



U.S. Medical Devices: Imports and Exports, the Role of Tariffs and of the FDA

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FIME 

By Informa Markets

The team behind the **Florida International Medical Expo (FIME)** is proud to bring you a tailored report with key information related to medical device imports and exports for the United States, how recently implemented tariffs are affecting the industry, and what requirements manufacturers should be aware of to gain FDA approval for its devices and equipment before importing or exporting.

U.S. medical device market synopsis

According to research from Fitch Solutions, the medical device market in the United States (U.S.) is projected to register a Compound Annual Growth Rate (CAGR) of **4.6% from 2018-2023**, with a value of \$106.9 billion by 2023. During this period, the United States will remain the world's largest medical device market, accounting for around two-fifths of the market.

Despite an economic slowdown in 2019, as a result of higher tariffs, heightened trade tensions and tightening credit conditions, Fitch Solutions expects increasing healthcare demand to support medical device import growth. The monthly trade data for Q2 2019 reveals that imports totaled **\$13.9 billion**, a year-on-year increase of 8.5%.

Meanwhile, U.S. medical device exporters are being faced with a tougher environment in 2019, as the latest monthly trade data reveals that exports totaled \$12.5 billion in Q1 2019, a year-on-year increase of only 3.3%.

U.S. Imports

Fitch Solutions also recently revealed that medical device imports account for approximately 30% of the U.S. medical device market. In 2018, they increased by 9.9% to reach a record high of \$51.6 billion. A significant component of the rise has been a consequence of the relocation of U.S. companies' production facilities to cheaper manufacturing locations abroad, such as Mexico and Ireland, Fitch Solutions said.

The largest product area is 'other medical devices' representing over a quarter of total imports, registering an increase of CAGR 14% in 2018.

Diagnostic imaging is the second-largest category, with a fifth of imports, followed by **consumables, orthopedics & prosthetics, patient aids and lastly, dental products**, which accounts for less than 5% of the total medical device imports to the U.S.



The medical device market is set to reach **106.9 billion** by 2023



The United States accounts for 2/5 of global medical device market



30% of medical devices are imported into the United States



17% of total U.S. imports are from Mexico



U.S. medical device exports increased by **5.8%** in 2018



Consumables and diagnostic imaging each represent around 1/5 of exports



37% of total U.S. exports are to the European Union

Mexico was the leading supplier in 2018, primarily as a consequence of it being a low-cost foreign manufacturing base for U.S. companies, representing almost **17% of total imports**. Mexican suppliers were dominant in the consumables (notably syringes, needles & catheters) and other medical devices product areas.

The U.S. imported medical devices valued at **\$19.8 billion from the EU-28 in 2018**, equal to 38% of the total.

China was ranked as the fourth-largest supplier in 2018, accounting for 11% (\$5.7 billion) of the total. **Chinese suppliers featured prominently in the patient aids sector**, accounting for almost a quarter of the import total. According to Fitch Solutions, despite the ongoing trade tariff dispute, Chinese medical device exports to the U.S. are continuing to rise, as the U.S. remains China's largest export market by some margin.

U.S. Exports

Fitch Solutions data has revealed that **U.S. medical device exports increased by 5.8% to \$47.5 billion** in 2018, marking the most substantial growth since 2011. The 2013-2018 CAGR was 1.7%. Before 2017, the U.S. had long held a sizeable balance of trade surplus in medical devices. However, in 2017, the surplus was transformed into a deficit of \$2.1 billion, which widened to \$4.1 billion in 2018. The only product areas not to show a balance of trade deficit in 2018 were **consumables and other medical devices**. The ongoing decline in the trade balance is further evidence of the shift away from manufacturing in the to lower-cost locations overseas.

Other medical devices accounted for over 30% of total exports in 2018. Consumables and diagnostic

imaging each represent around one-fifth of exports. Orthopedics & prosthetics made up just fewer than 14% of exports in 2018, while patient aids and dental products are smaller areas, each with less than 10% of the total.

The patient aids product area registered the strongest growth in 2018 and was the only one to increase by over 10%. Exports of consumables were marginally under 10%, ahead of all the other product areas, which also posted single-digit growth

Exports to the EU-28 totaled \$17.6 billion in 2018, representing **37% of total exports**. The EU-28 received over a third of total exports in every sector in 2018. The leading destination was the Netherlands (\$6 billion in 2018), followed by Belgium (\$3.6 billion), Germany (\$3.3 billion) and Switzerland (\$1.2 billion).

Japan received 10% of total exports in 2018, valued at \$4.9 billion.

