

## Course Material No.7

# ROK Market Opportunity: Chemicals, Plastics & Rubber, Machinery Parts, Medical Instruments

**Course 7: ROK Market Opportunity – Chemicals, Plastics & Rubber, Machinery Parts, Medical Instruments** aims to provide a comprehensive market overview of industrial products in the Republic of Korea (ROK).

This Course focuses on major products with high export potential from Central America to ROK: **Herbicide**(HS Code 380893), **Plastic Film**(HS Code 392020), **Ignition Wiring Sets for Vehicles** (HS Code 902139), **Catheter and Cannulae**(HS Code 901839), **Breast Implants** (HS Code 902139).

By the end of the course, learners will be able to:

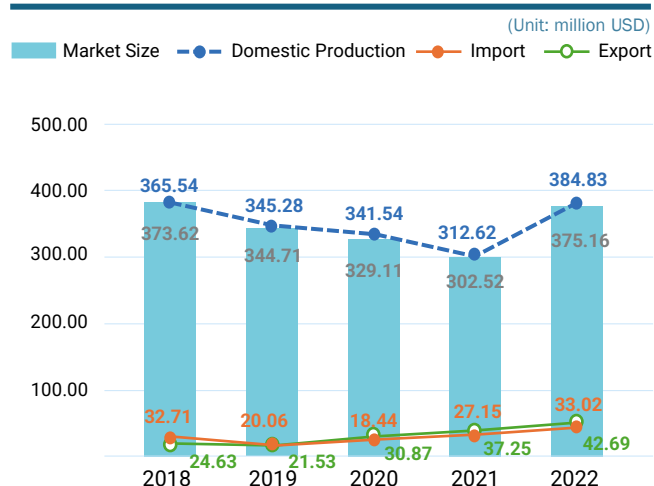
- Understand the ROK market trend and prospect of major products;
- Identify ROK market drivers, competitiveness, opportunities and risks and
- Acknowledge the regulatory requirements for export to ROK market.

## HERBICIDE

### Key Facts

- ❖ The herbicide market shows a relatively stable market size despite a small drop and recovery in 2021 and 2022, and reached 375 million USD in 2022.
  - While the Korean herbicide market appears to heavily rely on domestic production, imports accounted for 23% of total value in 2022 showing a gradual increasing trend.
- ❖ The herbicide market in Korea is largely dominated by imports from Chile, Indonesia, and India, which collectively account for 83% of the total market.
  - Korea's major trade partner, China, benefits from full tariff elimination.

### ROK herbicides market trend in value (2018-2022)



\* Source : Author

### Import volume of Herbicides per country (2018-2022)

(Unit: Ton)

	2018	2019	2020	2021	2022
China	3,001	830	800	1,122	1,769
Indonesia	1,272	0	318	696	636
India	74	137	139	244	611
Malaysia	423	0	396	248	328
USA	102	89	86	125	111
France	59	52	59	66	48
Others	449	250	267	165	111
Total	5,380	1,358	2,065	2,666	3,614

\* Source : Korean Statistical Office(K-STAT)

- ❖ Under the K-CA FTA, all CA countries benefit from the complete elimination of tariffs.

### Tariff on HS Code 380893 as of 2024

Country	HS Code	Product	Current rate(2024)	Elimination of custom duties
Costa Rica	380893.1000	Herbicide	0%	2019.11.01
El Salvador	380893.1000	Herbicide	0%	2020.01.01
Panama	380893.1000	Herbicide	0%	2021.03.01
Honduras	380893.1000	Herbicide	0%	2019.10.01
Nicaragua	380893.1000	Herbicide	0%	2019.10.01
Guatemala	380893.1000	Herbicide	0%	-
China	380893.1000	Herbicide	0%	2015.12.20

\* Source : K-CA FTA text, FTA Korea

- ❖ In ROK herbicide market, the increasing interest in natural and eco-friendly herbicides is underscored by various policy measures, as the agricultural herbicide sector faces significant environmental regulations regarding production amounts, methods, and pricing.
- ❖ To export herbicides to Korea, two import requirements must be addressed in accordance with relevant laws and regulations.
  - First, exporters must have the necessary facilities, equipment, self-inspection officers, and qualified sales managers, along with a business registration certificate.
  - They must prepare a pesticide registration application and samples for testing, which must be submitted to the Rural Development Administration (RDA) for import registration.
  - Second, under the Chemicals Control Act, certain substances, including 2,4,5-T, Trifluralin, Paraquat salts, and 4,5-Dichloro-2-N-octyl-4-isothiazolin-3-one, as well as mixtures containing these substances in concentrations of 1% or more, cannot be imported.
  - Additionally, the background color of the label and the lid of the container must be yellow.

## ▶▶ Market Insights

- ❖ Central American exporters can benefit from tariff reductions under the K-CA FTA, making their herbicide products more competitive in the Korean market.
- ❖ Although the growing consumer preference on eco-friendly products may limit demand for traditional herbicides, the opportunity of supplying high-functionality, high-value products and low-toxicity eco-friendly options could be explored.

