

3D Printing Presents New Opportunities for the Medical Devices Industry

Abstract

The medical devices industry has been under a deluge of evolving regulations, leading to protracted lead times and high device development costs for new and enhanced medical devices. These costs assume worrying proportions for low volume product markets. 3D printing technology presents a promising option and involves leveraging additive manufacturing processes that use a layer-by-layer material build-up process to create 3-dimensional objects.

3D printing is currently a \$700 million industry, with only 1.6% invested in medical applications.¹

However, recent projections suggest that within a decade, 3D printing will rapidly develop into a multi-billion dollar industry, with nearly 25% spent on medical applications.

The doctors at Mayo Clinic are using 3D printers to enable customized joint replacement surgeries².

The Potential of 3D Printing for Medical Devices

3D printing is emerging as a cost effective, efficient, and customizable manufacturing option for the medical devices industry for devices including dental implants, hearing aids, prostheses, custom-made knee and hip implants, and surgical instruments.

This technology delivers on counts such as personalization, flexibility in design and manufacturing, decreased material wastage, elimination of specialized tooling, and low lifecycle costs. 3D printing can be used to develop many new medical devices that were earlier deemed difficult to create, expensive, or not patient-friendly. 3D printing also has the potential to substantially reduce tooling costs and accelerate lead time and regulatory submissions.

Delivering Disruptive Innovation to the Medical Devices Industry

3D printing is poised to revolutionize the medical devices industry by:

- Encouraging new entrants
- Optimizing device design and development
- Reconfiguring the supply chain
- Enabling precision planning for surgeries

FDA-approved Patient-Specific Facial Device from Oxford Performance Materials was used to reconstruct up to 75% of a patient's skull at a low cost. The patient-specific maxillofacial implants are 3D printed in polymeric materials based on the digital image files shared by the surgeon.⁴

The Business Value of 3D Printing

Medical device manufacturers can leverage the multiple business opportunities created by this technology including:

- Addressing the market need for truly individualized yet economical medical devices and solutions³
- Increasing innovation by integrating complex features
- Reducing time-to-market by creating 'clinical trial-ready' products directly from CAD data
- Reducing lifecycle costs by reducing material wastage in the form of process scrap

Emerging Business Models and Use Cases

The adoption of 3D printing will introduce new business models including:

- **Patient-Specific or Personalized Devices**
 - Hospitals can use imaging to collect patient-specific data and transfer it to OEMs over the cloud along with the purchase order for personalized devices.
 - Hospitals can have their own 3D printing facility where the device can be printed from personalized 3D data provided by the radiology department.
 - Patients' data can be sent for creating 3D printed organs or bones for surgical planning to a 3D printing vendor, who prints and ships the models to hospitals.
- **Generic Devices**
 - OEMs can have their own 3D printing facility or work with a 3D printing service provider to print and ship generic devices to the point of use.
 - Doctors can prescribe a generic medical device to the patient using a serial number or a Unique Device Identifier. The patient can purchase the digital file of the approved medical device from the OEM and print it at a certified vendor.
- **Cloud Manufacturing**
 - OEMs or hospitals can leverage the 'cloud manufacturing model' whereby personalized or mass-customized data of the device is uploaded to a secure website. Pre-selected

In FDA's own words, "[3D printing] has the advantage of facilitating the creation of anatomically-matched devices and surgical instrumentation by using a patient's own medical imaging. Another advantage is the ease in fabricating complex geometric structures, allowing the creation of engineered porous structures, tortuous internal channels, and internal support structures that would not be easily possible using traditional [non-additive] manufacturing approaches."⁷

3D printing vendors can use this data to create parts or sub-assemblies for the device and ship them to the point of use.

- This model can be used to manufacture one to a few thousand devices by leveraging a flexible network of 3D printing vendors. This network may multiply drastically as 3D printing becomes popular, thus creating an entirely new and flexible supply chain for medical device 3D printing.

Accounting for Potential Challenges

Like any other budding technology, 3D printing does have its own set of challenges:

- Lack of regulatory frameworks to enforce quality standards may delay widespread acceptance of 3D printing. To mitigate this, FDA has come up with a draft guidance document for 3D printed medical devices on 10 May 2016. UL is also working closely with the companies to create quality standards for 3D printing⁵.
- 3D printing has limitations including the lack of an exhaustive range of 3D printed materials, limited build size, difficulty in achieving tight manufacturing tolerances or fine surface finishes, and the slow speed of production compared to traditional subtractive manufacturing processes. To overcome these limitations, companies like HP are coming out with new technologies for polymers. In the case of metal, innovations in Directed Energy Deposition techniques are pushing the boundaries.
- The FDA has identified mechanical properties, bio-compatibility, and interactive design of medical devices that are 3D printed as potential challenges. Nevertheless, FDA has approved more than 85 3D printed medical devices as of May 2016.⁶

Conclusion

As patients start appreciating the benefits of 3D printing such as reductions in surgery costs, time, trauma, and healing periods, the demand for personalized medical devices will increase. As with any emerging technology, the perceived roadblocks will only spur product enhancements, which could lead to the creation of more innovative 3D printed devices.

3D printing can give medical device manufacturers a strong competitive advantage, while also reducing the time-to-market and manufacturing costs. Going beyond surgeries, medical device manufacturers can collaborate closely with their partners to leverage this versatile technology to bring efficiency and value to all stakeholders.

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