CBI Product Factsheet:

Orthopaedic appliances and artificial joints in Germany, Austria and Switzerland
Introduction

The market for orthopaedic appliances and artificial joints is growing in Germany, Austria and Switzerland. There is an increasing demand for innovative, cost- and time-effective and minimally invasive solutions. Imports to Germany, Austria and Switzerland reached €1.6 billion in 2014. In the same year, the annual growth slowed to 1.3% mainly due to a slight decrease in imports to Switzerland, but as the same time, the import share from developing countries increased. The leading importer is Germany, with a considerable market for imports from developing countries, making it the most interesting country of these three German-speaking and neighbouring countries.

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 the joint is fixated (cement or un-cemented), 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

<table>
<thead>
<tr>
<th>CN code</th>
<th>Prodcom code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>902110</td>
<td>32502239</td>
<td>Orthopaedic or fracture appliances</td>
</tr>
<tr>
<td>902131</td>
<td>32502235</td>
<td>Artificial joints</td>
</tr>
</tbody>
</table>

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, state 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 label must state ‘custom-made device’;
- If the device is for clinical investigations, the label must state ‘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, crates, drums, pallets, box pallets, and dunnage.

The International Trade Centre (ITC) provides additional information on packaging for exporters.

Demand

Imports

Figure 1: Imports of orthopaedic appliances and artificial joints to Germany, Austria and Switzerland, by main origin, € million, 2010-2014

Source: Trademap
Figure 2: Leading suppliers of orthopaedic appliances and artificial joints to Germany, Austria and Switzerland, € million, 2014

Figure 3: Imports of orthopaedic appliances and artificial joints to Germany, Austria and Switzerland by main origin, € million, 2014

Figure 4: Absolute developing country import growth 2010-2014, € million

Source: Trademap
• Imports of orthopaedic appliances and artificial joints to Germany, Austria and Switzerland reached €1.6 billion in 2014. Average annual growth in 2010-2014 was 10%. In 2014, annual growth slowed down to 1.3%, mainly due to a slight decrease in imports to Switzerland.
• The developing country share in imports increased from 4.0 to 7.5% in the period 2010-2014. Most imports originate from countries in Europe (49%) and other countries (43%). For the foreseeable future, the developing country share is forecast to show small growth in the range of 1 to 3%.
• The leading importer is Germany at 71%, followed by Switzerland (21%) and Austria (7.9%). In terms of developing country imports, Germany leads ahead of Switzerland. Austria does not import orthopaedic appliances and artificial joints from developing countries.
• Imports of orthopaedic appliances and artificial joints are expected to show small growth in the next few years in the range of 1 to 3%.

Leading suppliers

• Most leading suppliers of orthopaedic appliances and artificial joints to Germany, Austria and Switzerland are developed countries. The top suppliers are USA, Switzerland itself (to Germany) and the Netherlands.
• The main developing countries on the list of leading suppliers are Mexico (€61 million) and China (€43 million).
• Other developing countries exporting orthopaedic appliances and artificial joints to Europe are Vietnam (€3.4 million), Belarus (€2.4 million), Turkey (€2.1 million), the Philippines (€2.0 million), Costa Rica (€1.1 million) and Malaysia (€1.0 million).

Tip:
• Benchmark your company against your peers in developed countries, Mexico, China, Vietnam, Belarus, Turkey, the Philippines, Costa Rica and Malaysia. 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.

Exports

Figure 5: Exports of orthopaedic appliances and artificial joints from Germany, Austria and Switzerland, by main destination, € million, 2010-2014
Exports of orthopaedic appliances and artificial joints from Germany, Austria and Switzerland have shown an upward trend in the last four years, and amounted to €3.3 billion in 2014. Average annual growth in 2010-2014 was 9.1%.

The developing country share in exports is 15%, as most exports (45%) are destined for countries in Europe. This also includes some re-exports of imports from developing countries. For the foreseeable future, the developing country share is forecast to remain fairly stable.

The leading exporter is Germany, accounting for 51%, just ahead of Switzerland (48%). Austria accounted for 1.3%.

Of the total €3.3 billion, €542 million go to the USA with Japan in second position (€152 million) followed by Germany itself (€126 million, from Switzerland).

Exports of orthopaedic appliances and artificial joints from Europe are expected to show moderate growth in the next few years, in the range of 3 to 7%.

Production and apparent demand

No production and demand data are available on orthopaedic appliances and artificial joints for Switzerland. Data here are for Germany and Austria.
• Production in Germany and Austria was fairly stable at around €1.5 billion in the period 2011-2014.
• Germany accounted for 96% of this production in 2014, and Austria for 4%.

**Tip:**
• The presence of producers in Germany and to some extent in Austria offers opportunities for subcontracting for developing country exporters. Links to databases on producers of orthopaedic appliances and artificial joints can be found under Useful Sources below.