### Strengths

- Tariff reductions under the K-CA FTA

### Weaknesses

- Declining total import volumes

### Opportunities

- Underperformance of natural product and remained customs of using chemical herbicides
- Eco-friendly and low toxic herbicide market

### Threats

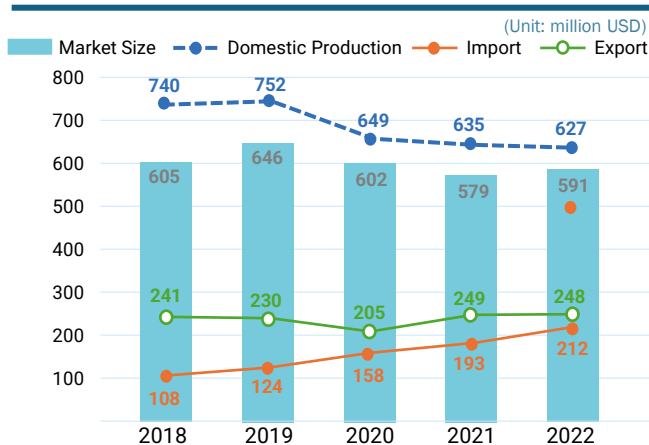
- Dominance of domestic production
- Strong competition from China and India

# PLASTIC FILM

## Key Facts

- ❖ Since 2013, the Korean government imposed anti-dumping tariffs on the plastic film products from China, Indonesia, and Thailand, creating opportunities for entry into the Korean market, a major importer of plastic packaging materials.
- ❖ The annual Plastic Film market maintained an average size of 600 million USD between 2018 and 2022.
  - Overall, the market is largely self-sufficient by domestic plastic film production,
- ❖ Currently, the major suppliers of plastic film to Korea are China, Indonesia, and Japan, accounting for 63% of the total imports.
  - China and Indonesia, the largest exporters of plastic film, benefit from full tariff elimination.

### ROK plastic film market trend in value (2018-2022)



\* Source : Author

### Import volume of plastic film per country (2018-2022)

(Unit: Ton)

	2018	2019	2020	2021	2022
China	7,104	8,546	11,113	17,599	18,705
Indonesia	3,236	3,183	3,715	4,459	4,309
Japan	3,800	3,990	3,654	3,175	3,216
India	3,099	4,248	4,492	5,324	2,741
Philippine	4,072	2,994	2,007	2,595	2,715
Malaysia	1,616	1,386	2,320	2,941	2,539
Thailand	1,834	2,086	2,165	2,472	2,309
Others	6,521	5,690	5,896	5,566	5,207
<b>Total</b>	<b>31,282</b>	<b>32,123</b>	<b>33,362</b>	<b>44,131</b>	<b>41,741</b>

\* Source : Korean Statistical Office(K-STAT)

- ❖ Under the K-CA FTA, all CA countries benefit from the complete elimination of tariffs.

### Tariff on HS Code 392020 as of 2024

Country	HS Code	Product	Current rate(2024)	Elimination of custom duties
Costa Rica	392020.0000	Plastic Film	0%	2019.11.01
El Salvador	392020.0000	Plastic Film	0%	2020.01.01
Panama	392020.0000	Plastic Film	0%	2021.03.01
Honduras	392020.0000	Plastic Film	0%	2019.10.01
Nicaragua	392020.0000	Plastic Film	0%	2019.10.01
Guatemala	392020.0000	Plastic Film	0%	-
China	392020.0000	Plastic Film	0~25.04%	2019.01.01
Indonesia	392020.0000	Plastic Film	0~25.04%	2023.01.01

\* Source : K-CA FTA text, FTA Korea

- ❖ Recognizing the serious impact of plastic use on the climate crisis and waste generation, Korean consumers are avoiding plastic packaging, and the government is actively engaging in ESG management.
  - There is a growing demand for biodegradable plastics, recyclable plastics, and related technologies, leading to new regulations for environmental protection.

### Korean government's measures to remove plastics for Circular Economy

ROK goals: Reduce Plastic waste by 20% until 2025			
Reduce	<ul style="list-style-type: none"> <li>Reduce excessive wrapping</li> <li>Offer alternative options</li> <li>Offer incentives to customers</li> </ul>	Recycle	<ul style="list-style-type: none"> <li>Offer plastic waste to be reproduced</li> <li>Promote recycle</li> </ul>
Recyclate	<ul style="list-style-type: none"> <li>Support develop recyclate materials (regradable)</li> <li>Promot new technology, business</li> </ul>	Account ability	<ul style="list-style-type: none"> <li>Proactively lead int'l agreements for removing plastics</li> </ul>

- ❖ Nevertheless, Korea remains one of the top 20 global importers of plastic packaging materials.
  - The rising popularity of Home Meal Replacement (HMR) products and food delivery has significantly contributed to the surge in demand for plastic film used in food packaging.



- ❖ Plastic film and foil used in the food industry must undergo precise inspection by the Commissioner of the Ministry of Food and Drug Safety (MFDS).
  - Before importation, the overseas manufacturing facility operator or importer must submit documents, including a foreign factory registration certificate, to register the overseas manufacturing facility with the MFDS.
- ❖ Once the registration of the overseas manufacturing facility is completed, the importer must proceed with business registration for importing and selling.
  - After passing the MFDS precise inspection, proper customs clearance procedures can be initiated.

