevalence, case numbers and change in population by World Bank country income group						
WB country income group	Percentage change in prevalence rates (1990–2019)	Percentage change in case numbers (1990–2019)	Percentage change in population (1990–2019)			
Low income	0.1%	114.0%	118.0%			
Lower-middle income	2.6%	70.0%	63.2%			
Upper-middle income	5.4%	33.0%	28.0%			
High income	2.2%	22.7%	20.6%			
Global	3.2%	49.3%	44.8%			

Source: WHO Global Oral Health Status Report; Frost & Sullivan

2.5.2. PREVALENCE OF ORAL HEALTH ISSUES IN INDIA

The prevalence of oral health issues such as prevalence of untreated caries of deciduous (milk teeth) and permanent teeth, severe periodontal disease, and incidence of lip and oral cavity cancer is high in India compared to countries such US, UK, France, Australia, and Germany. The higher prevalence of such oral health conditions due to poor oral hygiene practices, excessive consumption of sugary and junk foods, and tobacco consumption results in more demand for dental health services.

Source: WHO Global Oral Health Status Report; Frost & Sullivan

³⁰ WHO Global Oral Health Status Report, 2022

Table 2.5: Oral Disease Burden in India and other key counties, 2022							
Parameter	India	China	US	UK	France	Australia	Germany
Prevalence of	43.3	47.2	42.6	19.5	29.2	38.9	29.1
untreated caries [*] of							
deciduous teeth in							
children 1-9 years (%)							
Prevalence of	28.8	24.6	24.3	30.6	36.8	29.5	31.7
untreated caries							
of permanent teeth							
in people 5+ years (%)							
Prevalence of	21.8	17.5	15.7	10.6	16.2	14.5	27.4
severe periodontal							
disease ^{**} in people							
15+ years (%)							
Prevalence of	4.0	5.7	10.2	12.0	12.6	13.5	11.7
Edentulism ^{\$} in							
people 20+ years (%)							
Incidence rate of Lip and	9.8	1.3	4.2	5.1	5.4	6.5	4.3
oral cavity cancer (per							
100,000 population)							
*Dental caries are Cavities are holes, or areas of tooth decay, that form in your teeth surfaces.							

*Dental caries are Cavities are holes, or areas of tooth decay, that form in your teeth surfaces.

******Periodontal disease refers to inflammation and infection of the tissues that support your teeth.

\$ Eudentulism or Toothlessness is the condition of having no teeth.

Source: WHO, Oral Health Country Profile, 2022

2.5.3. DENTAL HEALTH EXPENDITURE

The Dental Healthcare expenditure in India is very low compared to countries such as US, UK, China, France, Australia, and Germany. While US spends US\$ 405 per capita on dental treatments, India spends a meagre US\$ 0.05.³¹ With increasing adoption of dental treatment due to factors such as growing awareness, rising disposable incomes and ageing population, the dental health expenditure is expected to significantly increase in coming years.

Table 2.6: Comparison of Dental Health in India and other key countries							
Parameter	India	China	US	UK	France	Australia	Germany
Total public expenditure on dental healthcare in Mn (US\$)	64	61,549	133,506	9,577	12,666	7,370	30,877
Per capita expenditure on dental healthcare (US\$)	0.05	44	405	143	195	288	372
Per capita current health expenditure in PPP, US\$ (2019)	211	880	10,921	5,087	5,493	5,294	6,739

Source: WHO, Oral Health Country Profile, 2022

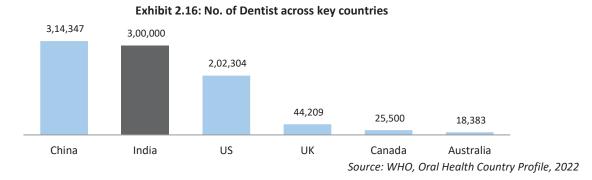
³¹ WHO, Oral Health Country Profile, 2022

2.5.4. DENTAL PROFESSIONALS

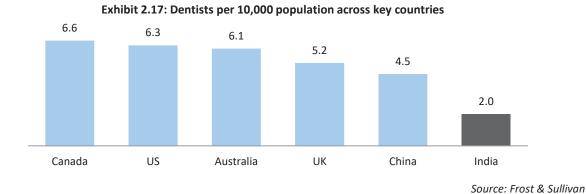
While India ranks second globally in terms of number of dentist, it has one of the lowest ranks in terms of dentist per population. Most of the top 10 states by registered dentists are in South and West regions of India.

The National Dental Commission Act 2023 regulates the profession of dentistry in India, provides quality and affordable dental education and to make high-quality oral healthcare accessible. The act aims to enhance standards in dental healthcare and education and ensuring optimal dental care for citizens. The act emphasizes technology innovation, industry collaboration, and maintaining an online National Register of licensed dentists and dental assistants.

India has the second-highest number of dentists in the world after China; approximately 3 lakh dentists are registered with the Dental Council of India (DCI).³² Further, there is growing number of dentists in India. The dentist-to-population ratio of India, which was 1:300,000 in the 1960s, now stands at



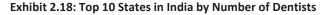
2:10,000. However, it is still very low in India compared to other countries such as Canada (6.6 per 10,000), US (6.3 per 10,000), Australia (6.1 per 10,000), UK (5.2 per 10,000) and China (4.5 per 10,000).³³ Maharashtra has the highest number of registered dentists in India, followed by other states such as Karnataka, Kerala, Tamil Nadu, Uttar Pradesh, and Gujarat.



³² Impact and Policy Research Institute (Delhi), Dental Council of India

³³ WHO, Global Health Observatory

46,243 43,869 32,922 29.569 24,668 22.719 21,355 11,978 10,645 10,641 Guiarat Andrea Pradesh Waltarashtra Tamil Madu Karnataka Uttal Pradesh Puniab Delhi telajs Bihar



Based on regions, South has the highest number of dentists (45%), followed by West (25%), North (21%), and East (8%)

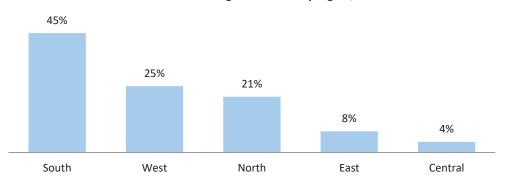


Exhibit 2.19: Percentage of dentists by region, India

2.5.5. GROWTH DRIVERS OF THE INDIAN DENTAL MARKET

2.5.5.1. HIGH PREVELANCE OF DENTAL PROBLEMS AND UNDERPEENTRATION OF DENTAL CARE

India has a high prevalence of dental disorders such as dental caries (over 95%), malocclusion (about 75%) and periodontal diseases (over 50%). While the prevalence of dental disorders is high, lack of awareness among the population on the importance of oral health and low dentist to population ratio have resulted in significant underpenetration of dental care.³⁴

2.5.5.2. GROWING AWARENESS OF ORAL HEALTHCARE AND COSMETIC DENTAL PROCEDURES

With increasing awareness of oral healthcare, it is anticipated that demand for dental care would rise over time. More procedures and products targeted at lessening patient discomfort are starting to be introduced to the market as more individuals choose cosmetic dentistry and prioritize oral health above medical problems. Due to the ongoing development of more sophisticated versions of dental products

Source: Dental Council of India

Source: Dental Council of India

³⁴ https://www.financialexpress.com/life/as-oral-illnesses-continue-to-be-major-burden-in-india-dental-care-is-still-not-a-priority-3105638/

such as aligners and crowns, patients and dentists are using them more frequently. There is increase in choice for patients opting for cosmetic dental procedures. Across several Metropolitan and Tier-I cites in India, growing number of dental practices are offering cosmetic and aesthetic dentistry services such as veneers dental crowns, teeth whitening, dental bonding, and dental braces.

2.5.5.3. DENTAL TOURISM

As the world grows more interconnected and competitive, dental tourism is expanding globally. This is because dental professionals in developing countries such as India can now offer dental care at a significantly lower prices when compared to their counterparts in developed nations, owing to the rapid spread of technique, materials, and technological advancements. Due to increasing medical expense and long waiting time for dental treatment, there is an increase in the number of dental tourists coming to India from the US, UK, Middle East, and other counties. The primary factor making India a popular destination for dental tourists from around the globe is the much cheaper prices for the same level of care. For example, while Dental Implant procedure costs about US\$ 900 in India, it costs higher in other medical tourism destinations such as Singapore (US\$ 2,700), Thailand (US\$ 1,720) and Malaysia (US\$ 1,500).³⁵ Further, the average price of implants is \$3,500 in the US, \$2,500 in the UK and \$2,000 in Australia.³⁶ Furthermore, practically all dental clinic employees and physicians in India speak English fluently, as the language is frequently used there. High treatment quality, improved accessibility, availability of advanced dental procedures and specializations, and low cost of treatment are fueling the growth of Indian dental tourism.

Table 2.7: Comparison of Dental Implant cost across select countries				
Country	Average cost of Dental Implant (US\$)			
US	3,500			
UK	2,500			
Singapore	2,700			
Australia	2,000			
Thailand	1,720			
Malaysia	1,500			
India	900			

Source: goodchoicedental.com Frost & Sullivan

2.5.5.4. INDIA EMERGING AS A MANUFACTURING HUB FOR DENTAL PRODUCTS

While a large portion of India's dental product needs are met by countries such as Japan, China, Germany, United States and France, the total import of shipments and import value have declined over years. Moreover, India is emerging as manufacturing hub, supplying dental products to countries such as US, UK, Europe and Middle East.³⁷ Due to growing demand for oral healthcare services, multinational companies are investing in the Indian dental products market and establishing their presence in India.

³⁵ India: Building Best Practices in Healthcare Services Globally. FICCI.

³⁶ goodchoicedental.com

³⁷ Italian Trade Agency, Morulaa

2.5.5.5. DENTAL INSURANCE

The Indian dental insurance market is at a nascent stage, and it is expected to grow due to increasing oral health awareness, rising disposable income and competitive offering among insurers. Increasingly, health insurance companies are including basic dental care services as a part of general health insurance and are creating standalone dental insurance products for specialized dental care needs. Health insurance companies are offering plans covering outpatient dental treatment, accidental dental treatment, and dental surgery. Dental insurance covers a portion of cost associated with preventive, minor, and a part of some major dental care. Few policies include coverage for preventive care like routine exams, cleanings, and X-rays. Many dental insurance plans also include coverage for basic services like fillings and extractions, and major services like root canals, crowns, implants, gum surgery, Jaw surgery, surgical Removal of Pathology, surgical treatment of Clefts and many more. Increasing competition among insurance carriers and increase choice of dental insurance plans for consumers is expected to drive adoption of dental care services in India.

2.5.6. TECHNOLOGICAL ADVANCEMENTS AND INNOVATIONS IN DENTISTRY

Growing technology adoption such as Cone beam computed tomography (CBCT), Digital Imaging and Radiography, 3D printing and Laser Dentistry leading to improved precision, efficiency and patient comfort is expected to increase demand for dental products and services.

Digital transformation has ushered new possibilities across sectors, including dentistry. Modern technology is now available to dental practitioners, enabling more precise diagnosis, quicker treatments, and customized treatment regimens. Modern dentistry is heavily reliant on digital technology, which will have a big impact on dental practices both now and in the future. There is growing adoption of intraoral scanners (IOS), CAD/CAM (Computer-aided design, Computer-aided manufacturing) and 3D printing technology. The penetration of IOS in the US is about 53%, and the major reasons for adoption of IOS are to improve clinical efficiency, intent to transition from analog to digital practice, and improve laboratory communication.³⁸ Adoption of digital technologies is expected to increase the volumes of dental procedures. Further, innovations in materials such as Zirconia is expected to increase patient experience and drive adoption of novel implant materials among dentists. Zirconia implants are made from Zirconium oxide, a form of ceramic that is more durable than metal alloys and porcelain. Zirconia implants are gaining popularity over traditional Titanium and Titanium alloys due to its natural strength and durability, better aesthetics improved biocompatibility and tissue integration, low affinity to plaque, and favorable biomechanical properties compared to Titanium.

	Table 2.8: Technology advancements in Dentistry				
Digital Imaging and Radiography	Traditional film-based X-rays have been superseded with digital radiography and imaging, which has several benefits. Patients spend less time waiting thanks to digital imaging technologies' instantaneous production of high-resolution pictures. Additionally, they ensure patient safety by producing notably less radiation. Moreover, the ease of sharing, storing, and manipulating these digital pictures helps with precise diagnosis and treatment planning.				
Laser Dentistry	Several facets of dental treatment have changed because of laser technology. Gum contouring, tongue tie release, and other soft tissue treatments can all be treated using minimally invasive laser dental techniques. In general, laser operations are less unpleasant, produce less blood, and hasten the healing				

³⁸ Journal of American Dental Association, American Dental Association Clinical Evaluators Panel survey, August 2021.

	process. Additionally, lasers offer accurate and effective treatment choices for cavities, dental decay removal, and teeth whitening.
Cone beam computed tomography (CBCT)	The maxillofacial and oral regions can be seen in fine detail in three dimensions using CBCT imaging. Dentists can precisely diagnose issues (e.g., low jawbone density, impacted teeth, and temporomandibular joint abnormalities) using CBCT, which makes complicated anatomical components visible. CBCT scans are used to help with precise treatment planning for orthodontics, dental implants, and oral surgery, improving results and lowering risks.
3D Printing	The integration of 3D printing in Dentistry enables high precision and personalized solutions, enhancing treatment outcomes and patient satisfaction. Using 3D printing, Dentists can create dental models, surgical guides, and even customized implants. Further, it streamlines the workflow in Dental Laboratories, reducing production time and costs.
CAD/CAM technology	CAD/CAM technology enables Dentists to create rapid precise digital impressions of patients' teeth resulting in better aesthetics, durability, and accurate fit of the restorations, saving time for both the dentist and the patient.
Teledentistry	Teledentistry has improved access to dental care by enabling Dentists to remotely diagnose and monitor patients' oral health using digital platforms.

2.5.7. GROWING ADOPTION OF COSMETIC TREATMENT AND BRANDED PRODUCTS

Due to growing awareness of dental aesthetics among patients, the demand for cosmetic dental procedures such as teeth whitening, dental veneers, dental crowns, and dental aligners have increased over the years. Further, due to direct-to-consumer marketing, there is increasing preference for novel branded products such as Clear Aligners compared to traditional braces for malocclusion cases (misalignment of teeth). Clear Aligners offer advantages such as the less painful treatment, improved aesthetics due to invisible nature, less time-consuming procedure, easy removability, leading to better patient acceptance compared to traditional braces resulting.

