Capitalizing on Robotically Assisted Surgical Devices

The Benefits of a Vertically Integrated Manufacturer

BIOMERICS

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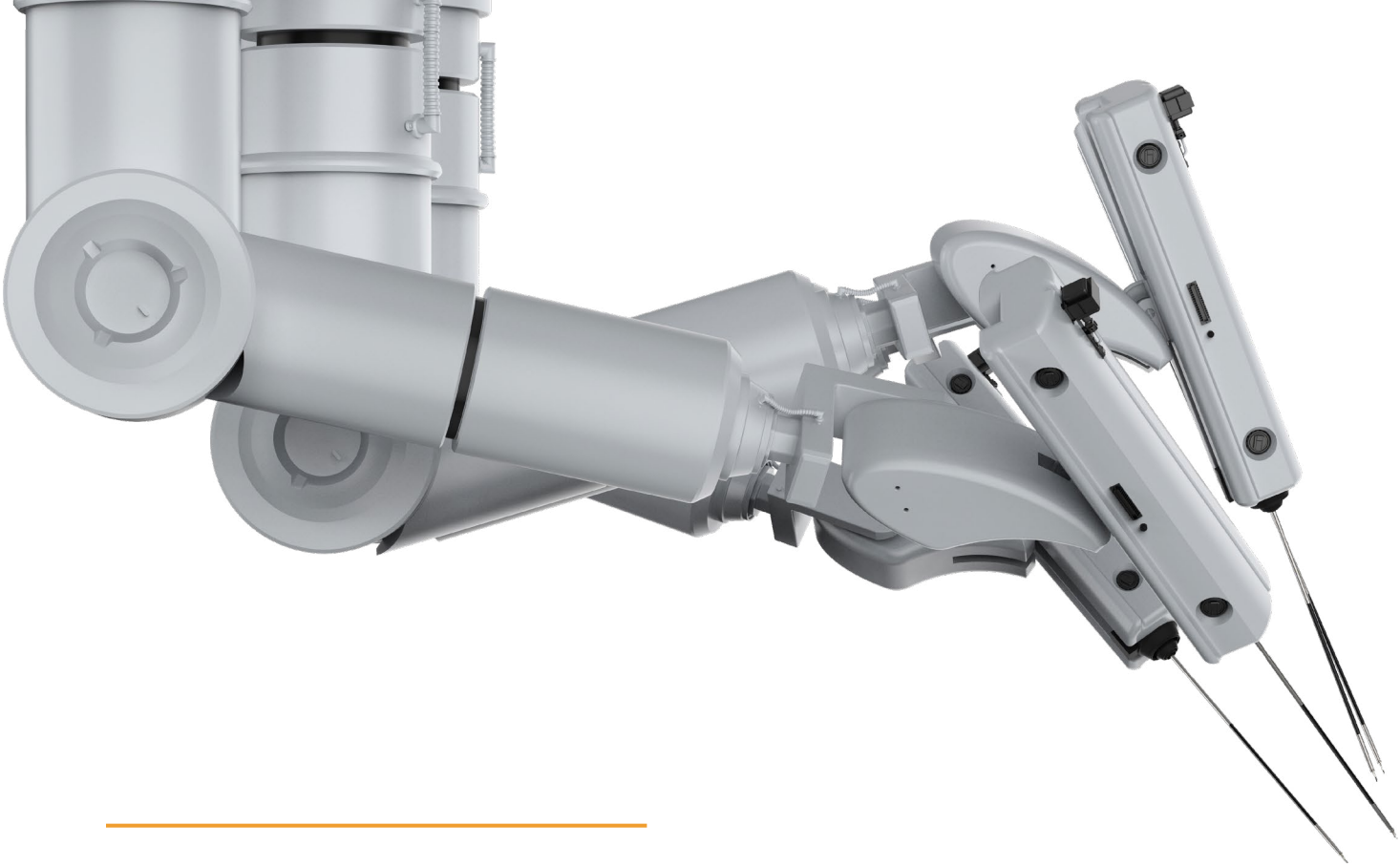


Executive Summary

This white paper is intended for a technical audience of R&D engineers, managers, and vice presidents at original equipment manufacturers (OEMs) and other institutions that are considering building or investing in robotic surgery capabilities.

As of 2017, robotic surgery was a $5.3 billion business, with a projected compound annual growth rate of 21.4%. The global market for robotically assisted surgical devices (RASDs) is expected to grow to $12.6 billion by 2025. RASDs are becoming more sophisticated and less expensive.