## ▶▶ Market Insights

- ❖ A social trend to reduce plastic use is emerging, which is anticipated to lead to a decline of the plastic market.
- ❖ While domestic production of plastics is decreasing, it remains significantly larger than imports, with domestic production valued at 630 million USD, compared to imports valued at 210 million USD.
- ❖ Small businesses tend to be less sensitive to government regulations and shifting social trends, presenting opportunities for Central America exporters to secure long-term contracts.
  - To successfully enter the Korean plastic market, targeting small business, such as individual coffee shops and restaurants, is crucial.
  - In fact, the top 10 exporters primarily supply these smaller establishments.
- ❖ Additionally, the growing demand for the mono-materialization of polypropylene(PP) or polyethylene(PE) for resource recycling is expected to enhance the popularity of BOPP(Biaxially Oriented Polypropylene) films, which can be recycled without emitting harmful substances.

### Strengths

- Tariff reductions under the K-CA FTA

### Opportunities

- Sustained demand from smaller businesses
- Increased interest in recyclable BOPP films

### Weaknesses

- Trend towards reduced plastic use

### Threats

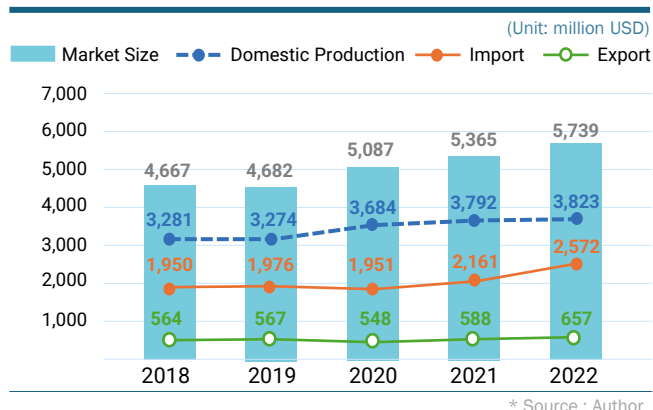
- Still a high level of domestic production

# IGNITION WIRING SETS FOR VEHICLES

## Key Facts

- ❖ The ignition wiring sets market is expected to grow steadily, driven by electric vehicles growing at 37.7% annually, from 1.28 billion USD in 2021 to 6.33 billion USD by 2026.
- ❖ Annual ignition wiring sets market size in value has shown an annual growth rate of 5.35% rising from 4.67 billion USD in 2018 to 5.74 billion USD in 2022.
  - Domestic production accounts for 66.61% of total market value in 2022. While imports represent a significant portion, accounting for 45%, exports constitute a smaller proportion, making up 11%.
  - It indicates that the majority of wiring sets consume in the market are produced domestically with only small amounts are exported.
  - This suggests a balance between imported and domestically produced wiring sets, with the local manufacturing sector playing a crucial role in meeting domestic demand.
- ❖ The imported ignition wiring market in Korea is largely dominated by China, Vietnam, and the Philippines, which collectively account for 97% of the total market.
  - China, as the largest exporter, will benefit from full tariff elimination starting in 2024.

### ROK ignition wiring sets in value (2018-2022)



### Import volume of Ignition wiring sets per country (2018-2022)

(Unit: Ton)

	2018	2019	2020	2021	2022
China	94,830	92,460	84,687	86,450	88,584
Vietnam	3,778	5,767	7,724	11,202	19,756
Philippine	2,346	3,245	9,159	8,734	11,100
Cambodia	1,836	1,731	1,561	1,785	2,266
Romania	22	18	19	299	544
India	71	123	109	138	236
Spain	5	31	35	82	131
Turkey	3	8	5	37	70
Hungary	4	2	15	42	47
Others	243	242	224	167	220
<b>Total</b>	<b>103,137</b>	<b>103,616</b>	<b>103,538</b>	<b>108,937</b>	<b>122,953</b>

\* Source : Korean Statistical Office(K-STAT)

- ❖ The K-CA FTA is expected to provide significant benefits to Central American countries through reduced tariffs, with all participating countries—including Guatemala—set to enjoy these advantages by 2026.

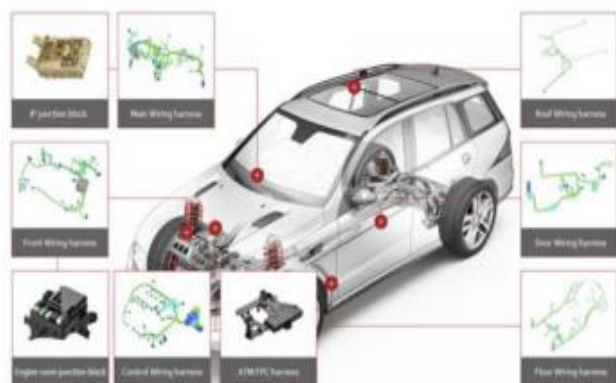
### Tariff on HS Code 854430 as of 2024

Country	HS Code	Product	Current rate(2024)	Elimination of custom duties
Costa Rica	854430.0000	Ignition Wiring sets for Vehicles	0%	2021.01.01
El Salvador	854430.0000	Ignition Wiring sets for Vehicles	0%	2022.01.01
Panama	854430.0000	Ignition Wiring sets for Vehicles	0%	2023.01.01
Honduras	854430.0000	Ignition Wiring sets for Vehicles	0%	2019.10.01
Nicaragua	854430.0000	Ignition Wiring sets for Vehicles	0%	2021.01.01
Guatemala	854430.0000	Ignition Wiring sets for Vehicles	5.33%	2026.01.01
China	854430.0000	Ignition Wiring sets for Vehicles	0%	2024.01.01

