

# ***Additive Manufacturing Processes of Innovative Biomedical Products***



***Răzvan PĂCURAR  
Ancuța PĂCURAR  
Sven MARICIC  
Raphael LICHTNECKER  
Johanna BRÜCKHUBER  
Aleksandar MILTENOVIĆ  
Radostaw WICHNIAREK  
Filip GÓRSKI***

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**Autori:**

Răzvan PĂCURAR, Ancuța PĂCURAR  
Sven MARICIC, Raphael LICHTNECKER  
Johanna BRUCKHUBER, Aleksandar MILTENOVIC  
Radosław WICHNIAREK, Filip GÓRSKI

Director editură: GHEORGHE POP

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### Additive Manufacturing Processes of Innovative Biomedical Products

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## 1 Introduction

Additive Manufacturing (AM), commonly known as 3D printing, has emerged as a revolutionary technology in the biomedical field, allowing for the development of highly customized and functionally optimized medical devices. Unlike traditional manufacturing methods, which rely on subtractive processes to materialize shapes from solid materials, AM builds objects layer by layer. This approach offers design flexibility, material efficiency, and patient-specific customization, which are critical in producing implants, prosthetics, surgical tools, and even scaffolds for tissue engineering.

This chapter provides an in-depth exploration of AM processes used in biomedical production, focusing particularly on Materials Extrusion (MEX), Powder Bed Fusion (PBF), Photopolymerization technologies, etc. These methods, including Selective Laser Sintering (SLS), Selective Laser Melting (SLM), Electron Beam Melting (EBM), Multi Jet Fusion (MJF), and Direct Energy Deposition (DED), have played a crucial role in advancing healthcare manufacturing. Each of these technologies is examined in detail to understand their working principles, their suitability for medical applications, and the post-processing treatments required to ensure biocompatibility, mechanical strength, and regulatory compliance.

In recent years, AM has gained widespread adoption in healthcare, particularly in the production of orthopedic and cranial implants, dental prosthetics, and customized surgical guides. The ability to fabricate patient-specific titanium implants, for example, has led to improved surgical outcomes by ensuring a perfect anatomical fit. Similarly, SLM and EBM are used to create high-precision dental restorations, such as crowns and bridges, made of cobalt-chrome and titanium alloys. Beyond implants, AM is increasingly utilized to manufacture lightweight and highly customized prosthetic limbs and sockets, offering greater comfort and functionality for users. Another growing application is the fabrication of tissue engineering scaffolds, where biocompatible polymers and ceramics are structured to support cell growth and regeneration. Furthermore, AM has enabled the production of detailed anatomical models for pre-surgical planning, allowing surgeons to visualize and rehearse complex procedures with greater accuracy.

One of the most significant advantages of AM in biomedical applications consists in its ability to produce highly intricate geometries and porous structures that traditional manufacturing methods cannot achieve. The ability to design implants with porous lattices, for instance, enhances osseointegration by promoting bone ingrowth, leading to better implant stability and longevity. Additionally, AM reduces material waste by using only the necessary amount of raw material, making it a cost-effective and sustainable approach to manufacturing. The speed of AM also enables rapid prototyping, significantly reducing the time required to develop and test new medical devices, which accelerates innovation in the healthcare industry.

By exploring the various AM technologies used in biomedical engineering, this chapter aims to provide a comprehensive understanding of their strengths, limitations, and applications. It also discusses the post-processing techniques that are essential for medical use, including heat treatments, surface modifications, coatings, and sterilization methods required to meet clinical and regulatory standards. Through this analysis, students will gain insight into how AM can be optimized for medical applications and how it continues to revolutionize the healthcare industry by enabling personalized medical solutions.

## 2 Additive Manufacturing Technologies for Biomedical Applications

### 2.1 Overview of AM Technologies

With additive manufacturing (AM) approach, producing three-dimensional models continuously from digital designs marks an important shift in modern production methods. This layer-by-layer approach offers a degree of flexibility and customization usually not feasible with traditional manufacturing techniques, thus enabling the manufacture of complex shapes and customized designs, offering great potential, as shown on Figure 2.1, for the biomedical sector. Additive manufacturing's growing importance in the biomedical field as previously stated is clear from its increasing application in the manufacture of tailored implants, prostheses, tissue engineering scaffolds, drug delivery systems, and surgical tools.