As new OEMs enter the marketplace, they may not have the expertise in house to develop every part of their RASDs. Looking for new partners in the supply chain, they often discover that compatibility between parts from different suppliers can be an issue, and the work of negotiating or explaining design requirements with multiple suppliers is onerous, resulting in longer time to market and higher costs.

However, with a vertically integrated manufacturer, OEMs can produce more of their RASD components with one supplier. Biomerics is the leading medical device component developer with complete vertical integration. Biomerics' nine manufacturing divisions, or Centers of Excellence (COEs), have the requisite materials and product component design, development, and manufacturing expertise in house, with decades of experience designing steerables, assemblies, and mechanical, imaging, and interventional components that fit into robotics applications. Experienced with robotic devices, Biomerics is ready to help OEMs develop a vast array of components for fully robotic surgical systems.

Benefits of Robotic-Assisted Surgery

Robotic-assisted surgery (RAS) is the use of computer, software, and robotic technology to allow surgeons to control and move surgical instruments through small incisions. The robotically assisted surgical devices (RASDs) behind RAS facilitate minimally invasive surgery and assist with complex tasks in confined areas of the body. However, while robotic-assisted surgery was first performed in 1985, the cost of robotic devices and a shortage of RAS-trained surgeons have delayed its widespread use until now.[1] Today, robotic-assisted surgery uses exciting, revolutionary technology that improves patient outcomes and reduces strain on hospital systems and surgeons.

Advanced Surgical Methods

Because robotic-assisted surgery is usually performed laparoscopically, it retains the benefits of the minimally invasive nature of laparoscopic surgery, such as smaller incisions and less blood loss, pain, and scarring. However, RAS improves further on the minimally invasive nature of manual laparoscopic surgery to provide greater dexterity, better intracorporeal access, and enhanced visualization of the operating site.[2]

In robotic-assisted surgery, the surgical instruments are attached to robotic arms, which allows surgeons to control the instruments' movement remotely—often from just a few feet away. A surgeon's movements on a console are replicated by the instruments within the patient's body. This movement replication can be scaled to allow precise motions within small spaces in the body, thereby increasing surgical precision. The bendability of RASD instruments also allows surgeons to reach confined spaces that traditional, fixed laparoscopes cannot.[3]

Image guided intervention technology, like endoscopes and ultrasonic equipment, is also incorporated into the robotic system, helping the surgeon visualize the target area, such as the heart or the colon. Surgeons see high-resolution images of the operation as they perform it. Although non-robotic laparoscopic surgery takes advantage of visualization technology, current RASD systems are an important part of image guided intervention's continued advancement.[4]

Robotically assisted surgery's smaller incisions, increased precision and intracorporeal access, and improved visualization all combine to reduce patient infection and shorten hospital stays.

Improved Patient Outcomes

Robotic-assisted surgery's advanced surgical methods translate directly to improved patient recovery. Hospitals in the healthcare system are beginning to recognize this clinical value of robotic-assisted surgery and are investing in RAS.

In the US, HCA Houston Healthcare Tomball in Texas recently expanded their robotic surgery capabilities, adding a third robotic system to their two existing da Vinci Xi® systems.[5,6] Dr. Brian Harkins, a general surgeon at the hospital, performed his first robotic surgery on the hospital's first da Vinci Xi® in 2014. Dr. Harkins says that because of Intuitive Surgical's da Vinci Xi® robotic system, he was able to offer a minimally invasive approach to more patients and that patient complication rates remained low.[7] With HCA Houston Healthcare Tomball's installation of a third robotic system, 30 percent of their operating room capacity is now dedicated to robotic-assisted surgery.[8]

At MKUH, reduction in patient recovery time resulted in 450 fewer bed-days annually.

In another example of the accelerating adoption of RAS, the UK's Milton Keynes University Hospital (MKUH) implemented a Versius® RAS program in multiple surgical procedures. In the gynecology department, many patients who received RAS returned home in one to two days post surgery, versus the five-day stay that most open-surgery patients needed. Time off work to recover was also reduced for RAS-program patients, where the majority returned to work after two to four weeks instead of three or more months.[9]

Another early adopter of RAS, West Hertfordshire Teaching Hospitals NHS Trust (WHTH), announced in April 2022 that WHTH will be the first hospital in the UK to install *two* Versius® Surgical Robotic Systems. WHTH expects that adding the Versius® systems to their laparoscopic capabilities will increase the number of patients who receive minimally invasive surgery, thereby decreasing pain, blood loss, and scarring, as well as reducing recovery time and length of hospital stay for more patients.[10]

As RASDs are integrated into more hospitals, the standard of care for patients will continue improving in a wide range of laparoscopic applications.

