

ROK Market Brief No.20

Catheters and Cannulae Market

Opportunities under the Korea-Central America
Free Trade Agreement

The Korea-Central America FTA (K-CA FTA) brings significant benefits for CA exporters. Under the agreement, the Republic of Korea and the Central American countries will immediately or gradually reduce tariff on more than 95 percent of traded products. Such benefit will help CA exporters compete with exporters from other countries which have trade deals with Korea.

This guide provides an overview of the catheters and cannulae for medical, surgical, and dental category that benefit from tariff reductions under the K-CA FTA and have market access.



Market Demand

The size of the ROK catheter and cannulae market has shown a moderate growth trend in the recent years. It has shown steady growth overall from 28,237 tons in 2018 to 35,773 tons in 2022, with an annual growth rate of 6.35%. In terms of value, the market size gradually increased from 918 million USD in 2018 to 1,253 million USD in 2022 with 8.31% annual growth rate.

Out of the total ROK catheter and cannulae market, it demonstrates a mixed reliance on both imported and domestically produced products. Domestic production contributes 57% and import accounts for 49% in volume as of 2022. Conversely, exports represent a smaller proportion, comprising only 5% in volume.

Figure 1. ROK catheter & cannulae market in volume (2018-2022)

(Unit: Ton)



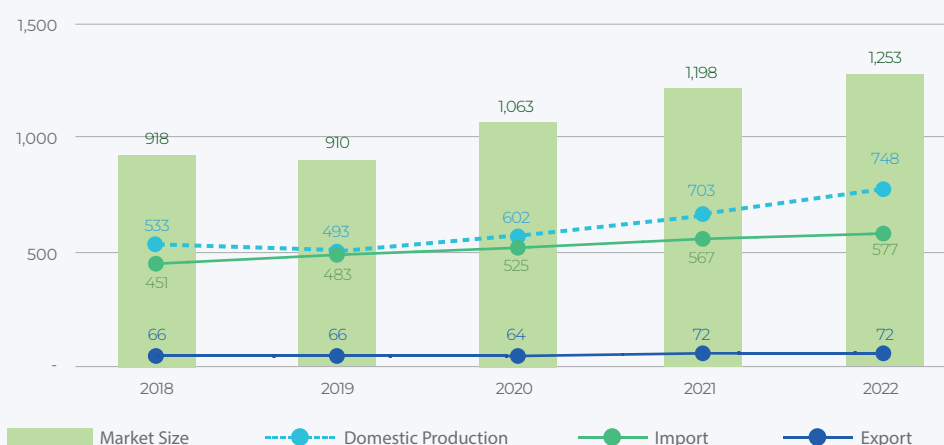
Source) Korea Customs Service Import and Export Statistics (2023)

Note1) Market Size = (Domestic production+Import) – Export

Note2) Domestic production is estimated by calculating the annual average price per ton based on the export statistics of HS CODE 901839, then substituting the calculated average price into the yearly production amount data.

Figure 2. ROK catheter & cannulae market in value (2018-2022)

(Unit: million USD)



Source) Korea Customs Service Import and Export Statistics (2023)

Note1) Market Size = (Domestic production+Import) – Export

Note2) Based on blood transfusion sets/fluid infusion sets, catheters/cannulas

Considering the increasing aged population and advanced medical technologies, the market growth rate is estimated to continue to grow with both domestic production and import size showing constant upward trend. The annual growth rate of the ROK catheter and cannulae market size is predicted to experience about 5% in value and 10% in volume for the next 5 years from 2022 to 2027.

Despite the fact that China and Vietnam, as the primary exporters of catheters and cannulae to Korea with the benefit from full tariff elimination, the preferential tariff treatment granted under the K-CA FTA provides a more favorable and competitive position for CA exporters compared and this may foster opportunities for growth in the medical instruments sector.

