

EBOOK

Personalize innovation. Optimize outcomes.

The definitive guide to delivering patient-specific
devices and streamlining procedural planning

Overcome industry challenges to elevate patient care

Each time new challenges in healthcare arise—like providing effective care during a worldwide pandemic—the medical device industry responds dynamically with new innovations to improve patient care and outcomes. In fact, it seems that advancements are introduced more rapidly than ever before. Yet surgical risks remain prevalent, with nearly seven million patients experiencing significant complications following surgery each year.¹ Additionally, radiotherapy treatment is used in approximately half of all cancer cases to target and kill cancerous cells,^{2,3} yet protecting healthy cells remains a challenge.

Health systems around the globe continue to explore ways to reduce expenses while improving treatment methods, patient satisfaction and outcomes. If manufacturers can help providers achieve these shared goals, health systems can maximize reimbursements and ultimately lower the total cost of care.

One approach to saving time, reducing costs and boosting outcomes that demonstrates significant promise is the ability to 3D print patient-specific devices and create personalized treatment plans. This definitive guide examines how additive manufacturing can deliver comprehensive personalized healthcare solutions that help address systemic industry challenges.



Experience the impact of additive manufacturing for patient-specific devices

Patient-specific implants are ideally suited for additive manufacturing due to the extreme flexibility this technology provides to produce bespoke products. Unlike traditional manufacturing techniques that require machine setup or tooling, which limit cost-effectiveness to large production volumes, additive manufacturing requires only a digital design file, the printer and the material to build it. This makes additive manufacturing a viable approach both for fabricating one-off personalized devices as well as scaling to include off-the-shelf implants that pair with patient-specific models, guides and instruments.



Transform procedural planning with 3D visualization and digital workflows

Additive manufacturing of patient-specific devices at 3D Systems begins with our FDA-cleared VSP® procedural planning solutions. VSP combines digital workflows with expertise in diagnostic imaging segmentation, surgical planning, device design and 3D printing.

How does it work? Using VSP® Connect—our centralized, cloud-based surgical planning portal—healthcare providers share patient CT scans and collaborate with a 3D Systems biomedical engineer. Through automated and intelligent workflows, the surgeon and engineers can securely view real-time case visualizations as they work to finalize the design of the patient-specific devices and associated surgical plans.

Using 3D printing software, models, instrumentation and implants are designed to match the unique anatomy of the patient. Then, the manufacturing team 3D prints, inspects and delivers the devices quickly to help expedite patient procedures.

This workflow works so well to personalize surgeries that it has now been applied to radiotherapy treatments, simplifying the process of customizing accessories. VSP® Bolus, for example, includes the complete design-to delivery workflow to deliver a patient-specific bolus and help clinicians optimize targeting.



3D Systems' VSP solutions for patient-specific devices can:

- Improve procedural planning^{4,5}
- Enhance provider confidence⁵
- Reduce procedure time⁶
- Improve outcomes and accuracy^{7,8}
- Enable more efficient workflows⁸

Integrate precision 3D technologies for better outcomes

Below is our VSP end-to-end workflow in action:

 3D Model	 Plan	 Design	 Manufacture	 Inspect	 Deliver
Process patient-specific medical data into digital 3D model.	Schedule online meeting between the provider and a 3D Systems biomedical engineer.	Create patient-specific 3D models, guides and templates.	3D print devices to smoothly transfer surgical plan into operating room or help optimize radiotherapy targeting.	Put models through 3D Systems' intensive quality control system.	Ensure timely delivery of quality, patient-specific devices and virtual surgical plans, as needed.

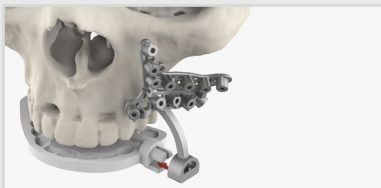
With the VSP Connect planning portal and our skilled team of biomedical engineers, 3D Systems makes the planning process seamless, from patient modeling to the operating or treatment room.

VSP procedural planning solutions

3D Systems applied its FDA-cleared VSP workflow to deliver over 150,000 patient-specific cases and devices across four different specialties:

Craniomaxillofacial

Combining expertise in medical imaging, surgical simulation and 3D printing, VSP provides pre-surgical planning, and accurate, patient-specific, 3D printed models and instrumentation.



Orthopaedics

Developed for orthopaedic oncology cases, VSP Orthopaedics provides pre-surgical planning, and patient-matched, sterilizable, surgical instruments.



Extremities

For foot and ankle applications, 3D Systems works with medical device companies to develop VSP surgical planning solutions to complement off-the-shelf implants.



Radiotherapy

To help optimize radiotherapy targeting, VSP Bolus is a flexible, patient-specific, 3D printed solution, which includes a complete design-to-delivery workflow.