Reduced Strain on Hospitals and Surgeons

Of course, not only patients but also hospitals and surgeons benefit with the improved patient outcomes that result from robotic-assisted surgery. At MKUH, reduction in patient recovery time resulted in 450 fewer bed-days annually.[11] As RAS is adopted by more hospitals, fewer bed-days could help alleviate the bed shortage that many hospitals are facing, allowing hospitals to treat more patients.

There are also advantages for surgeons who participate in robotic-assisted surgery. At MKUH, for example, the configuration of the Versius® system allows surgeons to sit while performing robotic surgery. This setup reduced surgeons' wrist, shoulder, and back strain compared to manual surgery.[12] Additionally, because of the image guided intervention technologies incorporated into RASDs, fewer radiographic scans need to be taken of patients during some surgeries. Importantly, this reduces radiation exposure for both the patient and the operating team.[13]

These key benefits of RAS for patients, hospitals, and surgeons are why new companies have begun to develop robotically assisted surgical device technology and why the market for RASDs is expanding.

OEM Opportunities in the RASD Industry

Robotic surgery began decades ago, with the first procedure occurring in the US in 1985—a neurosurgical biopsy using a PUMA 560® robotic arm.[14] Other early procedures were performed in Europe in 1992.[15] First used five years later, the da Vinci® platform developed by Intuitive Surgical. was the first to gain US Food and Drug Administration (FDA) approval for performing surgery.[16] The da Vinci® system has dominated the field of robotic surgery for the last decade, in 2021 reaching the milestone of ten million procedures performed worldwide.[17]

Over two decades after the first robotic-assisted surgery, there are still very few finished-product RASDs on the market. However, in recent years, there has been increased activity in the RASD marketplace, including mergers and acquisitions and new startups forming. New original equipment manufacturers (OEMs) have introduced new robotic surgical devices, increasing the competition in the field.[18] In Europe, Switzerland's Distalmotion has developed Dexter®, a hybrid robotic solution that allows surgeons to switch seamlessly between manual and robotic laparoscopic approaches.[19] In addition, France-based Quantum Surgical announced that they won FDA approval for their Epione® Robot in March of 2022.[20] Also in 2022, UK-based CMR Surgical hit the milestone of 5,000 surgeries completed using its Versius® system.[21] Continued improvements in RAS technology will likely lower costs, leading to wider adoption of RASDs and expanding the market for such devices.[22]

Market Growth of Robotic Surgery

Despite its decades-long history, robotic-assisted surgery has not yet reached widespread adoption because of a lack of RAS-trained surgeons and the high cost of obtaining a robotically assisted surgical device. However, technologies and methodologies are converging to create new developments in the robotic-assisted surgery field, which will likely lead to wider adoption of RAS.[23] As of 2017, robotic surgery was a $5.3 billion business globally, with a projected compound annual growth rate of 21.4%. The global market for RASDs is expected to grow to $12.6 billion by 2025.[24]

Technological Advancements in Robotic Surgery

Technological advancements in RASDs continue to push the boundaries of robotic-assisted surgery. A large driver of the technology-based cost reduction in RASDs is the robotics, which are becoming more advanced and less expensive. Developments in assistive navigation, 3D imaging, artificial intelligence, and big data are also key to the changes in the RAS field. As companies utilize these advances to produce more efficient RASDs, the cost of robotic-assisted surgery will likely come down closer to the cost of non-robotic laparoscopic surgery.[25]

Another innovation in robotic-assisted surgery is laparo-endoscopic single-site surgery (LESS), which inserts both camera and instruments through a single incision. And, if inserted through the umbilical site, LESS leaves no scar. Smaller robotic systems such as the SurgiBot-SPIDER (Single-Port Instrument Delivery Extended Research) system reduce the cost of robotic-assisted surgery but have not yet obtained FDA approval.[26]

