OsseoPrint3D Aseptic System Architecture and Sterility Strategy

Abstract

Three-dimensional (3D) printers based on thermoplastic extrusion are increasingly used in medical device development and manufacturing. However, conventional extrusion-based 3D printers do not operate under aseptic conditions. Medical devices produced on standard systems require terminal sterilization after printing before they can be considered suitable for implantation.

The objective of the OsseoPrint3D system is to enable fabrication of patient-specific bioresorbable scaffolds within a controlled ISO Class 7 aseptic enclosure at the point of care. The system is designed to support aseptic manufacturing using validated pre-sterilized disposable components and controlled environmental conditions, allowing the printed scaffold to be suitable for immediate clinical use without additional post-print sterilization.

This document describes the sterility strategy and aseptic design features of the OsseoPrint3D platform.

Design Challenges

Development of an aseptic point-of-care extrusion system requires control of contamination risks throughout the manufacturing process. The principal challenges include:

- Maintaining sterility along the extrusion path
- Ensuring sterility of the pre-loaded bioresorbable polymer
- Controlling endotoxin levels of materials and components
- Protecting the scaffold from print-chamber contamination
- Minimizing airborne particulate and microbial exposure during fabrication

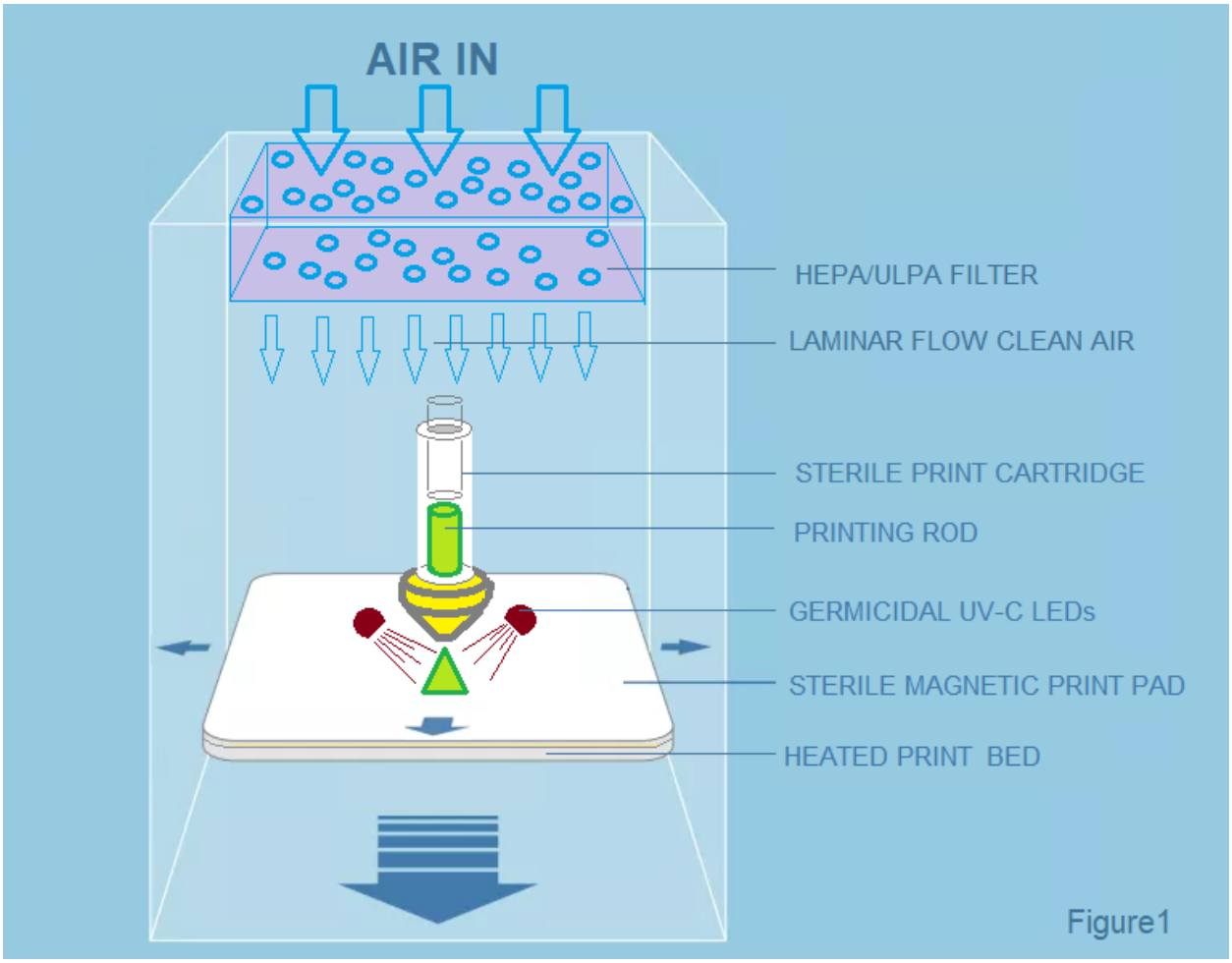
Core Aseptic Design Principles

To prevent contamination before and during fabrication, the proprietary single-use print cartridge is fully self-contained, terminally sterilized by the manufacturer, and opened only immediately prior to printing. The entire extrusion path is enclosed within the disposable cartridge, preventing polymer exposure to non-sterile printer components. A sterile disposable magnetic print pad is supplied and used for each procedure.