Hence, understanding the tariff structure is essential for Central American exporters looking to establish a foothold in the ROK market. Under the K-CA FTA, all of CA countries have or will soon have a comparative advantage due to lower tariffs on medical catheters/cannulae. The detailed tariffs are described in the table below:

Table 1. Tariff on HS Code 901839 as of 2024

Country	HS Code	Product	WTO bound rate	Current rate (2024)	Elimination of custom duties ¹
Costa Rica	901839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	8%	0%	2021.01.01
	901839.2000	Catheters (medical, surgical, dental or veterinary)	8%	0%	2019.11.01
	901839.9000	Parts and accessories (blood transfusion set or intravenous set, catheters, cannulae)	8%	0%	2021.01.01
El Salvador	901839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	8%	0%	2022.01.01
	901839.2000	Catheters (medical, surgical, dental or veterinary)	8%	0%	2022.01.01
	901839.9000	Parts and accessories (blood transfusion set or intravenous set, catheters, cannulae)	8%	0%	2022.01.01

¹ Effective date of the FTA: Nicaragua and Honduras (Oct. 2019), Costa Rica (Nov. 2019), El Salvador (Jan. 2020), Panama (Mar. 2021), For Guatemala, it is assumed in the report that the FTA will come into effect within the year 2024.

Country	HS Code	Product	WTO bound rate	Current rate (2024)	Elimination of custom duties
Panama	901839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	8%	0%	2023.01.01
	901839.2000	Catheters (medical, surgical, dental or veterinary)	8%	0%	2023.01.01
	901839.9000	Parts and accessories (blood transfusion set or intravenous set, catheters, cannulae)	8%	0%	2023.01.01
Honduras	901839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	8%	0%	2021.01.01
	901839.2000	Catheters (medical, surgical, dental or veterinary)	8%	0%	2021.01.01
	901839.9000	Parts and accessories (blood transfusion set or intravenous set, catheters, cannulae)	8%	0%	2021.01.01
Nicaragua	901839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	8%	0%	2021.01.01
	901839.2000	Catheters (medical, surgical, dental or veterinary)	8%	0%	2021.01.01
	901839.9000	Parts and accessories (blood transfusion set or intravenous set, catheters, cannulae)	8%	0%	2021.01.01
Guatemala	901839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	8%	5.33%	2025.01.01
	901839.2000	Catheters (medical, surgical, dental or veterinary)	8%	5.33%	2025.01.01
	901839.9000	Parts and accessories (blood transfusion set or intravenous set, catheters, cannulae)	8%	5.33%	2026.01.01
China	901839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	8%	0%	2024.01.01
	901839.2000	Catheters (medical, surgical, dental or veterinary)	8%	0%	2024.01.01
	901839.9000	Parts and accessories (blood transfusion set or intravenous set, catheters, cannulae)	8%	0%	2024.01.01
Vietnam	901839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	8%	0%	-
	901839.2000	Catheters (medical, surgical, dental or veterinary)	8%	0%	-
	901839.9000	Parts and accessories (blood transfusion set or intravenous set, catheters, cannulae)	8%	0%	-

Source) Customs Law Information Portal. (2024); FTA powerhouse, KOREA. (2024); FTA agreement and basic documents



Competitive Landscape

The ROK's import of medical instruments in terms of volume points to the conclusion that China, Vietnam, and Philippines are the major suppliers. The total import volume reached 17,482 tons in 2022 and about 8,415 tons were from the three major suppliers, accounting for 48% of total medical instruments imports. The detailed import statistics in volume from 2018 to 2022 is presented in the table below.

Table 2. Import volume of medical instruments per country (2018-2022)

(Unit: Ton)

	2018	2019	2020	2021	2022
China	2,559	2,861	3,122	3,374	4,025
Vietnam	1,902	2,419	2,665	2,519	3,094
Philippines	1,327	1,252	1,072	976	1,296
Mexico	901	1,029	1,097	1,056	1,243
Turkey	1,434	1,641	2,013	2,011	1,238
Thailand	1,322	1,186	926	1,036	1,102
USA	1,119	1,152	1,013	1,065	972
Serbia	0	0	3	200	882
Singapore	564	558	537	603	686
Others	2,223	2,289	2,435	2,527	2,945
Total	13,350	14,386	14,885	15,367	17,482

Source) Customs and Excise Department import and export statistics (2023). Export and import performance (by item)

Within imported medical instrument market in ROK, China products have shown firm presence both in terms of value and volume of imports over the past five years. In case of USA, although they have exported the highest value to ROK, their volume is relatively low.