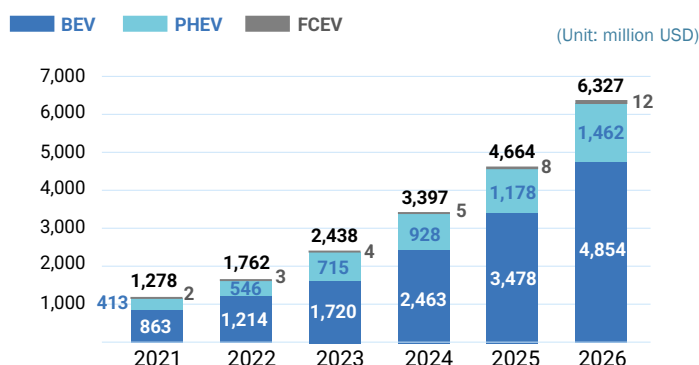
\* Source : K-CA FTA text, FTA Korea

- ❖ The global electric vehicle ignition wiring set (wiring harness) market is expected to grow from 1.28 billion USD in 2021 to 6.33 billion USD by 2026.
- Electric vehicles require about 30% more ignition wiring than conventional vehicles, and research on lightweight solutions using Flexible Printed Circuit Boards(FPCB) is currently underway.

## Wiring Harness Used in Automobiles



## Wiring harness market size forecast by electric vehicle type



\* Source : Korea IR Council. (2023.07) Daewon Cable Company Analysis; Yura Corporation website. (Year unknown). Company Overview

\* Source : Markets and Markets. Korea IR Council Research Center

- ❖ Given the extensive manual labor required, Korea's imports are typically conducted through Korean companies' overseas factories, resulting in a highly competitive and closed market. Entering this industry necessitates technological capabilities, production capacity, and established relationships with vehicle manufacturers.
- Large companies generally produce engines and transmissions, medium-sized firms manufacture functional parts, while smaller businesses often subcontract for simpler components.

## Market Insights

- ❖ Korea ignition wiring sets market is expected to grow rapidly, with an average annual growth rate of 37.7% by 2026. Most importantly, the K-CA FTA enhances this opportunity by fully eliminating tariffs.
- ❖ Korea's automotive parts industry has developed strong vertical integration with vehicle manufacturers, making long-term relationships with promising buyers essential for success.
- ❖ As electric vehicles (EVs) require approximately 30% more wiring than conventional vehicles, the demand for ignition wiring harness sets is expected to increase alongside the growth of the EV market.

### Strengths

- Anticipated rapid market growth by 2026
- Tariff reductions under the K-CA FTA

### Weaknesses

- Necessity of building long-term partnerships in a competitive environment

### Opportunities

- Increased demand driven by the wiring requirements of electric vehicles

### Threats

- Strong competition from major ignition wiring sets exporters in China, Vietnam, and the Philippines.

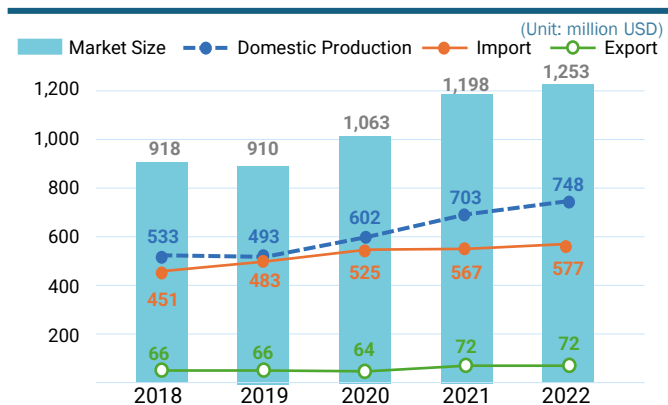


# CATHETER AND CANNULAE

## Key Facts

- ❖ The increasing aged population and advanced medical technologies, as well as increased income level have led to a sustained the rise of demand for medical instruments, such as catheter and cannulae.
- ❖ The annual market size for catheters and cannulae has shown a growth rate of 8.31%, rising from 918 million USD in 2018 to 1.25 billion USD in 2022.
- ❖ Major suppliers, including China, Vietnam, and Philippines, control 48% of the medical instruments market.
  - China and Vietnam, as the largest exporter of medical instruments, benefit from full tariff elimination.

