

# Exporting surgical instruments to Europe

The market for surgical instruments reached €12.3 billion in 2015, following 7.0% annual growth in the period 2011–2015. There is increasing demand for safe, cost- and time-effective solutions, as well as for instruments suited for minimally invasive surgery. Imports from developing countries showed relatively strong growth, resulting in a 12% share in the total imports over 2015. Belgium was the main importer of surgical instruments, followed by Germany.

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## 1. Product description

Surgical instruments are tools or devices designed to perform specific functions in surgery, such as cutting, grasping, clamping, retracting and suturing.

Generally surgical instruments are divided into the following categories:

- surgical sutures and staples;
- hand-held surgical devices (scalpels, forceps, retractors, scissors, dilators, graspers, and so on);
- electrosurgical devices (radio-frequency electrosurgery devices, electrocautery devices, electrosurgical accessories);
- other surgical devices.

Based on their application, surgical instruments are used 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.

One CN code has been selected for surgical instruments: 90189084. Using this code, the trade statistics have been compiled (source: Eurostat Comext). For production and demand, the Eurostat Prodcom database has been used. The two Prodcom codes that correspond to CN 90189084 are 32501370 and 32501379.

## Quality

Surgical instruments for the EU market must comply with the [Medical Devices Directive 93/42/EEC](#). For more information, see “Market Requirements” below.

## Labelling

The requirements for labelling medical devices for the European Union are set out in Annex I, Paragraph 13, of the [Medical Devices Directive 93/42/EEC](#).

The label must state 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 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.

## Materials

Surgical instruments are usually made of stainless steel, but other metals such as titanium, chromium, vanadium and molybdenum are also used.

## Packaging

Medical devices require sterile packaging in compliance with EN868 (Part 1). Part 2 to 10 relate to the requirements and test procedures for the packaging materials. These tests can be used to show that all requirements have been complied with.

There is also an ISO standard for sterile packaging of medical products, [ISO 11607](#). This ISO standard is very similar to EN868 and has two parts: Part 1 on the requirements and test procedures for packaging materials, and Part 2 on the validation requirements of packaging processes. While EN868 is mandatory, ISO is a voluntary standard and is often requested by customers.

More general legislation applicable to medical devices packaging is the European [Packaging and packaging waste](#) legislation. This legislation restricts the use of certain heavy metals and states other requirements. The EU also has requirements for [Wood packaging materials used for transport](#), such as packing cases, boxes, crates, drums, pallets, box pallets and dunnage.

### Tip:

Learn from International Trade Centre (ITC) information on [packaging for exporters](#).

## 2. Which European markets offer opportunities for surgical instruments?

### Imports

Imports of surgical instruments to Europe reached €12.3 billion in 2015. The average annual growth in the period 2011–2015 was 7.3%.

The share of developing countries in European imports increased from 10 to 12% in the period under review. For the foreseeable future, this share is forecast to show small annual growth in the range of 1 to 3%.

The leading European importer is Belgium (19%), followed by Germany (15%) and the Netherlands (12%). Belgium is also the largest importer from developing countries (€197 million).

Belgium has a leading position because the country is a trade hub for many global medical devices companies. It is especially a trade hub for surgical instruments produced in other European countries.

Imports of surgical instruments are expected to show continuous growth within the foreseeable future, in the range of 3 to 5% per year.

## Leading suppliers

The leading suppliers of surgical instruments to Europe vary, with the top three suppliers being the USA, the Netherlands and Belgium.

The only developing country on the list of leading suppliers is Mexico (€707 million). However, several other developing countries export substantial volumes of surgical instruments to Europe: China (€245 million), Malaysia (€216 million), Costa Rica (€123 million), Thailand (€78 million), India (€52 million) and Vietnam (31 million).

In the list of the leading suppliers, the highest annual export growth to Europe in the last five years was realised by Mexico (23%), Germany (14.3%) and Ireland (14%).

Apart from Mexico, other developing country suppliers with a high increase in their annual export rate to Europe were Costa Rica (109%), Vietnam (46.2%) and China (17.6%).

### Tips:

Benchmark your company against your peers in Mexico, China, Vietnam, Malaysia, Costa Rica and Thailand. Several factors can be taken into account, such as market segments served, perceived price and quality level, and countries served. A useful source to find exporters/producers of surgical instruments per country is the [ITC Trademap](#).

Identify the key importers of your product in selected large or rapidly growing markets. You can start by doing an internet search or reading more about supply chains in Europe in our study of [Market channels and segments for medical and laboratory devices](#).

## Exports

Exports of surgical instruments from Europe showed an upward trend in the last five years, amounting to €12.5 billion in 2015. The average annual growth in the period 2011–2015 was 5.4%.

The share of developing countries in European exports reached 14.6% in 2014. Most exports go to European countries (58.1%), including some re-exports of imports from developing countries. For the foreseeable future, the share of developing countries is forecast to show small growth in the range of 1 to 3% per year.

The leading European exporter is Germany (€2.5 billion), followed by Belgium (€2.4 billion) and the Netherlands (€1.7 billion).

The European exports of surgical instruments are expected to show moderate growth within the foreseeable future, in the range of 2 to 4%.

