



**PRODUCT REPORT**  
**SURGICAL INSTRUMENTS**  
**SPAIN**

July, 2018



Contents

1.	<b>Product Description.....</b>	<b>3</b>
2.	<b>World Market for Surgical Instruments.....</b>	<b>3</b>
3.	<b>European Market .....</b>	<b>4</b>
4.	<b>Spanish Market.....</b>	<b>4</b>
5.	<b>Trade .....</b>	<b>6</b>
6.	<b>Pakistan Surgical Instruments Industry.....</b>	<b>8</b>
7.	<b>Pakistan’s Surgical Instruments Competition.....</b>	<b>9</b>
8.	<b>Market Access.....</b>	<b>10</b>
9.	<b>Distribution Channels .....</b>	<b>11</b>
10.	<b>Recommendations for TDAP .....</b>	<b>12</b>
11.	<b>List of Spanish Surgical Instrument Companies (non exhaustive).....</b>	<b>13</b>
12.	<b>Trade Fairs .....</b>	<b>15</b>
13.	<b>Useful Links.....</b>	<b>16</b>
14.	<b>Sources / References.....</b>	<b>17</b>



## **1. Product Description**

This market brief applies to the instruments and appliances used in medical, surgical, dental or veterinary sciences sector, including scintigraphic apparatus, other electromedical apparatus and sight-testing instruments under Chapter 90/9018 of HS Tariff Codes<sup>1</sup>:

- Electrodiagnostic apparatus (including apparatus for functional exploratory examination or for checking physiological parameters) (HS Code 9018.11).
- Ultraviolet or infra-red ray apparatus (HS Code 9018.20).
- Syringes, needles, catheters, cannulae and the like (HS Code 9018.31).
- Other instruments and appliances, used in dental sciences (HS Code 9018.41)
- Other ophthalmic instruments and appliances (HS Code 9018.50)
- Other instruments and appliances (HS Code 9018.90)

Based on their application, these surgical instruments are utilized in cardiothoracic surgery, cosmetic surgery/bariatric surgery, gastrointestinal surgery, orthopaedic surgery, gynaecological surgery, vascular surgery, urological surgery, respiratory surgery, neurological surgery, dental surgery and paediatric surgery.<sup>2</sup>

## **2. World Market for Surgical Instruments**

It is estimated that the global market for surgical materials and equipment will grow at an annual rate of 11.1% to reach 12.1 billion dollars by 2020. The products that stand out in this specific market are the electrosurgical devices, the manual surgical instruments, and the surgical sutures and staples. Surgical sutures and staples have the largest market share due to the increasing number of surgeries performed, but this is expected to decline due to the increasing preference for more minimally invasive procedures. For this same reason, the segment of electrosurgical devices will be the one

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<sup>1</sup>

<http://exporthelp.europa.eu/thdapp/nomenclature/NomenclatureServlet?action=nomen&section=tariff&taricCode=9018000000&prodLine=80&limitLevel=10&simDate=20090817&languageId=en>

<sup>2</sup> <https://www.cbi.eu/market-information/medical-laboratory-devices/surgical-instruments/benelux/>



with the highest growth rate between 2016 and 2020. The lack of favourable regulatory frameworks in some regions is the main constraint on market growth.

Today, North America dominates the global industry of surgical materials and equipment, followed by Europe and Asia-Pacific. It is estimated that the latter will be the region with the highest growth between 2016 and 2020, with a compound annual rate of 16.1%; this rapid increase will be mainly due to the advance of medical tourism and the increase in the prevalence of chronic diseases that require surgical treatment.<sup>3</sup>

### **3. European Market**

In 2015, the European Market for surgical instruments amounted to €2.3 billion (\$US 14.7 billion), following annual growth of 7.0% from 2011 to 2015. This growth can be associated with the increasing demand for “safe, cost- and time-effective solutions”<sup>4</sup>, as well as the growing demand for minimally invasive surgeries. European imports from developing countries presented a rather strong and steady growth, making up 12% share of the total imports in 2015. The main importer of Surgical Instruments was Belgium, followed by Germany.

