THE OPERATING THEATER OF THE FUTURE – THE RISE OF ROBOTIC-ASSISTED SURGERY

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An industry set to triple in size by 2030

The market for robotic-assisted surgery (RAS) systems has developed considerably and is primed for further growth. Although RAS accounts for less than 1%¹⁾ of the 300 m [1] operations carried out annually around the world, advances in minimally invasive surgery will continue to drive double-digit revenue growth. An expected compound annual growth rate (CAGR) of 13.7% will almost triple total industry revenues to USD 21.5 bn by 2030.

Industry pioneer Intuitive Surgical is seeing its towering market position come under increasing pressure from established and new competitors. Companies like Medtronic, Stryker, Johnson & Johnson, Asensus and Zimmer Biomet should receive broader regulatory approvals for their products in the coming years. This will make pricing more competitive and spur further innovation – and encourage more hospitals to adopt RAS.

But all RAS systems manufacturers need to overcome significant hurdles that are slowing the advance of robots into operating theaters. A significant number of surgeons and other healthcare professionals remain equivocal about the technology and efficiency given perceived issues relating to cost and reimbursement. Our study recommends five steps RAS companies can take to counter these perceptions and benefit from market growth.

¹ RB RAS market model; May 2023

An exciting sector is evolving rapidly

Digitalization and automation are revealing the huge potential of new and disruptive surgical procedures in many fields of medicine. After new imaging and diagnostic methods, robotic-assisted surgery (RAS) is revolutionizing the operating theater. An increasing number of surgeons today regularly use (semi-) automated robotic systems to support high-precision procedures.

Robots vary in form and function. But they typically consist of one or more robotic arms, a console for remote-operator control and one or more monitors for surgeons to follow the robot's actions. These elements are connected by software to ensure seamless operation. Robot surgery was first used for long-distance treatment of critical injuries in battlefield settings, but soon proved useful for minimally invasive civilian surgery [2].

Each surgical robot's multifunctional mechanical arm or arms can be equipped with drills, staplers, imaging equipment and other instruments. Surgeons operate the device from a console, which removes human tremors, enables more precise movements, and allows remote operation for procedures that involve radiation or other potentially harmful materials.

This may enable RAS to achieve higher-quality results in less time than conventional surgery and to reduce physical strain and other health risks for surgeons [3]. It also benefits patients, as greater precision leads to fewer complications like blood loss, and so to shorter post-surgery hospital stays [4, 5].

Orthopedic implant surgery, for example, can use robotic surgical devices to make a 3D model of a patient's bone structure from imaging data. Surgeons then use the model to test different implant sizes before starting surgery.

In addition, conventional open surgery that requires large incisions is increasingly being replaced by robotic-assisted minimally invasive procedures that make do with small incisions. Here, as elsewhere, robotic surgical devices reduce health risks for patients and shorten recovery times and hospital stays. The potential to improve treatment outcomes while lowering costs means RAS has huge market potential [6].

A growing market that offers global opportunities

The global market for robotic-assisted surgery is estimated to have hit USD 7.7 bn in 2022. It is currently dominated by one company, Intuitive Surgical, which reported sales of USD 6.2 bn in 2022 [7], 80% of industry revenues. The RAS sector can be broken down into three major segments: robotic systems, instruments and accessories, and services.

The **robotic systems** segment combines the equipment, software and services necessary to operate a robotic surgical device. With RAS systems priced anywhere between USD 500,000 and USD 3 m [8], the segment accounted for 33% of the total robotic surgery technology market in 2022. This is a major capital spend for healthcare systems, in line with other high-ticket items such as diagnostic scanners and instrumentations.

The **instruments and accessories** segment accounted for 53% market value in 2022 and covers surgical tools like cameras, drills, scissors, staplers and the required software. Tools are attached to the mechanical arms of surgical robots and many are used only once to ensure instrument sterility. This means many purchases recur regularly, allowing companies in this segment to operate a lucrative "razor and razorblade" business model.

