RICOH
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Take your 3D printing capabilities to the next level

A hospital's guide to evaluating options, growth and better experiences

An informative analysis for selecting the best way to access 3D-printed anatomic models for healthcare facilities

Overview

As 3D printing in healthcare is ramping up for widespread expansion and adoption, healthcare providers are working to understand how to best implement this technology into their roadmaps. Today, 3D printing technology for anatomic models has reached higher levels of precision and accuracy. The technology offers many benefits with the goal of providing the best care, understanding and preparation possible.

3D printing is exceedingly important to precision medicine, where medical devices, procedures and interventions are being tailored to the individual patient. The creation of patient-specific anatomic models may soon be a requirement for surgeons during most surgical procedures, not a wish.

When used for diagnostic purposes, these patient-specific anatomic models are considered Class II medical devices, which require FDA compliance and clearance as well as other regulatory requirements. Therefore, special consideration must be taken to comply with all regulations.

In fact, as a medical professional, you may have already identified and experienced the many benefits of using 3D printing. It helps both patients and surgeons with understanding, problem-solving and skill — with potential cost and time savings as a bonus.

The benefits of 3D printing run deep with many documented positive patient and provider outcomes.[1] However, once these benefits are realized for developing 3D models, healthcare organizations must weigh the options for considering printing: in-house with your own resources vs. working with a partner, either in-house or outsourced.

[1] Examples include the following articles: NIH. Clinical outcomes of the use of 3D printing models in fracture management: a meta-analysis of randomized studies. August 12, 2021; NIH. The perioperative utility of 3D printed models in complex surgical care: feedback from 106 cases. January 9, 2023; NIH. The Role of 3D Printing in Planning Complex Medical Procedures and Training of Medical Professionals-Cross-Sectional Multispecialty Review. March 11, 2022.

As you explore evolving your 3D printing capabilities, this guide will examine:

1. **Market trends**
2. **Challenges**
3. **Involvement in setting up a 3D print facility**
4. **Finding the right partnership**
5. **Evaluation of your options**

Our goal is to help your healthcare organization make the most informed decision based on your requirements and strategic roadmap.

Jump to Evaluation Worksheet

1 Market influences in healthcare

Market research

CIOs, CTOs, administration, and operations heads are facing a fast-changing world with many demands from patients, clinicians, staff, and regulators. Much of this requires new technology, new processes, IT infrastructure, staff resources, increased budgets, and change management.

$1.2B market
for 3D printing in healthcare

The 3D printing market for healthcare providers in the U.S. is valued at $1.2B with a 3-year CAGR at 14.1%, putting 3D printing for healthcare into a high-growth category.[2]

Across all types of healthcare — acute/in-patient, ambulatory/outpatient care and post-acute/long-term care — organizations are prioritizing a variety of IT investments with 3D printing as a mid-range priority.[3]

In a recent IDC survey, U.S. post-acute care organizations are prioritizing these as the most important strategic business goals this year:[4]

- **Improved patient safety**
- **Medical equity, diversity, inclusion, and cultural competency**
- **Improved access to care**
- **Improved patient experience**
- **Organizational growth**
- **Cost reduction**

[2] IDC. IDC Worldwide 3rd Platform Spending Guide: Healthcare - Forecast 2022.
[3,4] IDC Survey: Provider Investment Plans for Technology - U.S. Post-Acute Care Settings, 2022-2023, Doc # US48586222, released in June 2022.

While the highest-ranking initiatives are not specifically 3D printing, implementing it into your roadmap can help support the success for many of these programs due to faster, more precise patient care and education, positively affecting the entire lifecycle experience, as we will demonstrate below. Further, 3D printing can help support patient engagement, communication, education, and informed consent. For physicians, it can help provide insights, cadaver-free training, confidence, and anatomical simulation, which can impact bottom-line provider costs by reducing surgery time and pre-operation prep.