Fig. 2.1. Overview of pros and cons

A key factor driving the acceptance of additive manufacturing in this industry is the ability to adapt medical items and therapies to the particular anatomical and physiological demands of individual patients. The meeting of the advanced design freedom of additive manufacturing with the vital need for tailored solutions in the biomedical industry marks a strong and increasing synergy. This indicates that biomedical professionals seeking to effectively leverage the potential of this transformative approach must have a comprehensive understanding of various AM technologies and their specific characteristics.

### 2.2 Core concepts and definitions

The ISO/ASTM 52900:2021 standard defines additive manufacturing as the application of layers of materials to make components from three-dimensional model data. In this way, AM creates objects by gradually adding small layers of material based on a sliced digital model. A three-dimensional digital model, commonly created by CAD software or 3D object scanners, drives this process. The digital model is computationally processed and split

into digital cross-sections to estimate layer trajectory and material deposition (see Figure 2.2).

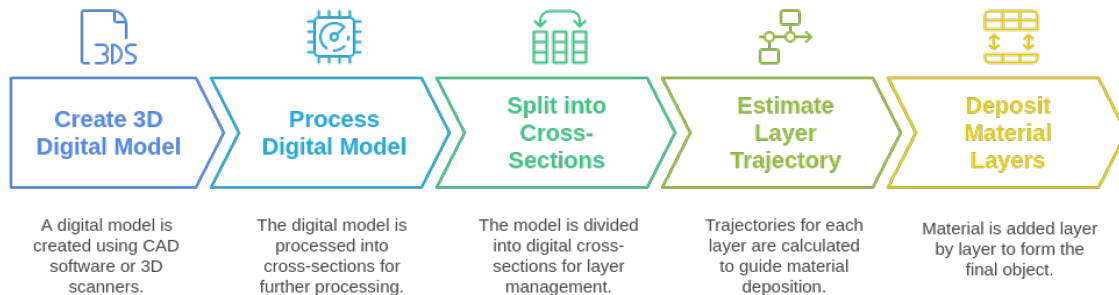


Fig. 2.2. Additive manufacturing process concept

Additive and conventional manufacturing methods differ greatly. As shown on Figure 2.2, the additive manufacturing process involves several precisely incorporating stages from creation of 3D model to deposit material in order to build a physical model. This differentiates from subtractive manufacturing, like machining or milling, which removes material from a solid block, and formative manufacturing, like moulding or casting, which shapes materials in a mould. AM can build complicated shapes and detailed interior parts that are difficult or impossible to create with subtractive or formative approaches due to their additive properties. Additive manufacturing was initially used for rapid prototyping to create scale models for design visualization and validation. The technology has expanded to include rapid tooling for mould and pattern development and direct manufacture of functional end-use components, known as rapid manufacturing or dispersed manufacturing. This shift from prototyping to manufacturing shows additive manufacturing's reliability and versatility. Additive manufacturing's ability to build functional components shows advances in material properties, process precision, and production scalability, making it important across industries, especially biomedicine. In addition, additive manufacturing's reliance on digital models streamlines the design-to-fabrication process. This streamlined digital workflow helps speed up biomedical solution development and manufacturing by eliminating expensive tooling and intermediary manufacturing.

### 2.3 Classification of technologies

The American Society for Testing and Materials (ASTM) has established a foundational framework for the additive manufacturing (AM) sector with the release of ASTM F2792. This standard outlines seven principal process types, providing a thorough classification of the many AM technologies presently accessible in the commercial sector. These categories are designed to offer a systematic and clear classification, enhancing interdisciplinary communication and standardization within the discipline.

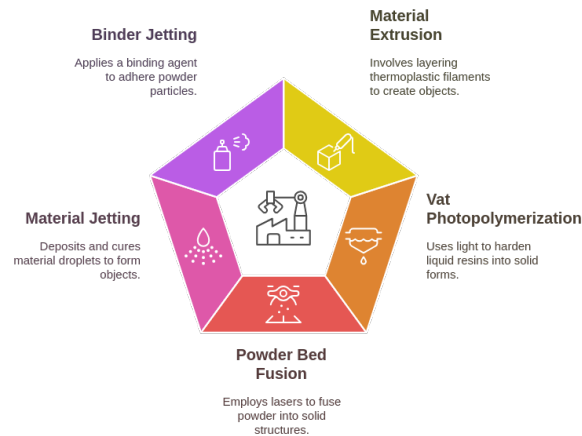


Fig. 2.3. Diverse techniques in additive manufacturing

The seven classifications shown in Figure 2.3, established by ASTM F2792, are described in detail as follows:

- **Material Extrusion (MEX):** This method entails the selective deposition of a continuous filament of thermoplastic material via a heated nozzle. The substance hardens as it cools, creating successive layers that comprise the final component. This technique is mostly utilized in fused deposition modeling (FDM) and analogous methods.
- **Vat Photopolymerization:** This category includes procedures that employ liquid photopolymer resins, which are selectively hardened by light sources, such as lasers or projectors. Stereolithography (SLA) and digital light processing (DLP) are notable instances.
- **Powder Bed Fusion:** This method employs a thermal energy source, such as a laser or electron beam, to selectively fuse areas of a powder bed. Selective laser sintering (SLS), selective laser melting (SLM), and electron beam melting (EBM) are categorized within this group.
- **Material Jetting:** This technique entails the precise deposition of droplets of construction material onto a fabrication platform. The material is then cured using ultraviolet (UV) radiation or alternative methods. PolyJet technology serves as a quintessential illustration.
- **Binder Jetting:** This technique involves the selective application of a liquid binding agent onto a powder bed, therefore adhering the powder particles together. Additional layers are applied, and the procedure is reiterated until the component is completed.
- **Directed Energy Deposition:** This category encompasses techniques that employ concentrated thermal energy to amalgamate materials by melting them during deposition. Laser metal deposition (LMD) and electron beam additive manufacturing (EBAM) serve as examples.

The creation of these standardized categories by ASTM F2792 is essential for promoting clarity and consistency in the additive manufacturing sector. This classification scheme as shown in Figure 2.4, enables following:

**Enhanced communication:** By establishing a common vocabulary, it facilitates effective discourse among researchers, engineers, and manufacturers on various biomedical additive manufacturing technologies.

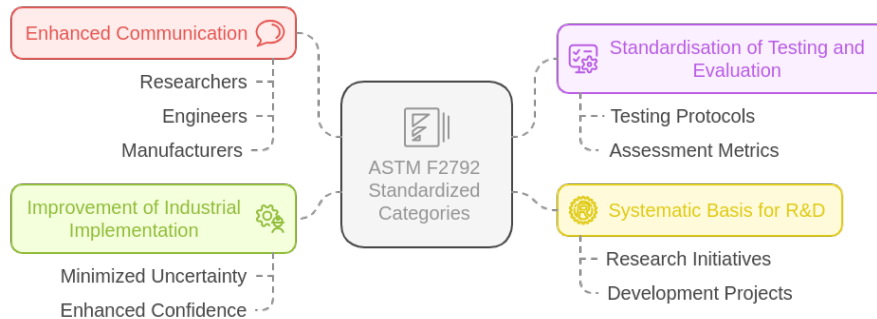


Fig. 2.4. Benefits of ASTM F2792 Standardized Categories in Additive Manufacturing

**Standardization of testing and evaluation:** The categories establish a framework for formulating standardized testing protocols and assessment metrics for additive manufacturing materials and processes. The classification system establishes a systematic basis for research and development initiatives in additive manufacturing.

**Improvement of industrial implementation:** Promoting standardization minimizes uncertainty and enhances confidence in additive manufacturing technologies.

Next, the e-book summarizes key aspects of Bioprinting—an important technology category distinct from the AM methods in Figure 2.3. Unlike those methods, Bioprinting focuses on precisely fabricating living tissues and organs using structural bioinks made of living cells and biomaterials. Figure 2.5 illustrates several major Bioprinting techniques, each using different mechanisms for high-resolution bioink deposition.

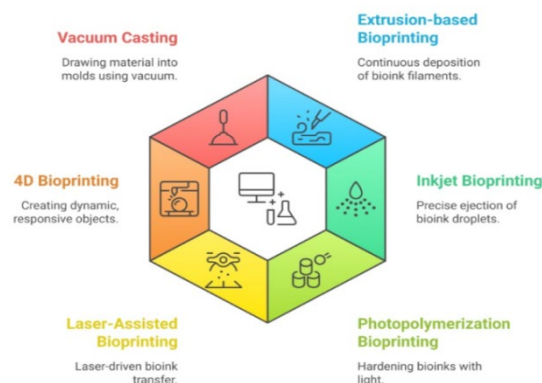


Fig. 2.5. Diverse methods of Bioprinting

The six classifications shown in Figure 2.5 are reflecting key technological approaches in Bioprinting:

- **Extrusion-Based Bioprinting:** This method uses the continuous deposition of bioink through a nozzle, typically under pneumatic pressure or mechanical force. The extruded material solidifies upon deposition, forming sequential layers that constitute the final construct. This technique is extensively used for fabricating tissue

scaffolds and biological structures due to its versatility in handling a wide range of viscosities.