The **services** segment covers all additional services offered by MedTech companies to ensure installation, maintenance, training and software updates. Representing only 15% of the RAS market in 2022, the segment is still an attractive business proposition given that many revenues recur. Companies can expect more and more AI-based services to become recurring revenue streams along the software-as-a-service (SAAS) model.

Global market development of RAS

The global market for robotic-assisted surgery is expected to grow by c.14% p.a. from 2022 until 2030



The RAS market grew 15.1% on average every year between 2018 and 2022. Revenue growth dipped in 2020 due to fewer elective surgeries, but otherwise the Covid-19 pandemic had minimal impact. Many hospitals even explored remote robotic systems to maintain social distancing during surgery [9]. The wide array of potential uses for RAS means the market outlook continues to be very promising. Annual sales are expected to grow 13.7% (CAGR) on average from 2022 to 2030, almost tripling industry revenues to USD 21.5 bn.

The largest regional market is North America, with 60% of sales in 2022. This regional strength has been largely driven by the strong position of Intuitive Surgical in its home market and looks set to continue [10, 11]. However, the fastest-growing region looks set to be Asia-Pacific, which is expected to make up 24% of the global market in 2030, a jump of 7 points compared to 2022. China [7, 11], Japan and South Korea appear to be driving growth in Asia [12, 13].

The RAS market will continue to grow strongly given two developments: an increase in the prevalence of diseases requiring minimally invasive surgery, and the more widespread adoption of RAS for a number of different reasons such as the advancements in the robotic systems, the higher acceptance from users and more competitive price points.

RAS serves all major fields of surgical medicine: general surgery (including gastroenterology), urology, gynecology, orthopedics, neurology, and cardiovascular surgery [14]. Below are some examples of specific procedures that can benefit from RAS:

- General surgery: gastric bypass and hernia surgery, cholecystectomy, appendectomy, pancreatectomy, obesity surgery;
- · Urology: prostatectomy, nephrectomy or cystectomy;
- · Gynecology: hysterectomy, myomectomy, endometriosis excision;
- · Orthopedics: knee, hip and other joint replacements (part or whole);
- Cardiology: cardiac tumor removal, mitral valve repair, coronary artery bypass grafting [15, 16];
- Neurology: deep brain stimulation (DBS), laser ablation [17];
- Others: lung biopsy, dental implants.



The graph above shows the degree to which different procedures lend themselves to RAS. Prostatectomy, for example, is highly suitable and RAS penetration is accordingly high. Appendectomy, on the other hand, can be easily performed robot-free using laparoscopic or open surgery.

Clinical suitability of RAS depends on the complexity of the procedure, potential time savings, and cost factors, for example, to what extent higher operating costs can be offset by shorter patient-recovery periods. Procedures reimbursed on a flat-fee basis according to diagnosis-related groups (DRGs) may hinder hospitals from recovering all RAS-related costs, especially any incremental per-procedure consumables expenses.

General surgery is the single biggest field of application for RAS, accounting for 41% market share in 2022 [10, 11]. Within this field, RAS is most commonly used by US healthcare providers for hernia surgery.

Urology and gynecology together accounted for 37% market share in 2022. In orthopedics, the replacement of knees, hips and other joints account for most RAS use cases. Orthopedic use of robot assistants has been growing strongly thanks to the launch of new systems like Mako (by Stryker), Rosa (Zimmer Biomet), Cori (Smith & Nephew) and ExcelsiusGPS (Globus Medical).

Neurology and cardiology are smaller segments. As RAS can currently be used for only a few procedures, the number of installed systems is very low.

New players are challenging the market leader

Intuitive Surgical has been the pioneer of robotic surgery for the past twenty years. Its Da Vinci system created the demand for RAS devices and captured more than 80% of market share [18]. It is a multi-arm platform that allows surgeons to perform different procedures in urology, gynecology, general surgery and other fields by equipping each arm with requisite tools.