Additionally, new body-compatible materials enable haptic feedback during surgery. New surgical robots take advantage of these recently developed materials, with parts inserted into the body being constructed of soft, flexible, and deformable materials. Biocompatible soft materials, superelastic

materials, and 3D-printed soft plastics, such as silicon elastomers, are also safer because they change robotic shape and mechanical properties in response to touch.[27]

Newer RASDs benefit from the bendability and stiffness controllability of these new materials. These robots can sense force applied during shape reconstruction, with the surgical implement's stiffness being controlled by the tension it senses. Variable stiffnesses at different points along an endoscope allow it to simultaneously move flexibly within the lumen of a soft organ and bend along a sharp turn.[28]

Imaging modalities are also being developed for use in RASDs, including near-infrared imaging, confocal microscopy, intraoperative ultrasound, Raman spectroscopy, biomarkers, dyes, and autofluorescence. These new imaging capabilities will improve identification of tissues, such as nerves, blood and lymphatic vessels, and malignancies.[29] Miniaturization, haptics, improved control, and better imaging will create safer, less invasive, and more cost-effective RASDs.

How OEMs Can Take Advantage of the Growing Market

The robotically assisted surgical devices necessary for RAS use exciting, revolutionary technologies that are now in the ascent phase of the technology life cycle, making RASDs a smart investment opportunity for many original equipment manufacturers.

As OEMs enter the RASD marketplace, they may not have the expertise in house to develop every part of their RASDs. Looking for new partners in the supply chain, they discover that there are dozens of component supply companies for robotic surgical systems. But most of these suppliers simply provide a small piece of the puzzle, requiring OEMs to source from multiple suppliers for different aspects of the RASD.

In addition, compatibility between parts from different suppliers can be an issue, and the work of negotiating or explaining design requirements with multiple suppliers is onerous. This results in longer time to market and higher costs. It is therefore important for OEMs to work with a supplier who can manufacture several types of components and has the expertise in RASD to develop the necessary precision-engineered RASD parts.

Building Robotically Assisted Surgical Devices

One of the key components for most RASDs is the robotic arm. Depending on the types of procedures the robotic system is designed to perform, a surgical robot could have up to four arms. In addition, some surgical robotic systems include a camera, a light source, and various instruments all within a single slender endoscopic sheath. With so many components that go in to manufacturing a robotically assisted surgical device, OEMs entering the market need to understand the components, manufacturing requirements, and current suppliers that could impact their RASD development.

Components of RASDs

While a robotic arm is an essential part of an RASD, these devices also require many other components that are crucial for the usability, effectiveness, and ultimate success of RASDs for their intended applications. Most RASDs require a controller (for directional movement and component manipulation), software, monitors, tray tables (for holding instruments), and possibly speaker systems and earphones,

depending on the type of surgery being performed and the distance of the surgeon from the patient. In addition, many RASDs involved in endoscopy use a steerable endoscope (with microcomponents for precision control), other tools and instruments, an imaging camera module, and lighting.

Manufacturing Requirements for RASDs

Arranging all of the RASD's tools together inside the endoscopic insertion tube is a complicated engineering challenge. Similarly critical are the characteristics of the steerable insertion tube itself, which are dictated by the application, depending on the type of surgery and the pathway in the body. Steerable tubes can vary in materials, size, shape, wall thickness, and flexibility. They can also differ in characteristics such as water repellence, radiopacity, passivation (antioxidation to prevent corrosion), torquability, and more, depending on the intended types of surgery the RASD will be involved in.

The manufacture of these RASD components requires highly specialized, precise processes such as micromachining and laser processing. Also crucial is knowledge of the chemistry of plastics and other materials used in the components, expertise in manufacturing electronics and controls, and experience creating non-robotic endoscopic surgical components.

Current RASD Component Suppliers

There are a few manufacturing options for RASDs. Developing a surgical robotic arm from scratch can be a challenging and expensive task. Surgical robotics OEMs often opt to work with experienced robotic arm manufacturers for this element of the system. Some robotic manufacturers offer standard robots specifically for medical applications. However, depending on the requirements for the robot arm, OEMs often need to find a partner who can develop a bespoke solution.

