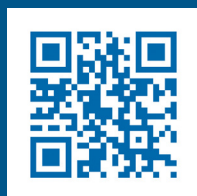# 2019 Top Markets Report
Medical Devices

A Market Assessment Tool for U.S. Exporters

July 2019

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2019 Top Markets Report **Medical Devices**
Sector Snapshot

Dental Equipment and Supplies

Introduction
The global dental equipment and supplies market offers tremendous opportunity for U.S. manufacturers and challenges for government policymakers supporting U.S. export competitiveness. Creating new and sustained export opportunities for U.S. companies will require a concerted effort to remove or diminish market access barriers, helping U.S. firms to capture a larger share of the world import market.

Continued strong U.S. export activity to the larger and more mature global dental markets is likely to continue, with Southeast Asia and Latin America emerging as promising regions for U.S. dental products. U.S. dental equipment and supplies manufacturers enjoy a good reputation internationally for their innovation, cutting-edge technology, and value.

Global economic expansion, increased government spending on dental care, higher median personal income, structural reforms in key markets, wider access to all levels of education, and rising uptake of health insurance are factors that will help grow markets for U.S. exporters of dental equipment and supplies. The global dental products market is expected to grow between 5.5 percent and 6.6 percent yearly between 2018 and 2023, as reflected in the table below.

Global Dental Products, Total Sales ($ millions)					
2018	**2019**[f]	**2020**[f]	**2021**[f]	**2022**[f]	**2023**[f]
29,157	30,808	32,850	34,926	36,904	38,940
Percent Increase	5.6	6.6	6.3	5.7	5.5

Source: BMI Research. [1] [f] Forecast.

Profile of the U.S. Dental Equipment and Supplies Industry
Dental equipment and supplies, provided for under North American Industry Classification System (NAICS) code 339114, consists of equipment, instruments, and supplies used by dentists, dental hygienists, and laboratories. Specific products include dental hand instruments, plaster, drills, amalgams, cements, sterilizers, and dental chairs.

U.S. Dental Equipment and Supplies Manufacturing			
Year	Number of employees	Annual Payroll ($1,000)	Total value of shipments and receipts for services ($1,000)
2015	14,689	909,116	4,904,668
2016	15,377	952,043	4,988,935
Percent Increase	4.6	4.7	1.7

Source: Dental Trade Alliance. [2] Bureau of the Census, NAICS code 339114. [3]

In 2016, the total value of U.S. industry shipments for dental equipment and supplies was almost $5 billion. This represents a 1.7 percent increase over the previous year. Median pay for medical technology jobs connected to NAICS code 339114 (dental) have historically been 15 percent higher than the average U.S. manufacturing job. In the 2016 Annual Survey of

Manufactures, the Bureau of the Census reported that the dental equipment and supplies industry employed more than 15,000 people in the United States, with an average salary of over $60,000. Most of the employers surveyed are small-to-medium-sized enterprises (SMEs). An SME is usually defined as an enterprise having fewer than 500 employees. Most medical technology firms are very small SMEs, as 80 percent are estimated to have fewer than 50 employees. And many, most notably innovative start-up companies, have little or no sales revenue.

Major U.S. dental manufacturers and distributors:
- *3M,* headquartered in Minnesota, produces innovative products for a variety of healthcare needs, offering flexible technologies meeting customer needs.
- *Danaher*, domiciled in Washington, DC, designs, manufactures, and markets dental products and services in over 60 countries.
- *Dentsply Sirona*, based in Pennsylvania, is a dental equipment and consumables manufacturer focusing on the professional dental market worldwide.
- *The Henry Schein Company*, located in New York, provides dental care products and services to practitioners, laboratories, government and institutional health care clinics, and other alternate care sites worldwide.
- *Patterson Companies*, based in Minnesota, distributes dental consumables, infection control products, restorative materials, hand instruments, orthodontic appliances, sterilization products, and advanced technology dental equipment globally.
- *Crosstex*, a Cantel medical company, based in Minnesota, is a world leader in infection control products, personal protection equipment, dental units, sterilization products, and disposables.

