3D printing for healthcare: who is the manufacturer?

By Kirsten Beasley, Head of Healthcare Broking, North America

3D printing of devices and implants could transform many medical procedures. But healthcare providers need to consider whether they are crossing the line from medicine into manufacturing.

What is 3D printing?

3D printing, also known as additive manufacturing (AM), is the process of making a three-dimensional physical object from a digital file by depositing material layer-by-layer. The process is ideally suited to creating complex, customised medical devices and components, which could improve quality and effectiveness in many areas of healthcare.

How is 3D printing being used in healthcare?

3D Printing is already being used for training and research purposes and in medical procedures with many new applications in development. Current uses include:

- Patient-specific anatomical and surgical models, such as in procedure planning.
- Prosthetic devices.
- Bioprinting of tissues, miniature organs, and blood vessels for medical research.
- Medical devices and instruments, such as medical and dental implants.

¹3D Printing of Medical Devices, Accessories, Components, and Parts During the COVID-19 Pandemic, US Food and Drug Association. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/3d-printing-medical-devices-accessories-components-and-parts-during-covid-19-pandemic

²Meet The Italian Engineers 3D-Printing Respirator Parts For Free To Help Keep Coronavirus Patients Alive, Forbes Media LLC. https://www.forbes.com/sites/ amyfeldman/2020/03/19/talking-with-the-italian-engineers-who-3d-printed-respiratorparts-for-hospitals-with-coronavirus-patients-for-free/ (Feldman,2020) ³The role of 3D printing during COVID-19 pandemic: a review, Longhitano et al. https://link.springer.com/article/10.1007/s40964-020-00159-x

⁴3D Printing in Healthcare Market Expected to Reach \$5.8 Billion by 2030, Allied Market Research. https://www.alliedmarketresearch.com/press-release/3d-printing-healthcare-market.html

The response to COVD-19 accelerated the development of some applications such as:

- Personal protective equipment (PPE).¹
- Ventilator valves and parts.²
- Nasopharyngeal swabs.³

The technology is developing fast. Future possibilities include 3D printed organs that could be used in transplant operations and personalised pharmaceuticals that could be printed in the doctor's office.

How big is the market for 3D printing?

The global market for medical 3D printing is expected to reach USD 5.8 billion by 2030.⁴

Demand is being driven not just by large healthcare providers, but individual medical and dental practices, which can use 3D printing on a smaller scale.



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How is 3D printing in healthcare regulated?

In most countries, 3D printed products are regulated if they fall under the definitions of a medical device or PPE.

Regulators face challenges in keeping up with the highly decentralised and bespoke nature of 3D printing production (see *How are 3D-printed items made for clinical settings*? below).

Current regulatory frameworks in major markets include:

U.S.

 Food and Drug Administration risk-based classifications for 3DP medical devices. There is limited guidance on bioprinting or printing of pharmaceuticals.

Europe

 Medical Devices Regulation (MDR) CE mark product safety certification.

Australia

• Therapeutic Goods Administration (custom made devices may be exempt).

UK

- Consumer Protection Act.
- Product safety certification under medical devices regulations.
- PPE Regulation 2016/245.

How are 3D-printed items made for clinical settings?

There are a number of business models, including:

- Outsourcing to an established 3D printing or medical device company.
- 3D printing in the clinical setting, or at the point of care.

The point of care model is becoming more popular, driven by regular demand for items such as prosthetics, implants and training aids. Currently, two models of point of care printing have emerged:

- 3D printing on premises, but in partnership with a contracted 3D printing company.
- In-house printing, where the healthcare provider or clinician builds their own dedicated 3D printing facility on their premises, staffed by a multi-disciplinary team of employees.



What kinds of liability could healthcare providers face?

3D printing has the potential to blur traditional distinctions between manufacturing and the practice of medicine. In particular, those that build in-house 3D printing labs may be taking on the role, and thus the liability, of manufacturer in the eyes of regulators and the law.

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This means they could be subject to product liability if their product causes harm.

In many countries strict liability applies to product faults, which would allow patients to sue for compensation without having to demonstrate medical negligence.

Other liabilities may come into play, depending on the type of product, contractual arrangement, or the role and behaviour of the clinicians involved. These could include:

- Intellectual property.
- Environmental.
- Technology errors and omissions (E&O).
- Medical malpractice.

Further complications could arise if litigation involves multiple stakeholders, such as the software designer, the printer manufacturer and the materials manufacturer. So far, there is little legal precedent for how liability would be decided in such a case.



Key considerations for healthcare providers using 3D printing

Who is the manufacturer of record of any product printed?

If you are the manufacturer, you need to be on top of all the legal responsibilities that come with that role.

Who is responsible for quality assurance?

Even if you don't directly make the product, you may be held liable for quality control of the manufacturing process to ensure that thresholds and specifications are met.

How is the product being used?

If the 3D printed item is being put in a patient's body, there is a higher likelihood of possible harm and therefore liability.

Does existing cover include product liability?

Most hospitals don't have specific product liability coverage, or only have some limited cover as part of a medical malpractice policy. Providers engaged in 3D printing may need to review their activity and whether they have the right insurance to cover it.

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