### **4. Spanish Market**

As Spain benefits from universal free healthcare, there is an increasing amount of patients who are demanding the best instruments available and for the latest high-tech innovations to be incorporated. The Spanish market for medical equipment and instruments ranks 5<sup>th</sup> within the EU-25, and 9<sup>th</sup> in the world<sup>5</sup>. Spanish healthcare spending amounts to 8% of the GDP, and is expected to increase in order to cover the demand for enhanced healthcare services.

Recently, a new system of management concession has been employed at hospitals, with private companies providing services to the public sector.

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<sup>3</sup> <http://www.elhospital.com/temas/Mercado-de-materiales-y-equipos-quirurgicos-alcanzara-12,1-millones-de-dolares-en-2020+112557>

<sup>4</sup> <https://www.cbi.eu/market-information/medical-laboratory-devices/surgical-instruments/benelux/>

<sup>5</sup> <http://www.abhi.org.uk/multimedia/e-newswire/issue85/SpainReport.pdf>



There are several methods for acquiring medical equipment, which include public tenders, direct purchases and acquisitions through leasing (equipment maintenance and replacement provided by the supplier).<sup>6</sup>

The diagnostic, orthopedics and single-use products sectors dominate most of the Spanish market with a 70% share. Electromedicine products, medical and dental furniture complete the market offer in Spain.

The forecast of the Spanish population by age reveals a progressive and continuous aging of the population. The percentage of the population over 65, which currently stands at 18.2%, will be 24.9% in 2029 and 38.7% in 2064, according to INE data. This forecast places the Spanish population as a market with great potential in terms of health care.<sup>7</sup> The Government is facing rising costs in the provision of healthcare services, as these are increasing at a higher rate than budgetary forecasts. These rising costs are due to:

- Increasing life expectancy: The large aging population creates further strains on public healthcare. The healthcare demands for the rising population over 65 is up to four times greater than for the rest of the population.
- Immigration: the rising immigrant population in Spain is also provided by the universal healthcare system, yet this population largely does not further contribute to the public spending.
- AIDS and drug addiction: With Spain having the highest number of AIDS cases in Europe, although decreasing, along with the drug addiction population, this only presents more difficulties for the public health care system.
- Tourists: Due to the universal healthcare system, Spain spends up to twice the amount treating tourist patients than it costs other countries to provide healthcare to Spanish patients.

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<sup>6</sup><http://www.spainbusiness.com/icex/cma/contentTypes/common/records/mostrarDocumento/?doc=4539535>

<sup>7</sup><http://www.investinspain.org/invest/wcm/idc/groups/public/documents/documento/mde1/njax/~edisp/doc2015601875.pdf>



- High- technological incorporations: The integration of high-technology equipment to detect and treat illnesses adds to the growing expenditure<sup>8</sup>.

Therefore, Spain could greatly benefit from importing Surgical Instruments at competitive prices from Pakistan.

## 5. Trade

### Spain's Exports

<b>Spain's Exports of Surgical Instruments to Pakistan (US\$ Million)</b>			
<b>FY 2013-14</b>	<b>FY 2014-15</b>	<b>FY 2015-16</b>	<b>FY 2016-17</b>
2.05	0.86	1.32	1.85

Spain's exports of Surgical Instruments amounted to US\$ 586.03 million in 2016, depicting an increase of 10.14% when compared to Spain's exports in 2015 (US\$ 532.07 million). Major export destinations in 2016 were Belgium (US\$ 159.62 million; 27.23% share), Portugal (US\$ 123.81 million; 21.12% share), France (US\$ 31.52 million; 5.37% share), The Netherlands (US\$ 29.74 million; 5.07% share), USA (US\$ 22.01 million; 3.75% share) and Germany. (US\$ 20.04 million; 3.41% share). Spain's exports to Pakistan amounted to US\$ 0.97 million in 2016, representing a share of 0.16% in Spain's global exports of Surgical Instruments for the mentioned period.

As the table below depicts, Spain's major customers are still in Europe, however, a process of expansion towards third countries is starting.