These are typical microcomponents used in a robotically assisted endoscopic procedure:

- Steerable endoscope
- Claw (grasper)
- Clip applier
- Needle driver (with wristed articulation to suture at multiple angles)
- Stapler
- Energy instruments (e.g., laser & electrocautery) for cutting & sealing
- Ultrasound transducer
- Suction & irrigation tools
- Light source
- Camera

For example, there are numerous robotics manufacturers for industrial applications, but when it comes to the unique needs of medical robotics, which interact with living human beings, the options are limited. Companies such as KUKA, Stäubli, DOBOT, and Universal Robots can manufacture robotic arms, but they lack the capability to design and manufacture the complete range of endoscopic components needed in an RASD. There are multiple suppliers for each component: sensors, mechanical parts, electrical and electronic systems, imaging and navigation devices, and surgical instruments. However, none of these specialist suppliers offers the complete end-to-end capabilities to supply OEMs looking to market RASDs.

Partnering with the Right Supplier

Despite the lack of RASD component suppliers that offer end-to-end capabilities, there are suppliers that can manufacture a wide variety of the components required for an RASD. Biomerics' complete vertical integration makes us an ideal fit for the development and manufacture of RASDs. We have all the requisite materials, as well as design, development, and manufacturing expertise in house, with depth of experience designing components and assemblies that suit robotic endoscopic applications. Experienced with robotic devices, we are ready to help OEMs develop critical components for their fully robotic surgical systems.

Vertical Integration for Start-to-Finish Development

Biomerics possesses the differentiated product and process technology ideally suited for RASDs. We have the design and engineering skills, the technical knowledge, and the facilities to manufacture components for a robotics system. We can manufacture optics systems, claws and other micro instruments, parts for physical and electronic connectivity, and disposable scopes.

With our nine manufacturing divisions, or Centers of Excellence (COEs), Biomerics can design, develop, and manufacture the components for an RASD into a vertically integrated system for our OEM partners. In the current marketplace, Biomerics is in the dominant position to do this. We are a one-stop shop that can accelerate the time it takes from idea to full-scale production, reduce risk at every stage, and maximize cost efficiencies, making us the first choice for OEMs looking to enter the RASD market.

Materials and Components

Biomerics is built on deep engineering expertise. We innovate from our experience in single-use endoscopy, the foundation of robotic surgery, to assist OEMs who are developing ground-breaking robotic surgery technologies. In particular, what may differentiate Biomerics from other robotic developers is our ability to produce *flexible* robotic-assisted steerable catheters. Additionally, our engineering and manufacturing expertise extends to medical-grade metals and polymers, custom polymers, advanced catheters and steerables, balloons and balloon catheters, image guided intervention devices, complex extrusions and injection molding, laser processing, micromachining, and finished devices.

Manufacturing, Assembly, and Packaging

Biomerics is the most comprehensive vertically integrated supply partner, poised to manufacture and assemble every aspect of component development for RASDs into a seamless whole, precisely engineered to our customers' specifications. Biomerics designs all required components to OEM specification, to fit precisely into the OEM's robotic base. All disposable components are sanitized and sterilized. Biomerics also offers custom packaging, printed and labeled with OEM branding, and has a robust delivery network. Our packaging services and delivery network combine to give customers reduced shipping costs and faster delivery times.

Regulatory Approval

After designing and developing based on OEM technical specifications—or leveraging our own internal resources to meet OEM design and development needs—Biomerics can help OEMs with the final stages of

product development: gaining regulatory approval and production launch. Biomerics is ISO 13485:2016 certified and FDA registered, enabling us to help OEMs with every aspect of regulatory strategy—pre-submissions, FDA 510(k) preparation for device clearance, and CE Mark technical file preparation for devices intended for the European Economic Area—as well as early and full-scale production.

