ROK Market Brief No.21

Breast Implant 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 breast implant category that benefit from tariff reductions under the K-CA FTA and have market access.

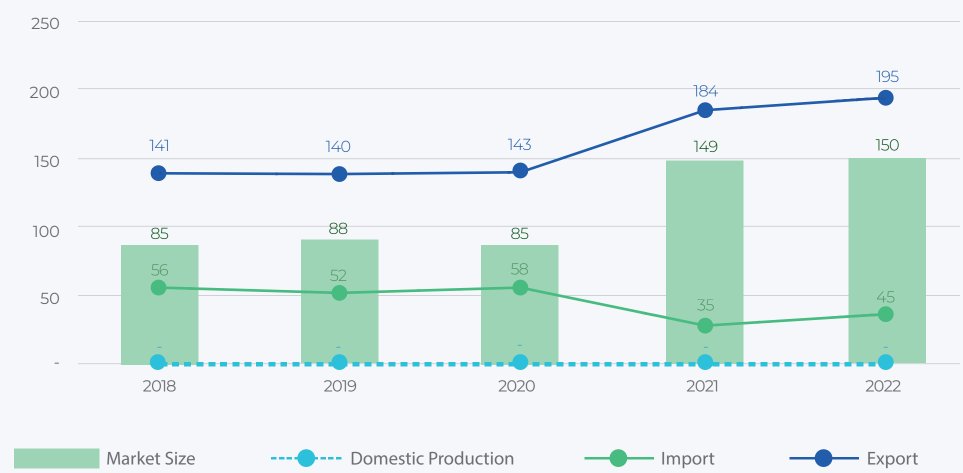
Market Snapshot

The size of the ROK breast implants market has shown a moderate growth trend in the recent years. In terms of volume, the market remained relatively stable from 2018 to 2020 and the overall trend suggests growth in demand for these products with a notable increase showing an annual growth rate of 19.02%. In terms of value, the market size gradually increased from $133 million USD in 2018 to $347 million USD in 2022 with 29.7% annual growth rate.

Out of total ROK breast implants market, the proportion of import is very significant, accounting for 130% in volume and 105% in value as of 2022. Conversely, the contribution of exports is also meaningful, accounting for 30% in volume and 5% in value as of 2022, whereas the proportion of the domestically produced breast implant product is almost non-existent.

Figure 1. ROK breast implants market in volume (2018-2022)

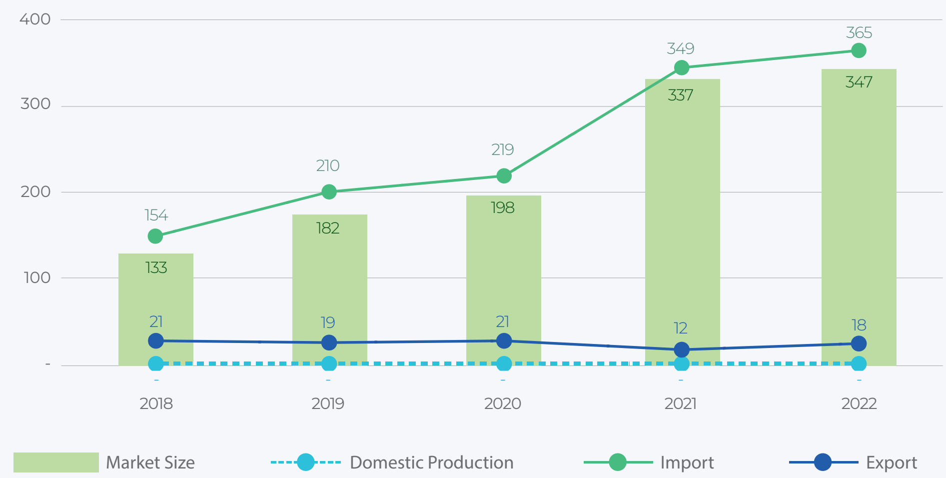
(Unit: Ton)



Source) Korea Customs Service Import and Export Statistics (2023)
Note1) Market Size = (Domestic production+Import) – Export
Note2) The absence of domestic production data for 2022 has led to its representation as zero on the chart.

Figure 2. ROK breast implants market in value (2018-2022)

(Unit: million USD)



Source) Korea Customs Service Import and Export Statistics (2023)
Note 1) Market Size = (Domestic production+Import) – Export
Note 2) The absence of domestic production data for 2022 has led to its representation as zero on the chart.

The ROK breast implant market size from 2018 to 2022 has dramatically increased at the average annual growth rate of 29.70% in value and 19.02% in volume; hence, when it comes to an annual growth rate of the market size, it is estimated that the market size will grow at 20% in volume and 25% in value for the next 5 years from 2022 to 2027. With heavy reliance on the import, the overall market size as well as the import size are expected to remain the similar upward trend.

The primary competitors in the Korean market for orthopedic appliances are the USA and Ireland, holding a significant position as leading exporters. Together, the two countries account for approximately 59% of the total orthopedic appliances' imports to Korea in terms of volume in 2022. Notably, similar to the Central American countries under the K-CA FTA, both the USA and Ireland enjoy a 0% tariff rate when exporting breast prosthesis under the KOR-US FTA and Korea-EU FTA respectively.

