The Business Case for 3D Printing Large Joint Devices

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Significant cost savings are in reach for large joint devices with no compromise in design requirements, thanks to a new approach that combines next-generation of 3D printers with a deep understanding of medical device design.

The market for large joint implants—hips, knees, and shoulders—has grown increasingly competitive over the past 15 years, a trend that accelerated sharply more recently. Although OEMs have added compelling features to their devices, hospitals and insurers increasingly think of large joints as commodities they can buy based on price. As a result, margins are falling.

OEMs have struggled to reduce production costs. Yet they have failed to achieve significant breakthroughs with conventional manufacturing or previous 3D printing technologies.

Orchid Orthopedic Solutions, a global leader in contract implant design and manufacturing, and GE Additive, a pioneer in metal additive manufacturing, have developed a way to alter this stalemate and address large joint implants.

By harnessing a new generation of high-productivity electron beam-based 3D printers, Orchid is attaining breakthrough economics for large joints in production runs of hundreds to hundreds of thousands of parts without any loss of quality or reliability. Orchid's breakthrough cost savings represent a promising route for OEMs to regain margins eroded by the changing nature of the implant market.

Evolving Markets Demand New Technologies

Over the past 15 years, the market for large joints has changed significantly. Younger patient populations demand joint implants that will last longer and allow them to resume their active lifestyles. New enterprises, such as ambulatory surgical centers (ASCs) that specialize in one-day surgeries for knee and total hip implants, have sprung up to meet those needs.

Empowered by venture capital and changes in healthcare reimbursement rules, ASCs have engaged hospitals in a price war for surgeries. Orthopedic devices have become collateral damage, with both hospitals and ASCs pressuring OEMs to lower device prices while treating them as interchangeable commodities.

OEMs fought those pressures by innovating to differentiate their products. They redesigned large joints to make them easier to implant and tried new material combinations. They developed devices with porous surfaces that friction-lock into place without cement, which reduces surgical time and reduces bone loss for patients. Cementless designs increase complexity and cost.

Unfortunately, such continuing innovation almost always increases the cost of each device. At the same time, insurance companies have insisted on paying a set fee for implants regardless of the technology chosen. As a result, margins remain under siege, leaving OEMs desperate to regain lost profitability. In addition, they must also cope with inflation, labor shortages, and supply chain disruptions. Everyone is looking for a solution that delivers a transformative benefit.

Could next-generation 3D printing be the answer?

Can 3D Printing Deliver Savings?

To understand why additive manufacturing is so promising, consider the conventional route to large joint devices. It involves multiple steps, such as machining, polishing, and coating. Each operation introduces complexity into the process, which increases the cost of the device.

Additive manufacturing has the potential to simplify this process by consolidating several production operations into one. The product is printed from digital models, one layer of metal powders at a time. The printing process allows for the simultaneous creation of complex features, including bone contacting surfaces, instrument slots, and lattice structures that enable bone in-growth.

Additive manufacturing takes place in a single printer. The process is more automated and requires fewer touches moving devices between processing equipment than forging or casting. This reduces variability and simplifies the supply chain. There are also fewer process steps to test and validate for regulatory compliance.

EBM technology improves the business case for large implants by increasing speed and build volume capacity while reducing post finishing steps.

There are several different metal additive manufacturing technologies. Laser 3D printing and electron beam melting are the two technologies best suited to medical implants. Both can process titanium and cobalt-chrome alloys, and both have proven themselves for more than a decade in the highly regulated medical and aerospace industries.

Laser 3D printers have proven very cost-effective for small, complex devices, such as vertebrae cages for spinal fusion. When made by conventional methods, these parts require a great deal of machining. Laser printers reproduce the parts' fine features with precision while eliminating machining steps and produce dozens of the devices in a single process run. Laser 3D printing produces most of the spinal cages used today.

Electron beam melting has been used to make acetabular cups for more than a decade. Today, however, a new generation of EBM printers delivers significant cost improvements for acetabular cups and other large joint implants at true industrial production scales.

The Evolution of EBM 3D Printing Technologies

EBM technology improves the business case for large implants by increasing speed and build volume capacity while reducing post finishing steps.