2.5.8. DENTAL CARE MARKET

The overall Dental Care market includes dental products and dental treatments or care services. The dental products comprise of General & Diagnostic equipment, Dental consumables, and other products. The dental treatment or care services includes Periodontic, Orthodontic, Prosthodontic and Endodontic procedures. Periodontics is a specialty involving different oral structures especially the gums, teeth, and bones. Orthodontics specialty addresses the diagnosis, prevention, management, and correction of malpositioned teeth and jaws, as well as misaligned bite patterns. Common orthodontic treatments include braces, Clear Aligners, and retainers. Prosthodontic treatments include dentures, dental implants, crowns, and bridges. Endodontics specialty is dedicated to dental pulp and tissues surrounding the roots of a tooth. The major end-users of dental products are hospitals and clinics, and academic and research institutes.

2.5.9. GLOBAL DENTAL CARE SERVICES MARKET

Increased adoption of dental care services is expected to drive demand for dental products, including dental consumables such as Aligners, Implants and Crowns. The total untapped dental market is

approximately more than 800 Mn people in the India and approximately more than 4 Bn people globally.

The dental care services include the provision of cosmetic, preventive and restorative dental care services by licensed dentists to patients. The Global Dental Care Services market is estimated to grow from US\$ 506.8 Bn in 2023 to US\$ 840.8 Bn in 2030, growing at a CAGR of 7.5%. Increasing disposable income, growing patient awareness, the rising prevalence of dental disorders, demand for cosmetic dental procedures, technological advancements such as digital dentistry and increasing access to care are some of the factors driving the market growth.

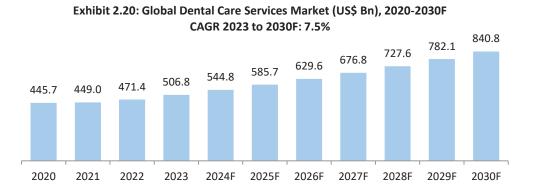


Exhibit 2.21: Regional share of Global Dental Care Services Market (by value) 4% 4% 4% 4% 40% 21% 21% 28% • North America • Europe • South Asia • Latin America • Middle East & Africa • Others

Source: Frost & Sullivan

2.5.10. INDIAN DENTAL CARE SERVICES MARKET

The Indian Dental Care Services market is at a nascent stage and is expected to witness rapid growth due to growing number of dental chains supported by Dental Labs, advent of new technology and increasing demand for the novel products, driven by the rising prevalence of the oral diseases, increasing awareness, and rising disposable income.

The Indian Dental Care Services market is one of the fastest growing markets globally, growing at a higher rate compared to global market. The market is expected to grow from US\$ 4.4 Bn in 2023 to US\$ 10.2 Bn in 2030 at a growth rate of 13.0%. The market for dental care services includes the dental prostheses and

Source: Frost & Sullivan

aesthetics, orthodontics, and other dental services such as preventative dentistry, and general dental diagnosis and treatment.

Source: Frost & Sullivan

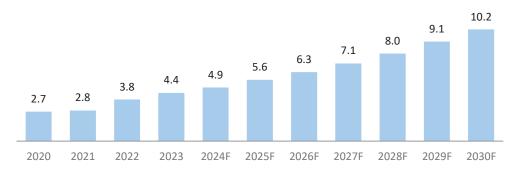


Exhibit 2.22: Indian Dental Care Services Market (US\$ Bn), 2020-2030F CAGR 2023 to 2030F: 13.0%

2.5.11. INDIAN DENTAL CARE MARKET BECOMING ORGANIZED FROM BEING FRAGMENTED

The fragmented Indian dental care market, where large hospitals and dental chains account for less than 10% of all practices, is expected to move towards organized market with growth of large dental networks. The number of dental clinic chain networks is expected to double in the next five years driven by funding from venture capital/private equity players.³⁹ Moreover, there is increased preference of organized professional dental clinic chains among patients due to factors such as branding and marketing, adoption of technology such as practice management software, standardized protocols/standard operating procedures across clinics, and focus on cleanliness and hygiene. Clove Dental's parent company Global Dental Services, which operated over 400 company-owned and managed dental clinics across 24 cities in 12 States, received US\$ 50 Mn investment from Qatar Investment authority in November 2022 and US\$ 66 Mn Investment from Bahrain's Investcorp.⁴⁰ Another dental chain Sabka dentist which operates over 100 clinics across various cities in India, received US\$ 1.8 Mn investment from LGT Capital Partners, Asian Healthcare Fund in 2021.

2.5.12. INDIAN DENTAL PRODUCTS MARKET

The Indian Dental Product Market comprises of Dental Consumables, General and Diagnostic Dental Equipment and Dental Instruments. The Dental consumable market, comprising of Dental Implants,

³⁹ https://www.investcorp.com/investcorp-leads-inr-545-crore-investment-in-global-dental-services/

⁴⁰ https://www.thehindubusinessline.com/companies/clove-dentals-parent-raises-50-m-in-equity-from-qatar-investment-authority/article67569163.ece

Dental Prosthetics, Orthodontic products, Periodontic products and other consumables, and it contributes to a major share of the dental products market.

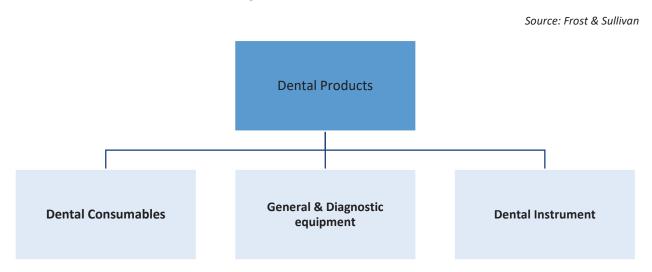
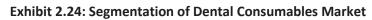
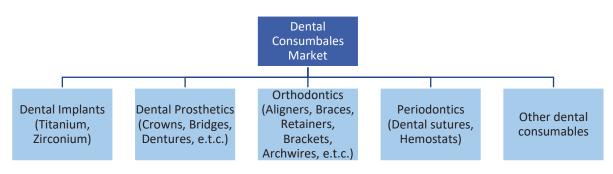


Exhibit 2.23: Segments of Indian Dental Products Market

2.5.13. DENTAL CONSUMABLES MARKET

The Dental consumable market comprises of Dental implants, Dental prosthetics, Orthodontic products, Periodontic products, and other dental consumables.





Source: Frost & Sullivan

The Global dental consumables market, in terms of retail sales revenue, is expected to grow from US\$ 177.4 Bn in 2023 to US\$ 356.8 Bn in 2030 at CAGR of 10.5% and the emerging countries such as India and China are expected to witness higher growth compared to developed countries. The global dental consumables market is expected to grow higher than the global dental services market (10.5% vs. 7.5%) in the forecast period due to growing number of branded premium products, and increased awareness and adoption of dental products such as Clear Aligners and dental crowns in emerging economies such as China, India and Brazil.

Source: Frost & Sullivan



Exhibit 2.25: Global Dental Consumables Market (US\$ Bn), 2020-2030F CAGR 2023 to 2030F: 10.5%

2.5.14. INDIAN DENTAL CONSUMABLES MARKET

The Indian Dental Consumables market, in terms of retail sales, is estimated to grow at from US\$ 2.4 Bn in 2023 to US\$ 6.1 Bn in 2030 at a high growth rate of 14.5% due to factors such as growing awareness on dental hygiene, improved access to dental treatments due to increasing number of dental clinic chains, and adoption of novel products such as Clear Aligners.

Source: Frost & Sullivan

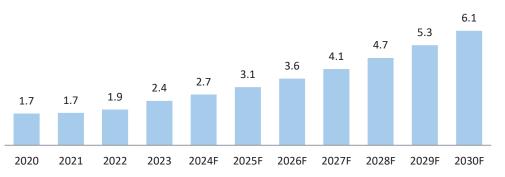


Exhibit 2.26: Indian Dental Consumables Market (US\$ Bn), 2020-2030F CAGR 2023 to 2030F: 14.5%

The per capita annual dental consumables expenditure in India has increased from US\$ 1.4 (INR 104) in 2020 to US\$ 1.9 (INR 157) in 2023.

2.5.15. GLOBAL CUSTOM-MADE CROWN AND BRIDGES MARKET

Dental crowns and bridges are fixed prosthetic devices used in dental restoration to treat missing or spoiled teeth. These devices are custom-made and fixed on the damaged tooth using dental cement to improve the strength and appearance of the tooth. A crown is a dental restoration device, which completely caps a damaged tooth or dental implant, while a bridge is used to fill in the missing tooth by attaching a dental implant or by fixing an artificial tooth permanently. The Global market for custom-made crowns and bridges, in terms of retail sales, is estimated to grow from US\$ 71.0 Bn in 2023 to about US\$ 121.6 Bn in 2030 at a growth rate of 8.0%.



Exhibit 2.27: Global Custom-made Crowns and Bridges Market (US\$ Bn), 2020-2030F CAGR 2023 to 2030F: 8.0%

Source: Frost & Sullivan

2.5.16. INDIAN CUSTOM-MADE CROWNS AND BRIDGES MARKET

The Indian market for custom-made crowns and bridges, in terms of retail sales, is estimated to grow from US\$ 1.4 Bn in 2023 to about US\$ 3.1 Bn in 2030 at a growth rate of 11.8%. The major factors driving the market growth are growing adoption of dental treatments, aging population, and the need for restorative treatments, increasing prevalence of periodontal disease and tooth decay, and introduction of biocompatible and metal-free materials, such as zirconia and all-ceramic crowns offering improved aesthetics and long-lasting dental restorations.

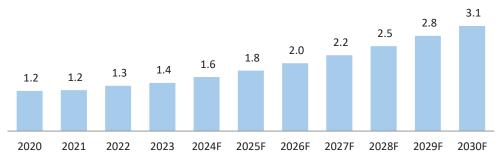


Exhibit 2.28. Indian Custome-made Crowns and Bridges Market (US\$ Bn), 2020-2030F CAGR 2023 to 2030F 11.8%

Source: Frost & Sullivan

2.5.17. GLOBAL ORTHODONTICS MARKET

Orthodontics is a specialty in dentistry which deals with the identification, management, prevention, and treatment of misaligned bite patterns and improperly positioned teeth and jaws. The Global Orthodontics market comprising of products such as aligners, braces, retainers is estimated to more than double from US\$ 68.9 Bn in 2023 to US\$ 167.1 Bn in 2030, in terms of retails sales, growing at a rate of 13.5%.

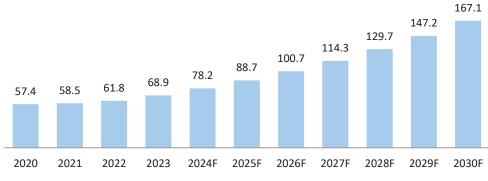


Exhibit 2.29: Global Orthodontics Market (US\$ Bn), 2020-2030F CAGR 2023 to 2030F: 13.5%

2.5.18. INDIAN ORTHODONTICS MARKET

The Indian Orthodontics market, in terms of retail sales, is estimated to grow at a higher rate of 16.5% compared to the global market, from US\$ 730.5 Mn in 2023 to US\$ 2127.6 Mn in 2030. The higher growth is due to huge unmet need formal occlusion treatment, increasing access to dental care services due to growing number of dental professionals and dental clinic chains, and increasing adoption of Orthodontic treatment services. In India, about 75% population have Malocclusion. While the prevalence of Malocclusion in India is higher than the US (75% vs. 67%), the penetration of Orthodontic treatment (number of cases opting for Orthodontic therapy) is very low compared to the US (0.1% vs. 3%). There are about 7,700 Orthodontists in India with a ratio of 0.54 per 100,000 people whereas the number of general dentists is about 21 per 100,0000 people. Increasingly, general dentists are offering Clear Aligner which is easy to perform procedure due to advancements in technology such as adoption of intra-oral scanners and CAD/CAM technology, resulting in increase in Malocclusion treatment rate.

Source: Frost & Sullivan



Exhibit 2.30: Indian Orthodontics Market (US\$ Mn), 2020-2030F CAGR 2023 to 2030F: 16.5%

Source: Frost & Sullivan

Penetration of Orthodontic treatment is expected to increase due to brand recognition among dental professionals and patients, increasing availability of installment payment plan for patients, increasing number of general dentist performing Clear Aligner procedure, and growing number of organized branded players in the market. The Orthodontics market in India include the traditional Orthodontic products (e.g., braces, brackets, retainers) and the Clear Aligner product. The growing adoption of Clear Aligner product due to improved aesthetics has accelerated the growth of the Orthodontics market.

Improving access to specialty dental care. In India, more dental clinics than ever before provide Orthodontic treatment. While the number of Orthodontists is only about 7,700, there is a huge pool of general dentists in India (3 lakh) and a large portion of them are catering to Orthodontic needs. Moreover, there is increasing number of academic institutes offering specialty courses in dentistry such as Orthodontics due to growing demand for dental care among population. Increasing preference among general dentists to specialize in orthodontists has resulted in increased accessibility of orthodontic treatment services.

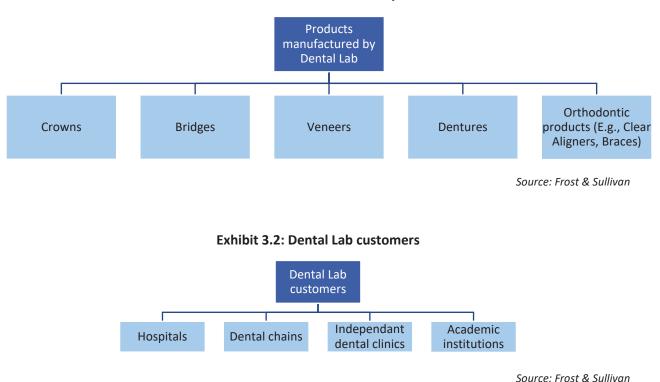
Increasing affordability. Increasingly, Indian patients can pay for the out-of-pocket costs and willing to pay more for dental care services, including orthodontic treatment due to rising increased purchasing power and disposable income.

Growing awareness of dental treatments. Due to the growing importance of dental health and aesthetics among all age groups, Indian patients are willing to undergo orthodontic treatment. Oral Health is increasingly being considered as an essential part of health and well-being. The increasing awareness of dental treatments is also fueled by digitization and adoption of new technologies.

