Additive Manufacturing Makes Complex, First-in-Industry Medical Devices Possible

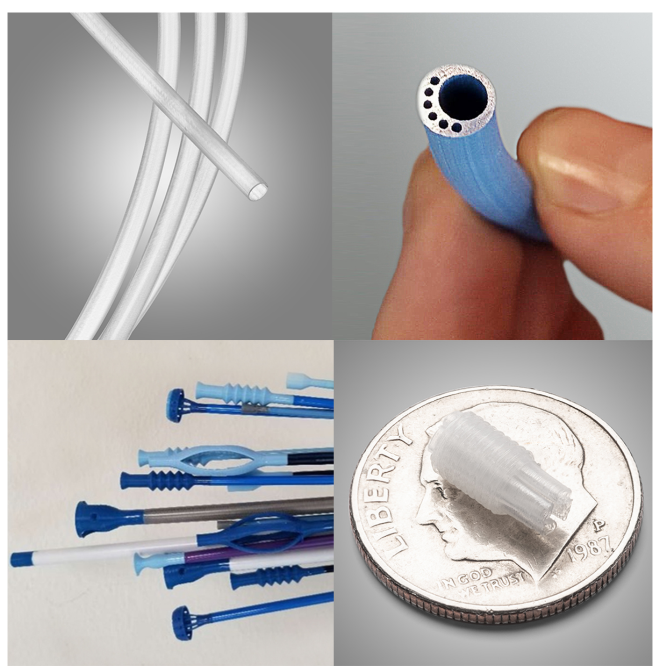
Tyler Stark – Senior Director of Additive Manufacturing and Innovation – Spectrum Plastics Group

Many innovative, next-generation medical devices and components can only be made with additive manufacturing

Additive manufacturing (AM), also known as 3D printing, comprises an innovative suite of advanced technologies that enable the fabrication of a variety of components and products, with remarkably complex and high-resolution features which often cannot be achieved within the constraints of traditional manufacturing methods. New AM technologies, equipment, and specialized materials continue to enter the market at a rapid pace. Ultimately, advanced AM fosters creative engineering, innovative rapid prototyping, and seamless transition to high-volume manufacturing, driving medical device design forward.

Popular AM technologies for medical devices include:

- Selective laser sintering (SLS)—thin layers of powdered material are fused together through SLS, direct metal laser sintering (DMLS), and selective laser melting using a high-powered laser. These processes, which typically utilize established materials, are well-suited for rapid prototyping, bridge manufacturing, and low-volume commercial production.
- Fused depositional modeling (FDM) —pellets or filament feedstock are dispensed through a nozzle via FDM or fused filament fabrication (FFF) technologies. An object is printed, layer by layer, through the extrusion of melted thermoplastic filaments. FDM is especially effective for making complex features with extremely tight tolerances from a wide range of thermoplastic materials.
- Stereolithography (SLA)—a liquid photopolymer is cured in a vat with ultraviolet light using SLA, also known as vat photo polymerization or digital light projection. Materials are light-reactive thermoset "resins" that are formulated to provide the same chemical, thermal, and mechanical characteristics that standard industrial thermoplastics have. This process delivers micro-scale features with smooth finishes, minimizing the need for secondary processes.
- Material jetting (Polyjet) —droplets of photosensitive material are dispensed to form ultra-thin layers that solidify with exposure to ultraviolet light, resulting in smooth, well-finished surfaces in a range of colors. Materials for this process are limited to several photopolymers that have the same general characteristics as more popular thermoplastics.
- Multi-jet fusion (MJF)—also known as binder jetting, this process uses a liquid bonding agent that is selectively deposited on layers of powdered material to eventually create a solid structure with high tensile strength and dimensional accuracy. A big advantage is speed—MJF can be up to 10 times faster than other AM systems, allowing for higher-volume production runs.
- Direct laser metal sintering (DLMS)—also known as directed energy deposition (DED), a laser beam or an electron beam fuses materials together by melting them as they are being deposited. Because DED can control grain structure, it is an ideal AM method for repairing functional parts. Although metals are typically used, DED can also process thermoplastics and ceramics.



Medical Applications for AM

Additive manufacturing technologies enable medical device companies to develop next-generation, innovative devices quickly, which can also be scaled to meet changing production demands.

