



3D Printing is Revolutionizing the Medical Devices World, but are Payers Ready?

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Recent progress in healthcare applications of 3D printing is changing modern medicine in unprecedented ways. As an example, 3D printed implantable medical devices have the potential for significant innovation and clinical advantages in addressing unmet needs, such as:

- Creating customized implants fit for purpose and tailored to meet a patient's individual anatomy,¹ which can result in faster recovery time and less complications²
- Providing a more cost-effective alternative to current devices and implants¹ by being better adapted to individual patient needs
- Allowing surgeons to visualize deformity, plan, and prepare for surgery, in addition to reducing time spent on fitting the device during surgery^{1,2}

However, 3D printed devices and implants also present an array of uncertainties and potential risks, including:

- Quality control in manufacturing³ and consequent challenges for licensing and safety control
- 3D printed devices need to be produced fit for purpose and are likely to result in additional preparation time for patients and surgeons

– conventional implants and devices are readily available²

So, how do we capture the value of the disruptive innovation of 3D printed medical devices for reimbursement? To understand the situation better, this article highlights the following questions.

- How are regulators evaluating 3D printed medical devices, and what impact may this have on how these devices enter the market?
- How are 3D printed devices evaluated from a reimbursement and market access perspective, and what are the implications for access considerations on overall market acceptance?
- What are the challenges from a market access perspective for new 3D printed medical implantable products, and what can device manufacturers do to address them?

To guide our answers, desk research and interviews with payers, surgeons, and industry experts in the U.S. and several European markets (France, Germany, Belgium, Sweden, Spain, and Switzerland) were conducted in late 2014 and early 2015.²

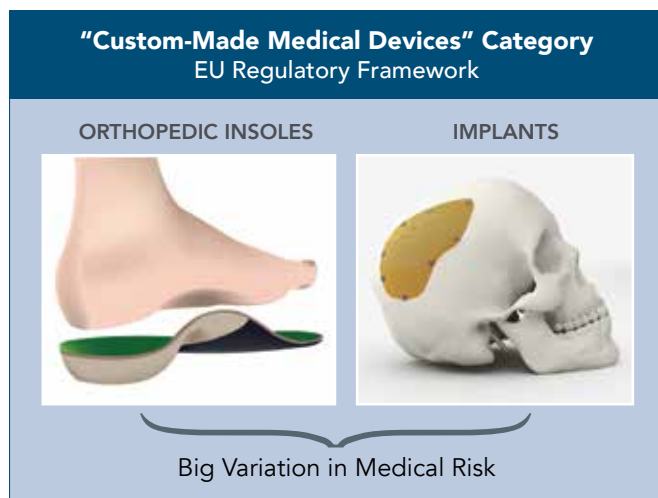
Where do regulators stand?

Europe - Regulation of 3D printed devices is not in the EU regulatory framework yet because regulatory burden is perceived to be "low"

"Manufacturers of medical devices for an individual patient, so-called 'custom-made devices', must ensure that their devices are safe and perform as intended, but their regulatory burden remains low." – *European Commission, 2012*⁴

Manufacturers, however, would like transparency and clarity around the regulation of 3D printed medical devices.

For example, Materialise, a provider of 3D printing software and services, points out that 3D printed medical devices are bundled under the same group as orthopaedic insoles.⁵



"Regulatory rules for orthopaedic insoles should be different from rules for 3D-printed surgical guides, implants and plates, since the latter will require more stringent quality requirements. For this reason, the very broad 'custom-made medical devices' category does not seem to accurately address the needs and potential risks of using 3D printing to design, produce and use patient-specific medical devices." – *Materialise, September 2014*⁵

Manufacturers should push for a clear EU regulatory guidance on 3D printed implantable devices so that patient safety is continuously ensured.

U.S. - Regulation of 3D printed medical devices is on the U.S. radar (FDA)

Currently, U.S. regulation of 3D printed devices is not significantly different from the regulation of conventional medical devices.⁶

"Not all devices or additive manufacturing technologies have the same risks or degrees of concern" – *FDA, October 2014*³

"We are regulating 3D printed devices the exact same way we regulate non-3D printed devices During the review process we have a few additional questions about how the manufacturing process could affect device performance. But right now there's no difference in regulation." – *Matthew Di Prima, a materials scientist with the FDA, Aug 2014*⁶

"What are going to be FDA's roles in looking at the controls for what would potentially be manufactured in a [healthcare] facility? On the shop floor, there may be one level of quality control, but in a medical institution, it may not be as well set up." – *Steven K. Pollack, director of the Office of Science & Engineering Labs at the FDA, June 2014*⁷

Manufacturers should use opportunities, such as public workshops on 3D devices, to collaborate with the FDA on the development of future 3D printing regulatory framework and to ensure that patient safety is preserved.