<b>Rank</b>	<b>Destination</b>	<b>Volume 2015 (US\$ Million)</b>	<b>Volume 2016 (US\$ Million)</b>	<b>Variation</b>
1.	Belgium	133.69	159.62	+19.39%
2.	Portugal	112.37	123.81	+10.18%
3.	France	32.32	31.52	-2.47%
4.	The Netherlands	30.25	29.74	-1.91%

<sup>8</sup> <http://www.abhi.org.uk/multimedia/e-newswire/issue85/SpainReport.pdf>



5.	USA	23.86	22.01	-7.75%
6.	Germany	17.35	20.04	+15.50%
7.	China	15.59	17.26	+10.71%
8.	Ecuador	0.45	12.84	+2,753.33%
9.	Italy	13.68	12.68	-7.30%
10.	UK	10.00	11.18	+11.80%
<b>48.</b>	<b>Pakistan</b>	<b>1.21</b>	<b>0.97</b>	<b>-19.83%</b>
-	<b>Total</b>	<b>532.07</b>	<b>586.03</b>	<b>+10.14%</b>

Source: Datacomex, Spanish Secretariat for Trade

### Spain's Imports

Spain's Imports of Surgical Instruments from Pakistan (US\$ Million)			
FY 2013-14	FY 2014-15	FY 2015-16	FY 2016-17
0.93	1.04	1.15	0.84

Spain's imports of Surgical Instruments amounted to US\$ 2,158.85 million in 2016, depicting an increase of 11.30% when compared to Spain's imports in 2015 (US\$ 1,939.68 million). Major import sources in 2016 were Germany (US\$ 466.93 million; 21.62% share), USA (US\$ 383.87 million; 17.78% share), The Netherlands (US\$ 353.97 million; 16.39% share), Belgium (US\$ 163.73 million; 7.58% share), France (US\$ 112.58 million; 5.21% share) and Mexico (US\$ 96.18 million; 4.45% share). Spain's imports from Pakistan amounted to US\$ 1.19 million in 2016. This figure is similar to competitor country Indonesia; however, countries like China and India have managed to be ranked among Spain's top fifteen sources of Surgical Instruments products.

Rank	Source	Volume 2015 (US\$ Million)	Volume 2016 (US\$ Million)	Variation
1.	Germany	324.71	466.93	+43.80%
2.	USA	360.53	383.87	+6.47%
3.	The Netherlands	335.72	353.97	+5.44%
4.	Belgium	147.07	163.73	+11.33%



5.	France	120.75	112.58	-6.77%
6.	Mexico	90.27	96.18	+6.55%
7.	Italy	84.09	82.36	-2.07%
8.	China	53.23	57.82	+8.64%
9.	Japan	43.09	49.78	+15.52%
10.	UK	48.35	43.68	-9.67%
<b>43.</b>	<b>Pakistan</b>	<b>1.02</b>	<b>1.19</b>	<b>+16.83%</b>
-	<b>Total</b>	<b>1,939.68</b>	<b>2,158.85</b>	<b>+11.30%</b>

Source: Datacomex, Spanish Secretariat for Trade

### 6. Pakistan Surgical Instruments Industry

Although Pakistan makes up a very small share of the world trade of Surgical Instruments, the local industry enjoys many skilled workers, providing for great potential to enhance exports of these products to Spain. Pakistan's surgical instrument are exported to highly developed markets such as: Germany, France, USA, UK, Italy, UAE, Japan, Russia, Mexico and Brasil.