Benefits of additive manufacturing over traditional manufacturing methods such as machining, injection molding, and extrusion include:

- Equipment and materials can be customized for a wide range of medical applications, allowing for the creation of small and highly complex components and products with challenging geometries and micro-sized features
- Instead of relying on metals, medical device designers can choose from a wide range of medical-grade thermoplastics that can be engineered to have very specific chemical and mechanical characteristics and are lighter in weight
- Rapid prototyping that delivers production-ready prototypes in a matter of days instead of weeks or months, accelerating product development and informed decision-making
- Creation of innovative, one-of-a-kind products or components, especially for minimally invasive surgical processes, that can only be achieved with AM methods
- Bridge manufacturing that utilizes AM to test low-volume production runs of a product before investing heavily in a mass-production process using standard methods of manufacturing

Thermoplastics and AM

High-performance, medical-grade thermoplastics commonly used in medical device manufacturing include ABS, acrylic, PLA, Nylon, polycarbonate, and polyethylene. Thermoplastics become soft and pliable when heated and re-solidify when cooling. These materials are dimensionally stable and can withstand the most demanding end-use applications, making them ideal for components that require strength and high chemical and temperature resistance. Thermoplastics can also be custom-engineered to provide enhanced properties such as biocompatibility, antimicrobial, and electrostatic dissipation.

Popular thermoplastic materials for AM production of medical parts and components include:

- Pebax—these elastomers are engineered to deliver a wide range of mechanical characteristics, including strength, hardness, and flexibility. Additives can enhance performance, such as barium sulfate for detection by x-ray.
- Nylon—this thermoplastic has a long history of use in the medical device field. Due to its strength and low coefficient of friction, nylon is an excellent replacement for metal or moving parts.
- Polypropylene—offers a wide range of properties, including chemical resistance, low moisture absorption, and toughness. It is easily combined with other polymers to create composites with broader material properties.
- Polycarbonate—a transparent, impact-resistant, and dimensionally stable thermoplastic, polycarbonate can withstand temperatures up to 250°F and is a popular choice for clear medical tubing.
- Acrylonitrile butadiene styrene—also known as ABS, this material exhibits dimensional stability, impact strength, stiffness, and exceptional resistance to corrosive chemicals. Because it is so sturdy, ABS is often used for housings for medical devices and equipment.
- Polyetheretherketone—PEEK is a high-performance plastic with excellent dimensional stability, mechanical strength, and resistance to harsh chemicals. PEEK's strength and load-bearing capabilities make it an ideal material for implants.
- Polyetherketone—also known as PEK, polyetherketone is a high-performance engineering thermoplastic. Similar to PEEK, PEK has high thermal dimensional stability and outstanding chemical resistance over a wide range of temperatures.
- High-impact polystyrene—HIPS is a form of polystyrene that has been modified by the addition of rubber, which imparts superior durability and impact resistance. It is also easily customized with a variety of colors and finishes.
- Urethanes—these elastomers are both flexible and abrasion- and impact-resistant, making them ideal for harsh, severe-wear operational environments. Urethane is also resistant to water and lubricants. Additives to urethane compounds can create a large variety of engineered mechanical characteristics for a variety of specialized applications.
- Custom materials—materials can be custom-engineered using different additives and processes to have very precise characteristics, such as strength, durometer, and flexibility, to meet the requirements for highly-specific parts that can be produced with AM.

Proprietary/Customized Processes

AM in the medical industry continues to advance, especially the number of new AM materials with highly specific engineered properties. Software and hardware advancements also improve flow rate precision and control, achieving highly accurate parts. Depending on part geometry and complexity, tolerances can be as tight as +/-0.0005 inches.

AM has become commonplace, but with limited capabilities and offerings to incorporate high-performance thermoplastics, which can provide far more design flexibility than metals because of the vast number of thermoplastic materials available. These materials can be altered through chemical or mechanical manipulation to improve physical properties such as impact resistance, mechanical strength, heat resistance, chemical resistance, lubricity, abrasion resistance, sterilization resistance, biocompatibility, transparency, and low water absorption.