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



\* Source : Author

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

	2018	2019	2020	2021	2022
China	2,599	2,861	3,122	3,374	4,025
Vietnam	1,902	2,419	2,665	2,519	3,094
Philippine	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
<b>Total</b>	<b>13,350</b>	<b>14,386</b>	<b>14,885</b>	<b>15,367</b>	<b>17,482</b>

\* Source : Korean Statistical Office(K-STAT)

- ❖ The CA countries have a comparative advantage due to the lower tariffs applied to medical instruments.
  - The K-CA FTA is expected to further benefit CA countries by reducing tariffs, with full elimination anticipated for Nicaragua by 2025, and Guatemala by 2026.

## Tariff on HS Code 901839 as of 2024

Country	HS Code	Product	Current rate (2024)	Elimination of custom duties
Costa Rica	9001839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2021.01.01
	9001839.2000	Catheters(medical, surgical, dental or veterinary)	0%	2019.11.01
	9001839.9000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2021.01.01
El Salvador	9001839.1000	Catheters(medical, surgical, dental or veterinary)	0%	2022.01.01
	9001839.2000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2022.01.01
	9001839.9000	Catheters(medical, surgical, dental or veterinary)	0%	2022.01.01
Panama	9001839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2023.01.01
	9001839.2000	Catheters(medical, surgical, dental or veterinary)	0%	2023.01.01
	9001839.9000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2023.01.01
Honduras	9001839.1000	Catheters(medical, surgical, dental or veterinary)	0%	2021.01.01
	9001839.2000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2021.01.01
	9001839.9000	Catheters(medical, surgical, dental or veterinary)	0%	2021.01.01
Nicaragua	9001839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2021.01.01
	9001839.2000	Catheters(medical, surgical, dental or veterinary)	0%	2021.01.01
	9001839.9000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2021.01.01
Guatemala	9001839.1000	Catheters(medical, surgical, dental or veterinary)	5.33%	2025.01.01
	9001839.2000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	5.33%	2025.01.01
	9001839.9000	Catheters(medical, surgical, dental or veterinary)	5.33%	2026.01.01
China	9001839.1000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2024.01.01
	9001839.2000	Catheters(medical, surgical, dental or veterinary)	0%	2024.01.01
	9001839.9000	Blood transfusion set or intravenous set (medical, surgical, dental or veterinary)	0%	2024.01.01

\* Source : K-CA FTA text, FTA Korea

- ❖ According to Health Insurance Review & Assessment Service and the National Health Insurance Service, the per capita medical expenses for the citizens increased from 7.41 million USD in 2018 to 5.03 million USD in 2022, representing an increase of about 30 percent
  - 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, indicating two-fold increase.
- ❖ Eco-friendly products are becoming increasingly popular in the medical device market.
  - For example, Medi Line Active Korea has developed the first liquid infusion set made from eco-friendly polyurethane.
- ❖ In the case of catheters, targeted products are being introduced.
  - Medtronic has created a drug-coated balloon catheter (IN.PACT™ AV DCB) that effectively treats blockages in hemodialysis patients.
  - Also, the Ministry of Food and Drug Safety has designated "vascular tubes and catheters for cardiovascular surgery" as urgently needed medical devices for children with heart conditions.

### Sample image of Catheter and Cannulae

Catheter



Cannulae



\* Source: E-Daily. (Jul. 2023).2; The Kukmin Ilbo. (Feb. 2021); Health Chosun. (Jul. 2023)

## Market Insights

- ❖ The medical device market in Korea is experiencing stable growth, supported by rising income levels and an aging population.
- ❖ This trend is further enhanced by the K-CA FTA enhances this opportunity by fully eliminating tariffs.
- ❖ Given the nature of medical devices, which directly or indirectly contact the human body, they are subject to rigorous regulations to ensure safety and efficacy.
- ❖ Competition in this sector is intense, with both global companies operating in Korea and domestic small and medium-sized enterprises vying for market share.
- ❖ Yet, there remains a significant opportunity in the import market, particularly for products like blood transfusion sets and catheters, where import shares are relatively high. This trends indicates a growing acceptance of imported medical devices, making it a promising area for expansion.

### Strengths

- A stable and promising market for medical devices in Korea for global exporters.
- Tariff reductions under the K-CA FTA

### Opportunities

- Consistent upward trend over the past five years.
- Relatively high import ratio compared to other product in ROK markets

### Weaknesses

- Strict regulations and quality standards

### Threats

- Strong competition between global companies and domestic small and medium-sized enterprises
- Price competition from major exporting countries

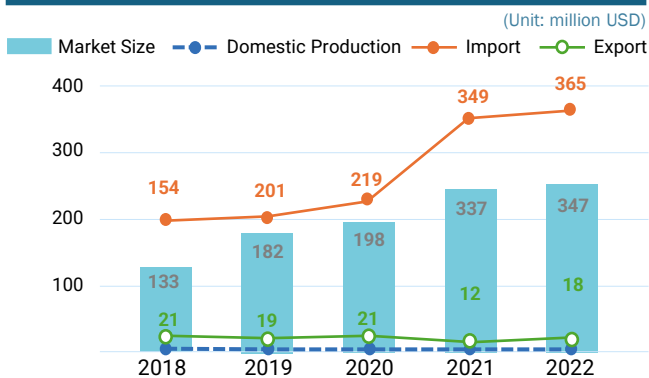


# BREAST IMPLANTS

## Key Facts

- ❖ Over the past 25 years, the number of Korean surgeries has increased ninefold. This trend creates greater opportunities for breast implants suppliers.
- ❖ The annual market size for breast implants has shown an impressive growth rate of 29.7%, rising from 183 million USD in 2018 to 347 million USD in 2022.
  - The share of domestically produced breast implants is nearly zero, indicating a complete dependence on imports.
- ❖ The breast implants market in Korea is largely dominated by imports from the U.S., Costa Rica, and Singapore which account for 73% of the total market.
  - The U.S. and Ireland, as the largest exporters, benefit from a 0% tariff rate under the KOR-US FTA and the Korea-EU FTA.