Hence, understanding the tariff structure is essential for Central American exporters looking to establish a foothold in the ROK market. All the K-CA FTA applied countries, but for Guatemala, have a comparative advantage due to lower tariffs on breast implant. The detailed tariffs are described in the table below:

Table 1. Tariff on HS Code 902139 as of 2024

Country	HS Code	WTO bound rate	Current rate (2024)	Elimination of custom duties[1]
Costa Rica	902139.0000	0%	0%	2019.11.01
El Salvador	902139.0000	0%	0%	2020.01.01
Panama	902139.0000	0%	0%	2021.03.01
Honduras	902139.0000	0%	0%	2019.10.01
Nicaragua	902139.0000	0%	0%	2019.10.01
Guatemala	902139.0000	0%	0%	-
USA	902139.0000	0%	0%	-
Ireland	902139.0000	0%	0%	-

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

[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.

Competitive Landscape

In ROK breast implant market, the top countries of origin for imported breast implants (HS code: 902139), in terms of import volume, the USA, Costa Rica, and Singapore are the major suppliers accounting for 73% of total breast implants imports. The detailed import statistics in volume from 2018 to 2022 is presented in the table below.

Table 2. 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
Austria	2	4	3	3	3
China	2	5	5	7	2
Others	16	12	17	16	10
Total	141	140	143	184	195

Source) Customs and Excise Department import and export statistics (2023); Export and import performance

Within imported products, American products show the strongest occupancy over the past five years. This can be attributed to several factors: First, USA-based breast prothesis company, Motiva, has maintained its firm market share in ROK since 2016. Second, as a similar point, Costa Rica-based company Mentor also showed high and steady share in the ROK breast implant product market.

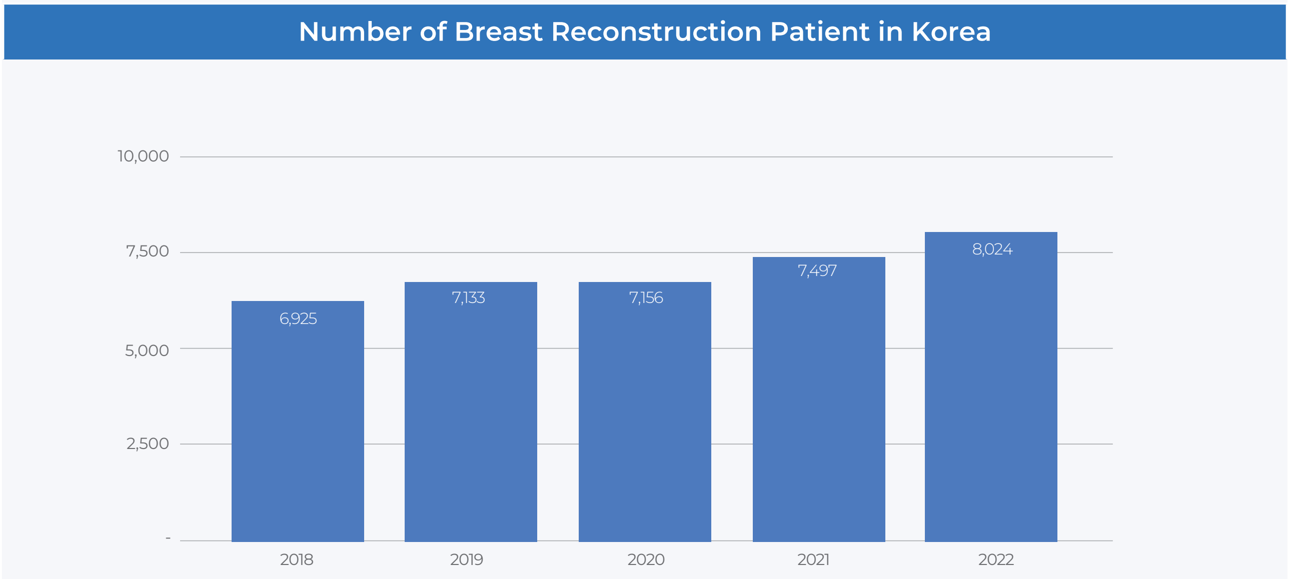
Consumer Preference

According to JoongAng in 2023, breast cancer emerged as the leading cancer among Korean women. By 2019, breast cancer constituted 24.6% of all female cancers in Korea, establishing itself as the predominant cancer in women since 2016.

A global trend has also emerged in having breast cancer surgery for the patients, shifting from traditional breast-conserving procedures to mastectomy. The transition from conservation to resection for oncological safety has naturally sparked heightened interest and demand for post-mastectomy reconstruction. This procedure significantly enhances the quality of life for women, among other benefits. Preventive mastectomy has seen a notable surge in South Korea as well.

According to the Korean Hereditary Breast Cancer Study (KOHBRA), there has been a conspicuous increase in the number of preventive mastectomies for individuals with BRCA mutations, escalating from 5 cases in 2013 to 29 cases in 2017, marking a 5.8-fold increase. Then, the domestic rate of breast reconstruction surgery has experienced a noteworthy increase over the past years. There was a 15.87% increase in the number of breast reconstruction patients, rising from 6,925 in 2018 to 8,024 by 2022. This upward trend persisted each year over the five-year span, as seen below.