The following table shows Pakistan's top export destinations in EU28 for Surgical Instruments:

	Country	Import Value to EU (€) 2013	Import Value to EU (€) 2014	Import Value to EU (€) 2015	Import Value to EU (€) 2016
1.	Germany	30,285,085	32,476,127	37,545,050	37,233,530
2.	United Kingdom	23,026,937	26,747,981	29,818,932	27,818,715
3.	France	9,107,828	10,658,083	11,271,928	11,167,284
4.	Czech Republic	3,304,698	3,980,956	6,171,352	5,740,570
5.	Italy	4,363,239	5,238,869	5,774,403	5,350,440
6.	Belgium	3,509,109	3,404,775	4,023,079	3,912,001
7.	Austria	2,604,738	2,386,948	3,587,715	3,009,513
8.	Denmark	1,031,127	1,215,315	1,318,114	2,001,402
9.	Netherlands	1,543,464	1,950,524	2,184,595	1,869,277





10.	Poland	1,078,274	1,206,996	1,636,228	1,784,043
12.	<b>Spain</b>	<b>474,789</b>	<b>767,864</b>	<b>904,129</b>	<b>1,057,341</b>
<b>Total</b>	<b>EU28</b>	<b>83313184</b>	<b>93155496</b>	<b>108534831</b>	<b>105627773</b>

Source: EuroStats. Market Access Database

Spain is Pakistan’s 12th top export destination in EU28 for Surgical Instruments during 2016 as the import value (€) to Spain rapidly increases every year. This displays Pakistan’s large potential to continue increasing exports of Surgical Instruments to Spain.

There are about 3000 companies participating in this industry, which produce over 10.000 different medical instruments, on average, 170 million pieces per year amounting to an estimated value of Rs. 22 Billion, out of which almost 95% of this production is exported.

### **7. Pakistan’s Surgical Instruments Competition**

The export of Surgical Instruments is one of Pakistan’s five prime export-oriented sectors. However, it has been facing numerous problems. The leakage of production technology, the rise in the cost of production and the export of steel scrap are creating large issues for the metal-related industries. According to the representatives of Surgical Instrument Manufacturers association of Pakistan (SIMAP), the export of surgical forgings and semi and unfinished products were the most important components for the decline in exports of Surgical Instruments. SIMAP is urging to impose a ban on these export products, as “both India and China, only repack or stamp Pakistan-made instruments and sell them as their own brand”<sup>9</sup>. Pakistan’s largest competitors, India and China, actually have no manufacturing or technical skills in the Surgical Instruments field, but are rapidly penetrating the business due to branding with full support of their governments. India, is reaching the \$US 140 billion mark of exports due to practical policies prepared along with the businesses in this sector.

<sup>9</sup> <http://dailytimes.com.pk/business/02-Jul-17/surgical-sector-facing-multiple-problems-exports-declining>



*Spain's imports of Surgical Instruments- Pakistan's Competition*

Rank	Source	Volume 2015 (US\$ Million)	Volume 2016 (US\$ Million)	Variation
15.	India	15.76	18.37	+16.61%
22.	Vietnam	11.29	12.43	+10.08%
26.	Malaysia	8.83	10.17	+15.16%
30.	Thailand	8.73	8.41	-3.70%
42.	Indonesia	1.29	1.48	+14.56%
<b>43.</b>	<b>Pakistan</b>	<b>1.02</b>	<b>1.19</b>	<b>+16.83%</b>
66.	Philippines	0.02	0.02	00.00%

Source: Datacomex, Spanish Secretariat for Trade

## **8. Market Access**

### **Quality**

In order to export Surgical instruments into the EU market, the exports must comply with the Medical Devices Directive 93/42/EEC, which can be found in the following link:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF>

### **European Market Labelling<sup>10</sup>:**

The requirements for labelling medical devices for exporting to the European Union are set out in Annex I, Paragraph 13, of the Medical Devices Directive 93/42/EEC.

The labelling must include the following:

- the name or trade name and address of the manufacturer. For devices imported into the EU and distributed in the EU, the label, the outer packaging and instructions for

<sup>10</sup> <https://www.cbi.eu/market-information/medical-laboratory-devices/surgical-instruments/benelux/>



use must contain the name and address of the authorised representative if the manufacturer does not have a registered place of business in the EU;

- information essential to identify the device and the contents of the packaging, especially for the users;
- where appropriate, the word STERILE;
- where appropriate, the batch code preceded by the word LOT or the serial number;
- where appropriate, the date by which the device should be used, in safety, expressed as year and month;
- where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the European Union;
- if the device is custom-made, the phrase “custom-made device”;
- if the device is for clinical investigations, the phrase “exclusively for clinical investigations”;
- any special storage and/or handling requirements;
- any special instructions for use;
- any warnings and/or precautions to be taken;
- year of manufacture for active devices other than those covered under (e). This indication may be included in the batch or serial number;
- where applicable, method of sterilisation.