Compared with previous EBM systems, GE Additive's Spectra L has a faster and more powerful electron beam, a 20 percent greater build volume, and enhanced computer controls.

This enables Spectra L to print parts faster and more closely packed together without any loss of quality. It is a consistent, reliable industrial-grade system ideally suited for production runs of hundreds to hundreds of thousands of devices per year, all done with outstanding productivity and bottom-line results. Instead of paying a premium for 3D printing the features that differentiate their large joint devices, OEMs will see significant cost savings.

EBM achieves these results because it takes place at uniformly elevated temperatures. This sharply reduces the thermal cycling--and thermal distortion—that occurs when melted powders solidify and cool. This enables printers to make full use of the entire space to stack parts atop one another using multiple layers. EBM can do this with only one power source (as opposed to multiple lasers), so there is less variability to manage.

The Spectra L's software enables it to pack parts closer together without any loss of quality. While builds take longer to complete than laser systems, GE Additive's test data suggests that their high-volume throughput yields 50 percent or more tibia or knee parts per hour. Such breakthrough productivity could truly move the needle for OEMs.

> Early on, we saw the value additive manufacturing could bring to customers when combined with our deep understanding of hip, knee, and shoulder implants.

Cost-Effectively Print Large Joint Implants

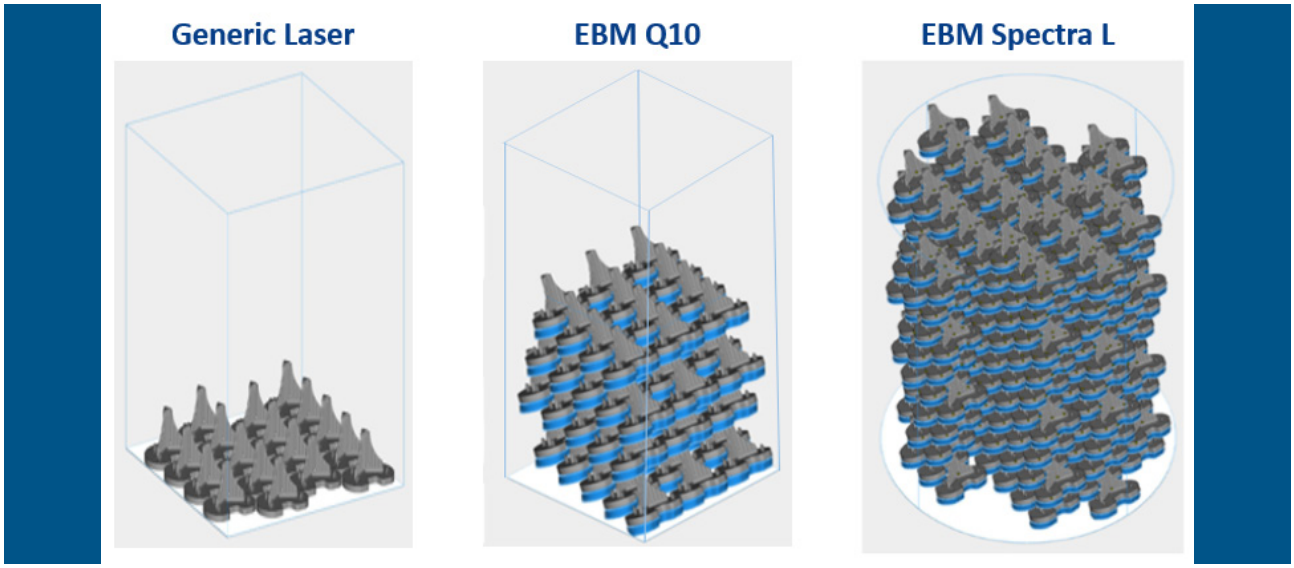
Orchid's approach to restoring margins began by focusing on requirements of the highly competitive large joint implant market, then identifying technology that could provide a solution. For large joint implants, the newest generation of EBM checks all the right boxes.

EBM consolidates multiple production steps into a single process, reducing variation and improving yield. It is fast, efficient, and capable of industrial-scale production runs.