Export Markets
Countries in Western Europe, as well as Japan and Canada, are extremely large and lucrative export markets for U.S. dental equipment and supplies. These stable and mature markets have relatively low annual growth rates of three to five percent. To facilitate market expansion, medical device companies therefore recognize that they must also look at developing markets such as China and Korea for future growth. In some of these markets, demand for dental equipment and supplies is growing at double-digit rates in contrast to the more predictable, larger, and slower growing developed markets.

U.S. Dental Equipment and Supplies, Exports 2013-2018 ($1,000)						
Market	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**
Canada	185,312	198,262	187,454	185,524	202,833	187,116
Japan	196,956	211,746	144,465	179,396	158,026	113,045
Germany	120,965	126,533	165,112	121,479	128,923	126,319
China	69,695	85,264	97,761	106,496	91,505	88,364
Korea	90,461	139,412	120,327	84,588	83,977	48,351
Other	510,424	523,576	527,831	516,204	489,053	491,475
TOTAL WORLD	**1,173,813**	**1,284,792**	**1,242,949**	**1,193,687**	**1,154,318**	**1,055,726**

Source: Bureau of the Census, NAICS code 339114. [4]

Significant yet underserved populations in developing markets are increasingly aware of health technology development and oral care. Furthermore, many developing markets have highly urbanized population centers with rising expendable wealth, making certain market sub-sectors appealing to exporters who can more easily reach these potential customers. A U.S. exporter of dental equipment and supplies would be best served to identify both large, developed markets and emerging, underserved markets to find the best export market mix.

Regulatory Considerations
The European Union's Medical Device Regulation (MDR) [5]
Medical device exporters to the European Union (EU) will face significant regulatory changes. The EU's decades-old regulatory framework, which governs market access is Medical Device Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC). These will be replaced by the EU Medical Device Regulation (MDR or the Regulation) in 2020.

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The MDR was published in the Official Journal of the European Union on May 5, 2017, came into force on May 25, 2017, will begin being enforced in May 26, 2020. Manufacturers of currently approved medical devices will have a three-year transition period until the scheduled enforcement date of May 26, 2020, to comply with and have products tested to the new MDR standards. MDR provides a transition period for products with a valid certification under the previous Medical Device Directives until 2022, or even 2024, as determined by the individual product certification. [6]

The MDR differs in several important ways from the EU's current directives for medical devices and active implantable medical devices. Some of the more significant changes that affect dental equipment and supplies in the MDR are:

- Product scope under the MDR will expand to include active implantable medical devices as well as devices that may not have a medical intended purpose, such as aesthetic implant devices and materials.
- More rigorous clinical evidence will be required for Class III and implantable medical devices.
- Manufacturers will need to refile their clinical evaluations for Class IIa and IIb medical devices to justify not conducting a clinical investigation.
- Notified bodies, which are accredited agencies responsible for issuing certificates of product conformity with the requirements of the Regulation, will be required to comply with more stringent new regulatory requirements.

Under the MDR, all currently approved devices must be recertified in accordance with the new requirements. [6]

Thirty-one (31) percent of European firms indicate plans to discontinue selling existing devices in the EU, as do 19 percent of North American firms. There are several possibilities for these expectations, such as manufacturers ending product lines believed less likely to meet MDR requirements and concerns that fewer Notified Bodies will be available for conformity assessment. [7]

"Basic Safety" and the Cost of IEC 60601-1 Edition 3.1
Although most medical device standards are voluntary, a handful of standards, such as IEC 60601-1, are universally used to ensure that medical electrical equipment is electrically and mechanically safe. Successive iterations of this standard have been accompanied by increasing testing costs from approximately $7,000 in the year 2000 to $11,000 in 2010. At an average of 4.6 percent per year, this is well above the rate of inflation in the EU during the same period.