Equipped with cameras, latest-generation robots such as DaVinci, Hugo, Monarch and Senhance telescopic arms are adept at passing through the smallest incisions to work inside the body. The systems are often significantly less invasive than traditional laparoscopic and open surgery.

Intuitive's devices support more than 1.8 m operations a year. Given that surgeons worldwide perform 13 m laparoscopies [19] and more than 300 m other traditional procedures [1], the additional addressable market for RAS is huge.

This potential coupled with positive market developments and broader acceptance of RAS by surgeons and patients has encouraged new players to enter the market and challenge Intuitive's dominance. Our overview of selected competitors shows Intuitive being challenged broadly by Medtronic and Johnson & Johnson in general surgery, urology and orthopedics, and more narrowly by other players, for example by Asensus in gynecology.

Johnson & Johnson's Ottava system, which is focused on soft-tissue procedures in general surgery, has introduced innovations that could challenge Intuitive's Da Vinci – six arms per device, integration into the operating room table. But the system's pre-launch setbacks [20] also highlight the technical challenges these highly innovative systems face.

Siemens Healthineers' CorPath GRX system focuses on percutaneous coronary, peripheral and neurovascular interventions – and it, too, is still facing challenges around market adoption and technology acceptance. An interesting offering in the endovascular interventions space could come from Sentante. With the system currently in trials, the company promises to enable fully remote manipulation of catheters and guidewires. In the orthopedics segment, Stryker's Mako system is the leader, followed by Zimmer Biomet's Rosa, Think's TSolution One and Smith & Nephew's Cori.

In the orthopedics subsegment of spinal surgeries, Globus Medical's Excelsius GPS is competing with Medtronic's Mazor, Zimmer Biomet's Rosa One and Brainlab's Cirq. Our market analysis shows that many companies prefer to chip away at Intuitive's dominance in specialized areas.

In terms of market penetration, US competitors Medtronic, Stryker and Zimmer Biomet have already established a combined market share of around 10%. Like Intuitive's Da Vinci, Medtronic's Hugo is also a multi-arm surgical robot platform. It features modular components supported by 3D visualization and cloud-based video capture. Currently, the system is marketed primarily in European markets as a lower-priced alternative to market leader Da Vinci.

More competition suggests that efficient operations will become an ever more important issue for the industry. Johnson & Johnson, Titan Medical and Vicarious Surgical recently announced job cuts in their surgical robotics units, and Intuitive faces challenges scaling its supply chain for Da Vinci and its bronchoscopy-focused Ion system [21, 22]. Siemens Healthineers even announced it was quitting the heart surgery business with Corindus, leading to a USD 362 m write-down [23]. Ensuring sufficient in-house capacity and a reliable network of high-quality contract manufacturing partners for the complex parts will be crucial tasks for all RAS systems manufacturers.

At the same time, advances in RAS are shifting the focus from products to procedures and broader solutions. As a result, RAS companies will increasingly have to excel in areas defined by traditional surgery – the three phases of pre-operative (including planning), intra-operative and post-operative.

Companies will have to develop ecosystems that allow better preparation of operations; improve decision making, precision and reproducibility during surgery; and analyze performance and ensure rehabilitation after surgery.

As a result, companies developing robotic surgery systems will need to develop strong software capabilities to spread best-in-class techniques by harnessing artificial intelligence (AI). Having traditionally focused on hardware-related engineering, manufacturing and sourcing activities, they will now have to harness technologies such as artificial intelligence and machine learning to revolutionize the way surgery is performed [24].

RAS is a crucial step towards realizing the fully connected operating theater.

