# NuVasive Taps AM Ecosystem to Optimize Spine Implant Technology

## Spinal device company goes from additive manufacturing novice to full product line of optimized 3D printed implants in one year

NuVasive saw an opportunity with additive manufacturing (AM) back in 2015. The orthopedic device company recognized that the unique capability of AM to produce complex and optimized shapes could open new avenues in its design and manufacturing of minimally invasive, procedurally integrated spine solutions. The only snag was that no one at the company possessed AM experience.

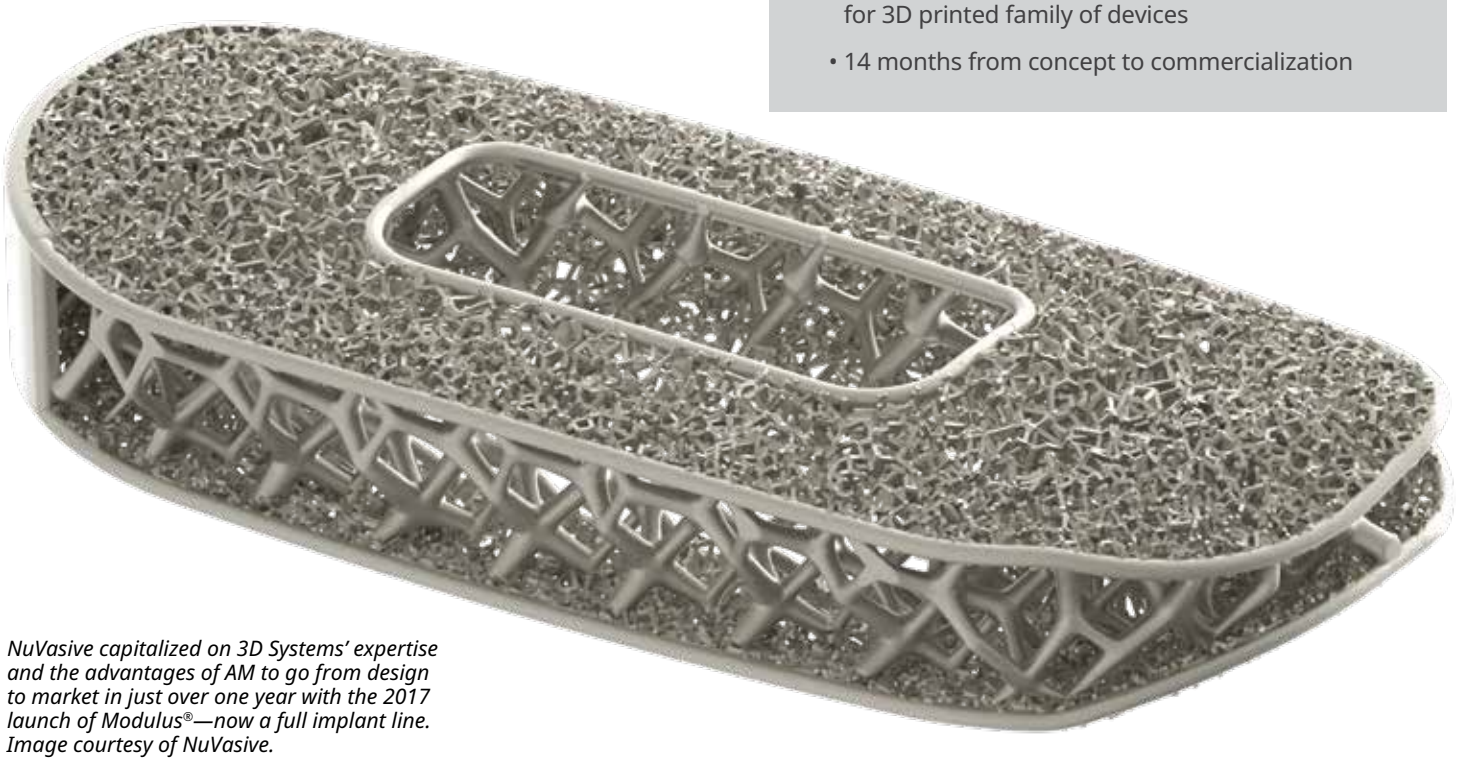
NuVasive knew that it needed to partner with a service and manufacturing provider for the AM process. The result of that ultimate collaboration was that NuVasive quickly capitalized on the advantages of AM, going from design to market in just over one year with the 2017 launch of Modulus®—now a full implant line.

**CHALLENGE:**
Utilize additive manufacturing to help drive improved clinical outcomes for spinal implant patients

**SOLUTION:**
Partner with 3D Systems' Customer Innovation Center to refine and qualify novel spinal device for production and commercialization

**RESULTS:**

- Topologically optimized Modulus® line of implants offers improved radiolucency while balancing porosity with load sharing
- Successful and streamlined FDA-clearance for 3D printed family of devices
- 14 months from concept to commercialization



*NuVasive capitalized on 3D Systems' expertise and the advantages of AM to go from design to market in just over one year with the 2017 launch of Modulus®—now a full implant line. Image courtesy of NuVasive.*


*3D Systems provided critical industry expertise on print strategies, metallurgy and residual powder removal, among other impactful AM aspects.*

**Picking a partner to grow expertise**

Even accounting for the talent and expertise housed within the NuVasive team, hard work combined with strategic innovation allowed the company to successfully design, qualify and bring to market an optimized family of AM implants in 14 months. If this were a subtractively manufactured product, this would be no surprise: NuVasive has a 180,000 square-foot manufacturing facility in West Carrollton, Ohio, where it performs traditional manufacturing day-in and day-out. AM is another story, and the novelty of the approach to the company and its workforce presented unique challenges.