The system utilizes extrusion-based printing due to its controlled material path and limited contamination variables. While extrusion temperatures are elevated, the process is not claimed as a sterilization method.

The printer operates within a sealed ISO Class 7 enclosure with HEPA/ULPA-filtered vertical laminar airflow and positive pressure to reduce particulate ingress. Environmental conditions are

continuously monitored via an integrated particle counter, and printing is permitted only within defined limits.
Narrow-band UV-C LEDs are incorporated as an adjunct environmental bioburden control measure. Mechanical components are physically separated from the print zone to minimize particulate generation near the scaffold.



HEPA/ULPA Filtration and Vertical Laminar Airflow System

o minimize particulate contamination, the enclosure incorporates a top-mounted Filter Fan Unit (FFU) providing controlled vertical laminar airflow. Filtered air is introduced from the top of the chamber and directed uniformly downward across the print zone, reducing turbulence and cross-currents.

The FFU maintains a positive pressure differential relative to the external environment to limit ingress of unfiltered air. Air passes through validated HEPA (≥99.99% @ 0.3 µm) or ULPA (≥99.999% @ 0.12 µm) filtration media prior to entering the chamber.

The vertical flow pattern continuously sweeps particulates away from the scaffold build area toward lower exhaust vents, reducing suspended particle residence time within the enclosure. This airflow architecture supports maintenance of ISO Class 7 environmental conditions during fabrication.