Critical procedure steps for RAS



Pre-operative

Pre-operative simulations – often enabled by machine learning databases – setting up surgeons and their teams to deliver ideal outcomes



Perceptive real-time guidance, providing decision-making support, improved collaboration, and information sharing during surgery



Post-operative

Analytics to optimize surgical performance over time, ensure patient follow-up during recovery and establish global standardization

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But all companies still have some hurdles to clear

Despite rapid growth and significant long-term potential, RAS still has to clear major hurdles before it can establish itself as the new surgical standard. First, the flip side of huge potential is that adoption rates are still extremely low. Second, surgeons and patients are aware that RAS has downsides as well as upsides. Third, robotic systems are expensive to buy and operate and health insurers are sometimes still undecided on whether they improve patient outcomes sufficiently to merit reimbursing their costs.

1. Adoption has been slower than expected

Adoption of RAS has been slower than expected, although take-up differs from field to field. In general surgery, urology, gynecology and orthopedics, surgeons have been more open to the technique than those in other areas. They most commonly use RAS for hernia repair, colorectal surgery, and cholecystectomy in general surgery, and knee and hip replacement in orthopedic surgery are among the most common procedures that use RAS.

The use of robotic surgery in Michigan, for example, rose from 1.8% in 2012 to 15.1% in 2018 [25], a cohort study of patients at 73 hospitals in the US state showed. Although this adoption rate seems promising, it does not include outpatient care and gives only partial insight into one market, albeit the world's biggest. Take-up elsewhere is likely to be lower to non-existent.

But with mature products – like Da Vinci by Intuitive Surgical, Mako by Stryker, and Hugo and Mazor by Medtronic – on the market, RAS looks set to continue growing steadily. Two factors on the demand side will also help: advocacy by key opinion leaders (KOLs) on hospital staff, and new ways of offsetting the higher cost of RAS to meet the criteria of health insurers, for example, through shorter hospital stays following minimally invasive procedures.

Nonetheless, the use of robotics is set to remain limited in some areas. In cardiac surgery, well under 100,000 robotic-assisted operations take place each year worldwide, compared with hundreds of thousands of procedures in general surgery. RAS in cardiology is currently only practiced in a handful of innovation centers and this won't change in the foreseeable future.

In neurosurgery, robotic assistance is also still in its infancy [26]. Based on a study of the 100 top-ranked neurosurgical departments in the US in 2021 and 2022, only 40 had robotic spinal programs and only 30 had robotic cranial programs [17]. How RAS will advance in this field remains to be seen.

2. Benefits go hand in hand with drawbacks

The clinical outcomes of RAS differ from procedure to procedure [27]. Its use in prostatectomy and some other procedures appears to improve the quality of recovery and reduce pain scores [28, 29, 30]. But many studies report no significant beneficial effects compared to laparoscopic or open surgery. In some cases, bleeding, aftercare and other complications led to the conclusion that RAS is more time consuming and more resource intensive.

Another complication is the danger that robots may malfunction. Studies indicate that devices have had problems in 0.5-3% of operations [27], with some procedures having to be rescheduled or switched to traditional methods.

To counter any possible erosion of trust in RAS, device manufacturers need to ensure excellence in quality assurance and improve servicing and training. Based on our interactions with leading healthcare providers, hospitals themselves are open to participating in more extensive training.

Given the increasing prevalence of robots in general surgery, more and more doctors in training are likely to be taught about RAS in the coming years. Some 80% of US residency program directors surveyed in 2021 said RAS-console operation should be a training requirement for general surgery [31]. Nearly 25% of US fellowship training programs said experience of using consoles in residencies increased applicants' chances of acceptance [32].

3. Reimbursement of costs is not always certain

Installing RAS systems is relatively expensive and hospitals' initial investment can be as high as USD 2 m [33, 34]. According to a 2018 study, hospitals in addition paid RAS suppliers around USD 3,500 per procedure, with half of this total going into instruments and accessories. In comparison, operating-room costs for traditional surgery were estimated to range from USD 3,000 to 7,000, with instruments contributing less than 20% [35].