### ROK breast implants market in value (2018-2022)



\* Source : Author

### Import volume of Prosthesis or artificial parts of the body per country (2018-2022)

(Unit: Ton)

	2018	2019	2020	2021	2022
USA	65	71	71	82	80
Costa Rica	16	12	14	27	44
Singapore	3	4	9	12	18
Ireland	0	1	1	2	10
France	17	13	6	12	10
Germany	10	9	13	11	9
Netherlands	10	9	4	12	9
Others	20	21	25	26	15
Total	141	140	143	184	195

\* Source : Korean Statistical Office(K-STAT)

- ❖ Under the K-CA FTA, all CA countries benefit from the complete elimination of tariffs.

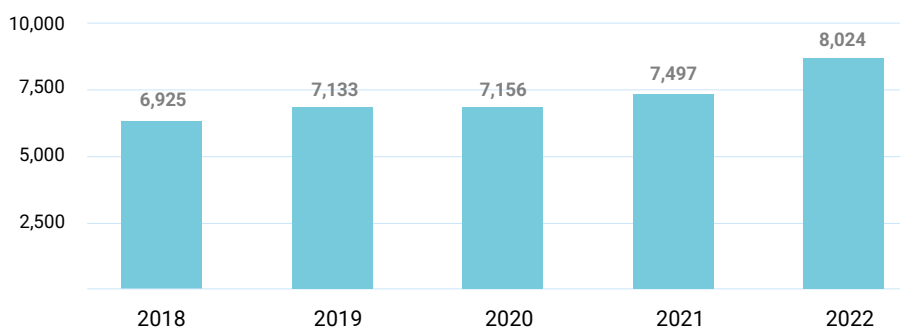
### Tariff on HS Code 902139 as of 2024

Country	HS Code	Product	Current rate (2024)	Elimination of custom duties
Costa Rica	902139.0000	Breast Implants	0%	2019.11.01
El Salvador	902139.0000	Breast Implants	0%	2020.01.01
Panama	902139.0000	Breast Implants	0%	2021.03.01
Honduras	902139.0000	Breast Implants	0%	2019.10.01
Nicaragua	902139.0000	Breast Implants	0%	2019.10.01
Guatemala	902139.0000	Breast Implants	0%	-
USA	902139.0000	Breast Implants	0%	-
Indonesia	902139.0000	Breast Implants	0%	-

\* Source : K-CA FTA text, FTA Korea

- ❖ Breast cancer has emerged as the most common cancer among Korean women, leading to a noticeable increase in preventive mastectomies.
  - Interest in mastectomy has increased for oncological safety, with the number of preventive mastectomies rising significantly.
  - Additionally, a health insurance policy that began subsidizing 50% of reconstruction surgery costs in 2015 has significantly increased the demand for post-mastectomy reconstruction surgeries.

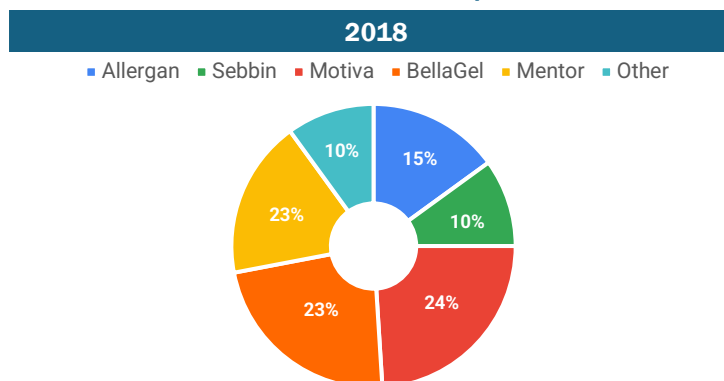
### Breast Reconstruction Patient Count in Korea



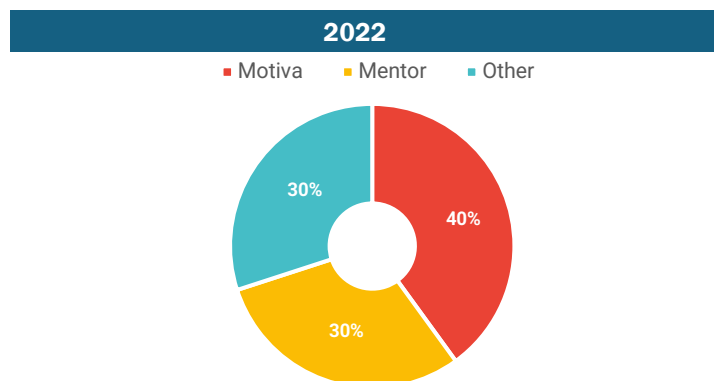
\* Source : Health Insurance Review and Assessment Service (HIRA), 2023

- ❖ Major brands like Motiva and BellaGel are leading the market, with consumer preferences highlighting product awareness and minimal side effects.
- Domestic companies such as HansBioMed are making strides by offering innovative products like BellaGel Smooth Fine, which provide significant advantages in texture and safety.

