Below table outlines the key metrics in Europe for craniomaxillofacial (CMF) devices.

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<th>Craniomaxillofacial Devices: Key Metrics in Europe</th>
<th>2013 Market Revenue ($m)</th>
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<tr>
<td>5EU Total Market Revenue for CMF Devices</td>
<td>$227.0m</td>
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<tr>
<td>CMF Plate and Screw Fixation</td>
<td>$159.6m</td>
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<td>CMF Distraction</td>
<td>$18.9m</td>
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<td>Cranial Flap Fixation</td>
<td>$23.3m</td>
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<td>TMJ Replacement</td>
<td>$2.2m</td>
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<tr>
<td>CMF Bone Graft Substitutes</td>
<td>$3.9m</td>
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<tr>
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<td>$19.1m</td>
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<tr>
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<td>CMF Distraction</td>
<td>$23.5m</td>
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<td>Cranial Flap Fixation</td>
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<td>CMF Bone Graft Substitutes</td>
<td>$4.6m</td>
</tr>
<tr>
<td>Thoracic Fixation</td>
<td>$25.4m</td>
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Source: GlobalData, based on secondary research and primary research, including interviews with Key Opinion Leaders and industry experts, and physician surveys covering four specialties (oral and maxillofacial, otolaryngology, plastic and reconstructive, and neurosurgery).

5EU = France, Germany, Italy, Spain, and UK; TMJ = temporomandibular joint

The CMF space represents one of the promising markets in the orthopedic industry. In 2013, revenue from the CMF market in the five European Union countries (5EU) (France, Germany, Italy, Spain, and UK), consisting of plate and screw fixation, distraction, cranial flap fixation, temporomandibular joint (TMJ) replacement, CMF bone graft substitutes, and thoracic fixation, was estimated to be $227m. The sales in the CMF market are expected to experience slow growth throughout the forecast period, reaching $275.6m at a Compound Annual Growth Rate (CAGR) of 2.8%.

Key drivers during the forecast period include:

- Rising trauma and sports injuries due to extensive urbanization and industrialization
- Improving patient awareness to foster demand for deformity correction surgeries
- The need for enhanced patient experience will drive the adoption of patient-specific implants and virtual surgical planning (VSP) technologies.
- Three-dimensional (3D) printing will allow manufacturers to integrate new materials for cranial and facial reconstruction.
- Increased cross-selling opportunities as a result of operating room (OR) supply standardization

Key barriers during the forecast period include:

- Economic softness and hospital cost-containment measures that delay surgeon uptake
- Restricted reimbursement for patient-specific devices to limit market growth potential
- Ever-intensifying market competition to worsen pricing erosion
Executive Summary

Below figure shows the CMF devices market by major markets for 2013 and 2020.

Together, the 5EU contributed 22% to the global market revenue, with Germany leading the pack. Despite the German economy’s recent return to growth, the other Eurozone countries are still struggling to get back on their feet after weathering the sovereign debt crisis. GlobalData estimates that the market share will remain relatively stable for the forecast period. While all of the major markets are expected to grow in sales units, the 5EU countries will be experiencing strong pricing pressures and delayed surgeon uptake stemming from their governments’ healthcare budget constraints.

Market Dynamics

The CMF devices market in developed countries (covering plate and screw fixation, distraction, cranial flap fixation, TMJ replacement, bone graft substitutes, and thoracic fixation) is heavily dependent on the revenue stream through the plate and screw fixation segment, which represents about 70% of the total market size. Future growth in the plate and screw fixation segment lies in the CMF trauma and reconstruction procedures, as most of these procedures are non-elective. Therefore, the CMF space remains an important avenue for growth for orthopedic companies, and has witnessed an increasing number of players that are introducing advanced technologies and investing heavily in physician training.
Executive Summary

Despite the promising growth in procedure volumes, the continued efforts of governments in tackling their escalating healthcare expenditures have resulted in pricing pressures, which, in turn, have dulled the revenue growth in the CMF space. In particular, the lingering sovereign debt crisis in the Eurozone adds an extra dimension of complexities for companies seeking sustainable growth in the 5EU countries. Due to the cost-containment considerations, the adoption rates for premium devices, such as patient-specific implants and virtual planning technologies in fixation surgeries are generally lower in Europe than the US.

Key Players in the 5EU CMF Devices Market

There is one clear leader in the CMF devices market: DePuy Synthes. As DePuy Synthes is the pioneer in orthopedic and neurosurgical technologies and has been constantly pushing the frontier in the CMF space, the company has sustained the leading position in the CMF market, especially in the plate and screw fixation segments. GlobalData estimates that DePuy Synthes currently contributes to about one third of the market for CMF devices. Following DePuy Synthes is Stryker, Biomet, KLS Martin, and OsteoMed. Moving forward, DePuy Synthes' dominance is widely considered not replicable due to its long history in the CMF field, its significant presence in orthopedic core markets, as well as its aggressive marketing efforts. While DePuy Synthes is very likely to dominate the market in the next few years, GlobalData anticipates an evolving competitive landscape among the top three players in this field. How Stryker and Biomet will leverage their platform technologies to diversify their current portfolio and enhance their competitive edges against DePuy Synthes will be the most interesting thing to follow in the coming years. Beyond these multinational players, the rest of the CMF market is occupied with a wide range of companies either focusing on specific segments, such as cranial flap fixation, or targeting the low-end market with me-too products.