Hospitals installing RAS equipment to supersede conventional surgery can end up with significantly higher capital and operational expenditures. RAS adoption has been slower as a result, as hospitals worry that the cost of RAS might not be justified considering current reimbursement rates.

Health insurance companies' equivocal reimbursement policy has become a significant source of uncertainty. Despite the Da Vinci system's proven track record over more than a decade, many insurance providers still do not cover urological procedures performed by robots [28]. Insurers will only move towards more comprehensive reimbursement if the RAS industry can present empirical studies demonstrating superior patient outcomes.

But beyond these cost issues, RAS remains an interesting option for hospitals looking to grow their revenues. Investing in the technology is a sure way for hospitals to raise their appeal to patients and differentiate themselves from many competitors. They will benefit from a general trend towards minimally invasive surgery in a world in which the vast majority of operations still rely on traditional procedures. The outlook for RAS remains positive.



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"The opportunities of the RAS market have attracted a growing number of players, which leads to more competitive pricing and encourages further innovation."

What robotic surgery companies should do next

To ensure their success in the dynamic market for RAS solutions, device manufacturers should focus on the following five business goals:



1. Focus on customer centricity

RAS has to put surgeons and nurses at the heart of product development. Working alongside robots should be intuitive and allow healthcare professionals to achieve new standards of pre-operative, intra-operative and post-operative excellence. Early exposure during training and fellowships allows surgeons to get used to drawing on the support of technology in operating theaters. Well-designed hardware will be key – as will software that guarantees steep learning curves and high convenience. Together they will need to master current challenges – large incisions, limited accuracy, surgeon fatigue – to stand out from sectoral and traditional rivals.

2. Produce convincing trial and real-world data

RAS companies have to focus on generating robust fundamental data with which they can help hospitals advance the quality of their operations. A recurring complaint is that data about RAS is much more limited than about laparoscopy or open surgery. Quantifying the benefits of robotic-assisted minimally invasive surgery is a crucial task for the RAS industry.

3. Win the access game

Understanding hospital economics in light of insurers' reimbursement policies and developing targeted value propositions will be crucial to securing access to surgeons and healthcare administrators. Beyond improving surgical procedures, hospitals are investing in robotic systems to attract more reputable surgeons and serve ever more patients. RAS companies that have a value proposition compelling to hospitals – and, by extension, to insurers and regulators – will have a chance to challenge RAS industry's leaders.

4. Partner with leading hospitals and academic centers

Before turning their attention to the mass market, RAS system manufacturers need to win over leading universities and research hospitals. Often represented by powerful KOLs, these organizations can publish data about their experiences with RAS. Therefore, these studies will create more awareness in the broader hospital industry. RAS companies should segment their potential market in order to prioritize institutions more likely to adopt the technology. They should also keep in mind that the need for robotics training in residencies and fellowships is growing, which will in turn boost RAS use.

5. Develop convincing value propositions for health systems

The advantage of RAS over traditional surgery must be communicated clearly. System providers have to present RAS's two compelling value propositions: it raises the quality of operations by reducing human error, and it improves the economics of surgery by increasing operating theater throughput and, prospectively by reducing the number of staff involved. Hospitals, in turn, may leverage RAS systems to differentiate against their competitors and win over patients for particularly challenging procedures.

At Roland Berger, we help companies address strategic questions so that they can assume or sustain leading positions in their industry. RAS systems providers have to address the issues slowing adoption of the technology and focus on the five opportunities we have identified in this promising market. We would be delighted to discuss how you as an industry player or investor active in or interested in entering the RAS space can win in the market. We know how to support your ambition in roboticassisted surgery systems.

Further reading

- → CAN THE MEDTECH SECTOR KEEP OUTPERFORMING?
- → <u>MEDTECH TO THE RESCUE?</u>
- → HOW COVID-19 AND THE HOSPITAL FUTURE ACT RESHUFFLED MEDTECH INVESTMENTS

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