Biomerics Offers Vertically Integrated Centers of Excellence

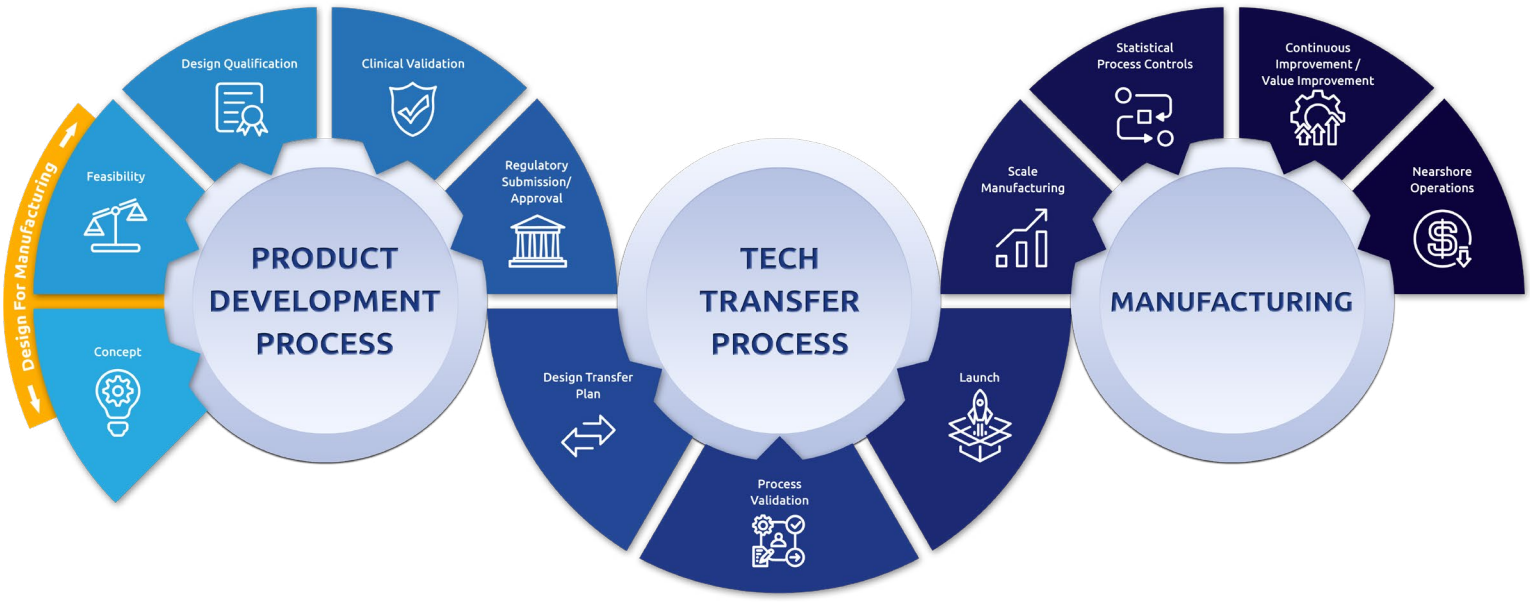
Making the diverse components needed for RASDs requires a tremendous range of specialized expertise in numerous fields and applications. Biomerics has developed nine vertically integrated Centers of Excellence, each representing a different type of engineering expertise, as shown on pages 9 through 12. In combination, Biomerics' COEs make everything needed to help the robotic-assisted surgeon enter the body and diagnose, ablate, take a biopsy, put in a balloon, and so on.

Biomerics' Commitment to Excellence

Biomerics strives to provide superior service while manufacturing products that meet or exceed our customers' expectations. In order to meet these ongoing objectives, we commit to provide

- defect-free products and services,
- on-time and in-full delivery,
- compliance with all relevant international standards and statutory and regulatory requirements, and
- continual improvement through employee development and ongoing refinement of our quality management systems.

Development to Manufacturing. Biomerics is your vertically integrated partner for start-to-finish production of your robotically assisted surgical device.