### Tips:

Learn from European exporters and find opportunities in other growing markets for surgical instruments, such as the United States, Switzerland or China. You can also explore your opportunities in the Asia-Pacific region, as this is the region with the highest expected growth in the near future.

Learn more about your competitors in our study of [Competition in the medical and laboratory devices](#).

## Production

The total production of surgical instruments in Europe amounted to €13.1 billion in 2015, following an average annual increase of 12.4% in the period 2011–2015.

Germany (€4.0 billion) accounted for 31% of the total European production in 2015, followed by Belgium (€2.4 billion, 18%) and the Netherlands (€ 1.9 billion, 14%).

Leading producers of surgical instruments in Europe include [B. Braun Melsungen](#) (Germany), [ERBE Elektromedizin](#) (Germany), [Smith & Nephew](#) (the United Kingdom), [Medtronic](#) (Ireland) and [RESORBA Medical](#) (Germany). The list of leading companies, however, depends a lot on the category of products:

- In the segment of surgical sutures, [Ethicon](#) – a subsidiary of Johnson & Johnson – is the leading brand for surgical sutures globally and accounts for the largest market share, while [B. Braun Melsungen](#) dominates the surgical sutures market in Europe.
- In the segment of surgical staples, the important companies on the European market are [Swann-Morton](#) (the United Kingdom) and [Geister](#) (Germany).
- Major European producers of gynaecological surgical instruments are [Karl Storz](#) (Germany), [Richard Wolf](#) (Germany) and [B. Braun Melsungen](#).
- Major European producers of electrosurgical instruments include [Medtronic](#) (Ireland), [B. Braun Melsungen](#) (Germany), [ERBE Elektromedizin](#) (Germany) and [Bowa-electronic](#) (Germany).

### Tip:

Explore the chances of subcontracting to producers in Europe.

## Demand

The total demand in Europe amounted to €12.9 billion in 2015, following an average annual increase of 13% in the period 2011–2015. Growth is expected to continue in the foreseeable future, with growth rates forecast to be in the range of 3–6% per year on average.

Germany is the dominant producer of surgical instruments in Europe and has the largest market share (25%), followed by Belgium (18%) and the Netherlands (12%).

**Tip:**

Search for relevant trade fairs in trade fair databases such as [Eventseye](#) (choose “Medicine” and “Healthcare & Pharmaceuticals”). Examples of trade fairs that can be relevant for you are [Medica](#) (Germany, the leading medical industry event in Europe) and [Medtec Europe](#) (Germany).

### 3. What trends offer opportunities on the European market for surgical instruments?

The European market for surgical instruments is expected to grow because of the increasing number of surgical procedures. This growth is driven by the increasing appearance of different chronic diseases and the ageing population. The share of the population aged 65 years and over is increasing in every European Union Member State. This development creates increasing demand for different types of surgical intervention, but most frequently for cardiovascular, orthopaedic, urological and dermatological interventions.

Other market drivers that influence the rising demand for surgical instruments include increasing growth rates of health-care expenditure (especially in Central and Eastern Europe), growing demand for plastic and reconstructive surgery, and the development of minimally invasive surgery.

#### **Safety**

Innovative techniques and products are constantly being developed to further increase patient safety. Such innovations include an electronic instrument that improves precision in spinal surgery and an actuating device that reduces needle misplacement errors.

#### **Disposability**

There is a trend towards disposable surgical instruments that are more cost- and time-effective than reusable products, that need sterilisation after each use. Disposable surgical instruments can be made from high-grade polymer as well as from stainless steel, as can most reusable instruments.

For example, disposable staples are a rapidly growing product group because they minimise the number of infections caused by surgical instruments. Disposable plastic staplers are also increasingly used for patients who are allergic to nickel or other metals.

#### **Increasing demand for electrosurgical instruments**

The use of electrosurgical instruments is growing. One example is the shift from manual staplers towards electric staplers. One-handed electrical push-button staplers allow doctors to be more efficient and more precise in surgery operations.

Electrosurgical devices and accessories are expected to show increasing and high-market demand in the near future within Europe.

#### **Minimally invasive surgery**

More and more traditional surgical procedures are replaced by minimally invasive techniques, or endoscopic surgery. These procedures are performed through tiny cuts instead of one large opening. Because the cuts are small, patients tend to have quicker recovery times and less discomfort than with conventional surgery. This development is creating increasing demand for radio-frequency and electrocautery devices that are used for cutting, coagulating, desiccating or fulgurating of tissues.

One of the most important market drivers for this trend is the growing amount of aesthetic and plastic surgery. Specifically, there is high demand for surgical instruments used in eyelid surgery, silicone breast augmentation and liposuction. According to the [International Society of Aesthetic Plastic Surgery](#), the highest amount of aesthetic and plastic surgery in Europe is performed in Germany, followed by France and Italy.

## Mergers and acquisitions

The growing use of robotics in surgery procedures demands high investments, which has led to several mergers and acquisitions in Europe. For example, [Vygon SA](#) – the France-based developer of single-use sterile medical devices and surgical products – acquired Perouse Medical SAS, the manufacturer of devices for cardiovascular surgery, oncology and interventional imaging.