The U.S. Food and Drug Administration (FDA) recommends that 3D manufacturers schedule a pre-submission meeting to discuss the product with the FDA review team.⁸ However, the rapid rise of 3D printing for medical applications raises a lot of questions. To address safety concerns, the FDA created a working group to assess technical considerations in 3D printing.⁸ The first public workshop, titled "Additive Manufacturing of Medical Devices: An Interactive Discussion on the Technical Consideration of 3D Printing" was held October 8-9, 2014.⁹ The goal of the workshop was for the FDA to better understand technical aspects of 3D printing technology, which will eventually contribute to how the regulatory landscape is established.

Are surgeons willing to drive uptake of 3D printed medical devices?

Where cost is less of an issue, "hassle factor," financial incentives, and P4P schemes may significantly affect the uptake of 3D printed medical devices for the mainstream patient²

- The more complicated process may prevent mainstream use of 3D printed customized medical devices (**hassle factor**)

- For surgeons financially incentivized by operating on more patients, **impact of 3D on operating theatre efficiency** will be key
- **Pay-for-performance (P4P)** metrics may be another strong driver for the surgeon and for the hospital (e.g., for prestige and profitability reasons)

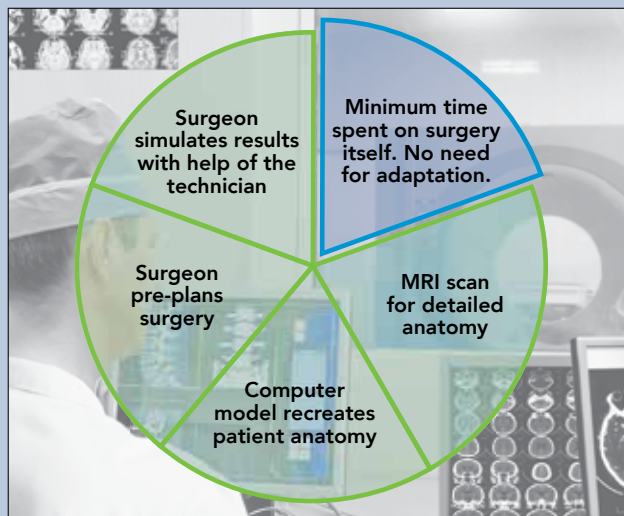
Whether it is challenges in reimbursement, incentive schemes, or the hassle factor, surgeons emphasize that they are more likely to use 3D printing technology only in special cases.²

With Standard Devices



If a patient requires a sophisticated surgery, fitting the device during the surgery may not be the most effective/easiest option due to possibility of poor fit, risk of complications, and more uncertainty in outcomes.

With 3D Printed Devices



With 3D printing technology, the majority of time is spent pre-planning the surgery.

■ Time spent performing surgical procedure

■ Time spent on other activities (e.g., pre-planning)

Case Study in Hip Replacement

Patient populations for which surgeons would recommend reimbursement of 3D printed custom-made medical devices

Hip Dysplasia

- Congenital or developmental deformation or misalignment of the hip joint
- Need for adapted devices (regular ones won't work)



Tumour (e.g., in pelvic bone)

- Need for adapted device to replace tumour area
- Surgeons appreciate a 3D anatomical model which gives a chance to visualize, plan surgery, and practice



Revision of Loosening

- Large amount of bone is lost because of revision, so having a custom device is a plus
- However, due to huge volume of this patient population, surgeons do not foresee widespread use in these cases

Private Sector

- Patients who can afford to pay for high cost of personalized medical devices

Last Resort

- When all other alternatives (e.g., pharmacotherapy, standard devices) are not (or no longer) an option

High risk of infections and/or complications

- Use of 3D printed custom-made device is likely to reduce surgery time, risk for complications, and recovery time

■ Applicable for a range of other disease areas

Are payers ready to pay more for the 3D printing revolution?

3D printing is not on payers' radar yet, as it is mostly reimbursed via DRG²



Payer

- Makes a decision whether to reimburse or not
- Can be a national, regional, or local payer (e.g., CFO, dept. head)

The majority of payers have not dealt (knowingly) with 3D printed devices.

