

# 3D Printing of Medical Devices

These IPC recommendations were developed by the Medical Device Purchasing Working Group in consultation with clinical experts involved in printing 3D medical devices.

**Note:** Terms in bold are defined in the **Definitions** section.

If you have any IPC questions or comments contact IPC at [ipcsurvstdadmin@ahs.ca](mailto:ipcsurvstdadmin@ahs.ca). For technical questions not answered within this document, contact the Institute for Reconstructive Sciences in Medicine (iRSM) by phone at 780-735-2660 or email at [irsm@covenanthealth.ca](mailto:irsm@covenanthealth.ca).

## Best practice recommendations

3D printing (**3DP**) or **additive manufacturing** is rapidly emerging through technology and innovative solutions. 3DP facilitates development of patient-specific medical devices or **patient-matched devices** (also called personalized medical devices, additive manufactured medical devices) to enhance the quality of patient treatment and speed of recovery from debilitating conditions. 3DP uses instructions in a digital file or data, which may be enhanced/facilitated using **segmentation software** to create an object, e.g., anatomically matched devices, using a patient's own medical imaging, 3D scanning, or custom accessories matched to an existing device (**custom-made device**). The 3D printer deposits, extrudes, jets, sinters, cures or fuses materials in layers, e.g., powder versions of ceramics, plastics, metal and even human tissues, based on the digital file. The [general categories and technologies of additive manufacturing](#) include, but are not limited to: vat polymerization, material extrusion, material jetting, binder jetting, powder bed fusion, direct energy deposition and sheet lamination.

## Purpose

- To support end-users in the safe purchase and use of 3DP medical devices.
- To outline the purchase process to align with IPC Purchasing Medical Devices recommendations:
  - [Roles and Responsibilities](#)
  - [Purchasing Medical Devices-Spaulling Risk Classification for End-Users](#)
  - [Pre-Purchase Criteria for End-Users](#)

## Application

These recommendations should be followed by all AHS staff, medical staff, volunteers, students and other persons acting on behalf of AHS, e.g., end-users printing 3DP medical devices.

### 1. Determine device [categorization and risk](#)

The medical device patient safety risk impacts manufacturing, **validated** cleaning, the disinfection or sterilization process and potential severity of adverse events, e.g., cranial implants and heart valves carry the highest risk to the patient.

#### 1.1. The **end-user**:

- 1.1.1. Determines if the 3D printed medical device is **non-critical** (contacts intact skin), **semi-critical** (contacts mucous membranes or non-intact skin) or **critical** (contacts sterile tissues) based on Spaulding's Classification. Refer to IPC Purchasing Medical Devices: [Spaulding Classification](#) for additional details.

- **Critical medical** and **semi-critical medical devices** pose the highest patient risk of infection if they are not handled, cleaned and high-level disinfected or sterilized according to Alberta Health [standards](#).

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- Some medical devices are assembled with components from more than one risk classification, e.g., 3D printed ventilators have semi-critical (breathing circuit) and non-critical components.
- 1.1.2. Determines if the 3DP medical device is intended for a single-use or if it is reusable. Refer to the AHS [Single-Use Medical Device policy](#). Considers devices difficult to clean and disinfect or sterilize, as **single-use**. For example:
- long, narrow (< 1 mm diameter) lumens and channels;
  - valves that cannot be disassembled;
  - crevices, joints, or surface pores;
  - instruments that cannot be opened or disassembled for cleaning;
  - instruments with hinges or ribbing, e.g., forceps, clamps;
  - rough, irregular, discontinuous surfaces that can entrap or retain soil;
  - porous materials.
- 1.1.3. Determines the [Health Canada risk class](#) of the 3DP medical device, which applies a risk-based approach to regulating medical devices. Medical devices are classified into one of four classes where Class I represents the lowest risk and Class IV the highest, depending on the nature of the device, its degree of invasiveness, duration of contact and its intended purpose. Examples of Class I devices include external prosthetics, face shields and nasopharyngeal swabs; Class II devices include denture materials and orthodontic appliances; Class III includes volume ventilators (critical care), dental and orthopedic implants; and Class IV includes cranial implants and heart valves.
- 1.1.4. [Consults with internal and external stakeholders](#) prior to developing a 3DP medical device to confirm:
- Materials used are suitable and safe for the intended purpose of the device, e.g., device [classification](#) and **biocompatibility**.
  - **Validated** instructions for cleaning, high-level disinfecting or sterilizing the device are in accordance with Alberta Health [standards](#). There are three potential avenues of obtaining validation of cleaning, disinfection and sterilization instructions:
    - from the manufacturer of the materials used to print the 3D medical device;
    - from a third-party laboratory when materials have not been validated by the producer/manufacturer. Nelson Laboratories is an example of a third-party laboratory currently consulted within AHS;
  - developed by the AHS facility in consultation with AHS experts (non-critical medical devices only).

