

Europe's orthopaedic implant industry being transformed by innovation, regulation, and price pressure

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As healthcare becomes ever more personalised it's impacting specialised markets, such as orthopaedics. This piece, authored by **Alina Trabattoni, Dr Kristoffer Kenta, and Dr Leonid Shapiro** of health and social care consultancy **Candesic**, reviews how things are evolving in this pan-EU market after speaking to implant manufacturers, surgeons and patients, and reviewing clinical and patient recorded outcomes.

At high level, Candesic uncovered changes in the market:

- (i) Innovation-powered revenue developments including 3D printing, custom implants and minimally invasive surgery together with standard implant products suffer continued price pressure and regulation tightening in the continent's fragmented national markets;
- (ii) Big players' overall European market share is expected to expand in coming years;
- (iii) To compete, implant producers must expand beyond simple product manufacturing into end-to-end offerings in Europe. Focus need be on support services, quality of instruments and relationships with Key Opinion Leaders (KOLs) to match, if not overtake, the expected international growth in implant sales.
- (iv) Customised 3D market to remain niche due to lengthy delivery times, low reimbursement levels and good outcomes of standard off-the-shelf products, and will be mainly used in massive bone loss, special revision cases.

Europe's orthopaedic industry is poised to undergo substantial change in coming years and is forecast to grow from an estimated \$11.4 billion this year to \$14.75 in 2025. Even so, innovation-powered revenue developments including 3D printing, custom implants and minimally invasive surgery together with standard implant products suffer continued price pressure and regulation tightening in the continent's fragmented national markets.

Overall, the global orthopaedic market is forecast to grow 3.5% per annum over coming years, lifted by a patient pool requesting higher volumes of implant surgeries in response to rising cases of orthopaedic disorders resulting from increasing longevity and unhealthy lifestyles,

Yet European implant producers will need to focus on support services, quality of instruments and relationships with expert opinionmakers to match, if not overtake, the expected international growth in implant sales which reflect a far more competitive market than the one that enjoyed 12% annual growth rates in the 1999-2008 period.

“As the average lifespan increases, so does the overall number of implants and they will continue to do so,” said Professor Carlo Ruosi, orthopaedic surgeon at the Federico II University Policlinic in Naples, Italy, in an interview. “Only 25 years ago, the average person (in Italy) would live until they were 73, today the average lifespan has increased to 83.6, and this spills over into the number of implants. This type of growth will continue for as long as we increase the longevity of the population.”

Currently, the European market is dominated by orthopaedic implant giants DePuySynthes, Zimmer Biomet, Stryker and Smith & Nephew. Combined, the big four control more than half of the continent’s hip and knee prosthesis sales, with the rest of the market made up of a fragmented assortment of small niche companies.

This trend could further accelerate in coming years, reflecting a wider one across the globe which saw the top five orthopaedics implant producers expand their market share to 62.2% from 52.8% between 1999 and 2015. Those that are on the cutting edge of services excellency and focus on quality of instruments and relationships with knowledgeable experts will be perfectly positioned to benefit from the increase in volume and demand, according to sector analysts.

Expert arthroplasty surgeons highlight support services to themselves and their hospital staff together with quality of instruments as being amongst key influencers in the product selection process, even as manufacturers suffer downward price pressures and tightening regulatory oversight being levied Europe-wide across the medical devices market.

Orthopaedic implant producers focussing efforts on improving support services for surgeons, quality of instrumentation, as well as relationships with knowledgeable experts, or Key Opinion Leaders (KOLs) in their field, will be facilitated in the push to increase revenue and market share over time, according to information that emerged from a survey of 31 orthopaedic surgeons across Europe including ones in Italy, France, the UK and the US.

“Quality of products including instrumentation is key, as are support services,” said Professor Giulio Maccauro, who heads the orthopaedics and traumatology department at the Rome University Policlinic, in an interview. “Getting deliveries and receiving the implants in a timely manner is also of utmost importance.”

“The point is that today, once you get to a certain level, implants are very similar and commoditised. The real difference is in the instruments, the support services and the addons,” Maccauro added.

To date, still, the European market is dominated by four big players, DePuy Synthes with an 18% share, Zimmer Biomet with 15%, Stryker with 13%, and Smith&Nephew with 7%, with the rest still relatively fragmented. With the increased commoditization of hip and

knee implants, producers have turned their investment focus onto innovative hip and knee implant positioning methods and tools.

In addition, small manufacturers are increasingly focussing on technological enhancements and niche markets to remain competitive whilst leveraging relationships with customers and partnerships with key surgeons, both critical to driving sales in a market with limited differentiation between manufacturers. They are often judged based on the flexibility of their customer service.

Investments into robotics, computer-assisted planning software, patient-specific instrumentation and experiments with augmented reality for implant positioning are only but a few of the new initiatives flourishing in this domain. A major aspect of these developments is the move to shorten recovery times and so limit patients' immobility periods.

“At this point in time, innovation is focussed on two lines of development, with everyone looking at fast track recovery with the near-immediate release of patients, and all that relates to this. This includes method of positioning, release from hospital, post-operations and the like,” said Dr. Alessandro Calistri, an orthopaedic surgeon who performs surgeries both in Italy and Belgium, in an interview. “This process started in the US a long time ago, and is now filtering through into Europe.”