The benefits are positively impacting many areas throughout the medical field. For example:

In orthopedic surgery, the use of 3D printed models has shown improved metrics such as shorter surgical time, less intraoperative loss of blood, and a reduced need for intraoperative fluoroscopy.

In the treatment of cardiovascular diseases, 3D models can assist in a more accurate selection of devices and sizing of stents to improve patient-specific planning for the replacement of a transcatheter aortic valve. They can also aid in procedures to treat congenital heart disease.

In neurosurgical applications, 3D models are used to accurately show the size and anatomy of cerebral aneurysms and to reduce surgical time.

Patient-specific anatomic models of the kidney and liver are commonly printed for surgical planning for abdominal, hepatobiliary, and gastrointestinal conditions.

And, there are even more ways 3D printing is bringing value to the healthcare community.[5]

[5] RSNA. Establishing 3D Printing at the Point of Care: Basic Principles and Tools for Success. February 4, 2022.

Consumer pressures

Another pervasive influence comes from patients — who are also consumers — living in a digital world, with high expectations for fast results and customized experiences. This reality is more far-reaching than personalized song playlists and custom sneakers. With 3D printing going mainstream, patients are learning about anatomic models that may help improve experiences.

The ability to leverage patient-specific data to build precision patient care approaches can help advance medical processes from multiple perspectives. **And with mass customization trending, on-demand services will democratize 3D printing, bringing costs down with widespread use.**

An interesting tie-in from consumers is using augmented and virtual reality (AR/VR) in healthcare. This technology sits alongside 3D printing, which is a growing field for educational purposes and visualization. Its role in healthcare is to further immerse patient education and complement 3D printing. While AR/VR technologies provide immersive and interactive experiences, 3D printing holds a unique position in the context of surgery with its ability to create physical, tangible models of anatomical structures. Surgeons can use these models for pre-operative planning, allowing them to visualize complex structures in a more intuitive and detailed manner. This hands-on approach can help enhance their understanding of patient-specific anatomy and aids in the development of precise surgical strategies.

Savvy, informed patients now understand that technology, imaging, radiology, devices, and more, are evolving to meet consumer demands, making new possibilities in the field a reality.

Continuous innovation

AI, automation and breakthrough technology are happening fast. The accuracy of colors, textures and scans is becoming more advanced. Material deposition and material jetting are helping to improve this process. And, as new technology and artificial intelligence tools emerge, change management must become part of the culture for hospital staff.

Companies in this field are currently working on developing new materials that closely mimic human organs and tissues. Innovators are using different combinations of materials to make more complex structures with the idea that the more realistic and precise the models are, the better the desired end state will be in terms of education, diagnostics, surgeries, or preparation.

Insurance reimbursement is a challenge

Another consideration for medical facilities and patients is working with insurance companies on reimbursement for 3D printing. Despite all the benefits, many insurers are not compensating (or inconsistently compensating) for usage.

In a recent webinar[6] from the Radiological Society of North America, experts in the field discuss this compelling issue and found that United Healthcare and Cigna did not need authorization while Aetna and Humana did require authorization — but had a clause that required pre-determination or pre-certification. In contrast, Blue Cross Blue Shield required authorization for all cases. Reimbursement results for all the above carriers were favorable, including Medicare; however, Medicaid was not reimbursed.

Will 3D anatomic printing become part of the standard procedure in most applicable complex surgeries? If yes, insurance carriers must help make it more affordable for mainstream use. According to one article, "Since 3D models for surgical planning are still nascent and there's no real equivalent, category I reimbursement codes don't yet exist." This is expected to change as workflows and costs are tracked.[7]

Takeaway: 3D printing can support healthcare goals across the care continuum for patients and providers.

[6] RSNA. 3D Printing Reimbursement Perspectives for both New & Established Labs. February 28, 2023.
[7] tct Magazine. Standard of care: Why hospital-based 3D printing labs are becoming so prevalent, by Sam Davies. May 31, 2021.

