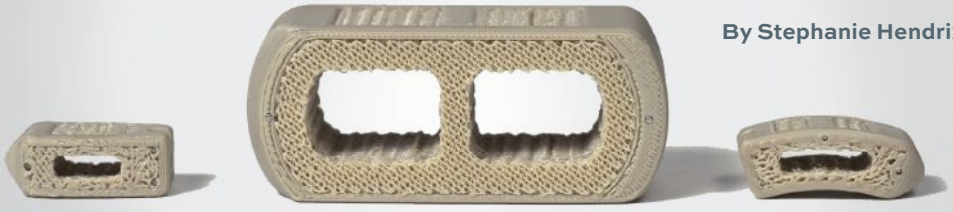
3D Printed PEEK Spine Implants Now in Production

Medical device manufacturer Curiteva is producing two families of spinal implants using a proprietary process for 3D printing porous polyether ether ketone (PEEK).



By Stephanie Hendrixson, Executive Editor

Polyether ether ketone (PEEK) has been used in medical implants for more than three decades. The thermoplastic offers biocompatibility and mechanical properties similar to bone, making it suitable for implants. As an added benefit, the material is radiolucent, meaning it does not appear in an X-ray — making it easier for the surgeon to monitor healing post-surgery.

But until recently, most PEEK implants were produced through machining or molding, which brought design constraints. Porosity is desirable in many implants, as it can enable the patient's own cells to grow into the device as the body heals. Some porosity can be achieved by compression molding of PEEK, but this process does not enable precise control of the geometry and material properties all throughout the part.

3D printing offers an alternative. Huntsville, Alabama-based medical device company Curiteva now manufactures two lines of 3D printed PEEK implants for the spine. Its Inspire implants for cervical and lower lumbar spine feature porous structures achieved through lattice-based designs and compressive strength throughout that is developed through the printing process, fused strand deposition (FSD).

A 3D Printing Process Just for PEEK

PEEK's semicrystalline structure provides desirable mechanical and thermal properties, but also makes it more difficult to 3D print. Rather than being heated all at once for injection into a mold, 3D printed PEEK must be heated a little at a time to temperatures above 140°C so the material can be extruded from the printer nozzle. As the polymer cools after deposition, it forms the crystalline structure which provides its strength, a process that can also result in significant warping or shrinkage.

▲Curiteva 3D prints PEEK implants for the cervical spine and lower lumbar spine (pictured). Around 30 variations are offered for cervical and more than 1,300 SKUs for lower lumbar.

To take advantage of PEEK's material properties and counter their downsides, Curiteva uses a modified form of fused filament fabrication (FFF) it calls fused strand deposition. This FSD is a proprietary process that was originally developed by Todd Reith under his company, Fossil Labs. Curiteva, which produces medical implants through multiple manufacturing processes, acquired Fossil Labs and its IP in 2020 in order to use FSD to produce its own products in-house. Reith joined the company as well and serves as vice president of emergent technologies and additive manufacturing.

"One of the most difficult things about printing PEEK is the large delta between the glass transition temperature and the melt temperature," Reith says. "The glass transition temperature is around 140-150° Celsius, and the melt starts around 350-380°C. Because of that, the material wants to move quickly into a crystalline state. We have tailored our technology around the deposition so that we can slow down this crystallization process. We're actually pulling strands, much like you would glass or other materials."

While standard FFF deposits filament at a consistent rate, FSD actually stretches the softened PEEK filament as it is extruded. The stretching controls crystallization, enabling better bonding between layers and aligning the polymer strands. The approach also creates tension within each layer which improves the printed material's strength and durability.

"Each layer can be put in compression," says Erik Erbe, chief scientific officer. "We achieve a compressive strength six times what is required for physiologic loads because of this 3D printing approach."

The 3D printing process enables Curiteva to take advantage of PEEK's unique material properties and apply this polymer in new geometries, including novel porous structures that can extend throughout an implant.

3D Printed Implants in Production

Curiteva achieved 510(K) FDA clearance for its first FSD PEEK product — its cervical spine implant line — in 2023. The process took more than 18 months and close collaboration with the FDA because of the new manufacturing method. In the first year since clearance, around 50 surgeons have adopted the devices, and more than 2,000 Inspire devices have been implanted in about 1,000 patients (with some having two or more implants) with no revision surgeries. In early 2024, the company achieved clearance for a second line of implants for the lower lumbar spine. Because of the groundwork laid with the earlier cervical line, the new lower lumbar implants were cleared in just 57 days.

Curiteva manufactures both spine implant lines at its production facility in Huntsville, Alabama, through FSD printers housed in a cleanroom environment. Each implant is printed one at a time to maintain precise control over its thermal history on FSD machines produced by Curiteva, using PEEK filament from Evonik. After printing, support structures are removed (consisting primarily of a "raft" which holds the part slightly above the build plate) and the parts are cleaned with isopropyl alcohol and annealed for stress relief.

Because the PEEK material is radiolucent and invisible to an X-ray, the next step in the process includes machining to finish surfaces and to drill holes in each implant to install titanium marker pins for visibility. (One positive side effect of 3D printing versus machining PEEK is there is far less material waste and expense. Curiteva sees only 2% waste from machining of these implants, which means that almost all of the PEEK it is purchasing as filament is used in the final part.)

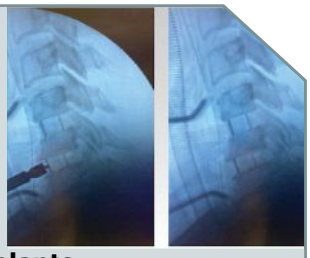
▲3D printed implant production takes place almost entirely inside this clean room at Curiteva's Huntsville, Alabama, facility. Nine FSD 3D printers can support the company's implant production, but the clean room has space for as many as 20 of these machines.

◀Curiteva develops and manufactures the 3D printers capable of performing fused strand deposition with PEEK. Source: Curiteva

After another round of cleaning and laser marking, parts leave the clean room to depart to a supplier for a hydroxyapatite coating — a step necessary to make the naturally hydrophobic PEEK more hydrophilic, and therefore better able to support osseointegration. Finally, implants return to Curiteva for sterile packaging and are held in inventory until ordered.

Curiteva currently runs two 10-hour shifts per day, five days a week to meet its 3D printing production needs. Its nine production-qualified FSD 3D printers are enough to fulfill demand for the implants at the moment. However, the clean room can hold up to 20 printers, and the company anticipates scaling up in the near future. AM

THE COOL PARTS show



FDA-Approved PEEK Implants

For more on Curiteva's cervical spine implants and links to our other coverage of 3D printed PEEK implants, see Episode #63 of The Cool Parts Show at **gbm.media/curiteva**.