“Also, the second big trend is robotics,” Calistri added.

Robotics and minimally invasive surgery not only improve the quality of the experience for the patient, but also reduce costs by shortening hospital stays with the continuation of patient treatment through day care. In France, for example, the anterior approach has become increasingly popular over past years due to the non-invasive nature of the implant surgery and the shorter patient recovery time. Similarly, short stems have been increasingly in demand compared to longer stems in the French market as they permit better access to the bone during surgery and also facilitate revision surgery.

The orthopaedics manufacturing process has also changed in past years, with 3d printing technology being adapted for the production of uncemented prosthesis for off-the-shelf and customised products. The advantage of 3d printing is that it allows surgeons to obtain good primary stability due to the roughness of the surface, orthopaedic surgeons say.

“With custom implants, the implants fit the bone anatomy so it's an advantage, but for most patients I believe the clinical benefit might be limited,” Dr Charles Rivière, orthopaedic surgeon at Clinique du Sport Bordeaux. “However, for patients with complex anatomy it might offer a real clinical benefit.”

The customised 3D market to date remains niche, and is expected to remain so due to the good outcomes of standard off-the-shelf products, the lengthy delivery times for personalised implants – in some instances 6-8 weeks from the date of the order – and their low reimbursement levels.

Today, and for the foreseeable future, customised implants are mainly used in special revision cases, often involving oncology patients suffering from massive boneloss. Overall, these limited cases make up around 2.5% of total revision procedures, which in turn total around 7% of total joint replacement surgeries. With favourable conditions, they have the potential to go up to about 10% of total revisions, according to analysts.

“Custom-made implants are a niche market that is mainly relevant to oncology patients and to those situations of damage which cannot be standardized, as well as to large revisions,” said Professor Carlo Ruosi. “If you think about it, about 50-60% of implants have to undergo revisions within some ten years, and again for a second time some ten years later. They are particularly useful in cases of second-scale revisions or oncology situations and the like.”

In terms of procurement, surgeons have highlighted that quality instruments, service and experience with products as the most important factors when making their purchasing decisions on implants, though more often than not hospital purchasing centres have to contend with pricing competition was well.

In the public sector markets of UK, France and Italy, tender bid processes are used for often collective implant purchases. In the French and Italian system, the leading surgeon of the department will likely have substantial sway over which implants are to be used within their department.

Yet cost of healthcare in past years has increased, forcing hospitals to become increasingly price sensitive when purchasing medical devices, and this has also been felt on the orthopaedics sector. This trend has been further heightened by the process of commoditization of implants, while in parallel, regulators have sought to tighten controls over the effectiveness and the safety of medical devices being introduced into the European market.

“If you reduce the implant costs, you also reduce the margins,” said Dr Augusto Palermo, who heads Orthopaedics at the Istituto Auxologico Italiano IRCCS Ospedale Capitanio in Milan, and also operates at the Pio XI Clinic in Rome and Villa Montallegro Clinic in Genova. “Unfortunately, with the price pressure on implants, you reduce the margin companies have that in turn sets up the risk of reducing the quality of service, and this at times creates a vicious circle.”

The types of services that make a difference include education and the training of wider staff beyond the surgeons, such as nurses and operating theatre staff. In addition, the relationship with sales representatives in terms of availability and attention to surgical needs and delivery times is critically important, surgeons say. Intraoperative assistance, whereby a product specialist is in the operating theatre during the surgery to provide the benefit of his product expertise in real time, is deemed to be of great relevance by some surgeons, providing the quality of the support is high.

“It can be very beneficial to have a product representative present during surgeries,” said Dr Michele Biserni, an orthopaedic surgeon who operates in private practise and clinics in Umbria and Tuscany. “They have to know their product very well though.”

Product reputation is also an important element that contributes to the final decision in terms of procurement. If respected expert surgeons (KOLs) draw up interesting data on the product, its value increases in the eyes of the potential user, according to surveyed surgeons. Younger surgeons appear to prefer innovation-driven companies, while more experienced surgeons tend to err on the side of caution and often question whether innovations are driven by the market as opposed to being pushed by a real need.

“The orthopaedic community as a whole remains wary of technological change after the metal on metal hip resurfacing problems 10 years ago,” said Harry Rourke, Consultant Surgeon in trauma and orthopaedics at the Royal Liverpool Hospital. “The results of commonly used implants are already really very good. Convincing surgeons to use innovative products that may offer additional advantages, requires robust evidence from respected centres and, ultimately, registry data.

The new EU Medical Device Regulation (2021) will enforce stricter equivalency and post market surveillance requirements, and this is expected to raise costs for companies. In addition, the increased administrative burden of post-market surveillance will also put further pressure on margins, and this could substantially impact the profitability of small players.

The new MDR, which came into force in May 2017, replaced the previous Directive on active implantable medical devices (90/385/EEC) and its Medical Device Directive (93/42/EEC) and the EU’s, and initially gave manufacturers of approved devices a transition time through May 2020 to comply with the requirements. This was since postponed to May 2021.

“Small companies will have to strengthen their clinical evaluation of orthopaedic implants due to the new MDR rules,” said Dr Cyrus Brodén, orthopaedic surgeon and researcher at Imperial College London in an interview. “This will require a lot of investment in research.”

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