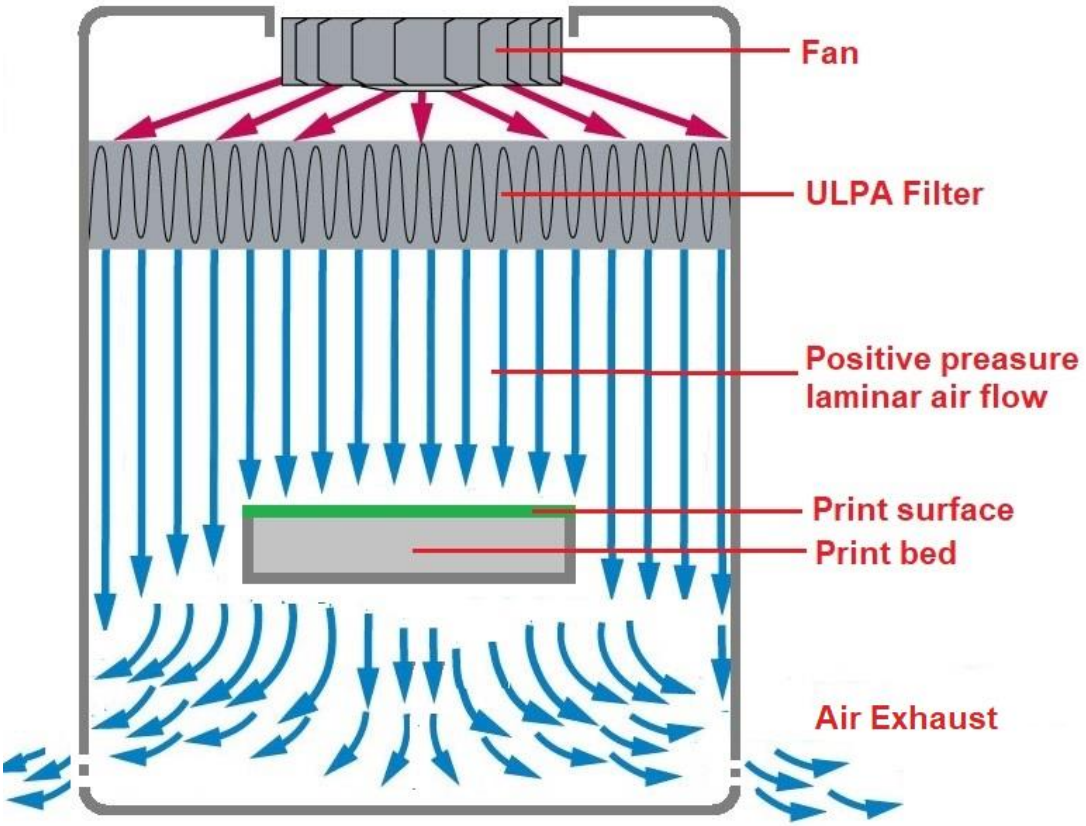


Figure 4

Particle Monitoring and Environmental Control

The printer is equipped with an integrated high-resolution particle counter aligned with the enclosure's filtration performance. The system continuously monitors airborne particulate levels in real time through policy-controlled software.

Printing is permitted only after predefined environmental thresholds are achieved. Particulate levels are monitored throughout the fabrication cycle and until scaffold removal. If environmental parameters exceed validated limits at any time, the process is automatically paused or aborted and the operator is alerted.

The system is designed to support ISO Class 7 environmental conditions within the enclosure; higher classifications are not claimed unless validated under controlled testing.

UV-C Environmental Bioburden Control

Ultraviolet-C (UV-C) irradiation is widely used for microbial control in healthcare and laboratory environments. Conventional low-pressure mercury UV lamps emit broad-spectrum radiation, including wavelengths that may generate ozone and contain regulated materials such as mercury.

The OsseoPrint3D enclosure incorporates narrow-band UV-C LED technology operating within the germicidal range of approximately 250–280 nm, with peak microbial absorption near 265 nm. LEDs under evaluation include 265 nm and 280 nm wavelengths to optimize germicidal efficiency while minimizing ozone generation.

The UV-C module is designed as an adjunct environmental bioburden reduction measure within the enclosure. It is not represented as a terminal sterilization method for the printed scaffold.

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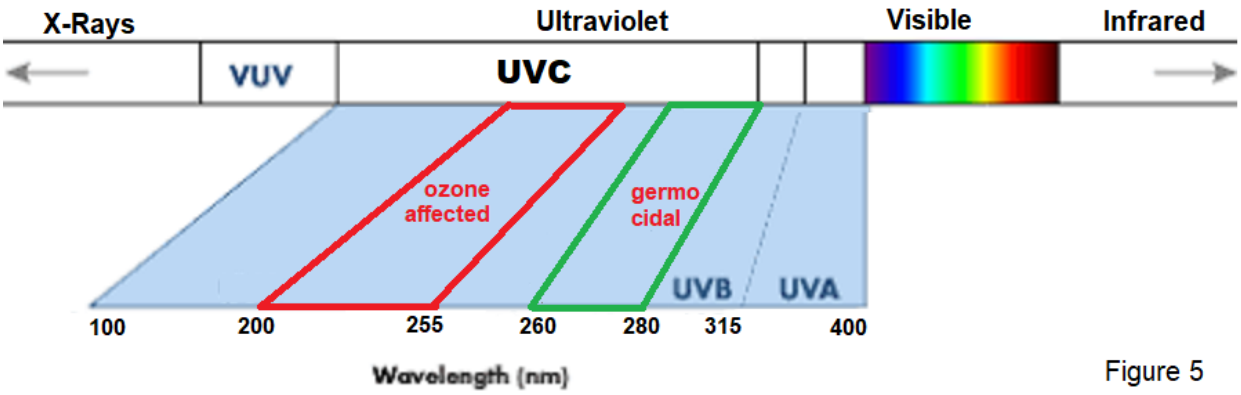

Figure 5

The UV-C system is designed to minimize ozone generation through wavelength selection and controlled emission spectrum.

