

Exporting orthopaedic appliances and artificial joints to Europe

The market for orthopaedic appliances and artificial joints is growing in Europe. There is an increasing demand for innovative, cost- and time-effective, and minimally invasive solutions. Imports to Europe reached €6.2 billion in 2015. In the period 2010–2015, the total European imports grew by 7.4% per year. The imports from developing countries showed exceptional performance with 19.1% growth per year, reaching €382 million in 2015. The high growth of imports from Malaysia, Mexico, the Philippines, Romania and China indicates that Europe offers good opportunities for products from relatively low-cost supplying locations.

Contents of this page

1. [Product description](#)
2. [Which European markets offer opportunities for orthopaedic appliances and artificial joints?](#)
3. [Which trends offer opportunities on the European market for orthopaedic appliances and artificial joints?](#)
4. [Which requirements should orthopaedic appliances and artificial joints comply with to be allowed on the European market?](#)
5. [Through which channels can you get orthopaedic appliances and artificial joints on the European market?](#)

1. Product description

Orthopaedic or fracture appliances

Orthopaedic appliances are worn, carried or implanted in the body to compensate for a defect. They include crutches, surgical belts and trusses, and appliances fixated during surgical procedures. Splints and other fracture appliances are orthopaedic appliances designed to perform a therapeutic or corrective function. Splints can be applied internally or externally.

Artificial joints

Artificial joints are used to replace painful, arthritic, worn or cancerous parts of the joint, with artificial surfaces shaped to allow joint movement. There are different types of artificial joints; for instance, for knee, elbow and hip. Furthermore, there are differences in the way that the joint is fixated (cemented or uncemented), leading to differences in design.

One CN code has been selected for orthopaedic appliances and artificial joints. See Table 1, which also shows the Prodcom code used in production statistics for orthopaedic appliances and artificial joints.

Table 1: Selected products based on CN and Prodcom nomenclature

CN code	Prodcom code	Description
902110	32502239	Orthopaedic or fracture appliances
902131	32502235	Artificial joints

Source: CN and Prodcom nomenclature.

In this survey, “orthopaedic appliances and artificial joints” refers to the product selection in Table 1, unless stated otherwise.

Quality

Orthopaedic appliances and artificial joints for the EU market must comply with the [Medical Devices Directive 93/42/EEC](#) and, depending on the specific product, with the [Active Implantable Medical Devices Directive \(AIMDD\) 90/385/EEC](#). For more information, see the “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 in the European Union for distribution in the European Union, the label, outer packaging and instructions for use must also contain the name and address of the authorised representative if the manufacturer does not have a registered place of business in the European Union;
- 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 may be included in the batch or serial number;
- where applicable, method of sterilisation.

Packaging

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

There is 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](#) (WPM), 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 orthopaedic appliances and artificial joints?

Imports

In the last five years, the total European imports of orthopaedic appliances and artificial joints grew in value by 7.4% annually, reaching €6.2 billion in 2015. The imports from developing countries grew at a very high rate (by 19.1%), reaching €382 million. It is expected that imports of orthopaedic appliances and artificial joints from developing countries to Europe will continue to grow in the next few years at a relatively high rate. A rough estimation, based on industry sources, predicts a growth of between 5 and 15% per year on average. The total imports to Europe will grow at between 3 and 9% annually in the next few years.

Germany is the largest importer of orthopaedic appliances and artificial joints, amounting to €1.3 billion in 2015. It is followed by France (€1.0 billion), Belgium (€741 million), the Netherlands (€734 million) and the UK (€710 million).

Leading suppliers

The United States of America is by far the largest supplier to Europe. The country represents more than 20% of European imports of orthopaedic appliances and artificial joints. It is followed by several European countries, of which Germany and Switzerland are the largest. China takes the ninth position as supplier (€162 million, +17.6% per year) and Mexico the tenth position (€122 million, +23.1% per year). Note that production in Mexico mostly comes from facilities owned by the large American manufacturers of medical devices. Other developing countries with exports to Europe are Tunisia (€23 million, +8.6% per year), Malaysia (€18 million, +35.5% per year), the Philippines (€14 million, +19.6% per year) and Turkey (€10 million, +17.3% per year).

Orthopaedic appliances and artificial joints imported from outside Europe are mostly exported directly to the target country. The reason is that the European market is rather scattered, with many companies operating in one country only. As a consequence, this trade flow does not lead to intra-European trade flows.