• Apparent demand in Germany and Austria totalled €1.0 billion in 2014, after peaking at €1.2 billion in 2013.
• Germany is the dominant producer of orthopaedic appliances and artificial joints at 87% and has the largest apparent demand, while 14% of demand comes from Austria.
The major determinant of demand for orthopaedic appliances and artificial joints is spending in the medical sector. In turn, this demand is stimulated by economic growth and an ageing population (an ageing population needs more medical care). In each focus country, Gross Domestic Product (GDP) and the number of senior citizens are expected to show continued growth year-on-year in the foreseeable future. This is a good basis for estimating demand for and growth in imports in the coming years.

Profitability of orthopaedic appliances and artificial joints imports is influenced by the euro/US dollar exchange rate, as many medical devices sourced globally are paid in US dollars. While the euro/US dollar exchange rate was not forecast to go beyond 0.80 until 2020, the exchange rate ranged from 0.88 to 0.93 in the period March-October 2015. This has a large impact on the price level of imports. If this situation remains so for some years, it will have a negative impact on European imports paid in US dollars versus local European production.
Trends offering opportunities

Ageing population

The population in Germany, Austria and Switzerland is ageing rapidly. Many seniors in these countries will need hip and knee implants, and 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 and experts predict a key role for 3D printing 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 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 faster turnaround of patients while reducing costs. In orthopaedics, arthroscopy is increasingly used to visualise, diagnose and treat problems inside a joint.

Tips:

- Many market trends for orthopaedic appliances and artificial joints are linked to improving time- and cost-efficiency. If you are considering developing new orthopaedic appliances and artificial joints, make sure they exceed the current options in time- and cost-efficiency.
- You can also greatly improve your competitiveness if you focus your export marketing on reducing maintenance costs for potential buyers and/or tailored solutions that offer less invasive treatments for patients.

For more information, see CBI Trends for Medical and Laboratory Devices.

Market requirements

Mandatory

The European Union has a Mutual Recognition Agreement (MRA) with Switzerland, covering the recognition of conformity assessments irrespective of the origin of products including medical devices. This means that certificates issued in the European Union, in accordance with European legislation, are equivalent to those issued in Switzerland, in accordance with Swiss legislation.
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. On 5 October 2015, the Ministers of the European Union countries agreed on a general approach on the package. The new regulations are expected to be implemented by 2018-2020.

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 re-use of 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. Other voluntary standards provide organisational (such as, ISO 13485), environmental and social (labour) requirements.

Governments, industries and consumers are becoming 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, with 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 device sector. 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:
- For more information on gaining access to the European market, see:
  - EU Export Helpdesk for requirements, tariffs, statistics and preferential arrangements
  - ITC Market Access Map for technical standards
  - ITC Standards Map for voluntary standards.
- In the ISO Catalogue, click on TC 76, 84, 194 and 210 for an overview of ISO standards.
- Search EN norms in the online shop of the British Standards Organisation.
- 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.
- Have 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.
**Competition**

As competition for orthopaedic appliances and artificial joints 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.

**Trade channels and market segments**

As the market channels 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.

Potential trading partners include:

**Germany**
- aap Implantate - manufacturer
- B. Braun - manufacturer
- Biedermann Motech - manufacturer
- FIOR & GENTZ - manufacturer and distributor
- implantcast - manufacturer
- K-implant - manufacturer
- Merete Medical - manufacturer
- Rebstock Instruments - manufacturer
- Teufel - manufacturer and distributor
- Waldemar LINK - manufacturer

**Austria**
- allomed - distributor
- Helnwein - distributor
- LARS - manufacturer and distributor
- mariohofer - manufacturer and distributor
- Sepin Orthopaedietechnik - manufacturer and distributor
- Spectromed - distributor
- Zeppelin - manufacturer and distributor

**Switzerland**
- epimedical - manufacturer
- Jossi Orthopedics - manufacturer
- Mathys - manufacturer and distributor
- Medacta International - manufacturer
- Orthotec - manufacturer
- Stemcup - manufacturer
- Symbios - manufacturer
- Synthes - manufacturer

**Useful sources**

- Finding prospects: [ESTA Healthcare](#), [MedicalExpo](#), [Qmed](#)
- National associations: [APO Switzerland](#), [Austrian Association of Medical Device Manufacturers and Suppliers](#), [Federation of Swiss Medical Devices Trade and Industry](#), [German Medical Dealers Association](#), [German Medical Technology Association](#), [ISPO-Austria](#), [ISPO-Deutschland](#), [SPECTARIS Trade Association Medical Technology](#)
- European associations: [Medtech Europe (Eucomed)](#), [European Federation of National Associations of Orthopaedics and Traumatology](#), [European Hospital and Healthcare Federation](#)
- Magazines and news: [Devicemed](#), [Medical Device and Diagnostic Industry](#), [Orthopaedic Product News](#)
- Trade fairs: [MEDICA](#) (Germany), [Medtec Europe](#) (Germany), [OTWorld](#) (Germany)

For more information, see [CBI Finding Buyers](#) in the Medical and Laboratory Devices sector.
This survey was compiled for CBI by Globally Cool – Creative Solutions for Sustainable Business in collaboration with CBI sector expert Leendert Santema.

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May 2016