### **Tips:**

Invest in R&D to develop safe, cost- and time-effective solutions.

Include surgical instruments in your product range especially suited for minimally invasive surgery.

Read magazines and news from European or international sources, such as [Devicemed](#) and [Medical Device and Diagnostic Industry](#).

Check our general overview of trends: [CBI Trends for Medical and Laboratory Devices](#).

## 4. Which requirements should surgical instruments comply with to be allowed on the European market?

### Mandatory

Surgical instruments for the EU market, including the Benelux, require CE marking. To obtain this, your products must comply with the [Medical Devices Directive 93/42/EEC](#) on safety and performance of medical devices. The requirements include a quality system for design, manufacture, and final product inspection and testing (such as [ISO 13485](#)).

In 2012, the European Commission presented a proposal to replace the three [European medical devices directives](#) with two EU regulations to “achieve a suitable, robust, transparent and sustainable regulatory framework” for the development of safe, effective and innovative medical devices. In October 2015, the Ministers of the European Union countries agreed on a general approach to the package. The new regulations are expected to be implemented by 2018–2020.

Suggested revisions include the extension of the scope of legislation, better supervision of independent assessment bodies, clear rights for economic operators and stronger requirements for clinical evidence.

The final formal adoption is expected on the side of both the Council and the Parliament during the first semester of 2017.

### **Tips:**

See our study of [Buyer Requirements for Medical Devices](#) for more information.

Consult the European Commission [Blue Guide](#), which sets out how to implement the EU product rules on medical devices.

See the accompanying [guidance documents](#) to assist stakeholders in implementing directives related

to medical devices. These documents offer more information on the Medical Devices Directive.

Keep up to date with the [revision of the Medical Devices Directives](#).

Depending on the specific product, your surgical instruments may also have to comply with the [Waste Electrical & Electronic Equipment \(WEEE\) Directive 2012/19/EU](#). This directive aims to increase recycling and/or reuse of the waste of electrical and electronic equipment.

### Tip:

Consult the Frequently Asked Questions (FAQ) on the [WEEE Directive](#).

## Additional requirements

Complying with voluntary standards, such as [IEC/EN 60601](#), could help you obtain CE marking for your product.

Other voluntary standards address organisational (such as [ISO 13485](#)), environmental and social/labour requirements.

Governments, industries and consumers are increasingly aware of sustainability issues. The [Ecodesign Directive 2009/125/EC](#) helps to improve the energy efficiency of products and is complemented by the [Energy Labelling Directive](#) for labelling requirements.

In 2014, the European Commission published the [Green Public Procurement \(GPP\) Criteria for Electrical and Electronic Medical Devices \(Healthcare EEE\)](#), a voluntary instrument with clear, verifiable, justifiable and ambitious environmental criteria based on a life cycle approach and scientific evidence.

Recently, the concept of [Corporate Social Responsibility](#) (CSR) has become more important in the medical devices sector. Buyers are increasingly selecting suppliers based on their ethical and social responsibility measures.

For surgical instruments, [no duty](#) is levied on EU imports from countries outside the EU.

### Tips:

Visit the [EU Export Helpdesk](#) for requirements, tariffs, statistics and preferential arrangements.

Check the [ITC Market Access Map](#) for technical standards and the [ITC Standards Map](#) for voluntary standards.

Click on TC 76, 84, 194 and 210 in the [ISO Catalogue](#) for an overview of ISO standards.

Search EN norms in the [online shop of the British Standards Institution](#).

Consult the Frequently Asked Questions (FAQ) on the [Ecodesign Directive](#).

Use sustainable materials in your products, such as biodegradable, bio-based and recycled plastics.

Consult the Frequently Asked Questions (FAQ) on [Green Public Procurement](#).

Keep your CSR policy in order and advertise it clearly; for instance, on your website and in brochures, preferably using quotes from your CE audit report.

## 5. What competition do I face on the European markets for surgical instruments?

As competition for surgical instruments does not differ significantly from the Medical and Laboratory Devices sector, see [CBI Competition for Medical and Laboratory Devices](#) and [CBI Top 10 Tips for Doing Business with European Buyers](#) for an overview.

## 6. Through which channels can you get surgical instruments on the European market?

As market channels and segments for surgical instruments do not differ significantly from the Medical and Laboratory Devices sector, see [CBI Market Channels and Segments for Medical and Laboratory Devices](#) for an overview.

### Tips:

Read our study of [Finding Buyers in the Medical and Laboratory Devices sector](#) to get many tips on finding the right match in Europe.


Make use of databases to find potential buyers. Examples are [ESTA Healthcare](#), [MedicalExpo](#) and [Qmed](#).


Check the websites of European associations for member lists or databases. European associations are [Medtech Europe \(Eucomed\)](#), the [European Surgical Association](#) and the [European Hospital and Healthcare Federation](#). Most European countries are also home to national associations; for example, the [Austrian Association of Medical Device Manufacturers and Suppliers](#) and the [German Medical Technology Association](#).


For more information, see [CBI Finding Buyers](#) in the Medical and Laboratory Devices sector.

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