In the list of the 20 leading European suppliers of orthopaedic appliances and artificial joints, the highest growth in annual import was recorded by a group of five relatively low-cost supplying countries: Malaysia, Mexico, the Philippines, Romania and China. This development shows that Europe offers a market for products from relatively low-cost supplying locations.

Tips:

Identify the key importers of your product in large 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](#). Also interesting to read is our study of [Competition on the European medical and laboratory devices market](#).

Target one of the “big six” markets in Europe, as these markets together represent the bulk of the European market: Germany, France, Belgium, the Netherlands, the UK or Italy.

Learn from your competitors in the largest developing countries supplying to the market: China and Mexico, Tunisia, Malaysia, the Philippines and Turkey. 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 orthopaedic appliances and artificial joints per country is the [ITC Trademap](#) (you have to register first).

Exports

The total European exports of orthopaedic appliances and artificial joints increased by 7.9% per year between 2011 and 2015 to €7.3 billion. Exports of European orthopaedic appliances and artificial joints were mainly destined for other European countries (55% share of the total exports). However, exports to developing countries and to the rest of the world showed higher annual growth (by 18.6% and 9.7% per year on average, respectively).

In 2015, European exports to developing countries amounted to €723 million, 10% of the total European exports. For the coming years, this share of developing countries is forecast to increase slightly.

Germany is the largest exporter of orthopaedic appliances and artificial joints in Europe (€1.8 billion in 2015, 25% of the total European exports), followed by Belgium (20%), France and the Netherlands (14%), and Ireland (12% share).

Tips:

Learn from European export flows. Apart from targeting your export to the European Union, you can learn from European exporters and find opportunities in other large markets for orthopaedic appliances and artificial joints such as the United States of America, Japan and Australia.

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

Production

The production of orthopaedic appliances and artificial joints in Europe peaked at €7.0 billion in 2015, following an average annual increase of 6.4% in the period 2011–2015. Germany is the largest producer of orthopaedic appliances and artificial joints in Europe (€1.4 billion in 2015), followed by Belgium (€1.3 billion) and the Netherlands (€1.1 billion).

The strongest production growth was seen in Ireland (by 20% per year) and the Netherlands (19%). In some other countries production declined, most notably in the United Kingdom (by 7.4%) and Sweden (7.8%).

Tip:

Consider a subcontracting strategy. In addition to Germany and Belgium, there is also considerable production output in the Netherlands, France, Ireland and the United Kingdom. The presence of producers in these countries offers subcontracting opportunities to exporters from developing countries.

Demand

With the exception of 2013, when demand showed a tiny dip, European demand increased every year in the period under review. The demand reached €5.9 billion in 2015, following an average annual increase of 4.8% in

the period 2011–2015. Germany (€995 million) and France (€954 million) are the largest markets for orthopaedic appliances and artificial joints, together representing 33% of the total European market. In terms of applications, knee replacements are the number one product on the European market, followed by hip replacements.

Other countries with high demand are the Netherlands (€954 million), the United Kingdom (€659 million), Belgium (€619 million) and Italy (€555 million). Of these countries, the Netherlands and France showed the highest annual growth on average (by 12.7% and 7.3%, respectively) between 2011 and 2015.

Tips:

Focus on the large and growing markets in the Netherlands and France.

Find importers and exporters of orthopaedic appliances and artificial joints per country through the portal of [ITC International Trade Statistics](#) (you have to register first).

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), [Medtec Europe](#) (Germany) and [OTWorld](#) (Germany, Europe’s leading orthopaedics industry event).

Pay attention to the European business cultures before you start exporting to Europe. [Commisceo Global](#) offers a lot of information about differences in business cultures and etiquette.

3. Which trends offer opportunities on the European market for orthopaedic appliances and artificial joints?

Ageing population

The population in many European countries is ageing rapidly. Many seniors will need hip and knee implants, as well as other orthopaedic appliances and/or artificial joints. This fuels demand for orthopaedic appliances and artificial joints in these countries.

Materials for implants

There are several trends in biomaterial needed to fabricate orthopaedic implants and artificial joints. For instance, implants infused with human growth proteins prompt the body to regenerate the lining. Over time, the implant will deteriorate as the body grows the missing tissue. Another innovation in materials for orthopaedic appliances is injectable bone substitutes that focus on bone infections, bone augmentation and vertebral applications.