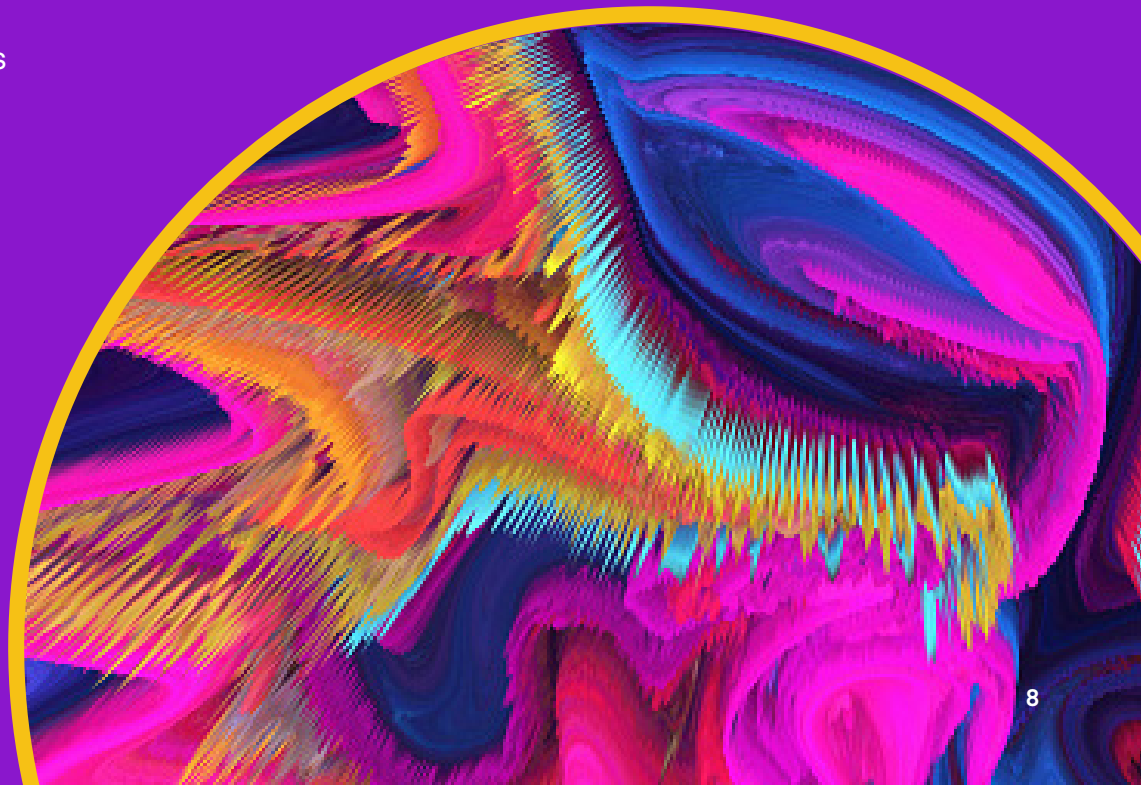
2 What's preventing regular 3D usage?

Statistics suggest the benefits of using anatomical models, in applicable complex surgeries, are substantial: 62 minutes on average time savings in operating rooms, $3,720 average cost-savings per case[8], 7.8% time-savings per case,[9] 50% of cases redefined their surgical approach with a 3D model[10], and better patient communication, education, and informed consent.

What is holding healthcare organizations back from the widespread use of anatomical models? Some of the reasons may include:

- Limited, unknown, or no access to 3D-printed models
- Time-consuming to go outside of normal workflows
- Bottlenecks around segmenting files: turning radiology 2D images from DICOM data (ex. MRI or CAT) into 3D printable files
- MRI and CAT scan image quality: you need high-resolution scans to get accurate models
- Ensuring medical device manufacturing and regulatory compliance
- Difficult to have 3D printing expertise on-site
- High upfront costs for setting up on-site 3D print labs

Takeaway: Navigating around these hurdles is possible with the right resources.