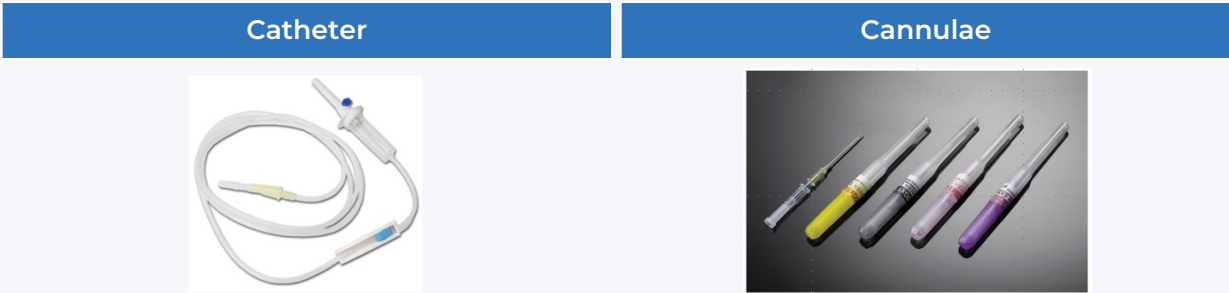
Consumer Preference

From the perspective of demand for medical services and medical devices, it is evident that overall medical demand is increasing due to improvements in income levels and an aging population. According to Health Insurance Review & Assessment Service and the National Health Insurance Service, the per capita medical expenses for the citizens increased from 5.03 million USD in 2018 to 7.41 million USD in 2022, representing an increase of about 30 percent.

Eco-friendly products are a trend even in the medical device market. Medi Line Active Korea has developed, for the first time in South Korea, a fluid infusion set made of environmentally friendly material, polyurethane, without using phthalates, known to be endocrine-disrupting substances. This product has obtained approval from the Ministry of Food and Drug Safety and has been acknowledged for its technological process to the extent of receiving patents in both South Korea and the United States.

In the case of catheters, products targeting specific objectives are being introduced or adopted. Medtronic has developed a drug-coated balloon catheter (IN.PACT™ AV DCB) effective in treating arteriovenous fistulas in hemodialysis patients with occlusive lesions, confirming its safety and efficacy. On another note, the Korean Ministry of Food and Drug Safety has newly designated 'vascular tubes and catheters for cardiovascular surgery' products as urgently required medical devices for surgeries in pediatric patients suffering from heart diseases. These products, with a connector diameter of 0.48 cm, are suitable for pediatric patients around the age of 1, as the connector is smaller than the 0.64 cm connectors of products distributed domestically.

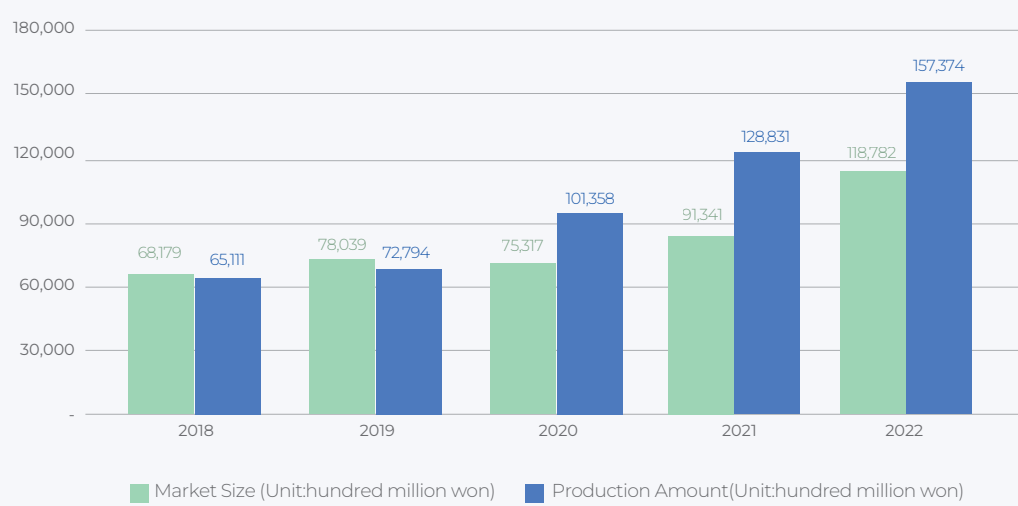
Figure 3. Sample image of Catheter and Cannulae



