Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

3-D printing (additive manufacturing) of medical devices

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Three dimensional (3-D) printing (an additive manufacturing process), is a process where computer-aided-design (CAD) software or a 3-D scanner is used to develop an object, which then informs a hardware manufacturing process where material is deposited in layers to form that specific three dimensional object. Additive manufacturing is being used more frequently to manufacture medical devices and their components. While there are often advantages to using 3-D printing for these kinds of products, there are also specific risks that arise that must be documented and reduced as much as possible by manufacturers in order to ensure their product is safe and fit for its intended purpose.

The following page provides information for manufacturers to assist them with addressing these risks and meeting the Australian regulatory requirements for medical devices.

Note

The information in this page relates to 3-D printing (additive manufacturing) of medical devices only. For more general information about the regulation of medical devices, including whether a product meets the definition of a medical device, please review the medical device inclusion process (https://www.tga.gov.au/node/285202) guidance.

Risk management

All medical devices are expected to be designed and manufactured in a manner that reduces risk as far as possible. Differences in material properties and processing requirements between 3-D printing and conventional manufacturing methods mean that new risks may be introduced to patients or users, even when the same device design is being manufactured.

Manufacturers must be able to demonstrate:

- how they have mitigated any risks associated with the production of their medical device; and
- that their medical device complies with all relevant essential principles.

The manufacturer must also apply appropriate conformity assessment procedures (see Regulation 2.1 and Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Details/F2019C00603)).

Using the right materials

Manufacturers of medical devices should ensure they use materials that are suitable for:

- the manufacturing process; and
- the intended use of the device.

That means:

- If the device will be used inside the body or a body orifice (such as a retainer that will be held in the mouth), you should ensure the materials are biocompatible and will not cause irritation, sensitisation or toxicity. You must also minimise the risk of any substances leaching from the device into the user's body during the intended use (e.g. material chemistry and biocompatibility should be evaluated, and material properties should be characterised).
- If the device is intended to be used over an extended period of time, you should ensure the material you are using will operate as intended for the expected life of the device.
- If the device is sterile, the materials of the device must be compatible with the manufacturing process, including the sterilisation method that will be used on the device.

> **Note**
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> Although the use of any particular standard is not mandatory, ISO 10993 can be used to demonstrate biocompatibility.

Cleaning the device

If your device is intended to be supplied in a non-sterile state you should ensure that it is subjected to a validated process to render it clean before it is packaged for supply, bearing in mind that cleaning can involve removal of physical and chemical residues as well as microbial

bioburden.

Manufacturers of 3-D printed medical devices that are supplied non-sterile but are intended for cleaning and/or sterilisation by the user should include details of at least one validated cleaning procedure and one validated sterilisation procedure (if applicable) in the Instructions for Use (IFU).

Sterilising the device

If your 3-D printed medical device is intended to be sterile, you should ensure that the devices are subjected to validated processes to render them clean (as above) and sterile. Guidance on appropriate standards for use in validation and routine control of sterilisation processes can be found in:
Therapeutic Goods (Manufacturing Principles) Determination 2020, (https://www.legislation.gov.au/Details/F2020L00864) which specifies that if a device is labelled sterile, it must be manufactured in compliance with EN556 to a Sterility Assurance Level (SAL) of 10^{-6}.

Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019 (https://www.legislation.gov.au/Series/F2019L00426), which specifies appropriate sterilisation standards that can be used.

Manufacturers should also note that the 3-D manufacturing process can result in air bubbles or pockets being present in the body of the device, which presents specific problems for sterilisation as these air bubbles or pockets are potentially non-sterile. If a sterile implantable device degrades or fractures, these pockets or bubbles could potentially expose a patient to microbiological risk.

You will need to document the potential risk of this outcome and measures you have taken to mitigate this risk in conjunction with sterilisation validation in your conformity assessment evidence.

Further information

The following resources may contain further information that could assist you with demonstrating that your 3-D printed device is safe and fit for its intended purpose:

US FDA - Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff (https://www.fda.gov/media/97633/download)

Topics:
Medical devices (https://www.tga.gov.au/products/medical-devices)