[8] American Radiology, Volume 27, Issue 8. Medical 3D Printing Cost-Savings in Orthopedic and Maxillofacial Surgery: Cost Analysis of Operating Room Time Saved with 3D Printed Anatomic Models and Surgical Guides. August 2020.
[9] NIH. Cost-Benefit Analysis of Three-Dimensional Craniofacial Models for Midfacial Distraction: A Pilot Study. August 3, 2016.
[10] NIH. Three-dimensional printed models for surgical planning of complex congenital heart defects: an international multicentre study. December 1, 2017.

3 The inside scoop: Setting up a 3D print facility at a hospital

Here are 10 considerations when creating an ideal point-of-care print facility:[11]

1. **Regulatory and legal compliance, including FDA clearance**
2. **Quality control**
3. **Risk and insurance**
4. **Facilities and machine maintenance**
5. **Specialized labor to run the print facility**
6. **Software, licenses, and an expert to convert MRI and CAT scan images to 3D print-ready files**
7. **Adequate space**
8. **Printer selection**
9. **Consumables: materials selection**
10. **Post-processing equipment**

In a report by the Society for Manufacturing Engineers (SME) on point-of-care 3D printing manufacturing, they suggest the top three challenges these centers face are reimbursement, funding and capital, and the regulatory environment.[12]

Searching Google for "3D printing costs in healthcare" will give you 28 million[13] results, but many articles we reviewed do not provide a clear-cut picture of what the investment will be. Articles often focus on the cost of materials used in consumer-grade desktop machines and do not note the total cost of ownership for additive manufacturing. This information may cause some people to think creating their own 3D printing labs is cheap and simple; the reality is often far different.

Depending on the complexity, sophistication, materials, grade, and other factors, 3D printer prices range from about $200 to over $500,000.[14] Those costs may not include handling detailed anatomy, materials, expert staff and wages, training, maintenance, square footage and storage space costs, and legal fees. Also, consider risk factors such as insurance, FDA, ISO, quality management systems, and regulations. Anatomic models themselves vary in cost depending on the size and complexity, materials used, the intended use of the model, and post-processing, which can run as high as $4,000 in some cases.[15]

One alternative to mitigating risks and challenges on your own is to consider a partner who can assist in all these areas.

Takeaway: Providers may experience high upfront costs for setting up on-site 3D print labs.

[11] 3D Heals. 3D Printing In Hospitals: A Beginner's Guide, by Jenny Chen, M.D. October 3, 2020.
[12] RSNA. Establishing 3D Printing at the Point of Care: Basic Principles and Tools for Success. February 4, 2022.
[13] Google. Search date August 22, 2023, at 8:00 am PT.
[14] Formlabs. How Much Does a 3D Printer Cost?
[15] RSNA. Establishing 3D Printing at the Point of Care: Basic Principles and Tools for Success. February 4, 2022.

4 Finding the right 3D printing partner

There's usually not a "single path" for every healthcare provider when it comes to delivering the best care. Partnerships can open up new ways of learning, working, managing costs, and training.

However, not all partnerships are created equally. Many vendors may only focus on one or two elements of 3D printing and not have end-to-end capabilities, especially for staffing. Some vendors only provide hardware (the actual printers) and materials; some develop software that transforms scans into 3D; some do software and hardware; and, even fewer vendors provide a full-scale approach to 3D printing.

These are the top considerations when evaluating a 3D print partner:[16]

- FDA 510(k)-cleared devices
- Software
- Hardware
- Printing materials
- Quality control
- Knowledgeable staff resources
- End-to-end integration and deployment resources
- On-demand production capability
- Financial affordability

Takeaway: Finding the right match of services, solutions, and relationship is the key to any successful partnership.

[16] 3DHeals. 3D Printing In Hospitals: A Beginner's Guide. October 2, 2020.