5EU Market Future Outlook

Similar to the US, the CMF space is also a growing market in Europe, though the 5EU market has failed to match the growth rates seen in the US. Inadequate surgeon training, reimbursement challenges, and the fact that some CMF deformities are not life-threatening conditions will continue to negatively affect the market's healthy volume growth, which may be compounded by the suppliers' focus on the fast-growing US market. Despite these industry headwinds, positive growth is expected in all segments of the market, as the patient demographics in Europe maintain a steady demand for such procedures.
What Do Physicians Think?

In addition to titanium and resorbable materials, porous polyethylene (PPE) represents another plating material; however, with PPE, it has been noted that a potential liability exists with the use of this material in CMF implants in that the ingrowth of soft tissue may render secondary removal difficult in cases that demand later operation.

“They are talking about porous polyethylene implants all the time. I just prefer not to use them, because if you ever have to take one [PPE implant] out, you’ll find it incorporated into the tissue. It is much more difficult to remove a PPE implant than a pure titanium one. Titanium implants work just fine without introducing another product. So, I feel that there isn’t any added benefit with the PPE implant.”

Key Opinion Leader

Rather than just the latest innovation, VSP is rapidly becoming an important component in the surgical treatment planning of CMF reconstruction and orthognathic surgeries. Compared with the US, Europe has a lower adoption rate of the VSP technology, mainly due to slow surgeon uptake and price sensitivity.

“I think everybody wants to use it [VSP technology], but it’s a matter of time and money. So, if you don’t have the time to use it for all patients, you reduce it to the very patients who will be benefited the most from it. And money is the next issue – if it is difficult to have the reimbursement from the insurers, you have to find some other ways in terms of financing. I think my colleagues are eager to use it, but these are the two main obstacles.”

Key Opinion Leader

Prosthetic TMJ replacement is currently reserved for patients with end-stage TMJ defects as a salvage option, and hence, has low procedure numbers with a limited number of surgeons performing this surgery worldwide. Nevertheless, pent-up patient demand and companies’ consistent investment in physician training will help to accelerate the expansion of this niche market in the next decade.

“We have some surgeons who are really conservative on TMJ [reconstruction], because they still remember bad results [of old TMJ reconstruction products] from the 1980s. I have been discussing the latest products with them for years, and they are now more open-minded about this procedure.”

Key Opinion Leader
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2 Introduction

2.1 Catalyst

Craniomaxillofacial (CMF) surgery is a highly specialized branch of orthopedic surgery that focuses on all aspects of facial and skull disorders. In this report, GlobalData covers the following segments: CMF plate and screw fixation, CMF distraction, cranial flap fixation, temporomandibular joint (TMJ) replacement, CMF bone graft substitutes, and thoracic fixation (rigid fixation only). Throughout the report, adoption patterns, procedure volumes, and market revenues for all the aforementioned segments are included. In addition, GlobalData included an analysis on the dural repair market, which consists of dural substitutes and dural sealants. However, procedure numbers and market revenues for dural repair are provided only for the US market in the global report.

Overall, the growth of orthopedics in developed markets is being driven by established healthcare infrastructure and expanded insurance coverage, as well as the trend of early intervention, while ongoing macroeconomic pressures continue to influence the healthy growth in the procedure numbers of high-volume surgeries. The current CMF devices market remains a growing space that promises opportunities, primarily due to the non-elective nature of most CMF trauma and neurosurgeries. Although standard/stock titanium plate and screw systems still represent the first choice in managing CMF surgery, the use of patient-specific implants has been expanding in the past decade and becomes particularly useful in situations with challenging anatomy distorted by tumors, post-traumatic reconstruction, or revision cases. Future trends will include continued development in bioabsorbable plating systems and advanced distraction systems, as well as an increased use of virtual planning technologies, patient-specific devices, and cost-effective thoracic fixation devices. In the meantime, additive manufacturing, such as three-dimensional (3D) printing, is taking manufacturing in a whole new direction without the boundaries of shape and structure; the future of custom CMF implants will lie in additive manufacturing, which will widen the spectrum of synthetic substitute materials suitable for this purpose.

Moving forward, industry consolidation and intense competition in the orthopedic arena will cause more and more companies to increase their research efforts to differentiate their products from the lower-end competitors. Despite the ongoing cost-containment pressures and pricing erosions in the orthopedic industry, the CMF devices market is dynamic and evolving, necessitating up-to-date market analysis for all players involved.
Introduction

2.2 Related Reports

10.6 About MediPoint

MediPoint is the flagship product for GlobalData’s Medical team. Each MediPoint report is built from the ground up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading Key Opinion Leaders (KOLs). Running throughout each report in the series are “What Do Physicians Think” quotes, which provide a unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

10.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports, and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

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