Figure 3. Breast Reconstruction Patient Count in Korea



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

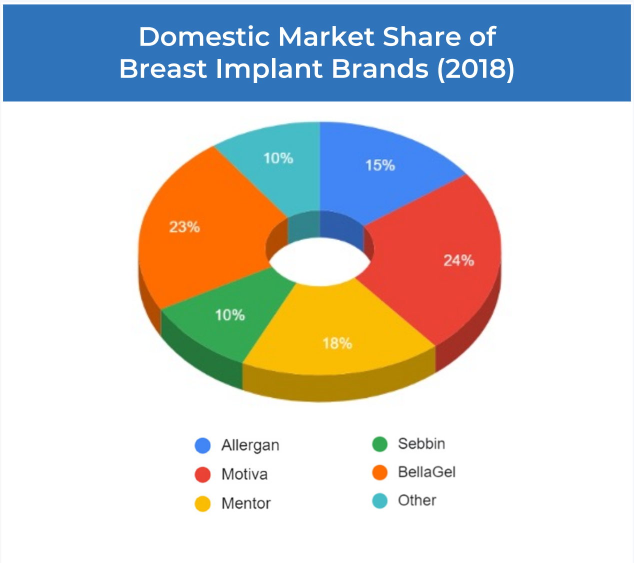
The surge in demand for breast surgery can also be attributed to the inclusion of insurance coverage for patients in need of breast reconstruction, particularly those with conditions like breast cancer since April 2015. In 2021, Medical Times reported that the landscape of breast cancer surgery methods, follow-up therapy, and even breast reconstruction surgery is undergoing a complete transformation influenced by the domestic health insurance benefit policy.

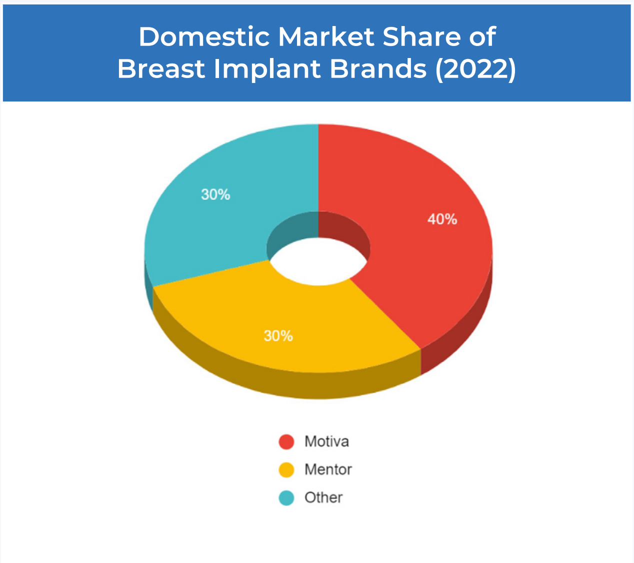
When examining 2,897 patients who underwent mastectomy for primary breast cancer between April 2011 and June 2016, researchers identified that the changes observed were indeed linked to the health insurance benefit policy. The government's decision to subsidize 50% of the reconstruction surgery costs for breast cancer patients starting in 2015 played a crucial role in transforming the sector, mostly because the surgical aspects and follow-up measures were markedly different between patients who received benefits and those who did not. For instance, patients with insurance benefits were more likely to undergo skin-sparing mastectomy (SSM) compared to those without benefits. A similar trend was observed in breast reconstruction surgery, where 39.8% of patients with insurance benefits underwent immediate reconstruction, while the non-benefit group was only at 30%. This trend was particularly noticeable among younger patients.

As of July 2017, products with import or manufacturing permits from the Ministry of Food and Drug Safety encompassed offerings from a total of seven companies: Allergan (Allergan is no longer distributed in Korea due to rare cancer issues.), Mentor, Polytech, Sebbin, Silimed, Eurosilicone, BellaGel, and Motiva.

In 2018, the Korean breast implant market was primarily led by Motiva, capturing a dominant share of 24%, closely followed by BellaGel, which secured a noteworthy 23% share. However, in 2022, the number of product lines in the ROK market decreased with Motiva continuing to dominate with a 40% share, retaining its top position:

Figure 4. Domestic Market Share of Breast Implant Brands (2018 and 2022)