Anatomic Models

Because each patient's anatomy is different, patient-specific anatomic models help visualize and plan surgeries prior to entering the operating room. Models can also be used to educate patients and their families on an upcoming procedure. Depending on the VSP case, anatomic models may be included.

Improve performance with advanced software

Personalizing implants, instruments and models requires advanced segmentation and 3D design software. Visualization and collaboration is made possible via an online portal. Integrating these technologies helps to streamline patient-specific device development and the procedural planning process.

D2P® SOFTWARE

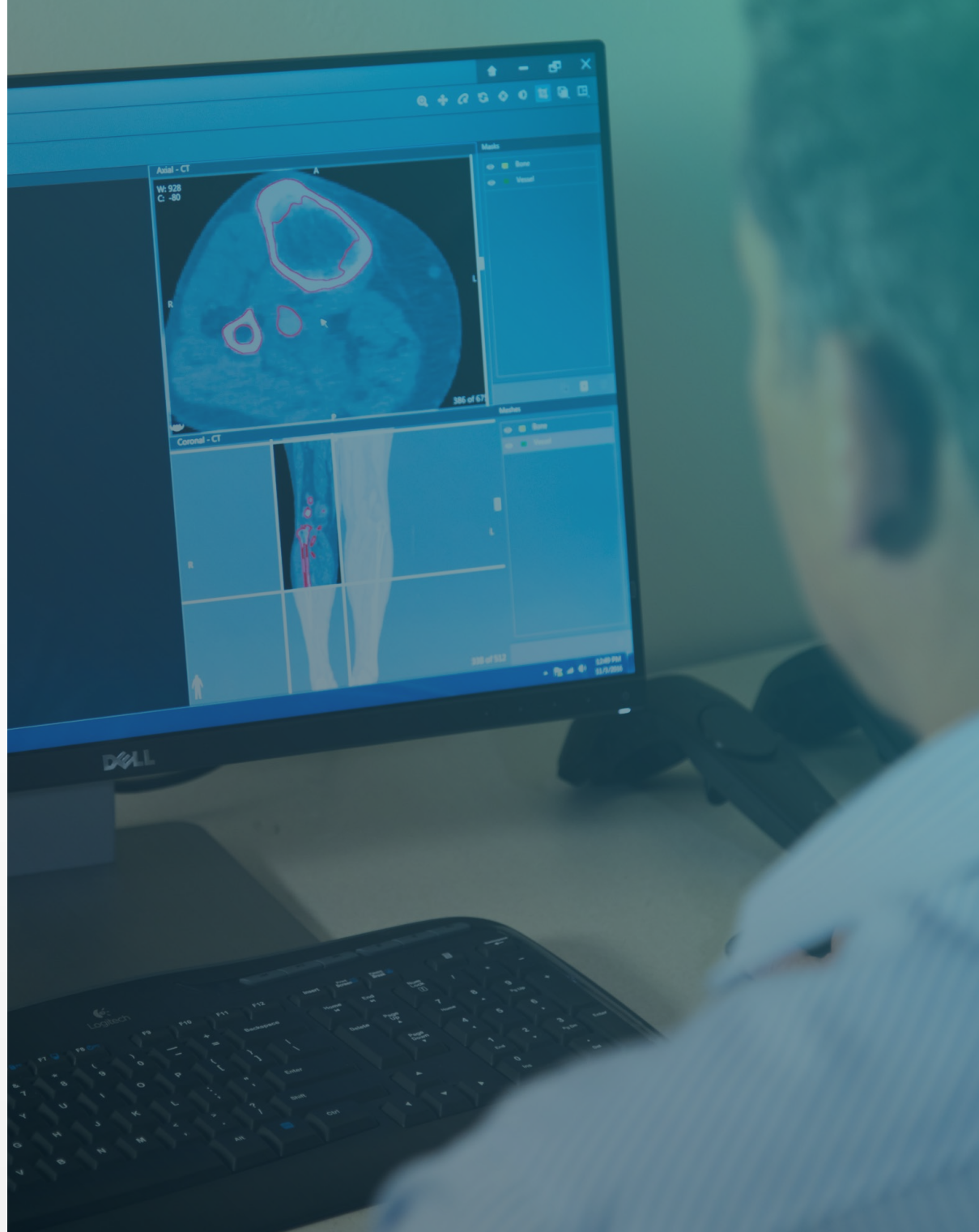
FDA 510(k) cleared D2P® 3D medical image processing software from Oqton enable surgeons, radiologists, lab technicians and device designers to create diagnostic-quality digital 3D models quickly and easily.

GEOMAGIC FREEFORM

Geomagic® Freeform® 3D design software from Oqton—combined with touch-based haptic devices—enables organic, digital design for patient-specific surgical planning.