In 2010, a newer "Edition 3" was released which has nearly tripled the cost of testing to $35,000. This is especially problematic as it is a cost that applies to individual devices, regardless of their risk classification. Furthermore, the newer Edition 3.1 added complicated requirements unrelated to electrical safety, and many dental companies simply cannot get their equipment through testing as they had before. An evaluation of a low-risk dental product showed that an evaluation that once took six to eight weeks under a previous edition of this standard, now takes six to eight months under the Edition 3.1. [8]

Complications with the Medical Device Single Audit Program (MDSAP)
As medical device authorities around the world have developed their own regimes, industry has faced the growing problem of having to meet several different regional- or country-specific quality system audits in multiple export markets. The MDSAP, a third-party audit program designed to meet the requirements of the U.S. Food and Drug Administration (USFDA), Health Canada, Brazil's ANVISA, Japan's MHLW, and Australia's Therapeutic Goods Administration, was created to address capacity questions of less-developed participating regulatory agencies as well as to reduce the burden of complying with multiple audits. The MDSAP combines multiple sets of audit criteria into one comprehensive inspection. An MDSAP audit, however, is costly. The dental equipment and supplies manufacturing industry has reported quotes for the MDSAP audit of up to $50,000. In contrast, one provider offers a comparable ISO 13485 quality management system audit at a cost of $16,000, one-third of the cost of the MDSAP audit. Many SME dental equipment and supplies manufacturers in the United States doing business

internationally report relying on ISO 13485 certification for use in several export markets, and maintain that in contrast, requiring MDSAP certification is prohibitively costly.

USFDA inspections remain free of charge, Australia recognizes ISO 13485 certification, and Brazil does not require GMP inspections for dental equipment manufacturers. However, as of January 1, 2019, Health Canada requires MDSAP certification exclusively, replacing less-costly certification under the Canadian Medical Devices Conformity Assessment System (CMDCAS), potentially increasing costs for SME producers inside and outside of Canada, especially for those U.S. manufacturers who export to only that market. [9] U.S. manufacturers of dental equipment fear that they may be shut out of the Canadian market entirely because of this increased cost.

Trends
3D Printing
As technology revolutionizes dentistry worldwide three-dimensional (3D) resin printing is becoming more common for custom dental solutions. While the concept of 3D printing is not entirely new, its use in dental applications at any scale is a relatively recent phenomenon. Initially, it was mostly dental labs that used it to create orthodontic devices. 3D printing is now used for general dentistry, implantology, prosthodontics, and even to create custom devices to help patients with sleep apnea. Resin is popular as a printing material as it provides an excellent finish and the capability to produce fine feature details of the kind that are required for dental devices. [10]

Patient Discretionary Spending
The increase in discretionary dental spending in international markets makes exporting more enticing for U.S. firms. Because many dental procedures are elective, insurance is not usually a factor. Profit margins are often higher for procedures not covered by insurance. Such elective services include teeth whitening, veneers, aligners, and implants. For dental practice to be successful, dentist and staff must attain proficiency for procedures on demand and make the case for value to their patients to increase treatment acceptance. These elective services and the companies that provide them and support them will continue to grow at a rapid rate. [11]

E-Commerce
U.S. dental equipment and supplies manufacturers will make it easier and quicker for customers to place orders and receive products. A growing majority of dentists expect to receive their orders within a week. Most expect delivery in two days or less. U.S. manufacturers will work even harder to improve the value they offer to dental professionals with customer service reflected in speedy delivery and customs clearance, wherever the client may be, keeping them competitive among other international manufacturers. [11]

Precision Dentistry
As oral care technology improves and spreads globally, precision dentistry has become an increasingly significant sub-sector within oral health. In general terms, the essence of precision dentistry is tailoring treatment to specific patient needs based on an individual's genetic biomarkers. By minimizing errors in diagnoses, improving outcomes, and reducing side effects, precision dentistry is poised to transform how clinicians approach healthcare. They can deliver more accurate diagnoses and create personalized treatment with improved predictability in outcomes. A fuller understanding of genomics and bioinformatics, combined with advanced digital technology help dental clinicians understand what might make a specific patient susceptible to disease or responsive to treatment. [12] As first-line health professionals and with access to the oral cavity, a dental team can identify patients who may present specific conditions that manifest in the mouth. Oral diseases, lesions, or absence of teeth can bear markers for predisposition of certain cancers or other disorders.