## **9. Distribution Channels**

As to distribution channels, there are the options of distributing to Retail Companies or supplying directly to private companies.



## **10. Recommendations**

- The export of steel scrap are causing great issues for the metal- related industries, as scrap is the major source of locally produced stainless steel. In addition, Representatives of Surgical Instrument Manufacturers Association (SIMAP) of Pakistan are of the view that exports of semi and unfinished products are critical components for the decline in exports of surgical instruments, as countries such as India and China, which lack manufacturing or technical skills in this field, import such product from Pakistan and apply branding approaches for the finished products. Therefore, the government should consider minimizing the export of steel scrap from Pakistan. Ministry of Commerce should impose a ban on the export of forgings, semi-finished and unfinished products, as there are only making India and China gain more share in the exports of Surgical Instruments to EU28 and Spain<sup>11</sup>, as has been urged by SIMAP.
- TDAP should focus efforts into developing Pakistani brands of Surgical Instruments. On the other hand, China and India have no manufacturing or technical skills themselves in the field of Surgical Instruments yet through the intensified efforts of brand development and promotion in China and India<sup>11</sup>, they have been able to improve exports into EU28.
- TDAP should consider sending a delegation of Surgical Instruments to Spain in the beginning of the next year.

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<sup>11</sup> <http://dailytimes.com.pk/business/02-Jul-17/surgical-sector-facing-multiple-problems-exports-declining>



**11. List of Spanish Surgical Instrument Companies (non exhaustive)**

In Spain, the sector for manufacturing Surgical Instruments is composed of 4.870 companies, out of which only 3 are large companies with more than 250 employees, even though they take over half the Spanish market for surgical instruments<sup>12</sup>.

**Name of companies and addresses**

1.            AGRUPACION MUGA, S.L.  
              Bismarck, 39  
              E-28024 Barcelona  
              Spain  
              Tel: (34) 3-435 13 65  
              Fax: (34) 3-435 13 65
  
2.            ALECOOP S. COOR.  
              Loramendi, s/n  
              E-20500 Mondragon, Guipuzcoa  
              Spain  
              Tel: (34) 43 79 50 11  
              Fax: (34) 43 79 92 12
  
3.            ANKO EUROPA, S.A.  
              Avda. Camino Lo Cortac. 21 Nv.7  
              E-28700 S. Sebastian los Reyes  
              Spain  
              Tel: (34) 1-653 96 22  
              Fax: (34) 1-653 51 02
  
4.            ANTIBIOTICOS FARMA, S.A.  
              Antonio Lopez, 109  
              E-28026 Madrid  
              Spain  
              Tel: (34) 1-589 51 00  
              Fax: (34) 1-476 57 98
  
5.            ANTONIO MATACHANA, S.A.  
              Almogaurres, 174-176  
              E-08018 Barcelona  
              Spain

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<sup>12</sup> [http://www.een-japan.eu/sites/default/files/Healthcare-sector-in-Valencian-community\\_0.pdf](http://www.een-japan.eu/sites/default/files/Healthcare-sector-in-Valencian-community_0.pdf)