Many payers mention they would not know if they are dealing with a 3D printed device (vs. device produced via regular manufacturing technique) because of the Diagnostics Related Groups (DRG) (i.e., bundled) method of payment.

"The first question we, payers, ask is 'Is it medically necessary?' The second question is 'Do we have a contract with you? Does patient's plan deny or allow payment out of network?' That being the case – whether you used the implant from one of the mainstream manufacturers like J&J or whether you do a homebrew 3D implant - we wouldn't know"
– Chief Medical Director at a major MCO, USA

~

"When we get the bill for a service executed along a DRG, we don't know the costs divisions. We don't know which cost is for which process or device"
– Payer at a major sickness fund, Germany



Surgeon

- Makes request for custom-made device
- Unlikely to be denied by payer if request does not break payer budget
- Advisory role on D&TC

There is "undiscovered need" for 3D printed devices amongst surgeon community.

"There is an undiscovered need for 3D printed medical devices, because a few of my colleagues are unaware of this. 3D printing companies need to be visible on congresses, but the best thing would be to have somebody like me, who has the experience of implanting 3D devices, to lecture to other surgeons. A lot of colleagues would be more impressed by having colleagues persuade them rather than sales reps."

– Surgeon at a public hospital, Sweden

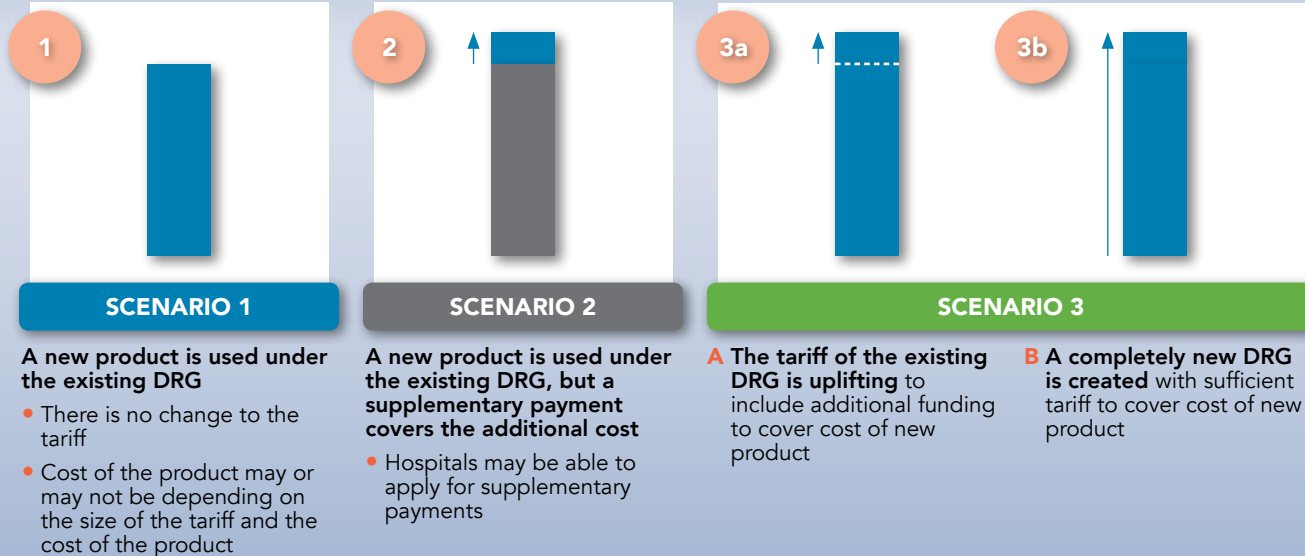
Having had a positive experience, surgeons expect that the demand for 3D printed devices will go up in the near future.

So far, surgeons have reserved requests for 3D printed medical devices only for special cases.

"If it is a desperate situation, we could accept a very high price for a 3D printed custom-made device. But if you start with a very high price, that's something I would need to negotiate carefully with my boss. If there is another option that seems reasonable with a much lesser price, I would go for that option." – Surgeon at a public hospital, Sweden

Potential DRG scenarios for a novel 3D printed medical device: another market access complication?²

Three potential scenarios for reimbursement of a new 3D printed medical device within the DRG system.



Having a solid understanding on the reimbursement route of 3D printed devices will be key for reimbursement, optimal value proposition, and preparing the substantiating evidence.