Pediatric Dentistry
New and improved restorative materials, allowing dental professionals to treat dental cavities without removing significant tooth structure, have characterized advances in pediatric dentistry worldwide. Coincidentally, by the year 2020, most countries will experience the fastest growth in their population among those aged 18 and younger, requiring a refocus of preparation for dental professionals and appropriate therapies. Likewise, as the costs of dental care and healthcare in general become increasingly scrutinized, there will be intensified

accountability to perform procedures that are based on sound scientific procedures and predictable outcomes. Future therapies are expected to be more preventative in nature, especially when restorative procedures are more expensive. Advances in materials, techniques, and increased knowledge will shift dental practice from a "reparative" model, and more toward a model based on monitoring and prevention. Dentistry across the world may reach the aspirational goal of creating a generation of patients with fewer caries and a more positive dental experience, hopefully including more children who live in traditionally underserved markets, and who previously may have had little chance of obtaining optimal dental healthcare. [13]

Although many countries have reported a decline in pediatric dental cavities, other challenges in reducing inequalities of oral health among children remain. Conditions associated with poverty, family structure, and other social factors have significant effects on dental and overall health. These factors vary greatly among export markets. Oral disease often stunts early childhood development and harms general health. In some instances, it is associated with a decreased quality of life in preschool children. Together with dental trauma, early childhood cavities represent a public health challenge in many parts of the world. In 2015, researchers from around the world met to discuss the expected needs of this increasingly significant sector of the population. They agreed that new health policies, dental education, as well as advancements in therapies and related technologies would be necessary. [14]

The Minamata Convention and the Reduction of the Use of Dental Amalgam Worldwide
The Minamata Convention on Mercury (the Convention) of 2017, a multilateral environmental agreement developed by the United Nations Environment Program aims to protect global human health and environment from the negative effects of mercury. To date, 128 countries have signed the agreement, including the United States, to control and monitor the mining, use, and disposal of this element. [15] U.S. exporters of dental amalgam, complementary devices for its application, including amalgamators and specific tools for its adherence should take note of this agreement. U.S. manufacturers of substitute products and therapies would also do well to understand the implications of the Convention.

The Convention contains certain stipulations for dental amalgam, a widely used material containing 50 percent mercury used for tooth fillings. Unique to dental amalgam's treatment in the Convention is that it is subject to a phase-down use, and not a complete phase-out, as alternatives to dental amalgam are not available everywhere. In many lower-income countries, dental amalgam is the only available material for certain dental restorations, and the environmental requirements — reliable electricity and water, for example — necessary for storage and use of more developed resin-based substitute materials, are not always readily available. [16]

The FDI World Dental Foundation suggests that for a successful phase-down of dental amalgam, there must be greater emphasis on preventative dental therapies, increased research on amalgam alternatives, and best practices for amalgam waste. [17] As the dental industry and practice shift from a more traditional model of amalgam-based restorative dentistry and to a paradigm featuring prevention and overall health worldwide, the phase-down of dental amalgam can become a turning point to an era of prioritizing oral health within overall well-being.

Conclusion
The dental equipment and supplies industry generates higher than average wages and is expected to continue growing. U.S. manufacturers can find new opportunities for exporting dental equipment and supplies if they consider regulatory issues and global trends in markets of interest. The world is ready for not only more dental care, but *better* and increasingly innovative therapies. Because U.S. manufacturers excel at innovation and offer high-quality products, they are well placed to capitalize on international opportunities.

Addendum: Resources for U.S. Exporters

The U.S. government has numerous resources available to help U.S. exporters. These include additional market research, guides to export financing, overseas trade mission opportunities, and access to trade professionals in offices nationwide and around the world. For additional information about services from the International Trade Administration (ITA), please visit www.export.gov.

Country Commercial Guides
http://export.gov/ccg/
Written by U.S. Embassy trade experts worldwide, the Country Commercial Guides provide an excellent starting point for what you need to know about exporting and doing business in a foreign market. The reports include sections addressing market overview, challenges, opportunities, and entry strategies; political environment; selling U.S. products and services; trade regulations, customs, and standards; and much more.

Basic Guide to Exporting
Basic Guide to Exporting addresses virtually every issue a company looking to export might face. Numerous sections, charts, lists, and definitions throughout the book's 19 chapters provide in-depth information and solid advice about the key activities and issues relevant to any prospective exporter.

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