Source) E-Daily. (Jul. 2023).; The Kukmin Ilbo. (Feb. 2021); Health Chosun. (Jul. 2023)

With the improvement of income levels and the progression of population aging, the medical device industry is experiencing continuous growth. Examining the performance trend of medical device production over the past five years, the market size of from 5.17 billion USD in 2018 to 11.93 billion USD in 2022 indicates two-fold increase.

Figure 4. Yearly medical device production performance and market size



Source) Medical World News. (May 2023)

As the overall medical device production has increased, the market size for blood transfusion sets, fluid infusion sets, catheters, and cannula products has also been analyzed to grow by approximately 36 percent over the past five years (See Figure 1).



Main Distribution Channels

Currently, the number of domestic medical device manufacturing companies is approximately 1,800, with about 96 percent being small-scale enterprises employing fewer than 100 employees. This industry structure is characterized by producing a wide variety of products in small quantities, encompassing around 6,000 items.

Key domestic manufacturers producing blood transfusion sets, fluid infusion sets, catheters, and cannula products include Medi Line Active Korea, Ace Medical, and Sewoon Medical. Each of these companies falls into the category of mid-sized enterprises, with annual revenues ranging from 22.8 million USD to 30.4 million USD.

In addition to the stated companies, foreign companies such as B. Braun Korea and Medtronic also supply fluid infusion sets, blood transfusion sets, catheters, and cannula products in the Korean market. They primarily import products from overseas rather than manufacturing them domestically and selling them in the domestic market. Major importers of catheters and cannulae are listed below:

Table 3. Major ROK importers of Catheter and cannulae

No.	Company name	Enterprise scale	Import value (Unit: million USD)	Industry classification	Major importing countries	Address	Tel	Website
1	Medtronic Korea Ltd.	Midsized business	Exceeds 100	Wholesale of Medical, Precision, and Scientific Equipment	United States, Mexico	Glass Tower 17F, 534, Teheran-ro, Gangnam-gu, Seoul, Republic of Korea	+82-(0)2-3404-3600	www.medtronic.com
2	Baxter Inc.	Midsized business	Exceeds 100	Wholesale of Medical, Precision, and Scientific Equipment	United States, China	10F, Unit 1001, 1, Jong-ro, Jongno-gu, Seoul, Republic of Korea	+82-(0)2-6262-7100	www.baxter.com
3	Fresenius Medical Care Korea Co., Ltd	Midsized business	Exceeds 100	Wholesale of Medical, Precision, and Scientific Equipment	United States, China	14F, 4F, 24, Yeoui-daero, Yeongdeungpo-gu, Seoul, Republic of Korea	+82-(0)2-214-6880	www.freseniusmedicalcare.kr
4	Becton Dickinson Korea Co., Ltd.	Midsized business	Exceeds 100	Wholesale of Medical, Precision, and Scientific Equipment	United States	16F, 142, Teheran-ro, Gangnam-gu, Seoul, Republic of Korea	+82-(0)2-3404-3700	www.bd.com
5	B. Braun Korea Co., Ltd.	SMEs	50 ~ 100	Wholesale of Medical, Precision, and Scientific Equipment	United States, China	440, Teheran-ro, Gangnam-gu, Seoul, Republic of Korea	+82-(0)2-3459-7800	www.bbraun.co.kr
6	Cook Medical Korea Co., Ltd.	SMEs	20 ~ 50	Wholesale of Medical, Precision, and Scientific Equipment	United States	32F, 10, Gukjegeumyung-ro, Yeongdeungpo-gu, Seoul, Republic of Korea	+82-(0)2-6292-3500	www.cookmedical.com
7	Edwards Lifesciences Korea Co., Ltd	SMEs	20 ~ 50	Wholesale of Medical, Precision, and Scientific Equipment	United States	13F, 36, Teheran-ro 87-gil, Gangnam-gu, Seoul, Republic of Korea	+82-(0)2-559-9400	www.edwards.com