Spectrum uses AM to process all medical-grade thermoplastic materials. Material consistency is critical for AM reliability and repeatability. To achieve the greatest control over material quality and consistency, Spectrum manufactures its own in-house filaments. All products are made from medical-grade USP Class VI and/or ISO 10993 materials and additives that are biocompatible, traceable, and certified.

Spectrum Additive Manufacturing

Spectrum has developed Spec+ Additive Manufacturing, its own proprietary AM equipment and processes for creating medical products that other companies cannot, such as high-precision, medical-grade single and multi-lumen tubing—a first in the industry. This proprietary technology produces prototyped multi-lumen tubing, expanding the limits of design, materials, and speed for medical-grade tubing. The Spec+ system can create a full-length multi-lumen tube to specification in a single day (in comparison, with the standard extrusion process it can take up to three or more die iterations and weeks before refining a prototype multi-lumen extrusion). Spec+ simply prints the entire extrusion profile out of the first shot of designated material.

Micro 3D printing

Miniaturization is an on-going trend in the medical device industry. Medical device engineers are designing miniaturized products that also require smaller and more complex components and assemblies. AM processes have evolved to the point where they can produce small, high-resolution parts at the micro-scale that are difficult to produce with conventional manufacturing methods, such as CNC machining.

Continued software and hardware advancements have enabled Spectrum to produce AM parts that are 0.05 inches in size and smaller, with tolerances in the micron range. Although micro 3D printing is often used for prototyping and pre-production testing, it can sometimes be used for production-ready parts or short-volume orders. For short-medium run production—say, 50,000 parts or fewer—micro 3D printing is often cost-effective and provides shorter time to production.

Quick-Turn Prototyping and 24/7 Production

Quick-turn prototyping is essential in medical device manufacturing today. Time to market is a top priority for medical device manufacturers—delivering functional prototypes into the hands of all stakeholders as soon as possible allows for more-informed decision-making and shorter time to market.

Spectrum lead times can be as short as:

- 3-5 days for most additive manufacturing prototypes
- 1-2 weeks for higher-volume orders or complex designs

Depending on the final design, material selection, and AM process, commercial production runs are often feasible. If required to meet higher-volume runs or short-notice deadlines, Spectrum has the capacity to easily scale production or run 24/7 to meet challenging schedules.

Future Trends

Additive manufacturing is a rapidly advancing field as new technologies, equipment, and specialized materials continue to enter the market. Miniaturization will likely continue as the dominant trend in the medical device industry in the near future, with AM making increasingly small parts and components for these products.

The advantages of AM are many, including rapid prototyping, product customization, and creating intricate surface structures and textures that reduce weight and enhance performance at the micro scale. AM also does not require the expensive set-up and tooling that traditional injection molding or CNC machining requires. This also makes it easier to access bridge tooling to test short runs before making expensive investments in tools.

AM materials will continue to evolve at a rapid rate, including bioresorbable materials. Implantable components are being trialed with different AM systems to see how various materials influence product performance, especially wear and durability. Materials are also being blended together during the AM process to form "in-situ" alloys. In-situ alloys can have better mechanical properties than pre-alloyed individual metals. Plastic composites can also be formed in-situ during AM, creating exciting possibilities of improved performance.

Perhaps the greatest advantage of AM is the design freedom it provides medical device engineers, which allows them to select from a wide range of medical-grade plastics, with specifically engineered material characteristics and design components, for multi-material and multi-dimensional builds. The ultimate benefit of AM is that medical device companies can invent innovative new products that deliver vastly improved time to market.

Innovation and Collaboration

Spectrum has developed groundbreaking additive manufacturing technologies, utilizing proprietary processes and medical-grade materials to create one-of-a-kind components with complex tolerances, geometries, and features.

Integrated AM processes and materials, combined with careful system controls, allow us to produce ultra-high-precision, micro-sized parts that are suitable both for rapid prototyping and seamless transition to high-volume manufacturing. Spectrum's proprietary AM technologies can print incredibly small parts from just about any type of thermoplastic—even multiple materials together in a single print—at dimensions so small they are often difficult to see with the naked eye.

As Spectrum's AM printing technologies integrate more with other fields, such as software, artificial intelligence, and materials science, we expect to be on the forward edge of AM manufacturing across multiple sectors, making products that improve quality of life around the world.