Availability of novel products such as Clear Aligners. The introduction of aesthetically appealing Clear Aligners or invisible braces has improved the adoption of orthodontic treatment for malocclusion or misalignment of teeth among adults who avoided treatment due to stigma of wearing metal braces.

3. DENTAL LABS

The Dental Labs fabricate crowns, bridges, dentures, and orthodontic products based on the prescription of a dentist. The Dental Laboratory designs and manufactures the dental prostheses using an impression (physician impression using mold or digital impression using IOS) of the patient's teeth provided by the dentist.⁴¹ Dental Labs offer services such as removable partial dentures or fixed bridges for patients who are missing only one or a few teeth; full dentures for patients who are missing all of their teeth; orthodontic appliances and splints to help straighten and protect teeth; veneers that enhance the esthetics and function of the patient; and crowns, which are caps for teeth that are designed to restore their original size and shape.⁴²





3.1. RECENT TRENDS IN DENTAL LABS

3.1.1. Adoption of Digital Solutions

Greater focus on quality improvements, labor cost reductions and time saving (reduced production or treatment time, shorter waiting times and higher patient satisfaction) among the Dental Labs have resulted in increasing adoption of digital workflows. With the advent of novel technologies and growing need for personalized prostheses, the dental care workflows are getting digitized such as getting digital oral impressions using Cone-Beam Computed Tomography (CBCT) or intraoral scanners, usage of software for computer assisted treatment planning, designing restorative products such as crowns and

⁴¹ American College of Prosthodontists

⁴² American Dental Association

aligners using Computer Aided Design (CAD), and manufacturing of prostheses using Computer Aided Manufacturing (CAM) process or 3D printing.

There is rapid adoption of digital impressions among dentists across many countries, including India due to increasing usage of intra-oral scanners (IOS). Globally, the penetration of IOS is about 23% and it is expected to grow to 28% in 2027 due to increase in number of brands and significant decrease in price.⁴³ There are more than 15 established IOS brands in the market compared to only 2 about a decade back, and IOS is available at on-fifth of the cost compared to a decade back.⁴¹ Unlike conventional physical dental impressions, digital impressions using IOS offer increased speed, better clinical efficiency, greater comfort for patients, and ease of use for clinicians while delivering comparable or even superior accuracy to physical impressions ⁴⁴

There is growing usage of IOS in India among dentists resulting in increased digital impression cases by Dental labs due to availability of low-cost brands. Most of the IOS are imported in the country. The value of IOS imports to India has grown from US\$ 1.6 Mn in 2019 to US\$ 6.2 Mn in 2023 at growth rate of 41%. The number of IOS units imported has grown from 580 in 2019 to 1,743 in 2023 at a growth rate of 32%.

Large organized dental labs in India integrate technology such as digital dentistry in their workflow, ensuring higher precision and better-quality Crowns and Aligners, serving large number of dentists in remote locations and saving logistics costs. Digital impressions require less than a minute of dentist's time, saves logistic costs, and reduce turnaround time and remake rate by 50% compared to analog impressions.⁴⁵ Digital impression cases for large, organized labs in India is growing.

By adoption of digital dentistry, large organized dental labs in India have seen significant reduction in turnaround time to deliver preventive and restorative dental solutions (e.g. Crowns, Aligners, Dentures) in India.⁴⁶ Indian Dental labs such as Laxmi Dental Limited and DentCare adopt digital dentistry in their workflow. Laxmi Dental is one among the leading importer of intra-oral scanners in India, adopting digital dentistry for a large part of its workflow.⁴⁷

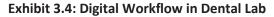
⁴³ AB Bernstein Analysis

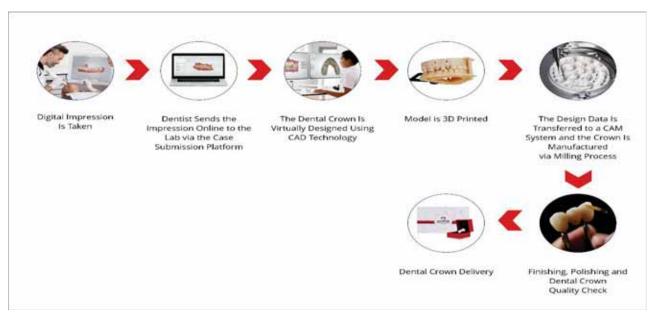
⁴⁴ https://www.aegisdentalnetwork.com/cced/2023/03/intraoral-scanners-the-key-to-dentistry-s-digital-revolution

⁴⁵ Dental Economics, Scanning for predictability and profitability, January 2024

⁴⁶ Based on Frost & Sullivan primary and secondary research and company statements.

⁴⁷ As per Frost & Sullivan analysis from Volza database





Source: Frost & Sullivan

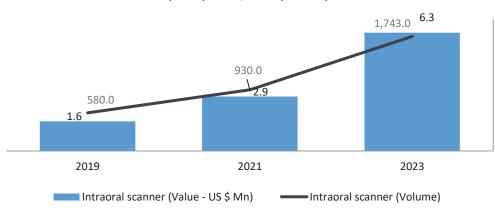


Exhibit 3.5: Imports of Intra-Oral Scanner systems and parts, India CAGR (Value) = 41%; CAGR (Volume) = 32%

Source: Volza, Frost & Sullivan

3.1.2. Advancement in Materials

Crowns made of Zirconia or other second-generation polymers are increasingly being preferred by dentists and patients driven by growing demand for aesthetics, concerns of toxicity and allergic reaction to metal alloys and to mitigate issues such as bite concerns post treatment. Zirconia crowns are made from a special kind of zirconium dioxide, which is translucent in nature, allows light to pass through the crown, making them look like natural teeth. Zirconia, which is less brittle and having high tensile strength, is not only a functional material, but also offer better aesthetics. Moreover, Zirconia crown can be fabricated with full-digital workflow. Zirconia has become a popular alternative to porcelain-fused-to-

	Table 3.1. Materials used in dental crowns							
Crown Type	Material	Strength	Aesthetics	Durability	Preparation	Suitability		
Zirconia Crown	Zirconia	Very High	High	Very High	Minimal	General		
PFM crown	Metal + Porcelain	High	High	Moderate	Moderate	General		
Emax crown	Lithium Disilicate	High	Very High	Moderate	Moderate	Aesthetically demanding		
Metal crown	Metal Alloy	High	Low(visible)	Very High	Moderate	Molars		
Porcelain crown	Porcelain	Moderate	Moderate	Moderate	Moderate	General		
Veneers	Composite Resin	Low	High	Low	Minimal	Anterior Teeth		
Ceramic Crowns	Ceramic	Moderate	High	Moderate	Moderate	Genera		

metal (PFM) crowns and is increasingly being used in fabricating crowns and bridge restoration and implant abutments.

Source: Frost & Sullivan

Glidewell, a leading dental lab chain in the US, launched the first branded monolithic Zirconia crown restoration, BruxZir[®] Zirconia, in 2009. As per the company, more than 28 million units of BruxZir[®] Zirconia have been prescribed by dentists globally until 2023 and the product makes up more than 70% share of the fixed restorative units fabricated at Glidewell.⁴⁸ Clinical validation studies have demonstrated the superior strength and diminished wear of BruxZir[®] Zirconia compared to Porcelain Fused to Metal (PFM) due to which dentists are increasingly preferring Zirconia over other PFM. Notably, PFM, which was popular among dentists before Zirconia, makes up only 7% of restorations made by Glidewell.⁴⁹

Large organized dental labs in India such as Laxmi Dental Limited and DentCare have launched branded zirconia Crowns. Laxmi Dental Limited is one of the early companies to launch branded Zirconia crowns under its brand name "Illusion Zirconia".

3.1.3. OUTSOURCING AND CONSOLIDATION IN DENTAL LAB

Like the US, the Indian Dental Lab industry is expected to witness consolidation with increasing share of organized players due to regulatory changes and growing emphasis on professionalization, adoption of digital workflows and patient-centric approach. This is expected to favor established players, gaining a larger share of outsourcing works from the US.

To have precise fitment of Dental prostheses, reduce visit time and improve patient experience, dental clinics are adopting digital workflows and demand Dental Labs to adopt new technologies and invest in digitalization. Due to this, Dental Labs are prioritizing investments in technology and automation. With increasing cost of technology investments and shortage of skilled dental technicians, traditional laboratories are struggling to remain competitive. In the US, a growing number of Dental Labs are

⁴⁸ https://glidewelldental.com/education/chairside-magazine/volume-18-issue-1/zirconia-update-2023-what-you-need-to-know

⁴⁹ https://glidewelldental.com/company/blog/choosing-between-zirconia-crowns-and-pfm-crowns

outsourcing the fabrication of their restorations to overseas laboratories in countries such as China, India, and Thailand to remain price competitive, improve efficiency and maintain their profits. Notably, 35% of lab work sold in the U.S. comes from outside the country.

3.2. GROWTH OF DENTAL LABS IN INDIA

The Dental Lab industry in India is expected to witness consolidation due to growing emphasis on professionalization, demand for wider portfolio of products including premium products, increased regulatory scrutiny and greater emphasis on safety and quality of dental products. As large organized Dental Labs would be in a better position to adopt digital workflows and automation tools, invest in technologies such as CAD/CAM, and attract skilled talent; traditional and small labs will find it challenging to compete in the market. To gain economies of scale and expand their service offerings, large Dental Labs will acquire small labs. Similar trend was witnessed in the US where the number of Dental Labs decreased by more than 20% from 2001 to 2022 due to the skills shortage, adoption of digital workflows and increasing preference among dental services organization to work with large, organized labs . Due to greater emphasis on quality (compliance to regulatory standards) and improved efficiency (adoption of automation and digital workflow), the market is moving towards more professionalization favoring the growth of organized dental lab networks.

Factors driving the overall dental care market such as increasing prevalence of dental diseases, growing interest in cosmetic dentistry, rising ageing population and increasing affluence are also driving the growth in the Dental Lab market. There are more than 5,000 Dental Laboratories and about 35 training institutions for dental technicians. Given the relatively low ratio of dental technician to dentist population, there is tremendous scope for quality laboratories in the country. More colleges are now offering dental technician course to match the growing demand.

India is increasingly exporting dental lab products to other countries. Notably, the country's exports of Artificial Dental teeth and fittings grew from US\$ 6.9 Mn in 2018 to US\$ 13.2 Mn in 2023 at a rate of 14.0%. The top countries of India's exports (2018 – 23) are US (61.4%), UK (12.3%), Italy (11.2%), Hong Kong (4.6%) and UAE (2.5%).

Table 3.2. Exports of Artificial Dental Teeth and Fittings, India (2018 - 2023)						
Dueduet	Export (US\$ Mn)			Top Export countries by value (2018 –		
Product	2018	2023	CAGR	2022)		
Artificial Dental Teeth and fittings	6.9	13.1	14%	US (64.3%), UK (14.8%), Italy (13.3%), UAE (2.9%)		

Source: Volza, Frost & Sullivan

Leading organized dental labs in India export large value of dental products to many countries including the US, UK and Europe. In terms of export revenue for the Fiscal 2023 among the Indian dental labs, Laxmi Dental Limited is the largest exporter of custom-made dental prosthesis, catering primarily to US and UK.^{50,51}

The dental laboratories market in India is characterised by the presence of fragmented and unorganized dental laboratories with less than ten technicians and a dearth of quality management standard compliant dental products. Very few labs in India have adopted digital dentistry and operate at scale, catering to a large network of dentists in domestic as well as export markets. While there is huge opportunity in Dental Lab market in India, survival of new entrants and small players is a challenge due to long gestation to establish a trusted network of dentists, high cost associated with the dental equipment and materials, labor shortage, rising costs, and increasing automation. Central Drugs Standard Control Organization ("CDSCO") of Ministry of Health and Family Welfare ("MoHFW"), Government of India included dental crowns, bridges and resins as Class B, low moderate risk medical devices and compliance with ISO 13485 has been made mandatory by March 31, 2023. ISO 13485 is required for organizations involved in the design, production, installation and servicing of medical devices and related services, and as of a valid license from the CDSCO is mandatory to manufacture, import, sell, or distribute dental products in India. Dentists are increasingly preferring organized laboratories over unorganized laboratories due to availability of wide and differentiated product portfolio, higher accuracy and compliance with international guality standards and better guality of service due to integrated product offerings. Due to the above factors, the Indian Dental Lab market is expected to be dominated organized Dental Labs.

Changing regulatory requirements in medical devices sector is expected to transition the fragmented and unorganized dental products and consumables market to organized and consolidated market dominated by companies focusing on quality, operational efficiency, and consumer experience.

Indian dental labs can be categorized in to large, medium and small labs. Among the 5,000+ dental labs in India, there only 2 large labs, having more than 200 technicians and more than INR 25 crore in annual revenue, and adopting a high-level digital workflow. There is high fragmentation in the Indian dental lab market with more than 5,000 small labs with less than 10 technicians, less than 1 crore in annual revenue, and low-level of digital workflow adoption.

Table 3.3. Type of Dental Labs in India						
Type of Lab	b Number of Annual Revenue		Adoption of Digital workflow	No. of Labs		
Large	200 - 1000	INR 25 – 100+ Crore	High	2		
Medium	10 - 200	INR 1 – 25 Crore	Moderate	Less than 50		
Small	1 - 10	Less than INR 1 Crore	Low	More than 5,000		

Source: Frost & Sullivan

⁵⁰ Volza, Frost & Sullivan analysis

⁵¹ Volza, Frost & Sullivan Analysis

3.3. GROWING TREND OF OUTSOURCING DENTAL LAB SERVICES TO INDIA Increasing Dental Lab closures in the US coupled with the growing demand for durable restorations and prostheses is expected to drive the growth in outsourcing of Dental Lab work to countries such as India.