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1.1.5. Confirms existing resources, protocols and AHS provided products can be used for cleaning, disinfecting or sterilizing the device. Refer to Purchasing Medical Devices – [Roles and Responsibilities](#) for additional details about consulting multi-disciplinary AHS stakeholders. For example:

- Manufacturer(s) provides details about materials and composites used in the development of the 3DP medical device including materials, manufacturing process and validation.
- End-users consult with multi-disciplinary representatives about device complexity, intended use, reprocessing area, technical, maintenance and infrastructure requirements, safety, and technology.
- When a third party validation is received, the end-user consults and collaborates with the medical device reprocessing department (MDRD) to ensure the sterilization protocols can be completed by MDRD. MDRD communicates the validated protocol within their department.

## 2. Quality process

Healthcare institutions that use 3D technology to print medical devices for use on their patients take on the role of manufacturer. If the institution outsources the design or development of a 3DP medical device to a third party, that third party takes on the role of manufacturer. Institutions not distributing or selling medical devices outside their institution do not require a [medical device establishment licence](#); however, all manufacturing activities are expected to meet safety and quality requirements for the device. Refer to Health Canada’s Guidance Document: [Information to Be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices](#) (June 2011) and AHS IPC Purchasing Medical Devices – [Pre-purchase Criteria for End-Users](#) for more details.

**Note:** Manufacturers are responsible to supply:

- a) details about the device design and intended use;
- b) directions for use;
- c) information on single-use components;
- d) device-specific recommendations for reprocessing including:
  - reprocessing instructions for all device components;
  - personnel training materials, e.g., photos or graphics on correct device reprocessing;
  - specifications for reprocessing parameters and their tolerances, e.g.,:
    - the number of times the device can be reprocessed if the device is deemed to be for limited use, i.e., reusable with appropriate tracking method;
    - recommendations for checking device integrity when applicable, e.g., sheath testing, sharpness of cutting edges, etc.;
    - possible degradation from reprocessing.

2.1 The end-user identifies and follows an established standardized quality process, appropriate to the device risk, based on expert guidance such as:

- Health Canada Guidance Document: [Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing](#);

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- [Radiological Society of North America 3D Printing Guidelines](#);
  - United States Food and Drug Administration (FDA): [Technical Considerations for Additive Manufactured Medical Devices](#).
  - Guidance for Industry and FDA Staff or Health Sciences Authority: [Guidance on 3D printing of Essential Medical Devices and Accessories for Use in COVID-19 Situation](#).
- 2.1.1. The quality process determines the quality of the final product, including features and characteristics that impact safety and performance. Key considerations include, but are not limited to:
- Using a flow diagram to outline, describe and document each step in the process from patient image acquisition, pre-operative planning and initial device design to preparation of the finished device.
  - For each step, describe and document the process, process parameters, and output specifications including:
    - key design parameters;
    - device parameters that may be altered to be patient-matched, if not the entire device;
    - critical features such as the range and boundaries of dimension, i.e., location and thickness of porous features;
    - physical parameters; and
    - compatibility and fit with the original equipment or devices.
  - Factors that influence characterization and testing necessary for the device may include whether it is an implant; an instrument, single-use versus reusable; load-bearing; and if it is available in pre-specified standard sizes or is patient matched.
  - Manufacturer instructions for printing and post-processing are available and followed.
  - Device validation including:
    - biocompatibility based on nature of contact with the patient using final finished device;
    - disinfection or sterilization considering device complexity under worst case conditions, e.g., residual manufacturing materials, porosity and internal voids; removal of material residues to acceptable levels; function and usability testing for the intended purpose of the device.
  - Labelling with sufficient information to identify or trace the device, e.g., patient identifier; intended use and specific instructions for safe and effective use along with any warnings; precautions and contraindications; final design version used to produce the device; lot or batch information and expiration, e.g., based on anatomical changes.
  - Information on the manufacturing method, process flow chart including post-processing steps; and manufacturing activities performed using a quality management system.
  - Monitoring the use of 3DP device for performance issues such as corrosion and wear; or adverse effects, e.g., allergies to the material; infection due to inadequate reprocessing; deterioration in health or death. Report medical device problems as per AHS Patient Safety and Medical Device Safety Policy Suites, and Health Canada Medical Devices Regulations. **Refer to Home>Teams>CPSM>Medical Device Safety>Medical Device Incident or Problem Reporting.**

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- Post-printing processing, cleaning and sterilization vary depending on the material, printing process and design of the finished device, e.g., if the 3DP device is manufactured from metal powder, the cleaning validation should include the capacity of the cleaning process to remove loose powder particles.