Simplifying 3D printing solutions in healthcare with Ricoh

RICOH 3D for Healthcare offers an array of solutions and services. As a leading, global manufacturer, Ricoh USA has the power to scale, offer managed services, both off-site and on-site, and utilize our large team of services and IT technicians in the U.S. We offer access to software, hardware, personnel, and robust quality assurance for point-of-care or centralized 3D model production. Having our own facilities delivers quick turnaround times, integrated services and technology, and shared experiences from working with many healthcare providers.

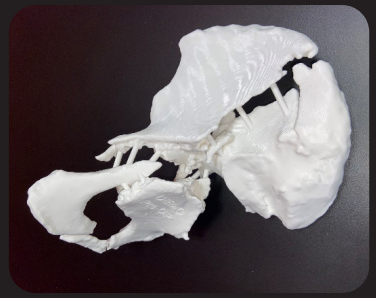
Ricoh is well-positioned to offer a comprehensive framework of combining, printing, technology, integrated workflow, staff, rapid turnaround, expertise, accurate modeling, and overall customer experience to thousands of healthcare customers.

Additionally, we have our own 3D printing centers, centrally located in the U.S. as well as a formal partnership with leaders in 3D printing software and materials. Since the outputs of 3D printing for use in healthcare are often considered a medical device, we have obtained an FDA 510(k)-cleared solution for seven diagnostic applications: craniomaxillofacial, orthopedic, cardiovascular, neurological, gastrointestinal, genitourinary, and breast. Many different and customized anatomical models can be printed under these use cases, covering a large majority of pathologies where 3D-printed models are considered most beneficial.

[17] Ricoh. RICOH 3D for Healthcare Receives Expanded FDA 510(k) Clearance for 3D Anatomic Modeling of Soft Tissue. May 3, 2023.
[18] NIH. Radiological Society of North America (RSNA) 3D printing Special Interest Group (SIG): guidelines for medical 3D printing and appropriateness for clinical scenarios. November 21, 2018.

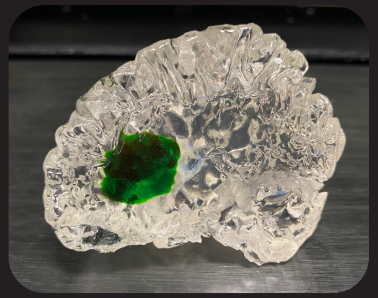
Here are some examples of how RICOH 3D for Healthcare can assist:

Craniomaxillofacial pediatric and adult patients include but are not limited to: head and neck cancer patients, acquired conditions like trauma, and congenital pathologies – such as facial deformities (i.e., lip and palatal clefts, or tumors)



Orthopedic pediatric and adult patients include but are not limited to: congenital pathologies, cancer, and trauma

Cardiovascular pediatric and adult patients include, but are not limited to: patients with congenital and/or structural malformations, such as septal defects, atrioventricular canal defect, valve defect, stenosis, atresia, Ebstein's anomaly, tetralogy of fallot, patent ductus arteriosus, truncus arteriosus, transposition of the great arteries, hypoplastic left heart syndrome, double outlet/inlet right/left ventricle, dextrocardia, heterotaxy, and vascular malformations



Neurological pediatric and adult patients include but are not limited to: tumors, lesions, vascular malformations, and aneurysms

Gastrointestinal pediatric and adult patients include but are not limited to: intra-hepatic masses, hilar cholangiocarcnoma, pancreatic adenocarcinoma, colorectal cancer, and retroperitoneal sarcomas