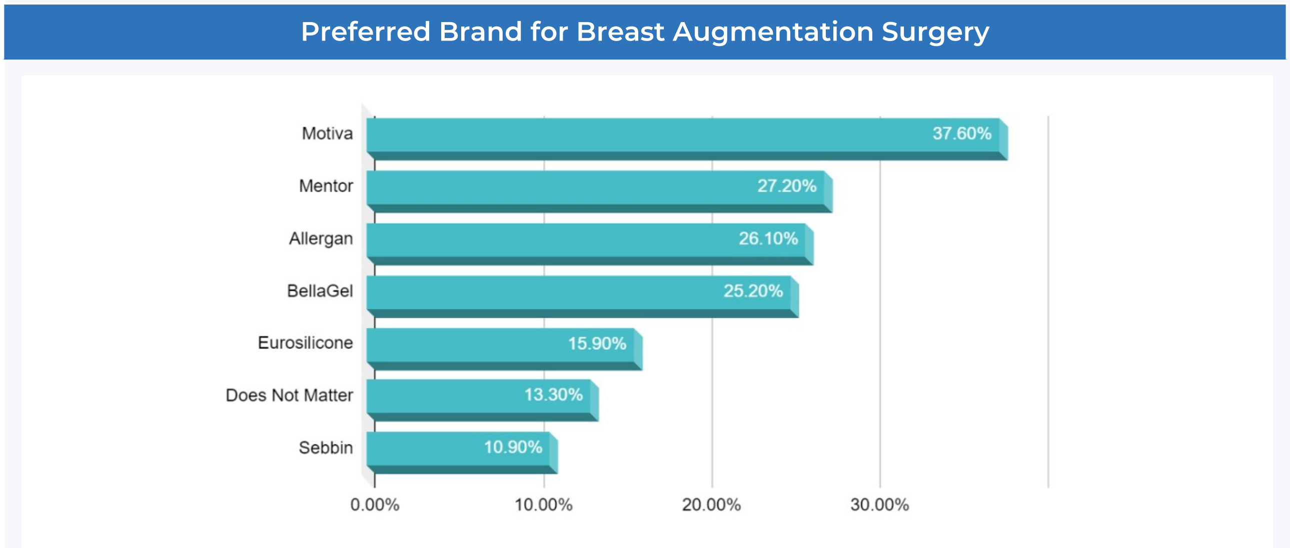




Source) KIMS Online, 2019

Regarding consumer perception, Motiva emerged as the top choice among Maekyung Health readers when asked about their preferred breast implant brand for potential breast augmentation surgery. Mentor secured the second position, demonstrating a correlation between consumer perception and the actual domestic market share:

Figure 5. Preferred Brand for Breast Augmentation Surgery



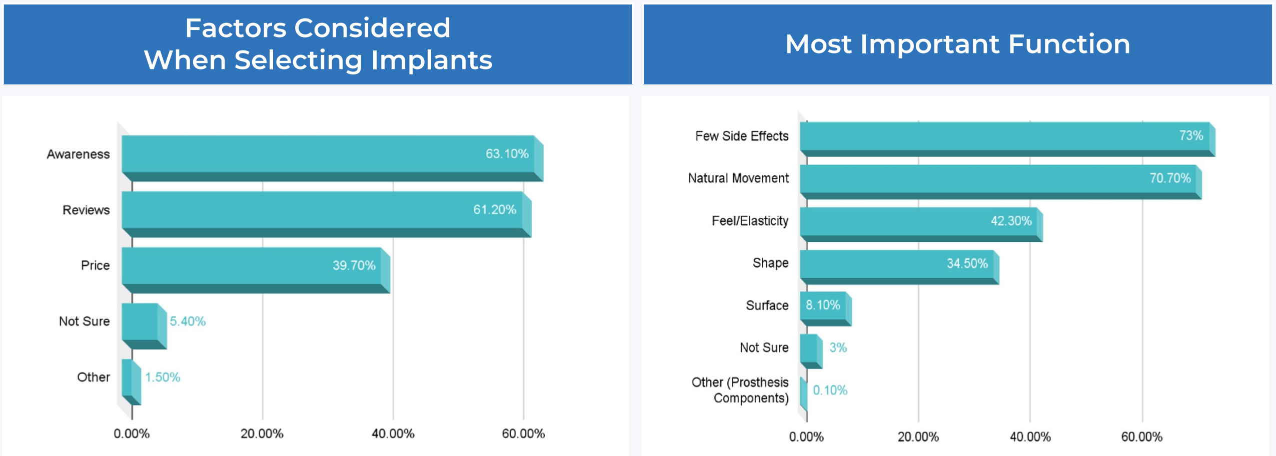
Source) KIMS Online, 2019

Note) Multiple selections possible

Based on the aforenamed Maekyung Health survey, respondents were asked about the factors influencing their choice of implants. The majority, 63.1%, selected product awareness as the primary indicator, while product reviews followed closely at 61.2%. Individuals in their 40s and 50s prioritized awareness, while those in their 20s to 40s focused on reviews. Additionally, respondents in their 20s emphasized price more compared to other age groups.

As for the most crucial function of the implant, respondents chose minimal side effects the most, ranking highest at 73%. Following closely, natural movement ranked as the second most important factor, with a selection rate of 70.7%. Regarding age groups, individuals in their 20s emphasized the shape of the implant, while those in their 30s and 40s stressed minimal side effects. For respondents in their 50s, natural movement appeared to be more significant than side effects:

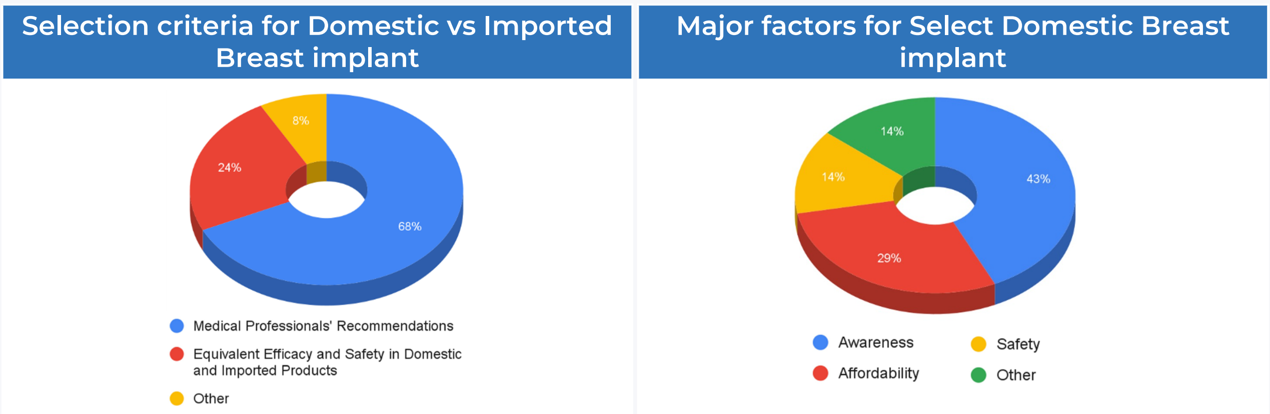
Figure 6. Factors Considered When Choosing Implants