## Definitions

**3D printing (3DP)**, also referred to as “Additive Manufacturing” means (as per [Health Canada definition](#)) a process that builds an object by iteratively building 2-dimensional (2D) layers and joining each to the layer below, allowing device manufacturers to rapidly alter designs without the need for retooling and to create complex devices built as a single piece.

**Additive manufacturing (AM)** means (as per [Health Canada definition](#)) a process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies.

Specific printing methods and processes commonly include laser sintering, stereolithography, powder bed fusion, digital light processing, extrusion or fused deposition modelling, binder and material jetting.

**Biocompatibility** means (according to [FDA guidance on ISO 10993](#)) the ability of a medical device or material to perform with an appropriate host response in a specific application. [Health Canada](#) requires biocompatibility testing on the final, finished device as per the requirements of ISO 10993. Testing is also expected to address the use of any additives, i.e., chemicals, machine oils, lubricants, reagents, solutions, during the manufacturing process. For multiple 3D-printed devices in a single application, with identical manufacturing/cleaning/sterilization processes, testing should be conducted on the worst case device.

**Custom-made device** means a device which is made to correspond with a health care professional's specific directions or needs. Custom-made devices are usually specifically produced for a particular patient or procedure.

**Critical medical device** means a medical device that enters sterile tissues, including the vascular system.

**End-user** means requester, purchaser, or decision-maker authorizing the purchase.

**Manufacturer’s instructions for use** means the validated, written directions provided by the manufacturer or distributor of a medical device or product that contain the necessary information for the safe and effective use of the medical device or product.

**Medical device** means any instrument, apparatus, appliance, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap;
- Investigation, replacement, or modification of the anatomy or of a physiological process; or
- Control of conception; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but that can be assisted in its function by such means.

**Non-critical medical device** means a medical device which either touches only intact skin but not mucous membranes or does not directly touch the patient.

**Patient-matched medical device (or Patient-specific medical device)** means, as defined by [Health Canada](#), a medical device that meets the following requirements:

- it is matched to a patient's anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references or by using the full anatomic features from patient

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imaging; and

- b) it is typically produced in a batch through a process that is capable of being validated and reproduced; and
- c) it is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.

**Note 1:** A written request from an authorized healthcare professional may be present; but is not mandatory.

**Note 2:** The number and type of design inputs in consultation with a healthcare professional may vary depending on the medical devices to be manufactured.

**Note 3:** The design must remain within the validated parameters of the specified design envelope.

**Reprocessing** means the steps performed to prepare a used medical device for reuse.

**Reusable medical device** means a device designed by the manufacturer, through the selection of materials and/or components, to be re-used.

**Semi-critical medical device** means a medical device that comes into contact with mucous membranes or non-intact skin, but ordinarily does not penetrate them.

**Single-use** means a device designated by the manufacturer for single-use only.

**Segmentation software** means software that visualizes, processes or analyzes a medical image or creates virtual 3D models, capable of running on general purpose computing platforms that is not part of a hardware device.

**Validated** means a documented procedure for obtaining, recording, and interpreting the results required to establish that a process for cleaning, disinfection or sterilization of a medical device will consistently yield safe products complying with the CSA Standard Z17664.

**Validation** means (as defined by [Alberta Health standards](#)) a confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Notes: 1. The objective evidence needed for validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents. 2. The term “validated” is used to designate the corresponding status. 3. The use conditions for validation can be real or simulated. Reference: CSA Z314-18, p. 33.

**Sterilization** means (as defined by [Alberta Health standards](#)), the validated process used to render a product free from viable microorganisms. Reference: CSA Z314-18, p. 32. For patient-matched devices, sterilization validation should consider the worst case configuration based on the critical boundaries of design, size and geometry of the finished device. Any changes from methods of sterilization as outlined in the requirements of recognized standards, e.g., Canadian Standards Association, should be described and justified in the sterilization validation.

**Class III and IV 3D** printed implantable medical devices validations may vary on the printing process and require evidence to support reproducibility and consistency in the printing process including analysis of worst case parameters and printer performance within and across build cycles; and the analysis of critical environmental conditions within the build space/volume, including in-process monitoring of build-space conditions, power of energy delivery systems and or test coupon evaluation.

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