Realizing that they needed outside counsel, NuVasive first identified several topline criteria for selecting its AM expert. The quality and reliability of the available 3D printing technology were both non-negotiable. The company needed software application support to effectively manufacture a novel device. Lastly, it sought a partner that had credibility within the AM industry and could grow alongside NuVasive.

"We were not willing to take any risks in this regard," said Jeremy Malik, Director of Product Development at NuVasive.

After conducting thorough research, NuVasive chose 3D Systems, with its Direct Metal Printing (DMP) technology and team of application engineers and AM experts, to commercialize Modulus.

**Proceeding from concept to commercialization**

The design philosophy behind the Modulus line was to utilize new technology in a meaningful way to deliver a final product that is innovative, as opposed to new. According to NuVasive, the company's goal was to provide the optimal spinal implant without making significant tradeoffs in the process.

The Modulus line balances porosity with load sharing, and each independent SKU is optimized for improved radiolucency. This was achieved through topological optimization, an algorithm-based design strategy that removes excess material that serves no structural or functional purpose. A component that has been topologically optimized is lighter-weight with no adverse impact on strength. In the case of the Modulus line, topological optimization also facilitates better imaging characteristics across all shapes and sizes of implants, giving surgeons a better view into bone fusion during follow-up. In addition, the optimized lattice structure provides a fully porous architecture that creates an environment conducive for bone in-growth.

"We wanted to do things we couldn't do before," Malik said. "There is more to this device than simply utilizing a new technology to bring it to market; we used new technology to help drive improved clinical outcomes for patients."

Together, the two companies generated a number of file iterations for different ways that the desired devices could be printed, and 3D Systems provided critical industry expertise on print strategies, metallurgy and residual powder removal, among other unfamiliar but impactful AM aspects.

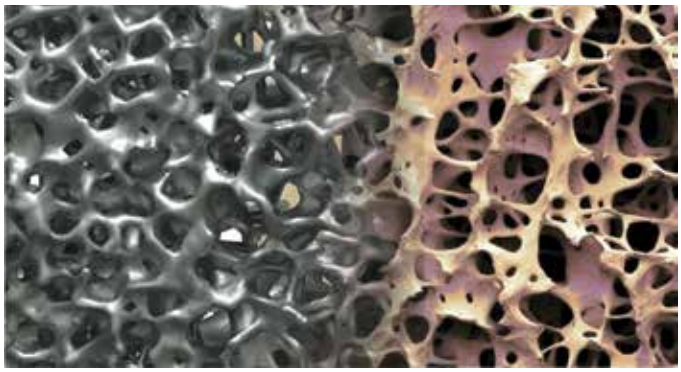
"We didn't know what we didn't know," Malik said. "3D Systems helped educate us on the additive process and worked with us to iron out our process beyond just the printing. We had a lot of open dialogue, and that communication was key to our success."

Through the process, NuVasive leveraged 3D Systems' Customer Innovation Centers (CICs). These facilities, and access to the expertise housed within them, provide an ecosystem of AM solutions that include design and manufacturing capabilities, along with premium hardware, software and materials. Covering everything from application development and frontend engineering, to equipment validation, process validation, part qualification and production, 3D Systems' CICs help companies with various experience levels accelerate innovation through additive technology.

From design to production, NuVasive was able to capitalize on what the technology had to offer in terms of improved functionality without making large initial investments.

The two companies also collaborated beyond design optimization to achieve a qualified AM production workflow. Notwithstanding NuVasive's track record in earning FDA clearance on products made with traditional manufacturing, using a new process introduced unique regulatory challenges.

According to Malik, NuVasive addressed those issues by leveraging 3D Systems' data on manufacturing reproducibility in order to bolster its justifications in its FDA submission.



*NuVasive used new technology to help drive improved clinical outcomes for patients. Image courtesy of NuVasive.*

"3D Systems had customers who cleared devices through FDA in the past, so we knew we partnered with someone who had in-house expertise to help us navigate these requirements," he said. "That was a nice safety net."

**Integrating additive into the portfolio**

Fast forward to today, NuVasive is a spine leader in AM with a fully 3D-printed family of FDA-cleared spine implants on the market. The Modulus line is the result of thoughtful design, and balances the benefits of porosity and performance requirements of interbody fusion devices.

In the end, it took NuVasive roughly 14 months to go from concept to commercialization with its Modulus product line. Although this is a fairly standard timeline for traditional manufacturing processes, the company was excited that it was able to maintain the same pacing in its first application of AM.

"It is a significant undertaking to build your production process in addition to designing and building your product," Malik said. "We were proud we had the ability to develop both, and relied on 3D Systems to help build out our datasets and justifications in order to get us to market."

As to product manufacturing and deployment, 3D Systems provides supply chain flexibility and fulfills volume production orders internally or through certified partners, as well as helps customers transition to additive production at their own facilities through knowledge and technology transfer.

NuVasive is beginning to do its own titanium 3D printing in-house, and is using DMP technology for R&D prototyping, as well as to better understand how the machines work to continue refining its production process.

"It's been a huge improvement for us to have that capability on site," Malik said. "Now we have a legitimate, scalable manufacturing process and the ability for continuous improvement in the future."

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