While the demand for Dental Lab services is increasing among dentists in the US due to rising adoption of branded products such as Dental Crowns and Clear Aligners, there is growing trend of dental clinics importing products from dental labs outside the US. Due to growing shortage of skilled dental technicians, increasing price competitiveness and increasing need to adopt digital workflows, organized dental clinic networks and dental labs from developed countries such as the US and the UK are offshoring the fabrication of dental products such as crowns, bridges, and dentures to labs in India, South Korea, China, Thailand, and Vietnam. About 25% of domestic dental laboratory sales and 38% of actual restorations are manufactured overseas.⁵² Offshoring enables the organized dental chains and dental labs to reduce operational costs and offer high quality products at competitive prices. Indian Dental Labs have adopted digital workflows to enhance precision and reduce turnaround time and have specialized technical skills to create customized dental restorations. A large part of the US dental lab outsourcing to China is shifting to other countries, and India has become one among the preferred markets due to availability of skilled labor, adoption of advanced technology and ability to deliver high quality restorative products such as zirconia crowns. With the adoption of international quality standards such as ANSI⁵³ and ISO⁵⁴, and meeting compliance requirements from regulatory agencies such as FDA, Indian dental labs deliver a high standard of care in restorative and cosmetic dentistry. Indian Dental Labs adopt high precision manufacturing by leveraging state-of-the-art technology to create personalized and high-quality zirconia crowns that meet international standards. Additionally, large organized Indian labs offer customizable options and a wide range of materials, shades, and restoration designs for the unique needs and preferences of patients. Moreover, by adopting digital workflows, large Indian dental Labs receive digital files such as patient scans, impressions and specifications, securely and efficiently, thereby reducing the turnaround time. Due to this zirconia crowns from Indian dental labs which are organized and have high technical expertise are a popular choice among Dental Labs and clinics in US, UK and other countries. Dental clinics rely on Dental Lab partners for guidance on esthetics, material selection, and occlusion to complete challenging cases. While many dental clinics (85%) in the US are relying on external Dental Labs for fabrication of dental prostheses, the number of Dental Labs in the US is decreasing due to talent shortage and high cost of operations. From 2001 to 2022, the number of Dental Laboratories with payrolls dropped by more than 20% in the US. The growing trend in Dental Lab closures in the US coupled with the growing demand for durable restorations and prostheses is expected to drive the growth in outsourcing of Dental Lab work to countries such as India.

⁵² https://dentallabs.org/nadl/

⁵³ American National Standards Institute

⁵⁴ International Organization for Standardization

3.4. CHANGES IN DENTAL LAB ENVIRONMENT IN THE US

3.4.1. INCREASE IN NUMBER OF DENTAL SERVICES ORGANIZATION

Dental Support Organization (DSO) or practice management organizations own and run several dental practices and support dentists with the nonclinical business aspects of managing a dental office, such as marketing, information technology, personnel resources, accounting and billing, and facility and equipment maintenance.

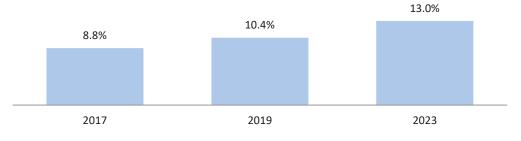


Exhibit 3.7. Percentage of Dentists affiliated with DSOs in the US

Source: American Dental Association, Frost & Sullivan

By centralizing operations and standardizing systems across sites, DSO aims to increase the productivity and profitability of dental practices. While a few DSOs are owned by a group of dentists, private equity firms own many large DSOs. There is growing interest from Dentists to affiliate with DSOs to focus on patient care, reduce administrative burdens, and improve financial stability. The percentage of Dentists affiliated with DSOs in the US has grown from 8.8% in 2017 to 13.0% in 2023. The top 5 DSOs in the US are Heartland Dental, The Aspen Group, Pacific Dental Services, Smile Brands and Sonrava Health.⁵⁵

Table 3.4: Sample list of major Dental Service Organizations (DSO) in the US, 2023					
DSO	Number of Clinics	Number of States			
Heartland Dental	1,650+	38			
The Aspen Group	1,037	45			
Pacific Dental Services	930	25			
Smile Brands	700	30			
Sonrava Health	600	21			

Source: Beckersdental, Frost & Sullivan

Leading dental labs in India have partnered with large DSOs in the US to export custom-made dental products. For instance, Laxmi Dental Limited is the preferred partner for one of the largest DSOs in the US.

⁵⁵ https://www.beckersdental.com/dso-dpms/41616-46-dsos-to-know-2023

3.4.2. REGULATION OF LABORATORIES/TECHNICIANS

As dental practices become more organized with growing number of DSO affiliation, there is greater need for qualified Dental Laboratory partners in the market to cater to increasing demand from patients and dentists. DSOs are looking for long Dental Lab partners who adopt digital workflows and comply to regulatory and quality standards from The National Association of Dental Laboratories (NADL). As NADL is working with state regulatory agencies throughout the U.S. to set minimum operating standards for Dental Labs within dental practice acts, big Dental Lab networks which are professional and organized will gain a large share of market from small players, driving market consolidation.

3.4.3. GROWING DOMINANCE OF ORGANIZED DENTAL LABS

Dental Lab market is witnessing increased rate of consolidation with capacity expansion of large Dental Lab networks. Leading Dental Labs such as Modern Dental Group, Glidewell and National Dentex Corporation dominate the Dental Lab market in the US. Notably, Glidewell which designs and manufacture crowns, bridges, dentures, implants and more for dentists around the globe, has diversified its portfolio by introducing branded zirconia restorations, branded bite splint, branded implant system and digital dentistry solutions.

Table 3.5: Sample list of major Dental Labs in the US						
ct Dental Lab acquisitions						
boratories, Labocast						
s, Citrus Dental Lab, IOS						
ntal Services Group, Biotech Dental er Dental Lab, Trident Dental Labs						
ab, Nu-Art Dental, Absolute Dental						
6						

Source: Pitchbook, Frost & Sullivan

3.4.3.1. GLIDEWELL DENTAL LAB

Glidewell, founded in 1970 and having revenue of about US\$ 500 to 700 Mn, introduced its branded BruxZir[®] Solid Zirconia in 2009 as an alternative to Porcelain Fused to Metal (PFM) and cast gold, offering improved durability and resistance to fractures. The percentage of restorations fabricated by Glidewell from BruxZir[®] Zirconia increased from 3% in 2009 to 78% in 2020, whereas the percentage of PFM and full-cast gold restorations by Glidewell stood at only 7.4% and 2%.⁵⁶ As per TRAC Research (the clinical studies division of the independent Gordon J. Christensen Clinicians Report[®]), BruxZir restorations exhibited a 100 percent survival rate and zero terminal fractures after a decade of scientific evaluation.⁵⁷

Since 2009, Glidewell has introduced several formulations—including the recent BruxZir Esthetic Milling Blanks—for a wider range of clinical indications.⁵⁸ Adoption of technologies like CAD/CAM, continuous

⁵⁶ https://glidewelldental.com/education/chairside-magazine/volume-16-issue-2/by-the-numbers

⁵⁷ https://glidewelldental.com/company/our-advantage/the-history-of-glidewell

⁵⁸ https://glidewelldirect.com/collections/bruxzir-solid-zirconia

investment in R&D and a focus on on-site vertical integration has enabled Glidewell to standardize restorative procedures and reduce costs for dentists, ensuring highest standards for quality and precision. In 2019, the company launched glidewell.io[™] In-Office Solution, a chairside CAD/CAM based restoration ecosystem that empowers doctors to produce high-quality BruxZir restorations in under 45 minutes. Subsequently, the company launched fastmill.io[™] (chairside mill enables dentists to deliver same-visit restorations made from BruxZir[®] NOW Milling Blocks) in 2020, fastscan.io[™] Intraoral Scanner (high-speed scanner to seamlessly upload digital impressions to the fastmill.io) in 2022, and fastprint.io[™] 3D Printing Solution in 2023.





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4. EMERGENCE OF BRANDED PRODUCTS IN ORTHODONTICS

4.1. PREVALENCE OF MALOCCLUSION

Malocclusion is one of the most prevalent condition and ranks third in importance to periodontal disease and caries in the WHO's list of oral health issues⁵⁹. Malocclusion refers to misalignment of the upper and/or lower teeth that is measurable enough to interfere with the person's ability to bite properly. Globally about 56% of the population are having Malocclusion (4.5 Bn)⁶⁰

Class I Malocclusion: It refers to cases where there is an overlap of teeth (upper teeth rest over the lower teeth while biting down) but the bite is normal or near normal. Class I Malocclusion prevalence out of total Malocclusion cases is 75%⁶¹

Class II Malocclusion: It refers to cases where the upper teeth are sticking out over the lower teeth, affecting the bite significantly and require Orthodontic intervention. Class II Malocclusion prevalence out of total Malocclusion cases is 20%.⁵³

Class III Malocclusion: It refers to cases where there are severe underbites resulting from protrusion of the lower teeth over the upper teeth, and it is characterized by alternating, overlapping lower and upper teeth. Class III Malocclusion prevalence out of total Malocclusion cases is 6%.⁵³

4.2. TREATMENT OF MALOCCLUSION

Malocclusion is treated using Orthodontic therapy which seeks to achieve esthetic and functional improvement via mechanical therapy that moves teeth into a more ideal position. Following a dental examination, dental practitioners often ascertain the best kind of orthodontic treatment for a particular patient by considering the patient's preferences, the degree of the problem, the patient's malocclusion status, and the anticipated outcomes of the therapy.

Traditional orthodontics treatment and Clear Aligner treatment are the two main approaches of orthodontics treatment. Orthodontic devices such as Braces (Ceramic, Lingual and Metal), Retainers (Removable devices), and Aligners are used to treat Malocclusion cases. While Metal, ceramic, lingual, and other visible aligners are used in the traditional treatment method, Clear Aligner treatment method involves designing custom-made, transparent, and removable aligners. The traditional Orthodontic treatment using Braces has drawbacks such as Oral discomfort, noticeability of Braces, frequent visit required to dentists, and high technical requirements of dentists. Due to invisible nature of Clear Aligners and convenience of treatment, the adoption of Orthodontic treatment for Malocclusion has increased, especially among adults who were hesitant to get treated with traditional methods. Notably, 80% of Malocclusion cases can be treated with Clear Aligners. While the Class I and II Malocclusion cases can be treated with Clear Aligners. While the Class I and II Malocclusion cases can be treated.

⁵⁹ Sharma R, Sharma K, et al. A Study to determine the Prevalence of Malocclusion and Chief Motivational Factor for Desire of Orthodontic Treatment in Jaipur City, India. World J Dent 2015; 6(2):8792.

⁶⁰ Lombardo G, Vena F, Negri P, et al. Worldwide prevalence of malocclusion in the different stages of dentition: A systematic review and metaanalysis. Eur J Paediatr Dent. 2020

⁶¹ American Orthodontics Society

Metal braces and wires have historically been used in orthodontic treatments to bring teeth into position. During the treatment (1 - 2 years), patients must see the orthodontist every 4–6 weeks to monitor the growth of their teeth, tighten wires, and make other necessary changes. In Clear Aligner treatment, the patient visits an orthodontist or dentist who takes digital or physical imprints of the patient's teeth using an intraoral scanner or a mold to make custom clear trays. The treatment planning software receives the scans and suggest a course of. After the treatment plan has been approved by the clinician, aligner trays are fabricated by dental labs and shipped to the dentist or orthodontist. Unlike metal braces, Clear Aligner does not require frequent visits to dentist to adjust the brackets and wires, thereby saving "chair time" to dentists.

	Table 4.1: Orthodontic treatments for Malocclusion					
	Traditional	Treatment Method/	Braces			
Particulars	Metal Braces	Lingual Braces	Ceramic Braces	Clear Aligners		
Description	Traditional metal braces consist of brackets placed on teeth that need to be corrected and an archwire that will hold the brackets together	Same as traditional braces, except the brackets are placed on the lingual surfaces of teeth as opposed to the buccal surfaces	Same as metal braces except that they come in an enamel- like colour so that the braces are less noticeable	Invisible braces which are ideal for patients who cannot have many in-person appointments or are concerned with aesthetics.		
Indication	Class I, II and III Malocclusion (Severe, moderate, and mild Malocclusion)	Class I and II Malocclusion (Mild and Moderate Malocclusion)	Class I and II Malocclusion (Mild and Moderate Malocclusion)	Class I and II Malocclusion (Mild and Moderate Malocclusion)		
Treatment Duration	18 – 24 months	18 – 24 months	18 – 24 months	8 – 24 months		
Frequency of dentist visit per year	10 - 11 times	11 - 12 times	10 - 11 times	4 – 5 times		
Duration per dental visit	30 – 45 minutes	45 – 60 minutes	30 – 45 minutes	10 - 15 minutes		
Aesthetics	Noticeable	Partially invisible	Semi-transparent	Transparent/invisible		
Comfort level	Fixed to tooth/non- removable and can rub against mouth surfaces	Fixed to tooth/non- removable and can impair tongue function	Fixed to tooth/non- removable and can rub mouth surfaces	Removable with improved comfort		
Hygiene	Difficult to clean and can trap food particles	Difficult to clean and can trap food particles	Difficult to clean and can trap food particles	Easy to clean		
Level of Dentist specialization required	High	High	High	Low		

Source: Frost & Sullivan

Increasing number of patients, adults in particular, are opting for Clear Aligner treatment compared to traditional braces as it offers greater convenience such as better aesthetics and comfort level, and fewer dentist visits compared to traditional braces. Further, increasing utilization of intraoral scanners and technological advancement in dental labs is likely to drive the adoption of Clear Aligner treatment to more complicated indications.

India has a huge unmet need for Malocclusion treatment with Clear Aligners. Compared to the US, the prevalence of Malocclusion cases is high, whereas the penetration is low. Less than 10% of the eligible Malocclusion cases are treated with Clear Aligners compared to 30% in the US. As patients transition from traditional braces to Clear Aligner treatment method, the penetration rate of Clear Aligners is expected to increase over the years.

4.3. DRIVERS FOR CLEAR ALIGNER ADOPTION

Key drivers for consumer adoption of Clear Aligners include increasing awareness on aesthetics and Clear Aligners, increased treatment adoption among kids and adults alike, especially adults with poor treatment rate in the past

Increasing awareness on aesthetics and Clear Aligners. Due to it improved aesthetics and convenience of treatment, despite its higher cost Clear Aligners is gaining increased acceptance among patients compared to traditional braces. Patients are seeking it as a preferred treatment option as they become aware of its benefits in treating complex Malocclusion cases through digital and traditional marketing channels.

Expansion of Orthodontic treatment to general dentists. Due to less expertise required for Clear Aligner treatment and ability of the product to address mild malocclusions, Aligner companies are expanding their reach to general dentists who have access to a large patient pool. The companies provide support to general dentists by offering training and clinical education programs and access to digital tools.