No.	Company name	Enterprise scale	Import value (Unit: million USD)	Industry classification	Major importing countries	Address	Tel	Website
8	TERUMO KOREA CORPORATION	SMEs	20 ~ 50	Wholesale of Medical, Precision, and Scientific Equipment	Vietnam	23F, Unit 1, 411, Seocho-daero, Seocho-gu, Seoul, Republic of Korea	+82-(0)2-565-9225	www.terumo.co.kr
9	Abbott Medical Korea Ltd.	SMEs	20 ~ 50	Wholesale of Medical, Precision, and Scientific Equipment	United States	337, Eonju-ro, Gangnam-gu, Seoul, Republic of Korea	+82-(0)2-3011-8556	www.abbott.com
10	Sewoon Medical Co., Ltd.	SMEs	10 ~ 20	Wholesale of Medical, Precision, and Scientific Equipment	Vietnam, China, United States	60, Dorim-gil, Ipjang-myeon, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea	+82-(0)41-584-2903	www.sewoonmedical.co.kr

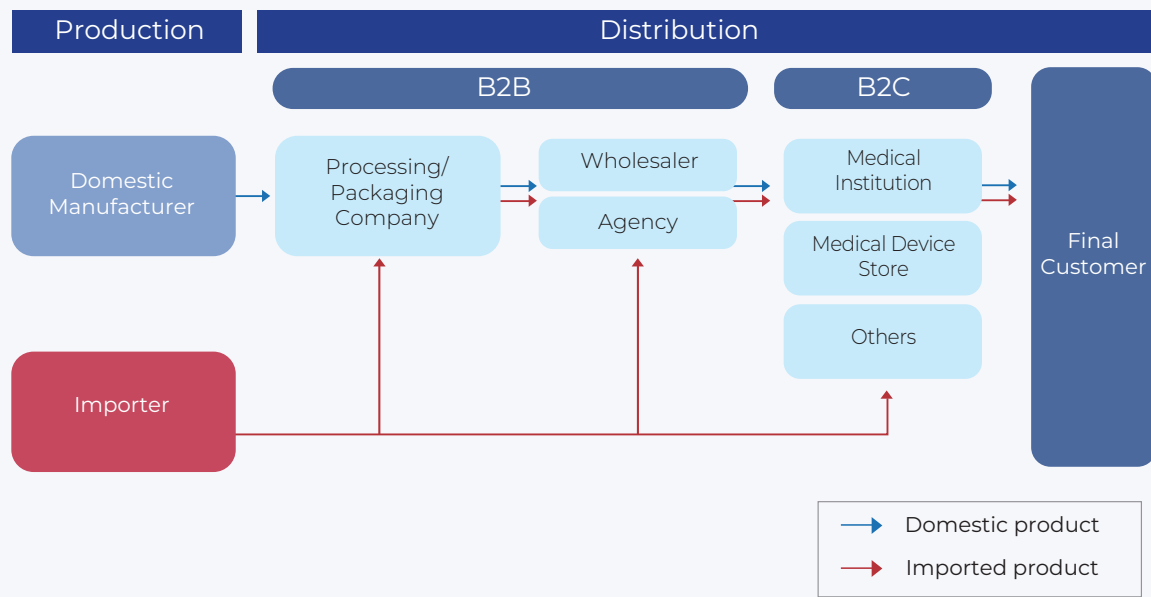
Source) KOIMA (www.koima.or.kr)

In Korea, the distribution process of domestically sourced medical instruments, specifically Catheters, Cannulas, and related products, initiates with a domestic manufacturer, specializing in the production of Catheters and Cannulas. After the manufacturing process, the products undergo essential preparation and packaging for subsequent distribution by dedicated processing or packaging companies.