- **Inkjet Bioprinting:** This category encompasses techniques that utilize thermal or piezoelectric actuation to eject fine droplets of bioink onto a substrate with high precision. The droplet-based nature of this process makes it particularly suitable for patterning cells and biomolecules in applications requiring high spatial resolution, such as tissue models and cell arrays.
- **Photopolymerization Bioprinting:** This technique involves the selective solidification of photo-sensitive bioinks using a light source, typically in the ultraviolet or visible spectrum. Controlled exposure to light enables the formation of well-defined three-dimensional structures, making this approach ideal for printing vascular and soft tissue constructs with intricate geometries.
- **Laser-Assisted Bioprinting:** This method employs focused laser energy to transfer droplets of bioink from a donor plate to a receiving substrate. The process, characterized by its nozzle-free configuration and precise droplet placement, enables the deposition of delicate cell types and high-resolution biological features without exerting mechanical stress.
- **4D Bioprinting:** This emerging category builds upon traditional three-dimensional bioprinting by incorporating time as a dynamic factor. Constructs fabricated via 4D bioprinting are designed to undergo predetermined transformations in response to external stimuli, such as temperature or pH, thereby enabling the creation of adaptive and functional tissue systems.
- **Vacuum Casting:** This process involves the use of negative pressure to draw liquid materials into molds, enabling the replication of intricate geometries with high fidelity. Though not a printing process in the strictest sense, it plays a vital role in the fabrication of anatomical models and customized biomedical parts.

## 2.4 Key Considerations for Biomedical AM

Several considerations should be taken into account when speaking within the application of AM in biomedical field:

**Biocompatibility:** The choice of materials is essential, emphasizing non-toxicity, reduced immune response, and tissue integration. Metals (titanium, stainless steel), polymers (PLA, PEEK), and ceramics provide distinct characteristics tailored for diverse uses. Understanding the long-lasting real-world effects is important.

**Sterilization:** Ensuring sterility to avert infections is essential. Selection of sterilization methods, such as autoclaving, chemical, and radiation techniques, should be based on material compatibility and the shape of the components. Intricate additive manufacturing designs present sterilization difficulties, requiring meticulous design considerations.

**Regulatory Framework:** Compliance with regulatory requirements is necessary, particularly for bespoke equipment. Current frameworks are inadequate for personalized additive manufacturing solutions, necessitating extensive testing, validation, and calibration. Lucid and progressive guidelines are needed.

**Mechanical qualities:** Attaining requisite mechanical qualities (strength, elasticity, wear resistance) is essential for device performance. The layer-by-layer methodology of

additive manufacturing may result in material heterogeneity and anisotropy, necessitating post-processing and meticulous parameter optimization.

**Precision and Accuracy:** Elevated precision is crucial for implants and surgical instruments to guarantee appropriate fit and functionality. Variables such as layer thickness and material contraction influence precision. Rigorous oversight and sophisticated monitoring are essential for consistent outcomes.

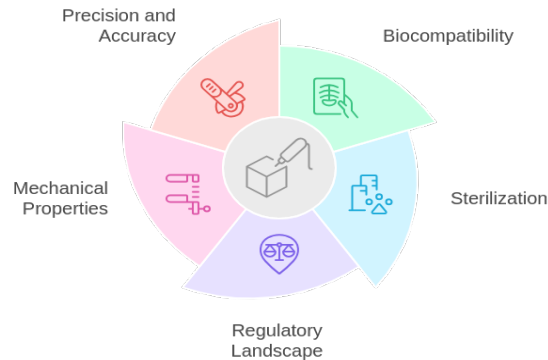


Fig. 2.6. Main considerations in biomedical AM

The additive manufacturing main consideration in biomedical AM landscape as shown in Figure 2.6 has many methods, each with distinct properties that make them suited for biomedical applications. Creating customized, patient-specific solutions can greatly improve medical treatments and outcomes. To utilize maximum potentials of AM technologies in biomedical field, biocompatibility, sterilization, control, mechanical characteristics, and precision must be addressed properly as the field evolves.