Expanding indications. Improvement in technology is expected to expand the Clear Aligner treatment to more complicated indications, resulting in increasing penetration and market opportunity.

Technological advancements. Technologies such as 3D printing, treatment planning software and intraoral scanner have enabled dentists to tailor the treatment to each patient's unique needs, improve accuracy, optimize treatment planning, and predict outcomes accurately, and reduce production time and costs making aligners accessible to a broader range of patients.

Increased treatment adoption among adults. Adults with malocclusions had a poor treatment rate in the past, mostly due to aesthetic concerns (visibility of traditional braces). Due to enhanced aesthetics and comfort, more adults are opting for malocclusion treatment.

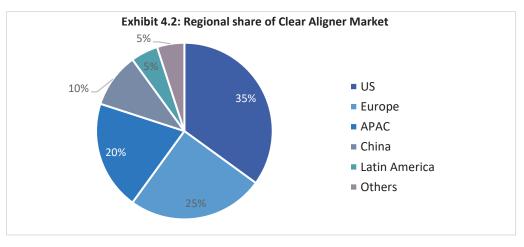
4.4. GLOBAL CLEAR ALIGNER MARKET

The global Clear Aligner market is sizable, and the Indian Clear Aligner market is expected to grow very rapidly over the next few years.

The global aligners market, in terms of retail sales, is an approximately US\$ 21 Bn industry which is projected to grow at a rate of 15.0% between 2023 and 2030 due to the factors driving adoption of the Clear Aligner market such as increased awareness, expansion of indications, and advancements in technology enabling improved fitment and decreased "chair time". While APAC is the third largest market for Clear Aligners, it is the fastest growing market.



Source: Frost & Sullivan

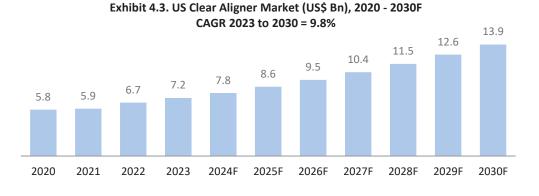


Source: Frost & Sullivan

The US Clear Aligner market which has 35% share in the total global Clear Aligners market, is expected to grow from \$7.2 Bn in 2020 to \$ 13.9 Bn in 2030 in terms of retail sales. The Clear Aligner market growth in the US is projected to grow more than the growth of the Orthodontics market (9.8% vs. 8.5%). The penetration rate of Clear Aligners, which is at 30% currently, is expected to increase significantly over the years. While 67% of the US population (~225 Mn) have Malocclusion⁶², only about 9 Mn seek Orthodontic treatment every year.⁶³

⁶² https://www.johcd.net/doi/JOHCD/pdf/10.5005/johcd-6-1-21

⁶³ https://bmcoralhealth.biomedcentral.com/articles/10.1186/s12903-021-01629-6



Source: Frost & Sullivan

4.5. INDIAN CLEAR ALIGNER MARKET

India is expected to have a high growth potential for Clear Aligner treatment due to low penetration compared to the US. The high growth of the industry and rising annual spend per capita is driven by growing awareness and adoption of orthodontic treatments, visible clinical results enabling a shift in traditional orthodontists adopting Clear Aligners, ability of general practitioners to perform malocclusion cases, increased demand for cosmetic dentistry, growing dental tourism in India, adoption of newer technologies, and increasing disposable income in India.

In India, about 75% population have Malocclusion. While the prevalence of Malocclusion in India is higher than the US (75% vs. 67%), the penetration of Orthodontic and the Clear Aligner treatment is very low in India compared to the US. While 30% of Orthodontic cases are treated with Clear Aligners in the US, it is less than 15% in India.

Below are some of the factors which are expected to drive growth of Clear Aligner market.

Low penetration. While India has a high prevalence (75%) of Malocclusion, less than 1% seek Orthodontic treatment. Further, among the Orthodontic cases, less than 15% opt for Clear Aligners. There is a huge unmet need for Clear Aligner treatment and India is still at a nascent stage with attractive potential opportunity for manufacturers of the product.

Growing consumer emphasis on dental aesthetics. Indian consumers are motivated to seek treatment for malocclusion to improve their appearance and an increasing number of adults are opting for Clear Aligner treatment due to better aesthetics compared to braces.

Increasing accessibility to dental care. Increase in the number of general practitioners providing care for Malocclusion is expected to drive adoption of Clear Aligners. Clear Aligner treatment easy to administer and requires less training compared to traditional Orthodontic treatment. While the number of Orthodontists is only about 7,700, there is a huge pool of general dentists in India (3 lakh) and a large portion of them are catering to Orthodontic needs. Further, about 30,000 dental graduates pass out

every year⁶⁴ adding to the huge pool of available general dentists, resulting in improved accessibility of dental care services including the treatment for Malocclusion.

The Indian Clear Aligner market is expected to grow at a much higher growth rate compared to the US and global market. The Growth in Indian Clear Aligner market is expected to be driven by factors such as the growing emphasis of Indian consumers on dental aesthetics (driving the adoption of Clear Aligner as an alternative to braces), increasing number of general practitioners providing care for malocclusion, rising disposable income and propensity to spend on health products with cosmetic elements, and increased awareness through social media. Tier 2 and Tier 3 cities⁶⁵ are expected to be the next big growth driver for Clear Aligners in India due to relative under penetration and increasing disposable income.

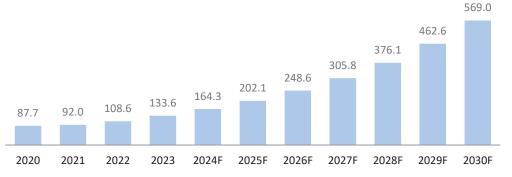


Exhibit 4.4. India Clear Aligner Market (US\$ Mn), 2020 - 2030F CAGR 2023 to 2030F = 23.0%

Source: Frost & Sullivan

The Indian Clear Aligner market, which is relatively underpenetrated, is expected to grow from US\$ 133.6 Mn in 2023 to US\$ 569.0 Mn in 2030 at a much higher rate of 23.0% compared to the global market. Recent research studies in India have shown that more than 75% of the Orthodontic cases would prefer Clear Aligners compared to traditional Orthodontic braces⁶⁶, and close to 50% are willing to pay higher cost for Clear Aligners.⁶⁷

In India, the annual Orthodontic cases per year is estimated to be 1.1 million. Currently, only about 15% (165,000) opt for Clear Aligners treatment. Due to increasing patient preference for Clear Aligner compared to traditional braces, the penetration rate is expected to increase driving the market opportunity. Moreover, due to better aesthetics of Clear Aligners more adults are seeking Orthodontic treatment creating market expansion opportunity. While 75% of the total Orthodontic cases are under 18 years of age, adults make a large proportion (75%) of Clear Aligner cases. When many adults opt for Orthodontic treatment with Clear Aligners, the market is expected to grow even higher. As per a

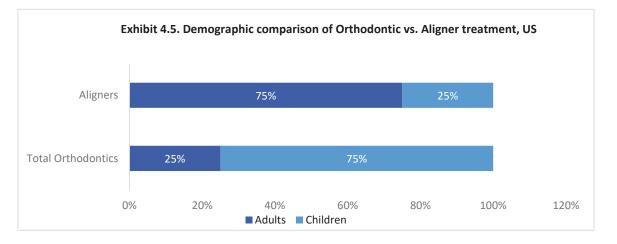
⁶⁴ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11001036/

⁶⁵ Classification of Tiers as per Ministry of Finance (Government of India) HRA classification of X – Tier 1 (Population of 50 Lakh and above), Y – Tier 2 (Population of 5 to 50 Lakh) and Z – Tier 3 (Population below 5 Lakh). Notification No. 2/5/17-E II(B), 7th July 2017

⁶⁶ Renuka Pawar, Tanya Prasad, et al. Awareness Regarding the use of Clear Aligners as an Orthodontic Treatment Modality among the General Population of Maharashtra, India: A Cross-sectional Survey. Journal of Clinical and Diagnostic Research. April 2024

⁶⁷ Harippriya Karthikeyan, Remmiya Mary Varghese, et al. Patients Preference to Clear Aligner Therapy Over Conventional Orthodontic Therapy. International Journal of Research in Pharmaceutical Sciences. 2020

research published in BMC Oral Health, the number of adults undergoing Orthodontic treatment is increasing.⁶⁸ In 2018, an estimated 1.61 million adults received treatment in the US, up from 1.55 million in 2016.



Source: Frost & Sullivan

The Indian Clear Aligner market is dominated by organized branded players, and there is a transition from international brands to domestic brands. Organized dental players in India have emerged to offer quality product with competitive pricing, leading to increased adoption. Organized domestic lab chains have introduced branded Clear Aligner by adopting rigorous quality assurance system that enables to monitor all aspects of production process, including maintenance of equipment and facilities, procurement of raw materials, production and quality inspection, and packaging and delivery. Further, with the in-house production of raw materials and manufacturing equipment, and automating the production lines, organized domestic dental labs cush as Laxmi Dental Limited operate at scale, improving production efficiency delivering faster turnaround time and minimizing errors.

Indian Clear Aligner brands are a popular choice among dentists and patients due to same quality being offered at relatively lower pricing. Leading Indian aligner brands such as Illusion Aligner (Laxmi Dental), Toothsi, 32 Watts and Snazzy offer Aligners at 30% to 50% lower cost compared to international brands. Moreover, brands such as Illusion (Laxmi Dental), DentCare and Toothsi are FDA cleared and are proven to meet international quality standards. Laxmi Dental's Illusion Aligners, launched in 2021, is the first Indian brand to receive 510(k) clearance from US FDA in 2021 to market Clear Aligner and the company is the largest indigenous manufacturer of Clear Aligners in India with a Business-to-Business-to-Consumer (B2B2C) business model.

⁶⁸ Hung, M., Su, S., Hon, E.S. et al. Examination of orthodontic expenditures and trends in the United States from 1996 to 2016: disparities across demographics and insurance payers. BMC Oral Health.

Table 4.2: Leading Indian Clear Aligner brands with FDA Clearance					
Company (HQ) Product FDA Clearance date					
Laxmi Dental	Illusion Aligner	05/04/2021			
DentCare	DentCare Aligners	26/09/2022			
AMPA Orthodontics	MakeOToothsi	01/11/2022			

Source: Frost & Sullivan

4.6. BUSINESS MODEL IN CLEAR ALIGNER

Most of the leading global companies in the Clear Aligner industry have adopted a B2B2C model to effectively penetrate the existing pool of dentists. The B2B2C model entails sale of aligners to the end consumer through the dentists. B2B2C business model ensures lower customer acquisition cost as compared to companies following a D2C model. Companies which have adopted Direct-to-Consumer (D2C) models have struggled to establish in the market due to suboptimal outcomes and failure to engage dentists in the treatment pathway.

Business to Business to Consumer (B2B2C). B2B2C or Doctor led model for Clear Aligners treatment involves in-person treatment and continuous monitoring by the dentist. In this model the company markets the technology to dentists as well as patients. The company provides aligner technology to partnering dentists, to complement their dental services to patients. Align Technology (Align), leader in Clear Aligner market, pioneered the doctor-led model for its brand Invisalign[®]. B2B2C or doctor led model ensures recurring revenue stream to the company from the dentist's patient population. Companies generate revenues from fixed laboratory fee per case and training fee charged to the dentists. Moreover, the model ensures treatment planning and regular monitoring from dentists resulting in best outcomes.

Align Technology also engages directly with consumers with its Invisalign[®] Brand Consumer Concierge program. The company's consumer marketing focuses on creating awareness with consumers about the Invisalign system and driving that demand to Invisalign doctors' offices. The program provides leads to dentists they otherwise may not obtain. The Concierge service teams are in more than 10 countries.

	Table 4.3. Invisalign global brand consumer marketing						
Year	Website Visitors (Mn)	Impression (Bn)	Consumers contacted	Consultations scheduled	Invisalign cases started		
2023	105.9	34.2	Not available	Not available	Not available		
2022	14.0	4.0	~ 4.7 Mn	+533,000	+111,000		
2021	21.8	8.0	~ 3.8 Mn	+437,000	+88,000		

Source: Frost & Sullivan

Direct to Consumer (D2C): Due to growing awareness about Clear Aligners among consumers, increased social medial penetration and a greater emphasis on convenience, companies such as SmileDirectClub and Byte in the US launched D2C models. The D2C models were introduced to increase accessibility and decrease cost by eliminating the need to visit dentist. However, the model was widely criticized as it led to sub-optimal results due to lack of in-person dental supervision and monitoring. Moreover, due to high customer acquisition cost compared to B2B or B2B2C models, D2C model is unsustainable. A resolution opposing direct-to-consumer tooth alignment was passed by the American Dental Association

in 2018. SmileDirectClub, which faced several lawsuits by both patients and doctors, as well as dental organizations, closed its operations in December 2023.

Recently, due to challenges involved in D2C model, D2C companies have changed their business model to involve consultation with dentists or Orthodontist who is employed by the company for an intra-oral scan. Moreover, Clear Aligners are Class IIa (medium risk) Medical Devices category, which requires product testing and quality system implementation (ISO 13485), and compliance to certifications, and companies with expertise and standardized business process would have competitive advantage in the market.

India, which has the second-highest number of dentists in the world (3 lakh dentists), offers a large addressable dentist population for B2BC companies to influence the customer adoption of dental products.