Exports to China represented 9.5% of the total, with shipments valued at \$4.5 billion. China was the leading destination for diagnostic imaging exports. However, looking forward, **U.S. exporters stand to lose out in the ongoing trade tariff dispute with China**, as the impact of the tariff hike has been significant for the first batch of products that had tariffs of 25% imposed in 2018. Chinese imports of MRI systems, X-ray equipment, patient monitors and ophthalmic instruments from the fell sharply in the fourth quarter of 2018 and the first half of 2019.

Canada was the fourth-largest individual export market in 2018, with shipments valued at \$4 billion and representing 8% of the total. Canada was the leading destination for bandages & dressings, dental products and therapeutic appliances.





The impact of tariffs: under closer inspection

The U.S.-China trade war

On July 6, 2019, the United States levied tariffs on \$34 billion worth of Chinese goods including a slew of medical devices, with China immediately retaliating kicking off duties of equal size for U.S. goods. A new round of tariffs on \$112 billion worth of U.S. imports from China took effect September 1, 2019, and China announced its own round of tariffs on U.S. made goods would also take effect on the same date. The September tariffs imposed by the U.S. were initially set at 10%, and they were later increased to 15% by the United States Trade Representative (USTR). Currently, talks are ongoing to look at ending a 15-month trade battle between the world's two largest economies.

The Chinese medical devices on the original list of products affected by the U.S. tariffs included pacemakers, X-ray generators, anesthetic devices and optical instruments. However, on July 9, nine types of medical devices were exempted from the 25% tariffs imposed on Chinese goods, including surgical, radiotherapy and dental devices.

While the U.S. list of items subject to tariffs contains just a few healthcare products (e.g., surgical

drapes and medical gloves), it does include raw materials such as several forms of aluminum, iron, stainless steel, and others, raising the question as to the impact on medical device manufacturing.

Medical device lobbying group AdvaMed has expressed concerns about the effect of the trade war on U.S. medical device manufacturers. The medical device industry has already felt the sting of the trade war between the U.S. and China, contending with tariff rates of up to 25% on both \$860 million in Chinese imports to the U.S. and nearly \$5 billion in exports to China, per AdvaMed. Further tariffs could undermine the strength of medical device suppliers as the U.S. currently makes up more than 30% of China's med device and diagnostics imports.

Although U.S. medical device exports are increasing globally, U.S. exporters stand to lose out in the ongoing trade tariff dispute with China, as exports to China fall while imports from China rise. Lower wages in China mean it can produce goods such as medical devices in a less costly way than in the U.S. Tariffs on Chinese goods, which will be paid by the importers upon entry to U.S. customs, mean that the prices of those goods increase at the consumer side to cover the cost.

List of medical devices not subject to the tariffs:

- ✚ Veterinary ultrasound devices with black-and-white image quality used as a medical diagnostic tool
- ✚ Microwave ablation antennas, whether or not with attached controls, as parts of ablation systems used to ablate live tumors
- ✚ Parts and accessories of electro-surgical instruments and appliances, other than extracorporeal shock wave lithotripters
- ✚ Vessel sealing and dividing devices that use electrical energy to separate and seal tissue during open or laparoscopic surgical procedures
- ✚ Smoke evacuation pencils with accompanying tubing and hoses designed to integrate smoke evacuation into electrosurgery by combining both features into a single handpiece
- ✚ Dental X-ray alignment and positioning apparatus, each valued over \$5,000
- ✚ Suction coagulators, consisting of a hand-piece with mechanical and/or electrical controls and a disposable shaft, used for the coagulation of tissue and aspiration of fluids during surgical procedures
- ✚ Multi-leaf collimators of radiotherapy systems based on the use of X-ray
- ✚ Overhead tube suspension used to hold and position X-ray generating equipment

Source: Office of the United States Trade Representative

So, who then stands to benefit from the U.S.-Chinese tariffs?

According to the UN Trade Agency (UNCTAD), tariffs “cost China \$35 billion in the first half of 2019” with other competitors – notably Taiwan – picking up some of the slack (\$4.2 billion in the first half of 2019).

Other trade winners from the measures include Mexico (\$3.5 billion), the European Union (\$2.7 billion) and Vietnam (\$2.6 billion) and the positive effects for them “have increased over time”, UNCTAD said. Korea, Canada and India also benefited, with “substantial” gains ranging from \$0.9 billion to \$1.5 billion. Other South East Asian countries scooped up the remainder of the tariff-induced casualties, UNCTAD said, while noting that African countries saw only “minimal” benefits.