### Domestic Market Share of Breast Implant Brands (2018 and 2022)

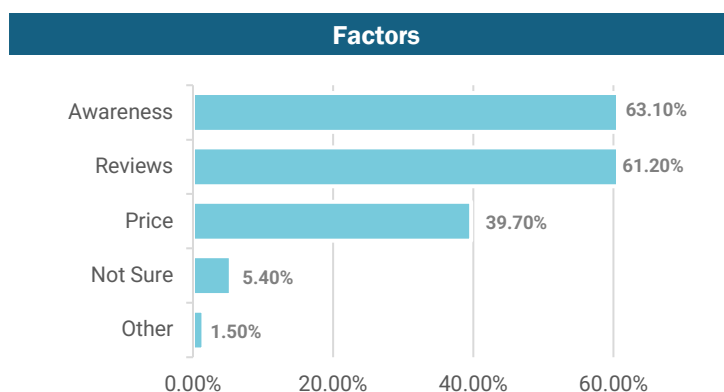


\* Source : Shinhan Securities, 2023

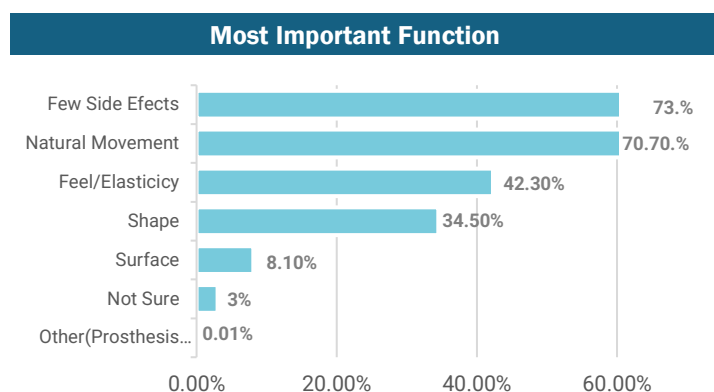


\* Source : Shinhan Securities, 2023

### Factors Considered When Choosing Implants



\* Source : Maekyung Health, 2021



\* Source : Maekyung Health, 2021

## Market Insights

- ❖ Korea has a deep-rooted culture of cosmetic surgery, which fosters a supportive environment for the domestic breast implant market.
- ❖ With a rising number of breast cancer patients among Korean women, there is a growing demand not only for treatment but also for restoring procedures to help patients regain their previous normal appearance.
- ❖ Most importantly, the K-CA FTA enhances this opportunity by fully eliminating tariffs.
- ❖ However, concerns about breast surgery persist. Many individuals are aware of potential health risks and the negative impacts such procedures may have on childbirth and breastfeeding.
- ❖ The regulatory landscape for medical devices in Korea is complex, presenting challenges to enter the market.
- ❖ Established foreign brands like Motiva and Mentor have made significant inroads in Korea.

### Strengths

- Cultural acceptance of breast surgery
- Tariff reduction of CA product under the K-CA FTA

### Weaknesses

- Awareness of the negative impacts of surgery
- Complex medical device regulations

### Opportunities

- Growing demand for breast surgery for health and esthetics reasons

### Threats

- Competition from established foreign brands
- Strengthening domestic brand competitiveness

## ▶▶ Import Regulations and Process

- ❖ Central American exporters must thoroughly review the relevant import regulations and processes
  - Exporters looking to export medical instruments are required to apply for an import business license from the Ministry of Food and Drug Safety (MFDS).
  - Once the import license is approved, it's necessary to submit technical documents, clinical trial data, or review results to apply for import certification.
  - Following the receipt of import certification or permission, a Korean label must be prepared to attach to the container or packaging of the medical device.