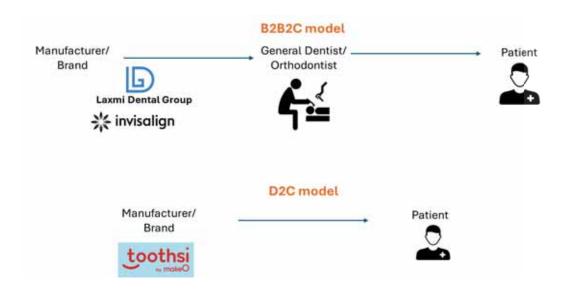


Exhibit 4.6. Business models of Clear Aligner sales

4.7. GROWTH OF ALIGN TECHNOLOGY IN CLEAR ALIGNER MARKET

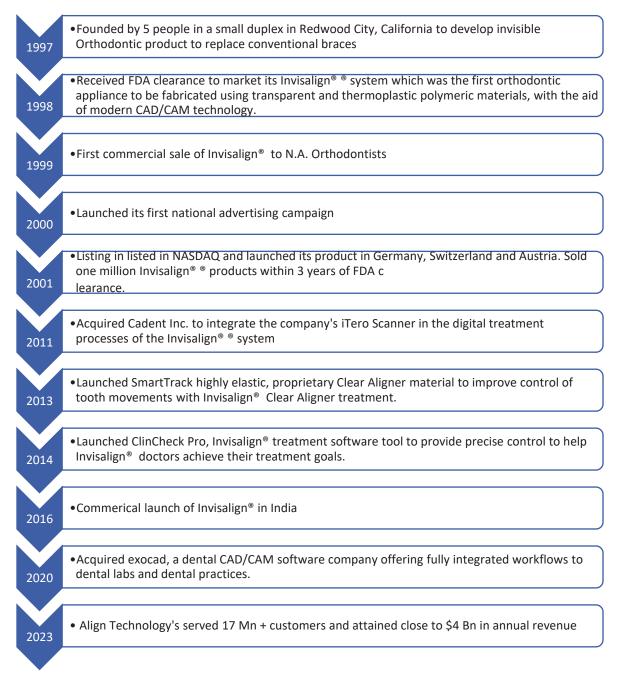


Exhibit 4.7. Key developments in the History of Align Technology

Source: Company website, Frost & Sullivan

Align Technology continues to develop new Clear Aligner products and digital workflow solutions. The company's goal is to help Dentists participate in a new and larger market by investing in innovative products and building brands to drive millions more consumers to their practice. The company partners with Dentists to move their practices forward by connecting them with new patients, providing digital

solutions to help increase practice efficiency and helping them deliver the best possible treatment outcomes and experiences.

It is to be noted that, although Align Technology's Clear Aligner is priced at a premium rate compared to other brands and there was emergence of new players in the market post Align Technology's patent expiry in 2017, Align Technology maintains a strong leadership position in the Clear Aligner market due

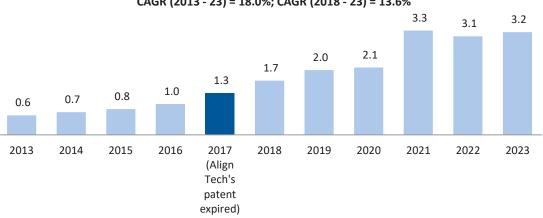


Exhibit 4.8. Align Technology's yearly revenue from Clear Aligners (US\$), 2013 - 2023 CAGR (2013 - 23) = 18.0%; CAGR (2018 - 23) = 13.6%

to its brand awareness and reputation among dentists. The brand started targeting Orthodontists in 1999 and began marketing to GPs in 2001. The revenues from Clear Aligners has grown from US\$ 1.3 Mn in 2017 to US\$ 3.2 Mn in 2023 at a growth rate of 13.6%.

4.7.1. STRATEGIC PRIORITIES OF ALIGN TECHNOLOGY

International Expansion. Expanding the presence globally by scaling and expanding operations and facilities.

General Practitioner (GP) adoption. Enabling General Dentists, having access to a large patient base, to easily identify potential Invisalign[®] cases, monitor patient progress or help refer cases to an orthodontist. In North America, the utilization rate (Number of cases sold per doctor)⁶⁹ for Invisalign Clear Aligners was 14.0 cases per general practitioner in 2023 compared to 13.9 cases in 2022. The utilization rate in international region was 16.3 cases per general practitioner in 2023 compared to 16.2 cases in 2022.

Patient demand & conversion. Create awareness for Invisalign[®] treatment among consumers, motivate potential patients to seek Invisalign[®] treatment and reach more consumers one-on-one, and ensuring patients have the best experience with the Invisalign[®] brand.

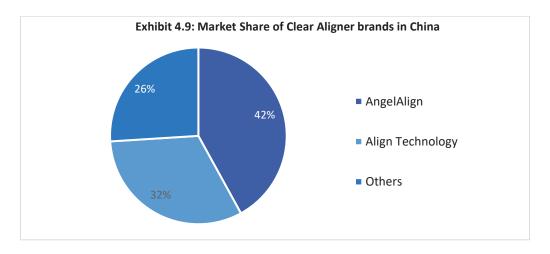
Orthodontist utilization. Enable Dentists or Orthodontists to address a wide range of cases, from simple to complex, with the Invisalign[®] system.

⁶⁹ Invisalign utilization rates are calculated by the number of cases shipped divided by the number of doctors to whom cases were shipped

4.8. GROWTH OF DOMESTIC PLAYER - ANGELALIGN TECHNOLOGY, IN CHINA CLEAR ALIGNER MARKET

In other emerging economies such as China, the indigenous company, Angelalign has emerged as a leading domestic B2B2C player replacing the global brands such as Invisalign in the Clear Aligner market by addressing the gap in the market for an affordable Clear Aligner brand. Founded in 2003 in China, the company offers custom-made removable Clear Aligners and Orthodontic treatment planning software. The company started global expansion in 2020, and as of 2023, the company's products and services are available in over 30 countries, with Europe being one of its fastest-growing markets. The company went public in 2021 and currently, it has the highest market share for invisible orthodontic products in China with nearly 42% share.⁷⁰

	Table 4.4. Angelalign Case Shipments and revenue						
N	Total case shipments				Revenue growth		
Year	Total	Domestic	International	Revenue (USD Mn)	(YoY)		
2023	245,000	212,000	33,000	206.6	16.2%		
2022	183,900	Not available	Not available	177.7	(6.8%)		
2021	183,200	Not available	Not available	190.7	56.7%		



Indian Clear Aligner market is expected to follow a similar trend seen in China, wherein emergence of domestic companies is expected to reduce the dominance of international players.

4.9. MATERIALS USED TO FABRICATE CLEAR ALIGNERS

Clear Aligners are produced using thermoplastic resin polymers such as polyurethane (PU), polyethylene terephthalate (PET), polyethylene terephthalate glycol (PETG), and polyvinyl chloride. Aligners can be

⁷⁰ https://www.globenewswire.com/news-release/2023/04/04/2641164/0/en/Angelalign-Technology-Accelerates-Globalization-as-the-Global-Invisible-Orthodontics-Market-Recovers.html

produced by molding the material on physical models, derived from a virtual planning software through 3D printing, or generated directly by 3D printing, without physical models.

4.9.1. THERMOPLASTIC MATERIALS.

Thermoplastic materials are polymers with different characteristics that respond differently to various types of mechanical stress such as chewing, physical stress such as heat and chemicals stress such as colouring agents, salivary enzymes, and mouthwashes. The most used polymers, individually or blended, to produce transparent orthodontic aligners are polyester, polyurethane, and polypropylene. Among polyesters, polyethylene terephthalate (PET) and polyethylene terephthalate glycol (PETG), a non-crystallizing amorphous copolymer of PET, are widely used in the production of Clear Aligners due to their excellent mechanical and optical properties.⁷¹

Thermoplastic polyurethane (TPU) is an extremely versatile material, featuring several favorable properties such as excellent mechanical and elastomeric characteristics, chemical and abrasion resistance, adhesion properties, simplicity of machining. Invisalign[®] aligners from AlignTech was the first digitally designed and manufactured aligners system produced from a single layer of polyurethane.

4.9.2. POLYMER BLENDS

Mechanical properties of the polymers are improved by mixing various types of polymers. Polyester, Polyurethane, and Polypropylene are the most used materials in the polymer blends employed in manufacturing of Clear Aligners. Polymer blending has proven to be a viable way to improve the physical and chemical properties of polymers, thereby enhancing the clinical performances of aligners.

4.9.3. RESINS

Epoxy Resins such as acrylonitrile-butadiene-styrene plastic and stereolithography materials are used for producing Clear Aligners through 3D printing. 3D printing is used as an alternative to conventional thermoplastic aligner fabrication process to avoid alteration of mechanical, dimensional, and aesthetic characteristics of the material during the thermoforming process.

⁷¹ https://doi.org/10.3389/fmats.2022.819121

4.10. ALIGNER SHEET MARKET

Polyurethane (PU) and Polyethylene Terephthalate Glycol (PETG) are the major materials used to produce Aligner sheets. The global Aligner Sheet market is expected to grow from US\$ 1032.9 Mn in 2023 to US\$ 2283.3 Mn in 2030 at a rate of 12.0%. Polyurethan (PU) material dominates the market with 72% share, flowed by Polyethylene Terephthalate Glycol (PETG) with 23% share. Increasing treatment adoption for Malocclusion among population, increasing awareness of Clear Aligners treatment, and emergence of branded products are major growth drivers of the Aligner sheets market.

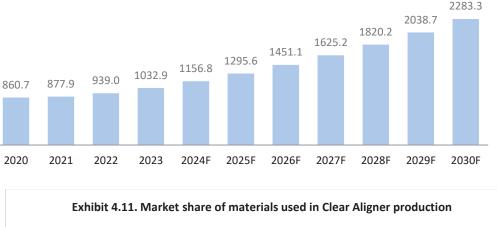
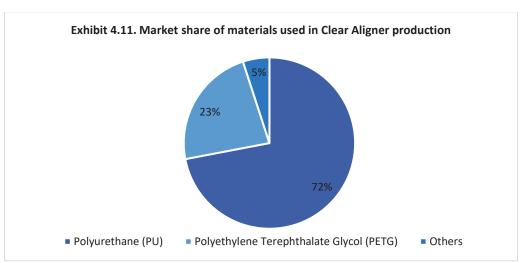


Exhibit 4.10. Global Aligner Sheet Market (US \$ Mn), 2020 - 2030F CAGR 2023 to 2030 = 12.0%



Source: Frost & Sullivan

Source: Frost & Sullivan

The major players in the Aligner sheet market are Dentisply Sirona (US), American Orthodontics (US), Ormco Corporation (US), Vedia Solution, a business unit of Laxmi Dental Limited (India), and Bay Materials LLC (US).

Table 4.5: Aligner sheet market size by key countries				
Country	2023 (US\$ Mn)	2030F (US\$ Mn)	CAGR (2023-2030F)	
China	161.9	203.4	8.5%	
India	63.0	90.9	6.2%	
Germany	38.6	68.5	5.4%	
UK	32.1	45.8	5.2%	
Italy	20.6	28.2	4.6%	
France	23.9	31.1	3.8%	
US	161.9	203.4	3.3%	

Source: Frost & Sullivan

Aligner sheet market in emerging markets such as China and India are expected to grow at a higher rate compared to developed markets due to low cost of manufacturing, increasing production of raw materials used to make the aligner sheet, and rapid technological advancements to achieve higher productivity and reduce the overall costs.

4.10.1. VERTICAL OR BACKWARD INTEGRATION IN CLEAR ALIGNER PRODUCTION

Multiple large Clear Aligner brands have followed backward integration approach by establishing proprietary manufacturing of Aligner Sheets to differentiate themselves in the market and improve gross margin. Moreover, the brands are aiming to develop materials with ideal features such as high resilience, low hardness, adequate elasticity ad resistance and high biocompatibility.⁷²

Table 4.6: Sample list of major Clear Aligner brands with proprietary materials				
Company (HQ)	Brand	Proprietary Name	Composition	
Align Technology (US)	Invisalign [®]	SmartTrack™ Material: LD30	Polyurethane	
3M (US)	Clarity	3 M™ Clarity™ Aligners Flex, 3 M™ Clarity™ Aligners Force:	Polyurethane	
Institut Straumann AG (Switzerland)	ClearCorrect	ClearQuartz Material	Polyurethane	
Ormco Corporation (US)	Spark	TruGEN™ and TruGEN XR Material	Unkown	
Dentsply Sirona (US)	SureSmile	Essix Plastics: Plus, C plus	Polypropylene/ethylene copolymer	
Henry Schein (US)	Reveal	ClearWear™ material	Unknown	
Laxmi Dental	Illusion Aligners	Pro and FLX	Polyurethane	

Source: Bioactive Materials Journal, Company presentation, Frost & Sullivan

⁷² https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9588987/

There are very few manufacturers of Aligner materials in India. Laxmi Dental Limited is one of the very few companies in India to manufacture and supply thermoforming sheets, thermoforming machine, dental consumables, biocompatible resins for 3D printing tailored for manufacturing Aligners.

4.11. PAEDIATRIC CROWN MARKET

Increasing prevalence of Dental disorders in children, introduction of aesthetic and biocompatible materials and increasing accessibility to specialist dental care are some of the major factors driving the Paediatric Dental Crown market

4.11.1. PREVALENCE OF ORAL DISEASE AMONG CHILDREN

Oral diseases affect 3.5 Bn people worldwide, and untreated dental caries (tooth decay) is among the major oral diseases and conditions representing highest diseases burden. Dental caries or tooth decay results when free sugars contained in food or drink are converted by bacteria into acids that destroy a tooth over time. Dental caries is a major public health problem globally as the disease affects all age groups, with an onset in early childhood and continued increase over the life course. Caries is mostly preventable, but nonetheless it is the most common noncommunicable disease globally. More than 33% of the global population have untreated dental caries. Over 2 Bn people worldwide have untreated dental caries in permanent teeth, and untreated caries in deciduous teeth is the single most common chronic childhood disease, affecting 514 million children worldwide.⁷³ The estimated global average prevalence of caries of deciduous teeth is 43%. Continued high intake of free sugars, inadequate exposure to fluoride and a lack of removal of plaque by toothbrushing can lead to caries, pain and sometimes tooth loss and infection. Severe untreated caries with systemic inflammatory reactions from pulp infections is also a contributing factor to underweight and stunting in children.⁷³

Dental caries affects all age groups, starting with the eruption of the first teeth (deciduous teeth/primary dentition) and increasing in prevalence until late adulthood, then remaining at high levels until older age. The onset of the disease in children younger than 6 years is early childhood caries, which at times progresses quickly to complete destruction of the primary dentition.⁷³

4.11.2. TREATMENT FOR DENTAL CARIES

Fluoride Treatment. In the early stages of tooth decay treatment with fluoride may help repair the enamel on the teeth and can stop a cavity. Fluoride included in professional fluoride treatments is higher than that of toothpaste, mouthwash, and tap water. Fluoride treatments can be applied to your teeth by brushing, placing a tiny tray over them, or using liquid, gel, foam, or varnish.

Dental Fillings. Fillings, also called restorations, are the main treatment option. Fillings are made of various materials, such as tooth-coloured composite resin or porcelain, silver amalgam, or gold.