Because additive manufacturing is a batch process that uses a digital model instead of an expensive mold or stamped blank, it is economical even when building a few hundred devices. Yet Orchid's fleet of EBM machines has the capacity to generate hundreds of thousands of devices annually. For many large devices, Spectra L's productivity eliminates the premium OEMs now pay to laser-print or forge their highly complex products.

At Orchid, we understand that our customers—OEMs—need a way to reduce costs without compromising the quality and reliability of their products. Early on, we saw the value additive

The newest EBM machines yield more product in a single build



manufacturing could bring to customers when combined with our deep understanding of hip, knee, and shoulder implants. To realize that value, Orchid developed an array of proprietary post-processing techniques to transform printed parts into advanced implantable devices. Yet, until now, we could not find a way to do this economically at scale.

The hard truth is that OEMs do not need another technology that nibbles away at rising costs. Competition and inflation are eroding margins too rapidly for that. They need a transformative way to lower production costs so they can continue to innovate and thrive. They require more than a new technology—they need a business strategy built around technology and large joint expertise to succeed.

A Product-Focused Manufacturing Strategy

This is what Orchid has created. We spent more than a year assessing different additive manufacturing technologies to find that breakthrough—one that specifically addresses large joint implants. The company looked at the latest large-bed, multi-laser systems and ran the business case numbers over and over. The economics were not compelling.

Then Orchid revisited electron beam technology. The company focused on GE Additive's Spectra L, which was designed to print industrial volumes of high-strength precision parts with outstanding repeatability and reliability. The technology was initially developed for aerospace, an industry that, like OEMs and contract manufacturers in the medical devices market, must meet steep regulatory requirements.

These characteristics were exactly what Orchid sought in a 3D printer. GE's ability to scale these machines to industrial volumes in aerospace gave Orchid confidence it could meet its target volumes for medical implants as well.

Orchid's choice of GE Additive goes beyond the technology itself. It is part of a larger strategy to create an industrial-scale additive manufacturing operation that builds on Orchid's specific expertise in hip, knee, and shoulder devices. Ordinarily, an enterprise like this would take years to nurture and build. By working with GE Additive, Orchid immediately leverages years and years of GE's EBM expertise and its own orthopedic and manufacturing expertise to implement this strategy much faster.

Femoral components in multiple stages after 3D printing: with print supports, without print supports and fully finished with an anti-wear ceramic bearing surface.

By learning from experts, Orchid has built rapidly upon its own expert knowledge in large joint implant machining, bone in-growth technologies, and finishing. The agreement with GE Additive also ensures Orchid will be able to optimize consistency, build speeds, and reliability right from the start.

Orchid's experience shows that the technology can exceed industry design requirements for a range of large joint predicate devices. Our data shows EBM-printed devices achieve properties equivalent to those made by conventional machining in a reliable, predictable way.

Evolve with Zero Compromise

Orchid has built something new in the medical device industry in collaboration with GE Additive: a high-mix, high-volume large joint additive manufacturing solution. The solution includes a deep bench of design and production expertise in the conventional aspects of device manufacturing as well as a rapidly evolving capability in the most advanced additive manufacturing technologies.

If OEMs are looking for a cost-effective way to make large joints that offsets inflation and expands margins without compromising quality or design, Orchid has a solution they should pursue.

Orchid Orthopedic Solutions (Orchid) is a leader of manufacturing solutions and innovative technologies for the orthopedic market. Orchid has the broadest capability portfolio in the industry, ranging from additive manufacturing, forging, casting, machining, finishing and bone in-growth coatings, offering end-to-end solutions for all steps in the supply chain.

Orchid is building on its legacy as a trusted provider of orthopedic implant manufacturing services through the adoption of EBM additive manufacturing technology and collaboration with GE Additive. By utilizing the newest technologies, the benefits of traditional manufacturing are uncompromised with additive manufacturing and allow for a reduced cost per part. Leverage a cost-effective supply chain for hip, knee and shoulder implants and evolve your business with zero compromise!

For more 3D printing resources, visit the Orchid Additive Manufacturing Showcase