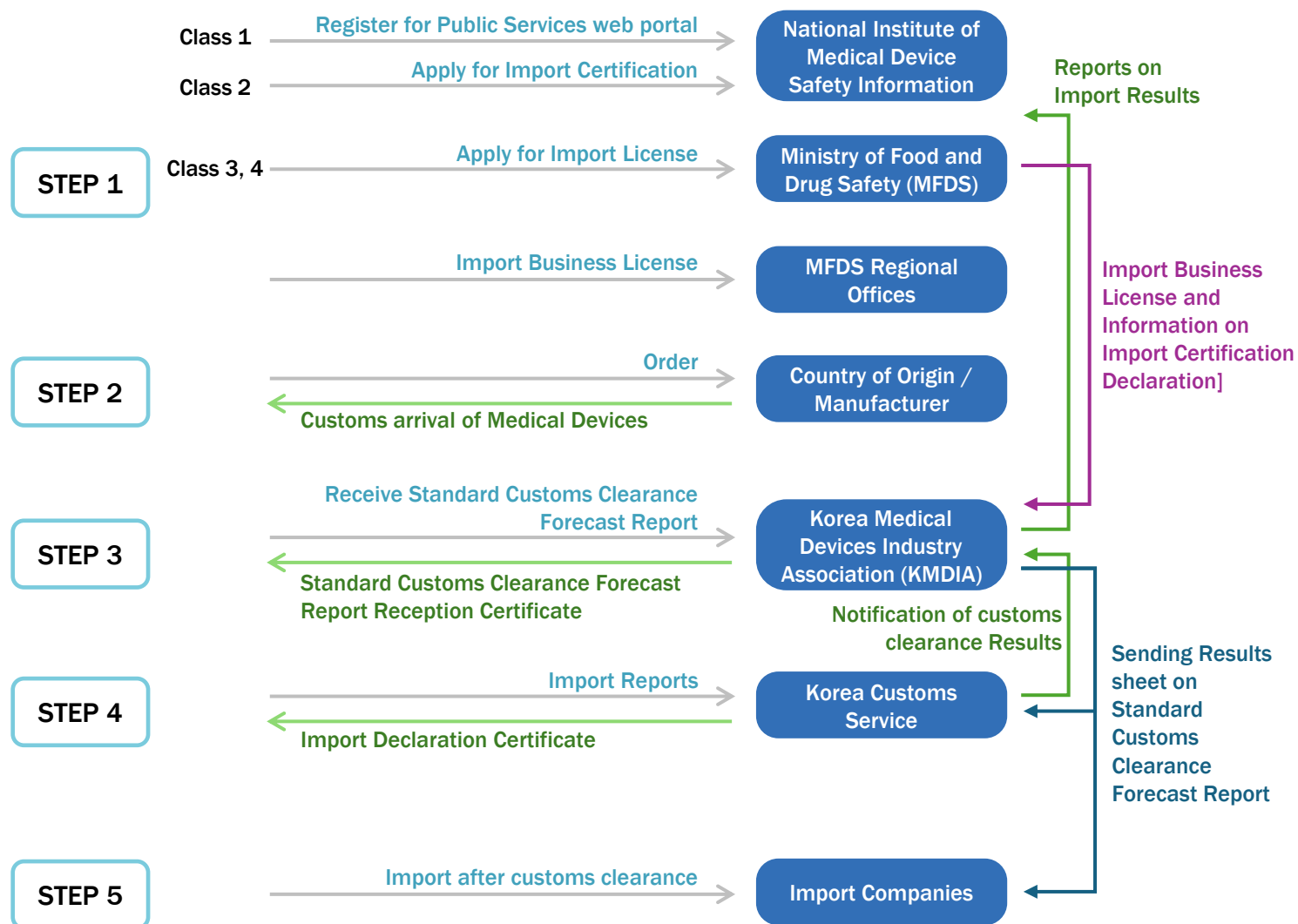
### Labeling Requirements for Medical Devices

Label Location	Details
Labeling on Containers	<ol style="list-style-type: none"> <li>1. The trade name and address of the manufacturer or importer;</li> <li>2. If imported, the origin of manufacture (the name of the country of manufacture and of the manufacturer).</li> <li>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;</li> <li>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);</li> <li>5. Weight or packaging unit;</li> <li>6. A label stating "medical device";</li> <li>7. A "single-use only" and "do not reuse" label for a single-use medical device;</li> <li>8. Medical device standard code prescribed by the Minister of Food and Drug Safety, in consultation with the Minister of Health and Welfare;</li> <li>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)</li> </ol>
Labeling on Outer Package	<ol style="list-style-type: none"> <li>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</li> </ol>
Labeling on Package Inserts	<ol style="list-style-type: none"> <li>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"> <li>a. The method of, and precautions for, use;</li> <li>b. Instructions for maintenance and inspections, if maintenance and inspections are required;</li> <li>c. Matters that the Minister of Food and Drug Safety requires to be described pursuant to Article 19;</li> <li>d. Other matters prescribed by Ordinance of the Prime Minister.</li> </ol> </li> <li>2. The package inserts under paragraph (1) may be furnished in any of the following forms:           <ol style="list-style-type: none"> <li>a. USB, CD-ROM, or other electronic media;</li> <li>b. Printed manual (paper, booklet, etc.);</li> <li>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).</li> </ol> </li> </ol>

\* Source: Korean Law Information Center, Medical Devices Act

- ❖ After completing all preparations, a standard customs clearance forecast report must be submitted to the Korea Medical Devices Industry Association based on the shipment documents. This will allow for the issuance of an ENTRY NOTICE OF IMPORTED PRODUCTS to proceed with customs clearance.

## Import Process of Medical Device



## Labeling

- ❖ Proper Labeling requires a Korean label with specific details, including product name, country of origin, production or packaging date, and importer information to ensure transparency and consumer safety.

### Information to be included in the Product label

Product Name	
Raw ingredients and contents	
Country of Origin	
Date of production or date of packaging	
Packaging Material	
Storage Method	
Name and Location of the Importer	
Import sales business contact information	
Returns and exchanges information	

We look forward to supporting your success in the ROK market.