Source) KIMS Online, 2019
Note) Multiple selections possible

According to a survey by KIMS Online, there was a prevailing inclination among patients to prioritize the recommendations provided by medical professionals during consultations. This underscores that, despite of other product selection factors, the opinions of plastic surgeons are integral to the actual decision-making process.

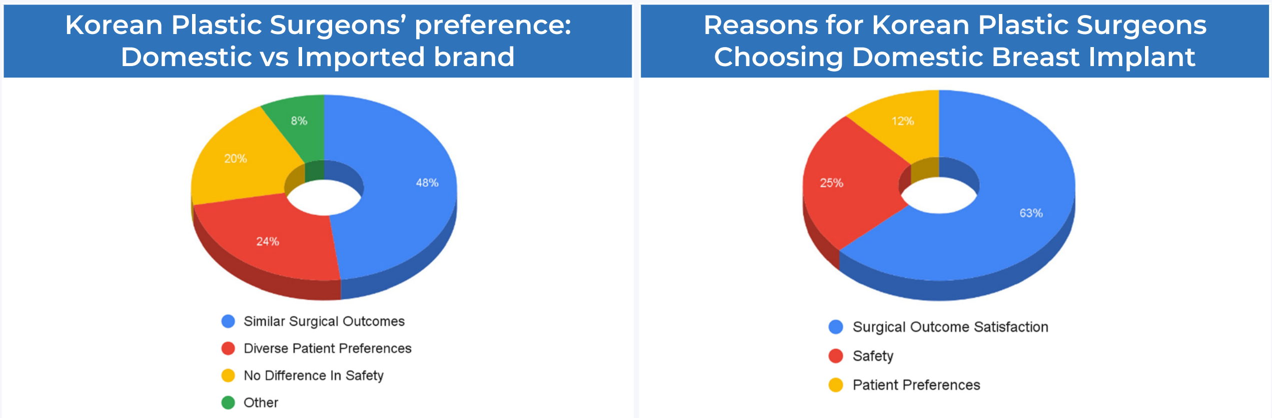
Figure 7. Korean Outpatients' preference for Domestic and Imported Breast Implant



Source) KIMS Online, 2019

On the other hand, most domestic plastic surgeons demonstrated neutrality between domestically produced and imported breast implants as 48% perceived that there is no disparity in the outcomes between the two. As for the main factor in choosing domestic product, the majority of the plastic surgeons indicated that the most pivotal factor was the satisfaction with surgical results, accounting for 63%.

Figure 8. Korean Plastic Surgeons' Preference for Domestic and Imported Breast Implant



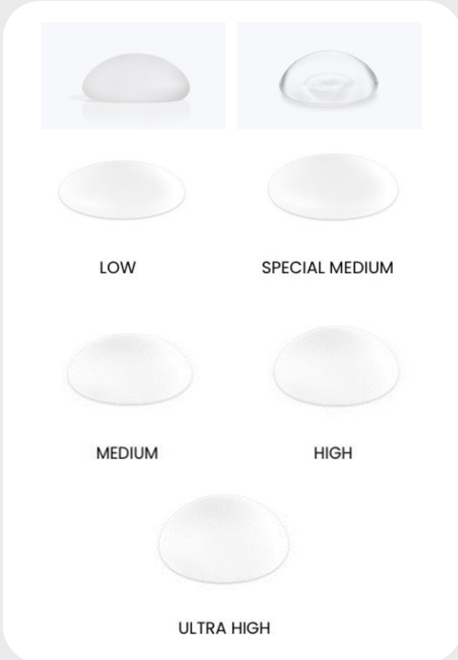
Source) KIMS Online, 2019

In line with the corporate analysis report from Shinhan Securities, the Korean breast implant market is centered around the nano-textured type, with BellaGel, a breast prosthesis manufactured by HansBioMed, being a prominent player.

Domestic enterprises are also increasingly establishing themselves as formidable contenders, intensifying the competition. For example, HansBioMed had garnered noteworthy favor and trust among a considerable number of local patients before the BellaGel recall. The safety of HansBioMed's breast implant products lies in the fact that they are not identified by the human body as external substances, unlike conventional products, preventing the formation of collagen around the prosthetic material. Indeed, the introduction of the third-generation micro-texture product by the company has contributed to the reduction of capsular contracture. Following its debut in the domestic market in 2017, it swiftly attained the top position, securing a first-place market share in just one year and six months.

HansBioMed's recent product, "BellaGel Smooth Fine," utilizes nanoparticle-based implant packaging technology, gaining a competitive edge in texture and shape, with average sales growth rate from 2017 to 2019 standing at an impressive 65%.

Table 3. HansBioMed's Breast Implant

Product	Features	Product Images
BellaGel	·An artificial breast implant made of silicone gel. ·Possesses two types based on surface characteristics: Smooth and SmoothFine  ·Provides a selection of five projection choices and more than 100 size options. ·Offers a Lifetime Warranty Program.	