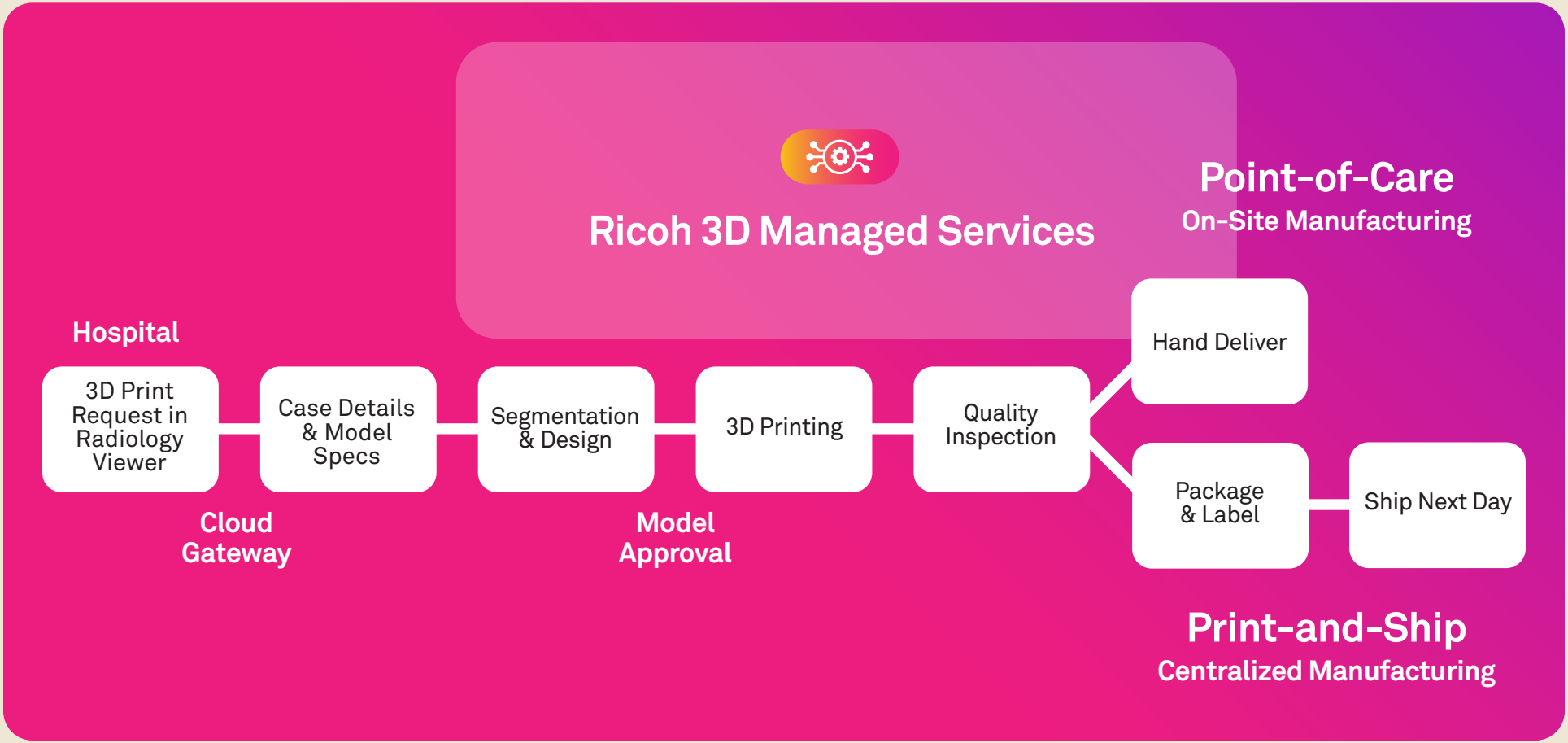
Genitourinary pediatric and adult patients include but are not limited to: urolithiasis, renal cancer, prostate cancer, and pediatric retroperitoneal genitourinary tumors

Breast pediatric and adult patients include but are not limited to: breast lesions or breast cancer

We can achieve very complex replicas of patient-specific anatomy with verifiable accuracy by processing a range of materials on a variety of technologies. Similarly, we can help clinicians see inside the anatomic models with transparent and clear materials that can complement full-color models for added insight. Ricoh scans the final model to ensure it matches the file that we sent to the printer, which was approved by the surgeon.