Dental Crowns. A dental crowns are pre-formed or custom-fitted covering for an existing tooth. It can improve the way a decayed or broken tooth looks and functions. The crown helps protect the soundness of the tooth and lowers the risk of fracture. Crowns are made of materials such as porcelain, resin, Zirconia ceramic, polycarbonate, stainless steel, and other metals.

⁷³ WHI Oral Health Report, 2022

Root canal therapy. When decay reaches the tooth pulp, root canal treatment is performed to repair and save a badly damaged or infected tooth instead of removing it. In some cases, dental crowns are required to strengthen the affected tooth.

4.11.3. GLOBAL PAEDIATRIC DENTAL CROWN MARKET

The major indications for Crown treatment in children are Dental Caries and Enamel disorders. Due to increasing prevalence of Early Childhood Carriers (ECC) due to poor dental hygiene and genetic predisposition, there is growing demand for preventive and restorative dental treatments. Dental Crowns protects children's teeth from further decay. The Global Paediatric Crown Dental Market, in terms of retail sales, is estimated to grow from US\$ 2.1 Bn in 2023 to US\$ 3.5 Bn in 2030 at a growth rate of 7.5%.

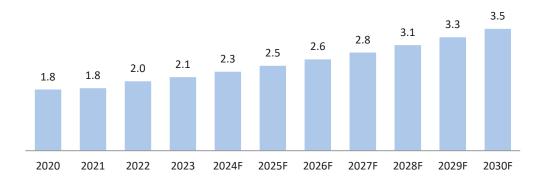


Exhibit 4.12. Global Paediatric Dental Crown Market (US\$ Bn), 2020 - 2030F CAGR 2023 to 2030F= 7.5 %

Source: Frost & Sullivan

4.11.4. GROWTH DRIVERS FOR PAEDIATRIC DENTAL CROWN MARKET

Rising prevalence of oral disorders in children. Children are prone to develop oral health issues such as dental caries and gum disease due to poor oral hygiene, bacterial infection, and poor nourishment. The dmarket for Paediatric dental crowns is seeing a notable upswing in demand, mostly driven by the rising incidence of dental disorders in young children. Growing awareness of early intervention and restorative dental procedures for young children are increasing adoption of dental crown treatment. Dental crowns offer a strong and long-lasting covering for broken primary teeth. Additionally, Paediatric dental crowns prevent tooth from deteriorating further and maintain its integrity by crowning the affected teeth.

Introduction of advanced materials. Introduction of aesthetic and biocompatible materials such as Zirconia and resin-based composites has offered novel choices for parents. Zirconia crowns offers improved biocompatibility, resistance, and aesthetics, Resin-based composite strip crowns offer a balance of aesthetics and function but have challenges in long-term stability.

Growing number of Paediatric dentists. The number of Paediatric dentists in the US is expected to grow by more than 60% from 2019 to 2030⁷⁴, catering to the needs of underserved Paediatric population and reducing the barriers to oral healthcare.

Increasing access to specialist dental care. Due to growing number of dental facilities, parents have access to specialized dental treatments for children. Due to increasing awareness and affordability, parents are seeking specialized dental care for children. Paediatric dental facilities offer wide range of treatment options catering to increasing demands from parents.

Adoption of digital solutions. Usage of digital technologies such as intraoral scanners and treatment planning software by Dentists has reduced the procedure time and improved treatment outcomes. The technology adoption has enabled Dentists to serve more patients.

4.11.5. INDIAN PAEDIATRIC DENTAL CROWN MARKET

The Indian Paediatric crown market is witnessing an attractive growth due to rising prevalence of dental disorders among children, increasing awareness of disorders such as dental caries among parents and improving access to specialty dental providers. The Indian market for Paediatric dental crowns, in terms of retail sales, is estimated to grow from US\$ 63.9 Mn in 2023 to US\$ 164.8 Mn in 2030 at a growth rate of 14.5%.



Exhibit 4.13. Indian Paediatric Dental Crown Market (US\$ Mn), 2020 - 2030F CAGR 2023 to 2030F= 14.5 %

Source: Frost & Sullivan

4.11.6. UNIQUE NEEDS IN PAEDIATRIC DENTAL CROWN MARKET

Dental crowns are essential for children's general oral health and psychological wellbeing in addition to helping to restore teeth that are decaying or broken. Dental crowns are essential to treating deterioration through creative means, and their significance in Paediatric dentistry goes beyond simple repair. The rehabilitation of primary teeth with severe structural loss is improved by the switch from conventional materials like stainless steel to more aesthetically pleasing and biocompatible substitutes like zirconia, resin-based composites, and Bioflx[™] crowns. While Stainless steel crowns (SSCs) are valued for durability and cost-effectiveness, they may cause hypersensitivity. Zirconia crowns are favored for

⁷⁴ https://www.dentistrytoday.com/Paediatric-dentists-to-grow-by-60-in-the-next-decade/

biocompatibility, resistance, and aesthetics. Resin-based composite strip crowns offer a balance of aesthetics and function but have challenges in long-term stability.⁷⁵

The global Paediatric market is characterised by increased concerns over metal restorations due to toxicity and allergies, lesser inclination towards anaesthesia needles and invasive procedures, anxiety amongst children for undergoing dental treatment, high prevalence of dental caries amongst lower income groups posing affordability issues for taking treatments and presence of fewer domestic players focusing on Paediatric dental restorations.

4.11.7. MARKET SHARE AND GROWTH OF PAEDIATRIC DENTAL CROWN MATERIALS

Among the materials use in Crowns, Stainless Steel While Stainless steel has a major market share with about 45%. However, materials such as Zirconia and Resin Veneer are gaining adoption as an alternative to Stainless Steel. The growth rate of Zirconia Crowns is higher than Stainless Steel (8.5% vs. 6.0%).

Factors for longevity of crowns depends on dental material properties, operator ability and age and cooperation of the child to accept the treatment. While composite strip crowns have lower success rate and higher gingival inflammation, prefabricated zirconia crowns are retentive and gingival friendly.

Table 4.7: Market	Table 4.7: Market share and growth of Dental Crown materials								
Material	Share	Growth (2023 – 2030)							
Stainless Steel	45%	6.0%							
Composite strip	20%	4.5%							
Zirconia	18%	8.5%							
Resin Veneer	8%	5.5%							
Polycarbonate	6%	4.0%							
Metal	3%	2.5%							

Source: Frost & Sullivan

In India, there are very limited companies focusing on Paediatric dental products. Kids-e-Dental[™] LLP (Joint Venture of Laxmi Dental Limited) is the only Indian company specialized in Paediatric dental products and manufacturing of pre-formed metal free Paediatric dental crowns. In terms of revenue from operations as of March 31st 2024, Kids-e-Dental[™] is one of the leading Paediatric dental product brands in India.. The company is the only Indian manufacturer of US FDA cleared Silver Diamine Fluoride (SDF) to treat dental caries among Children, and it has a registered design on Bioflx[™] (a semi-flexible tooth coloured pre-formed dental crown for children) in India. To scale up the distribution of Paediatric branded product offerings, Kids-e-Dental[™] has partnered with a leading Paediatric dental company for the distribution of Bioflx[™] crowns, manufactured by the company, globally across 81 countries.

⁷⁵Almajed O S (January 26, 2024) Shaping Smiles: A Narrative Review of Crown Advancements in Paediatric Dentistry. Cureus 16(1): e52997. DOI 10.7759/cureus.52997

5. COMPETITIVE LANDSCAPE IN DENTAL LABS AND BRANDED PRODUCTS MARKET

5.1. MARKET LANDSCAPE IN DENTAL LAB SEGMENT AND BRANDED PRODUCTS SEGMENT

5.1.1. DENTAL LABS

There are more than 5,000 dental labs in India and the market is highly fragmented. Notably, there are very few organized and professionally operated dental labs adopting digital dentistry, have sufficient scale of operations and sizeable workforce, and adhere to international quality standards. The highly fragmented market is yet to undergo major consolidation as seen in the US. It is expected that, similar to the US, Indian dental lab market is expected to be dominated by large, organized players as many small-scale labs close due to shortage of manpower, demand to adopt digital workflows, increasing investments in technology and pressure on margins. In the US, due to similar factors, the number of dental Labs decreased by more than 20% from 2001 to 2022⁷⁶ and there is growing dominance from few major organized players like Glidewell, Modern Dental Laboratory, National Dentex Corporation and Frontier Dental Laboratory. Moreover, Indian dental labs which do not build capabilities for vertical integration will face pricing pressure and fail to stay relevant in the market. Successful dental lab and branded products companies in the US have a diverse portfolio of products and are vertically integrated to lower costs and streamline operational process.

The dental laboratories market in India is characterised by the presence of fragmented and unorganized dental laboratories with less than ten technicians and a dearth of quality management standard compliant dental products. Very few organized players in dental lab segment such as Laxmi Dental Limited and DentCare have sufficient scale of operation, follow quality standards and cater to both domestic and international markets.

5.1.2. BRANDED PRODUCTS

Growing awareness of dental aesthetics among consumers and rising levels of disposable income is expected to shift consumer preference towards branded products.

Globally, the penetration of branded dental products such as Clear Aligners, branded Dental Crowns and Paediatric Crowns is growing. Increasing premiumisation and propensity to spend will drive the adoption of branded products. Companies such as Align Technology in the US and Angel Align in China have rapidly expanded their geographical footprint and introduced new products. Align Technology, founded in 1997 with a single branded Clear Aligner product (Invisalign®), has served more than 17 million patients, expanded to 100+ markets and launched new products such as intra-oral scanner, palatal expander system and treatment planning software. Similarly, Angel Aligner, founded in 2003, has served more than 1 million patients and expanded its presence to Europe, Australia, New Zealand, and North America.⁷⁷

⁷⁶ https://www.aegisdentalnetwork.com/id/2023/05/the-future-of-laboratory-workflows

⁷⁷ Company website and investor presentation

Successful companies in the branded products segments have built established doctor led or B2B2C models to establish trust, improve market penetration and growth their market share. Several D2C players have struggled to establish their presence in their market and transitioned their model to B2B2C emulating the success of leading brands such as Align Technology and Angel Align. In markets such as the US and China, B2B2C players have more than 80% market share.

While traditionally international brands dominated the emerging markets such as China and India, the domestic brands are catching up and gaining market share. Angel Aligner emerged as a leading domestic B2B2C player replacing the global brands in China by addressing the gap in the market for an affordable Clear Aligners brand. Angel Aligner's annual total Clear Aligner case shipments grew by 33.2% in 2023 reaching 245,000 and out of it, the domestic shipments were 85% which has grown at a rate of 15.3%. The company has been capturing dominant market share in China's Clear Aligner industry for three consecutive years, outgrowing internation brands such as Align Technology's Invisalign. As per Angel Aligner's statement, the Clear Aligner market is still at a nascent stage, and a massive population could benefit from Clear Aligner treatments for malocclusion, considering a prevailing malocclusion condition yet a low penetration rate of the Clear Aligner treatment worldwide.

The Dental branded product market in India, which is currently dominated by international players such as Align Technology and Straumann is expected to follow similar trend seen in China, with the emergence of domestic branded products. Currently, only few players such as Laxmi Dental Limited (Illusion Aligners) and Ampa Orthodontics (makeO Toothsi), DentCare, and Rejove (32 Watts) offer branded Clear Aligner products in India. Moreover, majority of branded players in the market offer only single product and focus on Clear Aligner segment. Laxmi Dental Limited Care and DentCare are the only dental labs in India which offer branded products such as Clear Aligners and Crowns. While majority of Indian companies with branded product offerings offer only a single product with a focus on Clear Aligner segment, Laxmi Dental Limited is the only Indian company to offer full range of branded dental products including pre-formed Paediatric Crowns and Bridges, Clear Aligners and Aligner manufacturing materials. A strong network among dental clinics, dental companies and dentists acts as a strong moat and barrier to entry for new entrants in the Indian dental products market.

5.1.3. BUSINESS PROFILE OF KEY GLOBAL DENTAL PRODUCT COMPANIES

Among the international players in the dental products segment, companies such as Align Technology, Angel Align specialize in Clear Aligner and have introduced Intra-oral scanner and treatment planning software (CAD/CAM solution) to enable dental practitioners improve workflow and fitment of the product to patient, resulting in better treatment outcomes. Moreover, due to adoption of doctor led B2B2C models, the companies have achieved improved customer engagement and faster penetration in the market. Straumann is a leading international dental company which offer a wider portfolio of products in dental treatment such as Dental Implant solutions, Prosthetic solutions, Restorative products, Clear Aligner and digital treatment solutions.

		Table 5.1: P	Profile of Key	y Global De	ntal Product Companies	
Company (HQ)	Revenue CY2023 (US\$ Mn)	Revenue CAGR (2019-23)	PAT CY2023 (US\$ Mn)	PAT Margin, CY2023	Business Segment (Revenue mix 2023)	Geographic presence (Revenue mix 2023)
Align Technology (Arizona, US)	3,862.2	12.6%	445.0	11.5%	 Clear Aligner (83%) Systems and Services (17%) 	 Americas (50.2%) International - APAC, EMEA (49.8%)
Angel Align (Shanghai, China)	206.6	23.0%	6.8	3.3%	 Clear Aligner treatment solutions (86.9%) Sales of products (11.9%) Other Services (1.2%) 	 China (90.2%) Other regions - APAC, Brazil, Europe, US (9.8%)
Straumann (Basel, Switzerland)	2,866.6	14.8%	293.4	10.2%	 Implant Clear Aligner Prosthetics CAD/CAM equipment Regenerative 	 North America (28%) EMEA (44%) Latin America (9%) Asia Pacific (19%)

Source: Company website, annual reports

5.1.4. BUSINESS PROFILE OF KEY GLOBAL DENTAL LAB COMPANY

Та	ble 5.2: Brief	profile of k	ey Global p	layer in the D	ental Lab and Branded	product segment
Company (HQ)	Revenue CY2023 (US\$ Mn)	Revenue CAGR (2019-23)	PAT CY2023 (US\$ Mn)	PAT Margin, CY2023	Business Segment Mix	Geographic presence
Modern Dental Group	406.2	7.2%	51.5	12.7%	 Crowns and Bridges Removable Dentures Orthodontic devices Sports guards Anti-snoring devices Clear Aligners Retainers 	 China North America Western & Northern Europe Australia & New Zealand Southeast Asia

Source: Company website, annual reports

5.1.5. BUSINESS PROFILE OF KEY PLAYERS IN THE INDIAN CLEAR ALIGNER MARKET

Table	Table 5.3: Business profile of key players in the Indian Clear Aligner Market							
Company	Business Segment Mix	Geographic presence	Vertical Integration	Business Model				
Invisalign India (Align Technology)	Clear AlignerRetainer	 Americas Asia-pacific Europe, Middle East and Africa 	No	B2B2C				
Ampa Orthodontics (Make O Toothsi)	Clear AlignerOral Care Products	 India Gulf Cooperation Council (GCC) 	No	D2C				
Bizdent Devices ⁷⁸	Clear Aligner	• India	Yes	B2B2C				

Source: Company website, news articles, press releases

Table 5.4	Table 5.4: Financial metrics of key players in the Indian Clear Aligner Market, FY23 and FY24										
Parameter	Invisalign India			Amp	Ampa Orthodontics			Bizdent Devices ⁷⁸			
Parameter	H1 FY25	FY24	FY23	H1 FY25	FY24	FY23	H1 FY25	FY24	FY23		
Operating Revenue (INR Mn.)	NA	NA	2,212	NA	NA	1,684	254	376	187		
PAT (INR Mn.)	NA	NA	90.0	NA	NA	(2202.5)	28.9	55.4	2.5		
PAT Margin ⁷⁹	NA	NA	4.1%	NA	NA	(130.8)%	11.4%	14.7%	1.3%		
RoE ⁸⁰	NA	NA	29.1%	NA	NA	(250.3)%	NA	127.2%	15.2%		

The total revenue from aligners solution (including Illusion Aligners and Taglus) is INR 549 Mn in FY24 and INR 363 Mn in FY23.