Tel: (34) 3-300 80 12

Fax: (34) 1-401 43 08

6. ANTONIO DUERALTO ROSAL  
C/ Ibiza, 41  
E-28009 Madrid  
Spain  
Tel: (34) 1-574 05 62  
Fax: (34) 1-457 58 58
7. B. O. G. SISTEMAS MEDICOS  
J. Miguel Barandiaran, 5, Bajo  
E-48006 Bilbao  
Spain  
Tel: (34) 1-433 39 00  
Fax: (34) 1-433 90 14
8. BAXTER, S.A.  
D'els Gremis, 7  
E-46014 Valencia  
Spain  
Tel: (34) 6-386 08 00  
Fax: (34) 6-379 77 18
9. BECKMAN INSTRUMENTS ESPANA, S.A.  
Av. Llano Castellano, 15, 1  
E-28034 Madrid  
Spain  
Tel: (34) 1-358 00 51  
Fax: (34) 1-729 36 52
10. BECTON DICKINSON, S.A.  
Camino de Valdeoliva, s/n,  
E-28750 Madrid  
Spain  
Tel: (34) 1-848 81 00/1  
Fax: (34) 1-841 81 39
11. BOC MEDISHIELD, S.A.  
Manuel Tovar, 26  
E-28034 Madrid  
Spain  
Tel: (34) 1-729 47 47  
Fax: (34) 1-729 39 77
12. DOGE MEDICAL, S. A.  
J. Miguel de Barandiaran, 5  
E-48006 Bilbao  
Spain  
Tel: (34) 4-433 39 00



Fax: (34) 4-433 90 14

13. C. I. A. M., S.A.  
Almogavers, 188  
E-08018 Barcelona  
Spain  
Tel: (34) 3-309 18 19  
Fax: 834) 3-309 71 45
  
14. CAIMANA, S.L.  
C/ Fermin Caballero, 75  
E-28034 Madrid  
Spain  
Tel: (34) 1-738 28 35  
Fax: (34) 1-739 66 66
  
15. COM. MEDICO QUIRURGICA, S.A.  
C/ Cartagena, 299-301  
E-08025 Barcelona  
Spain  
Tel: (34) 3-435 76 10  
Fax: (34) 3-433 17 29

## **12. Trade Fairs**

### **1. EXPODENTAL**

Madrid (Spain)

International Dental Equipment, Supplies and Services Show

Location: Feria de Madrid – Juan Carlos I Exhibition Ground -

[www.expodental.ifema.es](http://www.expodental.ifema.es)

### **2. ORPROTEC**

Madrid (Spain)

International Fair for Orthopedics and Assisted Living. Technology



for the Disabled and Senior Citizens

Location: Juan Carlos I fair ground

[www.orprotec.feriavalencia.com](http://www.orprotec.feriavalencia.com)

### **3. MEDICAL EXPO FORUM**

Madrid and Barcelona (Spain)

International Medical Devices and Hospital Equipment Exhibition

Location: Juan Carlos I fair ground -

[www.medicalforumexpo.com](http://www.medicalforumexpo.com)

Spanish distributors of health care equipment are regular visitors to the important “Medica” trade fair as well as to “Rehacare”, both held in Düsseldorf.

## **13. Useful Links**

### **1. MINISTRY OF HEALTH AND CONSUMER AFFAIRS**

Department of Pharmacy and Healthcare Products/Office of Healthcare Products

[www.msc.es](http://www.msc.es)

### **2. CARLOS III HEALTH INSTITUTE**

[www.isciii.es](http://www.isciii.es)

### **3. SEEIC**

Spanish Electromedicine and Clinical Engineering Society

[www.seeic.org](http://www.seeic.org)

### **4. MADRI+D FOUNDATION**





[www.madrimasd.org](http://www.madrimasd.org)

**5. SPANISH CARDIOLOGY SOCIETY**

[www.secardiologia.es](http://www.secardiologia.es)

**6. NATIONAL BIOTECHNOLOGY CENTER**

[www.cnb.csic.es](http://www.cnb.csic.es)

**14. Sources / References**

- European Commission. Trade. Export Helpdesk.
- European Commission. Market Access Database.
- DataComex, Spanish Secretariat for Trade, Ministry of Economy, Industry and Competitiveness.
- Ifema.com. Venue in Madrid for trade fairs, exhibitions and conferences.
- Firabarcelona.com. Venue in Barcelona for trade fairs, exhibitions and conferences.
- Directorio Cámaras. Export and Import Spanish Companies Directory.
- Spain Business.  
<http://www.spainbusiness.com/icex/cma/contentTypes/common/records/mostrarDocumento/?doc=4539534>