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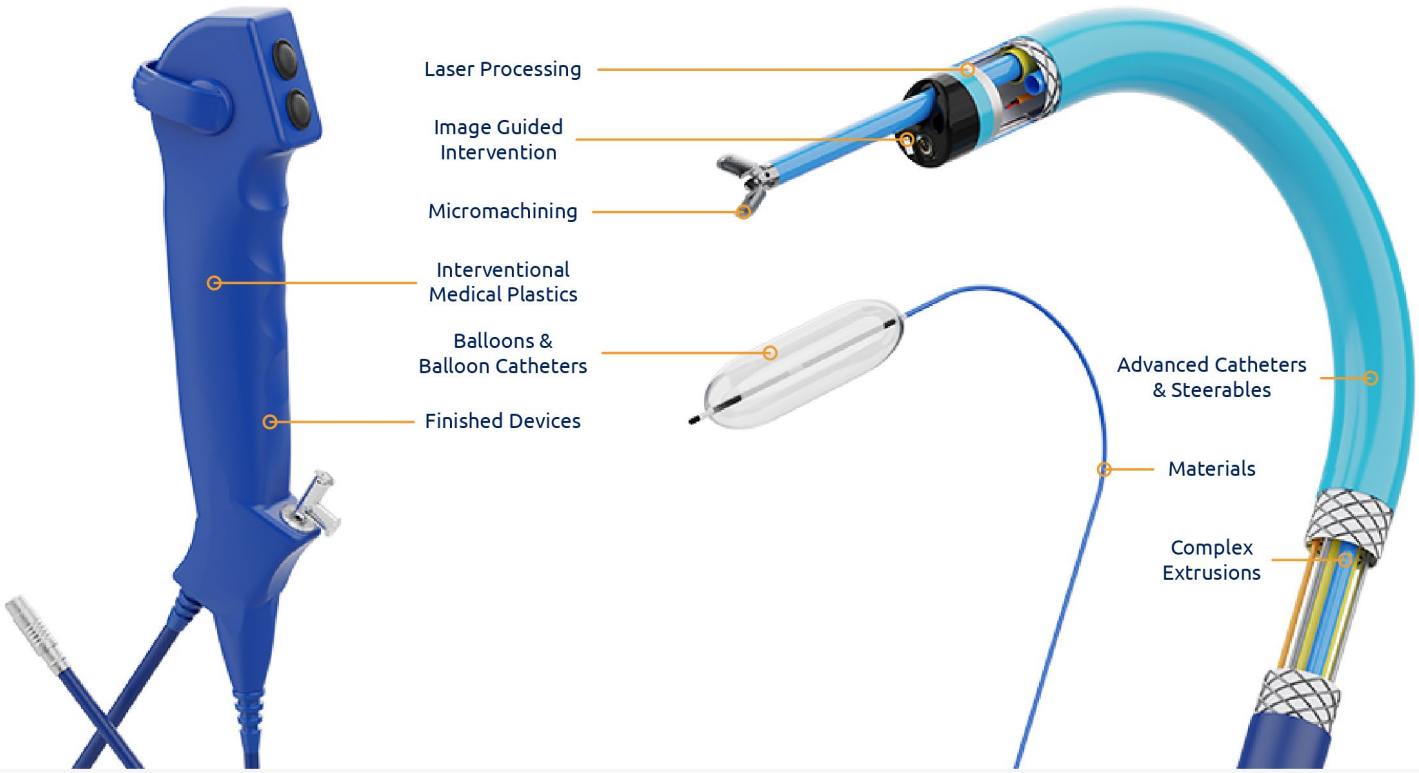
CENTERS OF EXCELLENCE

Biomerics' nine vertically integrated Centers of Excellence work together to develop complete components for robotically assisted surgical devices. Each indicated component below represents a different process that Biomerics' COEs specialize in. Read on to learn more about the materials, processes, and services available at each of Biomerics' Centers of Excellence.

VERTICALLY INTEGRATED CONTRACT MANUFACTURING

Design Services | Materials | Engineered Components | Finished Devices

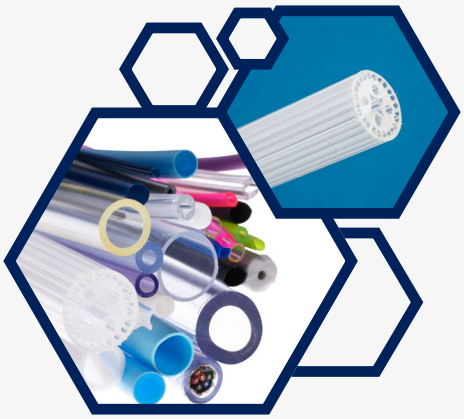


Materials

- Custom medical-grade polymers
- Medical-grade metals, including:
  - Stainless steel
  - Titanium
  - Aluminum
  - Chrome
  - Cobalt
  - Inconel
  - Nickel
  - Nitinol
- Custom compounding & polymerization
- Proprietary medical-grade polyurethanes
  - Quadraflex®
  - Quadrathane®
  - Quadraplast®
  - Quadrasil™
  - Quadraban™
  - Quadraphilic™
  - Elast-Eon™
- Pharma compounding
- Coating materials & technologies
- Full in-house analytical chemistry & metrology lab

Complex Extrusions

- Complex extrusion processes
- Solid, single- & multilumen extrusions
- Braided high-pressure tubes (Prolix™)
- Microextrusions (braiding)
- Layered coextrusions
- Coextrusion of up to 5 materials
- Jacketing
- Balloon catheter tubing
- Versatile Prolix™ medical fluid management tubing
- Multilayer & multiple-pass extrusions (1st, 2nd & 3rd)
- Profile extrusions
- Solid core
- Coated wire
- Precision-cut to length
- Simple & complex tubing set solutions
- Steerable guidance
- Tapered extrusions