Source) HansBioMed

Main Distribution Channels

Until 2016, the ROK breast implant market was primarily dominated by USA-based Allergan and Mentor, a Johnson & Johnson subsidiary, constituting 80% of the market share. Then with the entry of Korean company, HansBioMed, into the market, the scenario of ROK breast implant market had more variety of players. Up until early 2020, HansBioMed and Motiva held a dominant position in ROK breast prothesis market, each claiming a 35% market share.

The major importers of breast implant in Korea are in medical supplies wholesale and manufacturing businesses. The largest importer is Abbvie with an annual import value of 50 to 100 million USD in average.

The major importers of prosthesis or artificial parts of the body, mainly breast implants (902139), in Korea are listed in the table below.

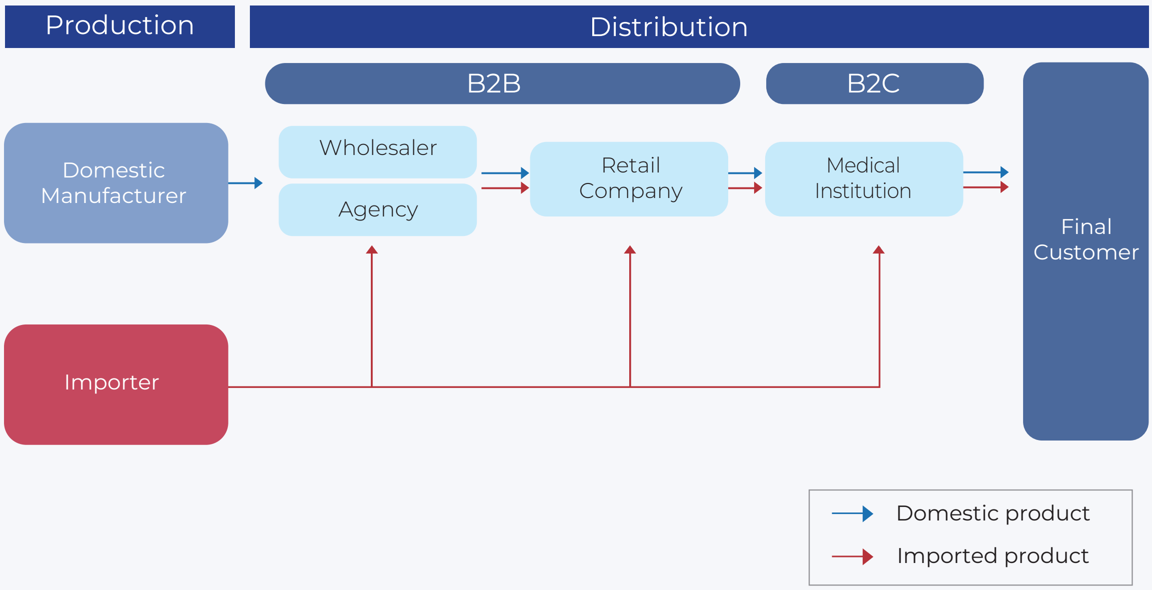
Table 4. Major ROK importers of Prosthesis or artificial parts of the body, mainly breast implants

No.	Company name	Enterprise scale	Import value (Unit: million USD)	Industry classification	Major importing countries	Address	Tel	Website
1	ABBVIE Ltd.	SMEs	50 ~ 100	Pharmaceutical wholesaler	Germany, Ireland, Italy	421, Yeongdong-daero, Gangnam-gu, Seoul, Republic of Korea	+82-(0)2-3429-9300	www.abbvie.co.kr
2	Yooyoung Pharm Co., Ltd	Midsize business	10 ~ 20	Finished pharmaceutical manufacturing	Belgium, USA, Germany	33, Yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, Republic of Korea	+82-(0)43-539-8800	www.yypharm.co.kr
3	Green Cosko Co., Ltd.	SMEs	1 ~ 10	Artificial breast implants, fillers manufacturing and distribution	France, Italy, UK	35, Samseong-ro 95-gil, Gangnam-gu, Seoul, Republic of Korea	+82-(0)2-545-2654	http://www.greencosko.com/
4	Shinwon Pharmacy Co., Ltd.	SMEs	1 ~ 10	Medical supplies wholesale	USA, Denmark, China	104, Macheon-ro, Songpa-gu, Seoul, Republic of Korea	+82-(0)2-3401-6700	http://www.eshinwon.com
5	Hans Bio Med Corp. Humedix Co., Ltd.	SMEs	1 ~ 10	Medical supplies manufacturing	USA, Netherlands, Japan	7, Jeongui-ro 8-gil, Songpa-gu, Seoul, Republic of Korea	+82-(0)2-466-2266	http://hansbiomed.com
6	Humedix Co., Ltd.	SMEs	1 ~ 10	Finished pharmaceutical manufacturing	China, Germany, Malaysia	17, Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do, Republic of Korea	+82-(0)70-7492-5600	www.humedix.com
7	Motiva Korea Ltd.	SMEs	1 ~ 10	Medical supplies wholesale	Costa Rica, Belgium, China	15, Teheran-ro 98-gil, Gangnam-gu, Seoul, Republic of Korea	+82-(0)2-725-5725	www.motivaimplants.co.kr/
8	Human Wellness Co., Ltd.	SMEs	Less than 1	Medical supplies wholesale	Italy, USA	15, Teheran-ro 98-gil, Gangnam-gu, Seoul, Republic of Korea	+82-(0)2-725-5725	http://www.humanwellness.kr/

Source) KOIMA

The distribution channels for medical devices including breast implant were categorized into direct sales, encompassing both hospitals and non-hospital outlets, and non-direct sales, including agencies and other distribution channels.