All eyes on Mexico

At the end of May 2019, the U.S. announced that it would impose a 5 % tariff on all imports from Mexico, beginning in early June, rising to 25 % . However, before the tariffs were set to go into effect, the U.S. announced that a deal had been reached and the tariffs were “indefinitely suspended”.

The imposition of tariffs on Mexican imports to the U.S. had the potential to cause disruption in the medical device sector, which relies on Mexico for 17% of its imports. However, according to RBC Capital Markets analyst Brandon Henry, the impact could be moderate, but that some companies could be disproportionately affected, such as a medical-device manufacturer that makes a large proportion of its instruments in Mexico.





The FDA's role in medical device import and export regulation

The Food and Drug Administration (FDA) regulates the sale of medical device products (including diagnostic tests) in the U.S. and monitors the safety of all regulated medical products. Before a medical device can be legally sold in the United States, the person or company that wants to sell the device must seek approval from the FDA. To gain approval, they must present evidence that the device is reasonably safe and effective for a particular use.

Imports

The FDA is responsible for ensuring that medical devices (including in vitro diagnostics) comply with applicable U.S. regulations when offered for importation into the U.S. The FDA's Center for Devices and Radiological Health (CDRH) is responsible for overseeing the medical device program.

Foreign manufacturers must meet applicable U.S. regulations in order to import a device into the U.S., including:

- Establishment Registration (including designated U.S. agent)
- Medical Device Listing
- Quality System

- Premarket Notification [510(k)], unless exempt, or Premarket Approval
- Labeling
- Medical Device Reporting

Under the Medical Device Reporting regulations, an importer is required to report incidents in which a device may have caused or contributed to a death or serious injury as well as certain malfunctions. Meanwhile, under the Medical Device Tracking regulation, certain devices must be tracked through the distribution chain.

All medical devices imported into the U.S. must meet the regulatory requirements of both the U.S. Bureau of Customs and Border Protection (CBP) and the FDA. Any entry for an FDA regulated product that is filed with CBP will also be electronically submitted to FDA for review.

A system called Import Alerts prevents potentially violative products from being distributed in the U.S. They also place the responsibility back on the importer to ensure that the products being imported comply with the FDA's laws and regulations.

Before importing into the U.S., importers should know if their products are subject to the Detention Without Physical Examination (DWPE) of products that appear to violate the FDA's laws and regulations.

Exports

The rules that companies must follow when exporting medical devices depend on whether or not their devices have been approved or cleared by the FDA. Medical devices that are legally marketed in the U.S. may be exported to anywhere in the world without prior FDA notification or approval. Devices that have not been approved or cleared in the U.S. must follow the export provisions of the Federal Food, Drug and

Cosmetic (FD&C) Act.

Depending on which section of the FD&C Act a firm is exporting under, it may need to request an FDA Certificate to Foreign Government (CFG), or it may need to submit a simple notification.

The CDRH Export Certification and Tracking System (CECATS) is a voluntary electronic system that allows manufacturers and initial importers to request export documents online as an alternative to paper submissions.

References:

United States Medical Devices Report I Q42019 BY Fitch Solutions

<https://www.fda.gov/medical-devices/>

<https://www.fda.gov/industry/actions-enforcement/import-alerts>

<https://www.fda.gov/industry/import-program-food-and-drug-administration-fda>

<https://www.mddionline.com/what-do-tariffs-mean-medtech>

<https://www.massdevice.com/these-medical-devices-are-exempt-from-the-trump-tariffs-on-china/>

<https://www.barrons.com/articles/how-the-new-tariffs-will-hit-u-s-medical-device-manufacturers-51559314685>

<https://www.reuters.com/article/us-usa-trade-china-exemptions/u-s-exempts-some-medical-electronic-devices-from-china-tariffs-idUSKCN1U42ER>

<https://news.un.org/en/story/2019/11/1050661>

<https://www.medicaldevice-network.com/features/us-china-trade-war-medical-devices/>

<https://www.businessinsider.com/trumps-china-tariffs-bring-instability-to-us-health-firms-2019-8>

<https://www.federalregister.gov/documents/2019/07/09/2019-14562/notice-of-product-exclusions-chinas-acts-policies-and-practices-related-to-technology-transfer>



The **Florida International Medical Expo (FIME)**, now in its 30th year, brings together all the industry players interested in the ever-changing dynamics of medical device and equipment imports and exports in the United States, and who are facing daily challenges with the topics discussed in this brief.

We hope this summary of key facts and figures is useful and we look forward to sharing more insights

and data, as we prepare for the 2020 edition of FIME, taking place **New dates:** August 25-27, 2020, at the Miami Beach Convention Center.

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