The distribution then transitions into the B2B domain, with wholesalers and agencies playing a pivotal role. These intermediaries receive the packaged medical instruments directly from the manufacturers, serving as crucial links in the distribution chain. Moving further down the supply chain, the medical instruments find their way to various outlets in the B2C sector. Medical institutions, medical device stores, and other relevant points of sale act as distribution hubs for end-users, including patients and healthcare professionals. The distribution of imported medical instruments follows a similar path.

Public hospitals, serving as primary client, actively engage in bidding processes to procure essential products. They directly receive supplies from manufacturers or authorized dealers, managing their operations accordingly. On the other hand, large private hospitals establish exclusive contracts with consignment companies, which act as intermediaries, supplying products directly or utilizing their distribution networks for delivery.

Figure 5. Distribution Channel of Catheters and Cannulae



Source) JW Pharmaceutical Corporation Quarterly Report (2023) ; Sewoon Medical Quarterly Report (2023) ; and KMDIANEWS. (2016)



Import Requirements

In accordance with the relevant laws of the Republic of Korea, Catheters and Cannulas (901839) are subject to *Article 42 of the Pharmaceutical Affairs Act and Article 15 of the Medical Device Act*, which requires importers to obtain an import business license and import certification or import permit, as detailed below.

If an importer intends to import a medical device, catheter, to the Republic of Korea, the importer must apply for an import business license to the Ministry of Food and Drug Safety (MFDS) after meeting the criteria for an import business license by establishing facilities, equipment, quality management system, and hiring a qualified quality officer. Once the import business license is granted, the importer must prepare technical documentation, clinical trial data, or notification of review results (data within two years from the date of issuance) and apply for import certification or import license. Catheters are classified as Class 2, Class 3, or Class 4 depending on the product. For class 2 products, import certification must be obtained through the NATIONAL INSTITUTE OF MEDICAL DEVICE SAFETY INFORMATION. For class 3 and 4 products, import permits must be obtained through the KFDA. If import certification or import license is obtained, Korean labeling must be prepared on the medical device as follows. The labeling must be on the container or on the packaging of the medical device.