VSP® CONNECT

Our procedural planning portal simplifies case submission and provides unprecedented visibility across personalization workflows. By integrating artificial intelligence and deep learning technologies—VSP Connect streamlines the delivery of personalized devices. Device manufacturers now have access to a scalable and integrated solution for expanding patient-specific solution portfolios.



Access validated 3D printing technology & materials

Part of enabling high quality and repeatability during medical device manufacturing is selecting the right platform and materials for your application. Our 3D printing platforms include:

POLYMER

EXT 220 MED (Extrusion)	SLA 750 and SLA 750 DUAL
ProJet® MJP 2500/2500 Plus	Figure 4® Standalone (DLP)
ProJet® 7000 HD (SLA)	SLS 380

METAL

DMP Flex 200
DMP Flex 350 & DMP Factory 350 - now with dual-laser configuration

FULL COLOR PRINTING

ProJet® CJP 660Pro



Access validated 3D printing technology and materials

3D Systems has ISO-certified manufacturing facilities continuously testing, validating and 3D printing devices using our platforms. We do the same research and testing with the plastic and metal materials for use in implants, instruments and models. To this end, we offer a broad range of biocompatible and sterilizable metals and polymers for healthcare applications and have learned methodologies for accelerating innovations by applying processes we know will help meet regulatory standards to expedite validation and approvals. Recent advancements include:

- Extrusion technology to print medical-grade, high-performance polymers, including PEEK, PPSU, PEI and PEKK
- A study on the impact of sterilization on 3D-printed polymers, such as mechanical properties, dimensional stability, color stability and cytotoxicity
- Documentation on how process characterization and validation with titanium alloy Ti6Al4V can accelerate additive manufacturing of metal implants
- Introduction of cobalt chrome for use in patient-specific articulating implants

Get to know the 3D Systems facilities



3D Systems operates ISO 13485 certified and FDA registered facilities in Littleton, Colorado and Leuven, Belgium.

Improve quality management and process controls

After selecting the right technologies and materials for an application, the next step is to establish workflows and protocols for the design and manufacturing of the device. In this guide, we explored our FDA-cleared VSP workflow, but for organizations deploying their own device personalization process, it must align with regulatory and safety requirements, including the latest FDA guidance for additive manufacturing.

It is critical to build a quality management program and set up control processes to ensure auditable traceability and documentation. 3D Systems' consulting team is available to help navigate the creation and maintenance of a quality management system, from staff education and facilities certifications to monitoring operations and resources for reporting and accountability.



Expedite the regulatory approval process

3D Systems has supported more than 100 FDA-cleared and CE-marked devices. Our professionals are experienced in working with the FDA on 510(k) clearances for patient-specific device systems, and we stay current on the latest guidance and adjustments as the regulatory climate evolves. Our teams are also experienced at clearing patient-specific and novel devices to meet diverse global regulatory requirements.

We work closely with our customers to optimize designs, define the manufacturing flow and calibrate testing to specific production processes and materials to achieve the exacting requirements for their devices. We also assist in regulatory approvals, technology transfer and implementation of in-house or off-site production.



Beyond surgery: advancing the science of personalized healthcare

As technology evolves, we believe patient-specific devices will become the gold standard in patient care. Advancements include:

- Access to technologies to acquire, transfer and visualize patient data and images to design devices and plan procedures
- Innovations in 3D printing platforms and materials to increase the accuracy and speed of fabricating personalized implants, instrumentation and models
- Increased regulatory guidance for the design and use of patient-specific devices

Partner with 3D Systems from concept to delivery

As a pioneer in personalized healthcare solutions, 3D Systems has worked with surgeons over the last decade to plan more than 150,000 patient-specific cases, manufacture more than two million implants and instruments, and support more than 100 CE-marked and FDA-cleared devices from its world-class, FDA registered, ISO 13485-certified facilities in Littleton, Colorado and Leuven, Belgium.

To address the growing demand for personalized devices, 3D Systems' VSP procedural planning solutions combine best-in-class digital workflows with the industry's broadest additive manufacturing portfolio of printers and materials to deliver comprehensive patient-matched solutions. We partner with device manufacturers, hospitals and surgeons to innovate these customer solutions that help translate virtual surgery into the OR, improve outcomes and elevate the patient experience. Our end-to-end workflow includes converting patient-specific medical images and data to 3D implant and instrumentation designs, procedural planning collaboration, device manufacturing and prompt delivery. Additionally, the VSP Connect portal empowers device manufacturers and surgeons with real-time patient case visualization and improved collaboration capabilities to reduce planning, and potentially OR times as well as facilitate more patient-specific surgeries.

2 million+
medical devices
manufactured

150K+
patient-specific cases
and devices delivered

100+
FDA-cleared and
CE-marked devices
supported



Begin your journey to personalized healthcare solutions

Learn how we can help.



Talk to an Expert

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