Partnership options with Ricoh

1. **Print-and-ship, centralized manufacturing.** We build a connection between your PACS system and our 3D production network when you need an anatomical model. We print it and ship it quickly back to you. Pay on a per-model basis.
2. **Point-of-care manufacturing with end-to-end managed services.** At your facility, we offer managed services with experienced 3D print staff to use the software and hardware as well as print the model at your facility. Cost depends on tailored services.



Ricoh services include:

- Case management and workflow portal
- Quality management system protocols
- Work directly with surgeons, radiologists, clinicians, administration, and others
- Scalability and production capability – use our place or yours
- Managed Services staff can work on-site at the point-of-care
- Ricoh team will manage requests, production, maintenance, and follow regulatory guidelines for either on-site or centralized production

Takeaway: As a full-service provider of 3D printing, Ricoh offers many options to support your growth and patient care.

5 Evaluation worksheet

What's the next step for your organization?

Use this worksheet to help guide your roadmap and 3D printing for healthcare.

Criteria	Point-of-care with Ricoh managed services	As-needed centralized production with Ricoh	Do it all myself on-site
Regulatory compliance	Ricoh handles its own regulatory compliance and has an FDA compliant Quality Management System	Ricoh handles its own regulatory compliance and has a Quality Management System and ISO 13485 certification	You are responsible for maintaining regulatory compliance
FDA 510(k)	Ricoh has FDA 510(k) clearances	Ricoh has FDA 510(k) clearances	• Average FDA 510(k) cost: $6.1M ($200K–$41M) • Average clearance time is 33 mo. (2 mo.–11 yrs.)[19]
Quality control	Uses Ricoh's scanning practices to ensure models meet quality standards	Uses Ricoh's scanning practices to ensure models meet quality standards	Up to you to determine and practice quality control
Space needed	• Ricoh can work with the space you have • Can supplement on-site space with the ability to print at centralized production facilities for any unusual models (very large or materials not available on-site)	None — Ricoh handles printing at their centralized production facilities	Space needed is determined by type of hardware (printers) and post-processing equipment needed to handle selected materials
Software (convert MRI or CAT scan images to 3D print-ready files)	Ricoh has multiple software options to meet your unique needs	Ricoh has multiple software options to meet your unique needs	You determine what software will work best to meet your needs
Hardware (printers)	• Ricoh uses multiple certified printer options to meet your unique needs • We work with you to determine best fit for on-site • Can supplement on-site printers with additional print options from our centralized production facilities	Ricoh uses multiple certified printer options to meet your unique needs	You determine what hardware will work best to meet your needs

Continued

[19] Medical Design & Outsourcing. How much time and money does it take for FDA 510(k) clearance versus De Novo classification? March 21, 2022.

Criteria	Point-of-care with Ricoh managed services	As-needed centralized production with Ricoh	Do it all myself on-site
Printing materials	• Ricoh has FDA 510(k) clearances on a wide variety of materials. We work with you to determine materials • Centralized production can cover any unusual materials that arise	Ricoh has FDA 510(k) clearances on a wide variety of materials	You research and determine what materials are needed
Cost to get started	Low cost to get started	Low cost to get started	High upfront capital expenses
Training on printers	Ricoh operates and maintains printers	None	Printer provider handles
Printer vendors	Existing and validated partnerships and materials in place	Existing and validated partnerships and materials in place	Lengthy time to validate partner, software, equipment, materials, certifications, QA test, set up new vendor, etc.
Experts to run 3D printing facility	Ricoh employees with expertise	Ricoh employees with expertise	Must have or hire resources
Accuracy	Verifiable accuracy and matching	Verifiable accuracy and matching	Up to internal resources
Time to deliver after surgeon approval	1–4 days*	2–5 days*	1–5 days*

* Dependent on print time and post-processing requirements

Reach out to our 3D printing experts by completing the Contact Us form.

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Ricoh USA, Inc. 300 Eagleview Boulevard, Exton, PA 19341 | 1-800-63-RICOH