Table 4. Labeling Requirements for Medical Devices

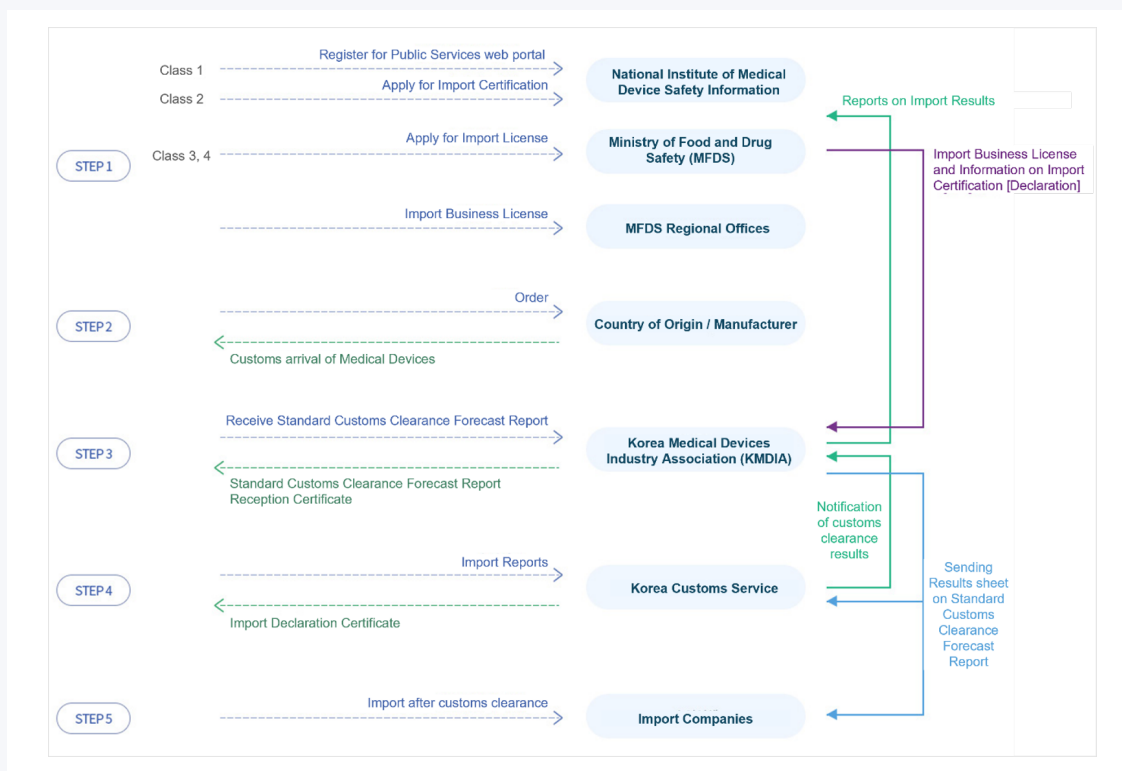
Label Location	Details
Labeling on Containers	<ol style="list-style-type: none">1. The trade name and address of the manufacturer or importer;2. If imported, the origin of manufacture (the name of the country of manufacture and of the manufacturer).3. Permission (certification or notification) number and name (name of a product, item or model). In such cases, the name of a product shall be limited to where there exists a name of a product;4. The manufacturing number and the date of manufacturing (the use-by date may be stated in lieu of the date of manufacturing, if the use-by date exists);5. Weight or packaging unit;6. A label stating "medical device";7. A "single-use only" and "do not reuse" label for a single-use medical device;8. Medical device standard code prescribed by the Minister of Food and Drug Safety, in consultation with the Minister of Health and Welfare;9. The fact that package inserts shall be provided in electronic form on a website, and the address of the website that provides the package inserts (limited to where the package inserts are provided on a website)
Labeling on Outer Package	<ol style="list-style-type: none">1. If it is impossible to read any description above, which is written on a container or an outer package of a medical device because it is covered by an outer container or another outer package, the same description shall be also written on the outer container or the other outer package
Labeling on Package Inserts	<ol style="list-style-type: none">1. Manufacturers and importers of medical devices shall include the following information in a package insert of a medical device:<ol style="list-style-type: none">a. The method of, and precautions for, use;b. Instructions for maintenance and inspections, if maintenance and inspections are required;c. Matters that the Minister of Food and Drug Safety requires to be described pursuant to Article 19;d. Other matters prescribed by Ordinance of the Prime Minister.2. The package inserts under paragraph (1) may be furnished in any of the following forms:<ol style="list-style-type: none">a. USB, CD-ROM, or other electronic media;b. Printed manual (paper, booklet, etc.);c. Websites (limited to medical devices being used mainly at medical institutions prescribed in Article 3 of the Medical Service Act, which are designated by the Minister of Food and Drug Safety).

Source) Korean Law Information Center, Medical Devices Act

Import Process

In order to import catheters in ROK, importers need to prepare a medical device import business license and import certification or import license related materials. Once the import certification or import license and Korean markings/labeling are prepared, a standard customs clearance forecast report must be submitted to the KOREA MEDICAL DEVICES INDUSTRY ASSOCIATION based on the shipment documents. If approved, an ENTRY NOTICE OF IMPORTED PRODUCTS must be issued to proceed with customs import clearance. After that, the importer can proceed with the customs clearance and receive the goods after paying the taxes if there are no abnormalities. The overall import procedure for medical catheters is as follows.

Figure 6. Import Process of Medical Device



Source) Ready Korea (<https://www.readykorea.co.kr/>), Korean Law Information Center (<https://www.law.go.kr/>)

Other Obligations and Cautions

Catheter and Cannulae to be sold in the ROK market after importation must be labeled with the country of origin. The country of origin may also be labeled on the plastic wrapping.

The country of origin must be marked in Korean, Chinese characters, or English, and must be labeled as "MADE IN [Country Name]". The method of marking depends on the packaging area, but it must be marked in at least 12 points font size.



SWOT Analysis



S

Strengths

The medical instruments market in general in ROK is gradually increasing with stable growth projection due to increased income levels and an aging population. In Korea, per capita medical expenses for Korean citizens have increased from 4,572 USD in 2018 to 5,238.25 USD in 2022, showing 30 percent increase.