Interventional Medical Plastics

- Broad molding capabilities
  - Mold construction
  - Prototype molding
  - Standard injection molding
  - Vertical & horizontal molding
  - Insert & overmolding
  - Rotary insert-molding
  - Micromolding
  - Large part & enclosure molding
  - Single- & multicavity molds
  - High- & low-volume molding
- Liquid resin casting
- Advanced thermoforming
- Additive plastic manufacturing

Balloons & Balloon Catheters

- High-pressure balloons
- Compliant, semicompliant & noncompliant balloons
- Advanced composite construction
- Optimized introducer compatibility
- 0.014”, 0.018”, 0.021”, 0.035” & 0.038” guidewire compatibility
- Tip optimized for radiopacity or sheathless access
- Rapid inflation & deflation times
- Multidurometer shaft transitions
- Pushability, torquability & trackability
- Coatings

Advanced Catheters & Steerables

- Braiding
- Reflowing
- Coil winding
- Laser cutting & welding
- Thermoforming
- Smart catheters
- Steerable & deflectable configurations
- Tapered shafts
- Multidurometer shafts
- Multilumen shafts
- Reinforced shafts
- Microcatheters
- Balloon catheters

Laser Processing

- Laser cutting
- Laser welding
- Laser marking
- Laser drilling
- Laser ablation
- Post-processing
  - Ultrasonic cleaning
  - Passivation
  - Electropolishing
  - Mechanical buffing
- Optical targeting
- Automated inspection
- Automated & semi-automated parts handling

Micromachining

- CNC multiaxis milling & turning
- Multiaxis machining
- Swiss screw machining
- Metals machining
- Plastics machining
- Secondary processes
  - Wire electrical discharge machining (EDM)
  - Microblasting
  - Tumbling & deburring
  - Passivation
  - Electropolishing
  - Buffing

Image Guided Intervention

- General
  - Analog & digital circuit design
  - Full range of software & firmware design
  - Mobile apps
  - Console interface
- Imaging
  - Imaging & image processing
  - Lighting
  - Electrical components & visualization
  - Shafts & insertion tubes
  - Braiding & reinforcement
  - Bending for steerability
- Guiding
  - Robotic maneuverability
  - In-body navigation & guidance
- Intervention
  - Ultrasonic design
  - Acoustic engineering
  - RF ablation

Finished Devices

- Adhesive, solvent & thermal bonding
- Tipping
- Pad printing
- Coating
- Ultrasonic & laser welding
- Comprehensive packaging solutions
  - Packaging design
  - Pouch & tray sealing
  - Backer cards
  - Laser labeling
  - IFU management
  - Kitting services
  - Shipper packaging
  - Palletization
- Packaging validation, including:
  - Peel testing
  - Dye penetration testing
  - Package integrity testing

Conclusion

As OEMs enter the exciting RASD marketplace, they may not have the expertise in house to develop every part of their systems. Looking for new partners in the supply chain, they discover that there are dozens of component supply companies for robotic surgical systems. But most of these suppliers provide only a small piece of the puzzle. Compatibility between parts from different suppliers can be an issue, and the work of negotiating or explaining design requirements with multiple suppliers is onerous. This results in longer time to market and higher costs. OEMs want to avoid the risks associated with sourcing from multiple suppliers for different aspects of their systems.

Biomerics is the leading vertically integrated medical device contract manufacturer in the interventional device market. We have leveraged a foundation built over the past 29 years to new RASD applications, making Biomerics the best option for OEMs in the robotically assisted surgical device market.

Biomerics has the agility and ability to see our partner OEMs' leading-edge robotic surgery products through from design and development into production, complete with packaging, sterilization management, and distribution. We provide a one-stop, hassle-free contract manufacturing source for our customers, with world-class engineering expertise, testing labs, process development, and validation services.

Contact Us

Biomerics has a team of experts available to help you develop the components required for your robotically assisted surgical devices, from endoscopes to imaging to interventional tools. Reach out to discuss a meaningful partnership with Biomerics.

Contact:
Daniel Craven
Director, Marketing & Communications
marketing@biomerics.com
+1 888-874-7787

find us online at:
Biomerics.com
or on social media:

Notes

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Additional Resource

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