3D printed medical devices with a higher price premium vs. conventional devices will face a higher degree of scrutiny.²

Level of price premium of 3D printed medical devices (vs. conventional devices)

NONE/VERY LOW

HIGH

No HTA assessment

Bundled under existing DRG code

REASONS

- No significant impact on budget
- Assumption that 3D printed, custom-made device is better, hence better value for money vs. currently available options
- Time constraints – payers have “other things to worry about”

“Normally [under ‘expensive scenario’] you would need to first seek approval of the Director of Orthopedics service, and then persuade Economics Director of the Hospital and in some cases Pharmacy Services as well since they have wealth of knowledge in evaluating expensive analogues in pharma. However, if the values of 3D printed devices are not that high, then you would only need to get a good opinion from the Director of Orthopedics Department.” – Payer, Spain

HTA assessment

Evaluated as an “innovative device” with request for additional evidence (e.g., observational studies, etc.)

REASONS

- High premium should be justified
- Payers want to minimize impact on budget by potentially restricting the device to specific patient population or imposing other conditions on the manufacturer

“It is likely that we will see that AMNOG approach will be applied to the medical devices market soon. Due to the scandals we’ve seen in France and Germany with breast implants, politicians say that we need better quality control and implementation of added benefit rating. The question is ‘When?’ What that means for 3D printing companies is that they will need to submit a dossier to the G-BA in addition to getting a CE mark.” – Advisor to head of Doctor’s Association (KV), Germany

Prioritizing next steps across markets for developing a comprehensive action plan for 3D printed devices

Regulation Clarity

- Push for a clear **EU Commission and FDA regulatory guidance** on 3D printed medical devices so that patient safety is continuously ensured; use opportunities, such as public workshops, to inform and collaborate

Price Exploration

- Understand **who pays? How do they pay? How are they paid?**
- Find out if DRG tariff allows for a premium over competitor implants
- Explore private sector and **ability to self-pay in certain markets**
- Consider **low-pricing strategy** for surgeons and payers to get them **accustomed** to 3D printing technology

Evidence Generation

- Publish **observational studies** to provide additional information on safety and efficacy
- Consider inclusion of 3D printed devices into **registries** in countries such as Sweden where they are increasingly widespread and where there is a heightened worry about safety of new medical devices
- Consider inclusion in **guidelines** for specific sub-populations of patients where 3D printing technology is key to successful surgery and recovery

Value Proposition

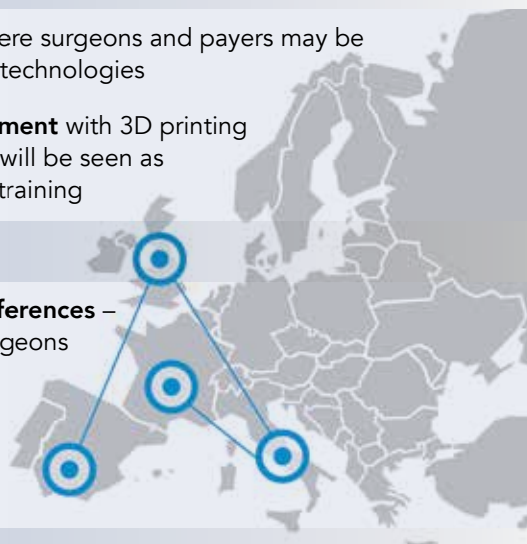
- Don't underestimate the value proposition of additional services, such as providing cutting guides and models, which help surgeons to visualize the deformity and provide the ability to practice in advance of surgery

Launch Strategy

- Focus initial efforts on **reference centers** where surgeons and payers may be more open to experimenting with advanced technologies
- **Involve surgeons who are willing to experiment** with 3D printing technology and have them train others. This will be seen as more credible than having sales reps do the training

Informing stake-holders

- Create a **strong presence at important conferences** – present prolifically to get the attention of surgeons and health care providers
- **Inform payers, health care providers, and patients** on the benefits of 3D printing technology as it is likely to be new to them



Lessons Learned

- 1 There are many opportunities for 3D printing of specific medical devices (anything that benefits from customization)
- 2 Success will depend on balance between consolidated workload (pre- and during surgery) and safety aspects (wear and tear)
- 3 The commercial problem is the current lack of regulations for in-hospital printed devices, which threatens the 3D industry and the patient (as quality control cannot be on same level as industrial made)
- 4 Payer interests will depend on pricing of 3D printed device vs. medical devices printed via conventional techniques
 - from no interest if within same DRG
 - to high interest if with additional budget
 - or need for higher DRG
- 5 Key point to find out is cost effectiveness (or efficiency) of 3D printed medical devices versus standard devices, e.g., impact on direct medical cost and length of surgery

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