⁷⁸ Bizdent Devices Private Ltd., a subsidiary of Laxmi Dental, is involved in the sale of Clear Aligners under the brand name "Illusion Aligners".

⁷⁹ Profit After Tax (PAT)/Operating Revenue

⁸⁰ Restated net profit after tax and adjustments, available for equity shareholders / Avg. shareholders equity

RoCE ⁸¹	NA	NA	39.8%	NA	NA	(366.9)%	NA	113.7%	37.0%
						C			•

Source: Company website, annual filings

Based on revenue from operations and PAT margin for Fiscal 2023, Laxmi Dental is the largest and most profitable vertically integrated and indigenous B2B2C dental aligner solutions company. The company benefits from the first mover advantage by being one of the very few companies in India to manufacture and supply thermoforming sheets, thermoforming machines, dental consumables, and biocompatible resins for 3D printing tailored for manufacturing of Clear Aligners.

5.1.6. PROFILE OF KEY INDIAN DENTAL LAB AND BRANDED PRODUCT COMPANIES

Tab	le 5.5: Brief profile of key Indian players in th	e Dental Lab and branded	products segment
Company (HQ)	Business Segment Mix	Geographic presence	Export Revenue, FY2023 (INR MN)
Laxmi Dental Limited (Mumbai, India)	 Crown and Bridge Paediatric Crowns Implant Prostheses Removable Prostheses Clear Aligner Veneers Thermoformed appliances Automated thermoforming machines Aligner sheets 3D printing resins Dental consumables 	 India United States United Kingdom Europe 	• 501.2
DentCare (Kerala, India)	 Crown and Bridge Implant Prostheses Removable Prostheses Veneers Orthodontic/Pedodontic Appliances Retainers Temporo-mandibular Joint (TMJ) appliances Thermoformed appliances 	 India Australia New Zealand UAE UK Canada US 	• 46.5

Source: Company website, Volza, news articles

⁸¹ EBIT / Avg. Capital Employed, where EBIT = PBT + Finance Costs; Avg. Capital Employed = (Opening capital employed + closing capital employed) / 2; Capital Employed = Total Equity + Net Debt

Table 5.6: Financi	Table 5.6: Financial metrics of major Indian Dental Companies with Lab Offerings, FY23, FY24 and H1 FY25										
Deverseter		DentCare			Laxmi Dental						
Parameter	H1 FY25	FY24	FY23	H1 FY25	FY24	FY23					
Operating Revenue (INR Mn)	NA	NA	1,900.0	1167.8	1935.6	1,616.3					
PAT (INR Mn)	NA	NA	99.4	227.4	252.3	(41.6)					
PAT Margin ⁸²	NA	NA	5.2%	19.5%	13.0%	(2.6)%					
RoE ⁸³	NA	NA	80.4%	40.7%*	78.8%	(19.6)%					
RoCE ⁸⁴	NA	NA	26.4%	24.6%*	20.0%	(0.3)%					

*Not Annualized; Source: Income statement, Company annual filings

In Indian market, companies such as Laxmi Dental (Bizdent), Ampa Orthodontics (MakeO Toothsi) and DentCare offer branded dental products. While Ampa Orthodontics is a product company, specializing in Clear Aligner offering through D2C business model, Laxmi Dental Limited and DentCare are dental lab companies which also sell branded products through doctor led B2BC model. Based on revenue for Fiscal 2024, Laxmi Dental Limited is amongst the top two largest Indian dental laboratories. Laxmi Dental Limited is the only aligner company in India which is fully vertically integrated having end-to-end capabilities from raw material to distribution, enabling significant control on the supply chain. Under the 'Taglus' brand, Laxmi Dental also sells thermoforming machines at a competitive price which are used for manufacturing aligners.

5.1.7. COMPARISON OF PRODUCT PORTFOLIO OF MAJOR GLOBAL AND INDIAN DENTAL PRODUCT COMPANIES HAVING PRESENCE IN INDIA

	Table 5.7. Portfolio comparison across major peers										
Company Type	Company	Custom- made fixed Prosthesis (Crowns, abutment)	Removable Prosthesis (Dentures	Clear Aligners	Aligner Sheet	Thermo- forming Machine	Intra- oral Scanner	Paediatric Crowns			
Global	Align										
Dental	Technology	×	×	\checkmark	×	×	\checkmark	×			
Product	(Invisalign)										
Company	Straumann	×	×	\checkmark	\checkmark	×	\checkmark	×			
Indian Dental Product	Ampa Orthodontics (Toothsi)	×	×	\checkmark	×	×	×	×			
Company	32 Watts	×	×	\checkmark	×	×	×	×			
	Snazzy	×	×	\checkmark	×	×	×	×			

⁸² Profit After Tax (PAT)/Operating Revenue

⁸³ Restated net profit after tax and adjustments, available for equity shareholders / Avg. shareholders equity

⁸⁴ EBIT / Avg. Capital Employed, where EBIT = PBT + Finance Costs; Avg. Capital Employed = (Opening capital employed + closing capital employed) / 2; Capital Employed = Total Equity + Net Debt

DentCare	\checkmark	\checkmark	\checkmark	×	×	×	×
Laxmi Dental	~	~	✓	✓	\checkmark	~	~

Source: Company website

Offering a comprehensive portfolio of dental products, Laxmi Dental Limited is India's only end-to-end integrated dental products company as at September, 2024. The company's product portfolio includes branded dental products such as Orthodontic Products, Prosthodontic Products, Restoration materials, Intra-oral scanners, and raw materials and machinery for Clear Aligner manufacturing such as 3D resins, Aligner sheets and Thermoforming Machine. Laxmi Dental is one among the few vertically integrated players globally with backward integrated (that is manufacturing the raw materials to designing of dental products) and forward integrated (that is offering solutions for treatment planning) business model.

5.2. GROWING INTEREST FROM PRIVATE EQUITY COMPANIES AND INCREASE IN M&A ACTIVITY IN DENTAL LAB AND CLEAR ALIGNER SEGMENTS

Increasingly, private equity (PE) players are showing interest to invest in dental lab market in the US. Moreover, there is increase in M&A activity in the US dental lab market due to shortage of talent, declining reimbursement and margin pressures and increase in digitization. In 2021, Comvest Partners invested in Leixir Dental Group which operates five dental laboratories across the U.S. in addition to a digital design and manufacturing facility in Gurugram, India. In 2020, Cerberus Capital acquired National Dentex Labs, the largest network of fully owned dental labs in the US. In 2019, O2 Investment Partners invested in Frontier Dental Labs, a full service, multi-site dental laboratory in the US. PE backed National Dentex and Frontier Dental Lab have acquired series of small dental labs to expand their presence achieve operating scale.

Similarly in the Clear Aligner segment, global dental companies such as Henry Schein, Straumann and Dentisply Sirona have acquired innovative Clear Aligner brands to complement their existing doctor-led consumer orthodontics offering, build more integrated offering and to expand faster in different markets.

Tabl	e 5.8: Select PE investments and a	acquisitions in Dental La	ab and Products segment
PE Firm	Dental Lab (Country)	Type of Transaction	Year
Oakley Capital	Flemming Dental (Germany), Excent (Netherlands), and Artinorway Group (Norway)	Acquisition	August 2023
Equicapita	Protec Dental Laboratories (Canada)	Acquisition	October 2021
Comvest Partners	Leixir Dental Group (US)	Investment	Apr 2021
Cerberus Capital	National Dentex Labs (US)	Acquisition	Oct 2020

02				
Investme	ent Frontier Dental Labs (US)	Acquisition	July 2019	
Partners				

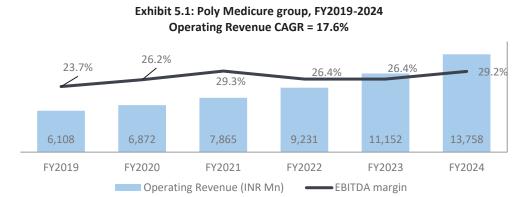
Source: News articles, press releases

Table 5.9: Select M&As in Dental Lab and Branded Products segment				
Segment	Company (HQ)	Ownership	Target (HQ)	Year
Dental Lab	National Dentex	PE Owned (Cerebrus Capital Management)	Swan Dental Lab (US)	April 2022
			Biotech Dental Prosthesis (US)	January 2022
			Dental Arts (US)	November 2021
			Fager Dental Labs (US)	November 2021
			Dental Services Group (US)	April 2021
	Frontier Dental Lab Group (US)	PE Owned (O2 Investment Partners)	Friendship Dental Laboratories (US)	February 2023
			D&S Dental Laboratory (US)	Aug 2022
			Burbank Dental Laboratory (US)	March 2022
			Dental Lab Aesthetics (US)	March 2022
			Nur-Art Dental (US)	October 2019
	Modern Dental Group (China)	Public Company	MicroDental (US)	October 2016
Clear Aligner	Henry Schein (US)	Public Company	Biotech Dental S.A.S (France)	December 2022
	Straumann (Switzerland)	Public Company	Plus Dental (Germany)	May 2022
	Dentisply Sirona (US)	Public Company	Byte (US)	January 2021
	Rejove Aligners (India)	Private Company	32 WATTS (India)	August 2023
	makeO (India)	Private Company	Smileneo (UAE)	February 2023

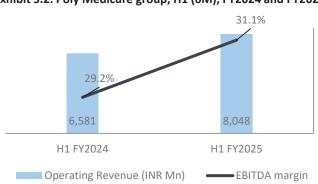
Source: News articles, press releases

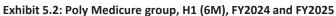
5.3. BRIEF ABOUT LISTED INDIAN COMPANY IN MEDICAL DEVICE (POLY MEDICURE)

Poly Medicure, which was incorporated in 1995 and listed in National Stock Exchange (NSE) in 2011, manufactures disposable medical items, such as IV cannula, blood bags, blood collection tubes, and infusion and transfusion sets. The company has 12 manufacturing facilities across 4 countries: 9 manufacturing facilities in India (6 facilities in Faridabad, 2 in Jaipur and 1 in Haridwar), 3 facilities overseas (1 facility in China – wholly owned subsidiary, 1 joint venture in Egypt, 1 facility in Italy). The company has over 300 registered patents across countries, and a strong market position in the organized medical disposable devices market with strong brand positioning due to high quality products used in infusion therapy, blood management, surgery, dialysis, and other segments. Poly Medicure's own branded products contributed to 70% of its sales in FY23. The company's operating revenue has grown from INR 6,108 million in FY2019 to INR 13,758 million in FY2019 to 29.2% in FY2024.



Poly Medicure's operating revenue in H1 (6M) FY2025 was INR 8,048 million compared to INR 6,581 million in H1 (6M) FY2024 (YoY growth of 22.3%), and the company's EBITDA margin increased from 29.2% in H1 (6M) FY 2024 to 31.1% in H1 (6M) FY2025.





6. INDUSTRY THREATS AND CHALLENGES

- Poor access to dental treatments in rural areas. There is a significant shortage of dental professionals in rural India. While India has second highest number of dentists after China, the country has only 21 dentist per 100,000 people, and the ratio is even lower in rural areas. Many dental clinics, especially in rural areas, lack the necessary infrastructure and modern equipment to provide comprehensive dental care. Poor access to dental care in rural areas could lead to low demand for dental lab services.
- **High cost of dental care.** Affordability remains a significant barrier to seeking dental care among people from low-income segment. People tend to avoid going to their local dentist because of economic constraints. Hence, the priority towards oral health among people of lower socioeconomic classes is very low. Dental treatments are not covered as a part of comprehensive medical insurance which impacts the demand. This could impact the demand for dental lab services.
- Willingness to seek dental care. Oral healthcare is frequently neglected in developing countries such as India due to poor awareness of dental care. Dental diseases are not considered to be serious or life threatening. Lack of treatment adoption or demand for dental care services could impact demand for dental lab services.
- Poor adoption of technology among dentists. Utilization of technologies such as Intra-oral scanners among dentists is low in Tier II and Tier III cities. Further, many dental schools have outdated curriculums that do not keep pace with advancements in dental technology and practices, and there is a lack of structured continuing education programs to help practicing dentists stay updated with the latest developments and technologies in the field. Technology adoption barriers could pose logistic issues and lead to poor operational efficiency for dental labs.
- Shortage of dental technicians. The country faces significant shortage of dental technicians due to factors such as lack of training programs, poor awareness among students about the profession, and lack of industry-ready curriculum. As per Indian Dental Association, nearly 60% of dental labs face difficulties in hiring adequately trained staff. Unavailability of skilled technicians could lead to high labor cost, posing operational challenges and impacting the serviceability of market demand.
- Investments required to increase adoption of branded products. Branded dental products often require high investments in consumer marketing to convey their benefits over generic alternatives. The marketing campaigns have to target the right set of customers and required consistent messaging in the formative years for brand establishment. If marketing campaigns do not effectively communicate the benefits of branded dental products, it could impact the product adoption.