Particularly for the ROK market of catheter and cannulae, there is a gradual increase in market size from 28,000 tons in 2018 to 35,800 tons in 2022, showing an average annual growth at 6.4 percent in volume over the recent five years – With the projection of market growth at 10% in volume over the next 3 years, Korea is a stable and promising market for global exporters.

Most importantly, the K-CA FTA would enable CA exporters to enjoy the full tariff-free status and the effective year per each CA country for the product based on HS Code 901839.2000 is as follow: Costa Rica (2019), El Salvador (2022), Honduras (2021), Nicaragua (2021), Panama (2023), and Guatemala (2026).



W

Weakness

In South Korea, medical devices are defined in the Medical Device Act as products used for the purpose of "diagnosis, treatment, alleviation, management, or prevention of diseases. As medical devices come into direct or indirect contact with the human body, safety and efficacy are considered the most crucial factors and are subject to intensive regulation by regulatory authorities.

To be specific, since 2017, domestically produced and imported fluid infusion sets and catheter products have faced regulatory scrutiny from government authorities for multiple times due to quality issues. In this regard, strong regulations and quality standard, as well as the required compliance pose barriers for CA's market entry.



Opportunities

The South Korean market for blood transfusion sets/fluid infusion sets and catheters/cannulas have shown a consistent upward trend over the past five years. For blood transfusion set, the import volume increased from 11,209 tons in 2018 to 14,563 tons in 2022; For catheter/cannulae, the import volume increased from 2,140 tons in 2018 to 2,919 tons in 2022.

Moreover, for blood transfusion sets and catheters (901839), the portion of import is shown as relatively high compared to the other ROK product market. As of 2022, the volume of domestic production by weight was 20,235 tons while the import was 17,482 tons. Since the volume of the export in 2022 was 1,944, this makes the size of import among the total market as approximately 49%; Given the growing trend of import volume as illustrated above, this tendency and market presence of import provides positive exportability to potential CA suppliers.



Threats

South Korea's market for catheters/cannulas is dominated by domestic production and there is already intense competition between global foreign companies' Korean branches and domestic mid-sized and small companies; As of 2022, there are approximately 1,800 domestic medical device manufacturing companies and 1,300 importing companies. This shows that the domestic medical device market is very competitive.

Not only facing the competition with domestic producer, but it is also expected to have competition with the major exporting countries. For catheters/cannulas, the United States, Mexico, and China is the Top 3 exporters to ROK, and among all exporting countries, the United States and Mexico combined account for around 32 percent of the total import value. Therefore, when Central American catheters/cannulas try to expand its export to ROK market, price competition between other origin of imported products is expected to be very fierce.



Business Case

ROK Market Insights

- ROK market on catheter and cannulae is in steady growth
- The import size of ROK catheter and cannulae market shows exportability to overseas suppliers

Niche

- To partner with importer doing business with ROK leading medical institution

Cultural Adaptation

- Understand Korean's purpose of usage of catheter and cannulae
- Understand Korean consumers' quality and price standard for catheter and cannulae

Strategy Snapshot



- To enhance the visibility and exportability of Central American countries' catheter and cannulae to ROK market, it is recommended to use and participate in the various B2B promotional campaigns hosted in ROK on the preferential basis.
- To foster a successful and sustainable export of Central American countries' catheter and cannulae to ROK market, it is recommended to partner with dependable ROK importers who has good relationships and networks with ROK large sized and/or stable medical institutions as final user companies.

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- KOIMA (www.koima.or.kr)
- <https://dart.fss.or.kr/dsaf001/main.do?rcpNo=20231114000598>
- <https://dart.fss.or.kr/dsaf001/main.do?rcpNo=20231114000794>
- <http://www.kmdianews.com/news/articleView.html?idxno=7004>
- <https://www.law.go.kr/LSW/eng/engMain.do?eventGubun=060124>
- Ready Korea (<https://www.readykorea.co.kr/>),
- Korean Law Information Center (<https://www.law.go.kr/>)
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