Figure 9. Distribution Channel of breast prosthesis



Source) Ministry of Food and Drug Safety, 2020

However, there have been controversies over the years on current distribution structure. For example, the current process allows intermediary agencies to receive supplies from manufacturers and simply pass them on to hospitals which could be perceived as a mere expansion of the distribution stage. But in fact, such process led to the spread of negative practices of agencies bribing medical professionals to use products they supply, as well as hospitals charging higher fees to patients for the products supplied by the engaged agencies.

For transparency within the medical device distribution structure and reinforcing the traceability of potentially hazardous products, the Ministry of Food and Drug Safety officially launched the "Medical Device Supply Details Reporting System," in 2020 mandating the comprehensive reporting of medical device supply process across manufacturing, importing, and distribution stages. Under this system, medical device manufacturers, importers, sellers, and lessors are obligated to submit supplier details, product specifics, and other pertinent information through an information system when distributing.

Import Requirements

In accordance with the relevant laws of the Republic of Korea, Breast Implants (902139) 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, breast implants, 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. Product number for Breast Implants is B04050.01 / B04050.02 and it is subject to the import permit as Class 4 medical device. If import certification or import license is obtained, the 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 5. Labeling Requirements for Medical Devices

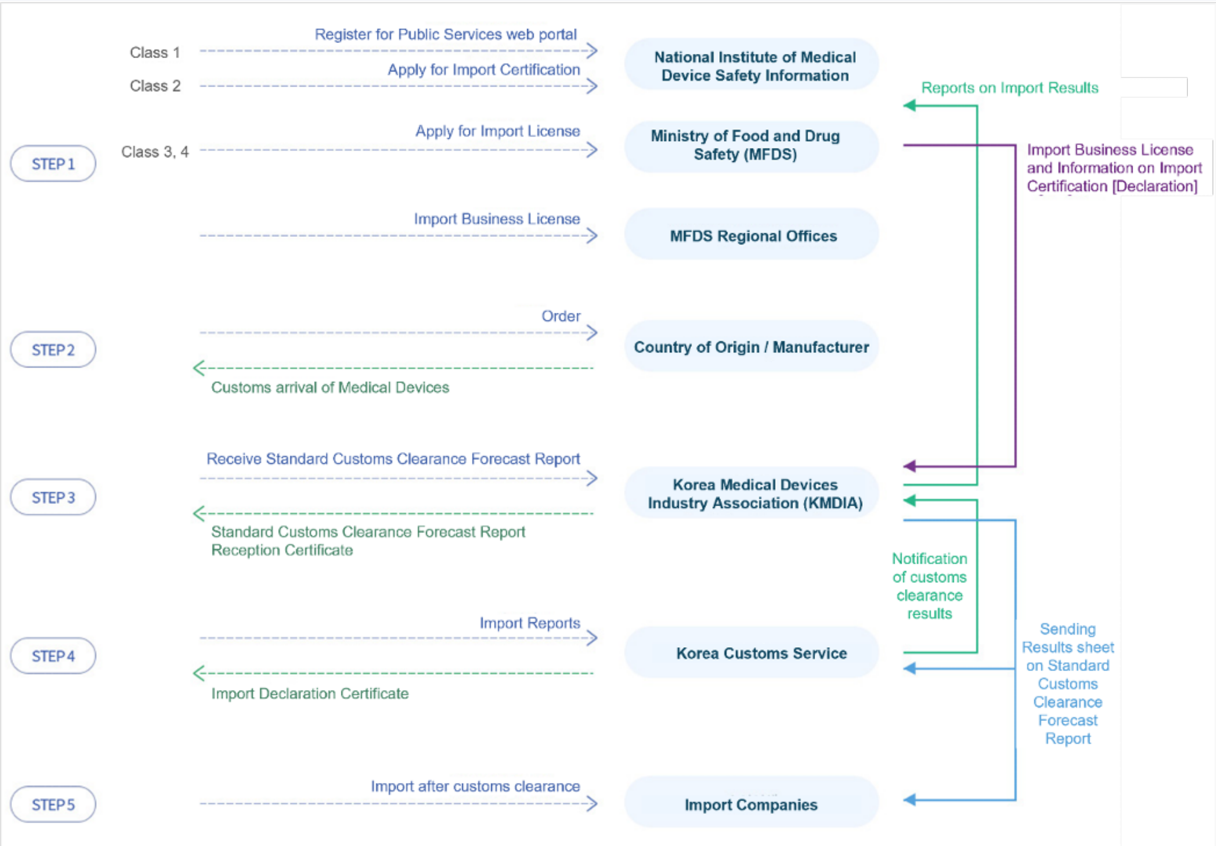
Label Location	Details
Labeling on Containers	1. The trade name and address of the manufacturer or importer; 2. If imported, the origin of manufacture (the name of the country of manufacture and of the manufacturer). 3. Permission (certification or notification) number and name (name of a product, item 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	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	1. Manufacturers and importers of medical devices shall include the following information in a package insert of a medical device: 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: 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) Rohan Customs Advisory Office (2024)

Import Process

In order to import breast implants 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 breast implants is as follows.