To maximize local germicidal exposure, UV-C LEDs are positioned in close proximity to the print head and directed toward the active build area. The inner surfaces of the printing chamber are finished with polished metal to enhance UV-C reflectivity and improve uniform irradiance distribution within the enclosure. This configuration increases irradiance at the scaffold surface while minimizing optical losses due to distance and geometric dispersion.
Layer-by-layer exposure occurs during fabrication, with additional post-print exposure within the enclosure to reduce environmental bioburden on accessible scaffold surfaces. UV-C dose requirements are estimated using standard irradiance–time relationships (Dose = Irradiance × Exposure Time) and are validated through irradiation mapping and testing.
The following formula was used to estimate needed LED power (Dr. Kevin Kahn, 2018)

$$\text{Dose}\left(\frac{\text{mJ}}{\text{cm}^2}\right) = \text{irradiance}\left(\frac{\text{mW}}{\text{cm}^2}\right) * \text{time (s)}$$

For conservative dose estimation, UV-C susceptibility data from relatively resistant non-enveloped viruses (e.g., rotavirus) were used as a reference model (see Fig. 6). Based on irradiance calculations and exposure time assumptions, preliminary estimates indicate that the selected LED configuration (2 × 30 mW nominal output) can achieve ≥99% reduction of representative UV-C–susceptible microorganisms on directly exposed surfaces under defined operating conditions.
Final performance claims will be supported by empirical dose mapping and biological validation testing.

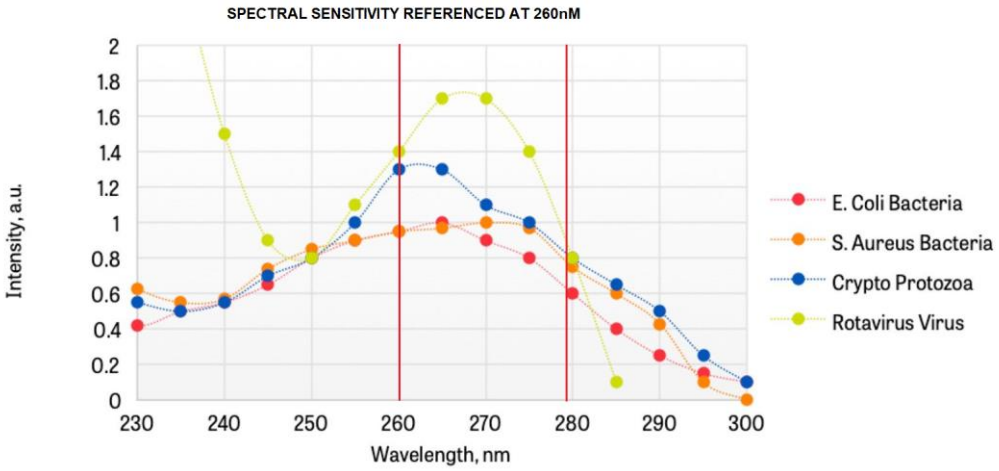

Figure 6

Mechanical Compartment Isolation and Moving Component Placement

The printer architecture physically separates the primary mechanical drive components from the sterile print zone. Motors, belts, and high-friction elements are positioned away from the build surface to reduce particulate shedding near the scaffold.

Any motion components located above the print plane are enclosed or shielded to minimize contamination risk. Flexible protective bellows are incorporated where required to provide additional mechanical isolation and visual separation between the drive system and the aseptic chamber.

Q&A

Can the printing process itself ensure sterility?

Extrusion-based printing operates at elevated temperatures (typically ~80°C–220°C, material-dependent), which may reduce microbial load in the melt path. Published studies have reported "functionally sterile" printed parts under certain conditions (e.g., Russell ,Neches et al., 2016). However, sterility of an implantable device cannot be assumed from temperature exposure alone, and sterility cannot be demonstrated by inference.

Accordingly, OsseoPrint3D does **not** claim that the FDM/extrusion process is a validated sterilization method. Sterility assurance is based on validated pre-sterilized disposable components and controlled aseptic environmental conditions; any future claim regarding intrinsic sterilization would require dedicated biological validation

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Should Humidity Be Monitored and Controlled Within the Print Chamber?

At present, the platform does not incorporate active dehumidification. The need for humidity control (and associated limits/interlocks) will be determined based on material-specific performance data and validation testing.

References

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