Efficient shaping/3D printing

There is a demand for manufacturing processes that shape orthopaedic appliances and artificial joints more efficiently and cost-effectively. One of these is [3D printing](#), for which experts predict a key role in orthopaedics.

Smart orthopaedic appliances

Numerous companies are working on smart orthopaedic appliances. They incorporate technology that enables data collection, which allows doctors and patients to monitor rehabilitation more effectively. In the future, orthopaedic implants could monitor how well implants are performing inside the patient’s body, measuring how well bone attaches to them or detecting problems such as inflammation or infection. Examples are [smart spinal implants](#) and [smart implants for orthopaedic surgery](#).

Minimally invasive surgery

Compared to regular procedures, minimally invasive surgery involves smaller incisions, lower risks of infection and a shorter recovery time. This type of surgery has benefits for the patient; for instance, minimal blood loss, skin scarring, duration of hospital stay and trauma. It can increase the number of operations in day surgery and ensure a faster turnaround of patients, while reducing costs. In orthopaedics, arthroscopy is increasingly used to visualise, diagnose and treat problems inside a joint.

Tips:

Take all the trends into account when you consider developing new orthopaedic appliances and artificial joints. Make sure that your new products surpass the current options in time- and cost-efficiency.

Read magazines and news from European or international sources: [Devicemed](#), [Medical Device and Diagnostic Industry](#) and [Orthopaedic Product News](#).

Follow the activities of the global market leaders such as [Zimmer-Biomet](#), [NuVasive](#), [DePuy Synthes](#), [Medtronic](#) and [Stryker](#).

Improve your competitiveness by focusing your export marketing on the reduction of maintenance costs for potential buyers and/or on tailored solutions that offer less invasive treatments for patients.

See [CBI Trends for Medical and Laboratory Devices](#) for more information on trends in the European market for medical devices.

4. Which requirements should orthopaedic appliances and artificial joints comply with to be allowed on the European market?

Requirements can be divided into (1) legal requirements, which you must meet in order to enter the market, and (2) non-legal requirements, which are those most of your competitors have already implemented; in other words, the ones that you need to comply with in order to keep up with the market. See our study of EU buyer requirements for medical and laboratory devices for a general overview of requirements. Below are the requirements that specifically apply to orthopaedic appliances and artificial joints.

Mandatory

Orthopaedic appliances and artificial joints for the EU market require CE marking. To obtain this, your products must comply with the [Medical Devices Directive \(MDD\) 93/42/EEC](#) or, depending on the specific product, the [Active Implantable Medical Devices Directive \(AIMDD\) 90/385/EEC](#). These directives ensure the 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 European regulations to “achieve a suitable, robust, transparent and sustainable regulatory framework” for the development of safe, effective and innovative medical devices. In June 2016, the Ministers of the European Union countries agreed on the final text of the new directive. The final formal adoption is expected in the first semester of 2017 and the new regulations will be implemented by 2018–2020. Among the most important implications of the new directive for producers of medical devices is the fact that the producer needs to deliver stronger clinical evidence, along with more data, to prove the safety of the device.

Tips:

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

For more information on the Medical Devices Directives, see the accompanying [guidance documents](#) to assist stakeholders in implementing directives related to medical devices.

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

Depending on the specific product, your orthopaedic appliances and artificial joints 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.

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.

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.

Governments, industries and consumers are becoming increasingly aware of sustainability issues. Recently, the concept of [Corporate Social Responsibility \(CSR\)](#) has become more important in the medical devices industry. Buyers are increasingly selecting suppliers based on their ethical and social responsibility measures.

For orthopaedic appliances and artificial joints, [no duty](#) is levied on EU imports from outside the EU.

Tips:

Check the [EU Export Helpdesk](#) for requirements, tariffs, statistics and preferential arrangements. Also make use of other databases that are freely available to entrepreneurs in developing countries: the [ITC Market Access Map](#) for technical standards and the [ITC Standards Map](#) for voluntary standards.

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

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

Provide products for which you can prove the environmental benefits such as recyclability and reusability.

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. Through which channels can you get orthopaedic appliances and artificial joints on the European market?

You should focus on European producers of orthopaedic appliances and artificial joints, and try to work for them as a subcontractor. This strategy is a much easier way of developing exports to Europe, as it is rather difficult to convince European companies requiring orthopaedic appliances and artificial joints to buy from a new supplier in a developing country. As the market channels and opportunities for orthopaedic appliances and artificial joints 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 Federation of National Associations of Orthopaedics and Traumatology](#) 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](#).

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