Figure 10. 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

After importation, breast implants to be sold in the ROK market must be labeled with the country of origin on its retail packaging. 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 laveled 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

In South Korea, a rooted culture of cosmetic surgery, including breast augmentation and reconstruction, contributes to a relatively more accepting environment for the domestic breast prosthesis market. The cultural inclination towards cosmetic enhancements makes individuals more open to exploring reconstructive options. The country is also renowned for its technological process, and this extends to the medical field. The application of state-of-the-art medical technologies in breast prosthesis manufacturing helps with the production of advanced, durable, and aesthetically pleasing products, thereby elevating the overall quality.

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 is as follow: Costa Rica (2019), El Salvador (2020), Honduras (2019), Nicaragua (2019), Panama (2021), and Guatemala (2024).

W

Weakness

Globally, breast prostheses are commonly associated with various risks. For instance, back in 2019, a notable incident took place with a breast implant product of Allergan, and these products led to the suspension of distribution. This event likely heightened apprehensions, particularly among those already cautious about breast augmentation procedures.

The predominant concern of breast augmentation surgery was side effects (75.7%), greatly exceeding other considerations. Beyond health considerations, there is a pervasive reluctance in the country to undergo such procedures for other reasons including its adverse impact on childbirth and breastfeeding, detecting abnormalities during CT or MRI scans and so forth. Such perceptions contribute to the weakening of the breast prosthesis market in Korea, likely deterring many women from pursuing breast reconstruction procedures.

In addition, Korean government has complicated regulatory requirements for medical instruments as these products are used on and inside human body which can possibly affect patients' health conditions. Complying and preparing all the requirements is critical for successful export of medical instruments to the ROK market. Such process poses a challenge for CA exporters.

O

Opportunities

Over the past 25 years, the number of Korean women choosing simultaneous breast reconstruction surgery alongside mastectomy has markedly increased, with a ninefold rise in breast cancer patients opting for immediate reconstruction surgery. Patients' expectations have significantly increased in recent times, and in instances of breast cancer, many are not just seeking just a cure for the disease but also aiming to restore their previous normal appearance. This trend has created greater opportunities for breast prosthesis companies in the country.

It is also widely acknowledged that the durability of breast implants tends to decrease after ten years post-surgery, elevating the likelihood of implant damage. Consequently, many patients were advised to consider removal or replacement, resulting in increased demand and creating opportunities for other companies. Despite the superior durability of cohesive gel implants and more recent micro-textured implants like Motiva, BellaGel, and Mentor, which mitigate the risk of damage, instances still arise where patients opt for breast revision surgeries due to dissatisfaction, discomfort, or other concerns. This, in turn, contribute to sustained market demand.

Additionally, Yonsei Cancer Hospital, recently achieved a global milestone by becoming the first institution worldwide to surpass 500 cases of robotic breast surgery as of August 2023. Given that robotic breast surgery not only reduces scar but also enhances surgical precision, an increased demand for breast surgeries, consequently leading to a heightened demand for breast prostheses, can be anticipated in Korea in the near future.

T

Threats

Up until 2017, South Korea depended on foreign brands to meet its breast prosthesis requirements. However, this scenario changed with the entry of HansBioMed into the market, introducing the first breast prosthesis product in all of Asia to receive the EU safety mark. Addressing diverse consumer needs with a variety of prosthesis sizes, offering an average selling price (ASP) 10-20% lower than Motiva, HansBioMed not only emerged as a leader in the Korean breast prosthesis market but also helped bolster the country's position against other international markets.

Besides the exclusive presence of a single domestic manufacturer, the landscape is predominantly occupied by well-established foreign brands such as Motiva and Mentor. These foreign players have already secured a substantial market share, posing challenges for both domestic and other foreign companies seeking to compete.

Furthermore, the competition intensifies with established foreign brands introducing new lines of breast prostheses. For instance, as of the beginning of 2023, GC Aesthetics, already a prominent player in the domestic market with its Eurosilicone line, was gearing up to launch the Dia line in Korea, with the subsequent introduction of the Pearl line. On the other hand, GC Aesthetics plans to consistently introduce various prostheses to the domestic market in addition to the two lines.

Increasing interests among Korean and global suppliers and continuous launches of new products in Korea market creates fierce competition posing a potential threat to new CA entrants.

Business Case

ROK Market Insights

- ROK consumers' high concern on side-effects as number one consideration factor
- ROK consumers' high reliance on product awareness as number one choice factor
- Growing trend of breast reconstruction in ROK

Niche

- To approach with a strategic branding with the image of side-effect safe/free and health-careful products

Cultural Adaptation

- Understand Korean's most pervasive awareness and careful interest in health issues when regarding the breast implants
- Understand Korean consumers' quality and price standard for breast implants

Strategy Snapshot

- To enhance the visibility and exportability of Central American countries' breast implant 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' breast implant to ROK market, it is recommended to partner with dependable ROK importers who has good relationship and network with ROK large sized and/or stable medical institutions as final user companies.
- To gain comparative advantage on CA countries' breast implant export to ROK market, it is recommended to establish branding strategies with the image of side-effect safe/free and health-careful products.

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