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Market Intel: Rivals Catching Up To Intuitive Surgical In Fast-Growing, Fast-Innovating Robotic-Assisted Devices Market

by Marion Webb

The global market for robotically assisted systems (RAS) is expected to reach $5.3bn by 2021, a CAGR of 11.7%. *Meddevicetracker* expects this hot market, long-dominated by Intuitive Surgical's *da Vinci* systems, to see rising competition from innovative companies developing robotic systems that are smaller, portable and less costly and offer surgeons innovative features that allow them to perform even more precise and user-friendly, complex surgeries. In this feature, we'll take a closer look at the overall market, highlighting the competitive landscape as well as limiters and growth opportunities. We'll also take a deep dive into RAS systems and their applications. Surgeons of various specialties provide key insights about the pros and cons of different systems.

In the minimally invasive surgery space, the robotically assisted systems (RAS) market is one of the hottest and fastest-growing areas, driven by Sunnyvale, California-based *Intuitive Surgical Inc.*, which has led this market for more than a decade in soft tissue applications and continues to innovate. *(Also see "Robotic-Assisted Surgery: Taking MIS By Storm*" - Medtech Insight, 26 May, 2016.)

The billion-dollar company, however, is facing rising competition from other RAS device makers developing next-generation products that are less costly and offer advanced features -- from advanced imaging, machine learning and data analytics, eye-tracking software and navigation systems -- designed to further decrease trauma and invasiveness of surgery while offering surgeons greater precision and efficiency.

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According to *Meddevicetracker's* "*Robotically Assisted Surgical Devices Market*" report, the global RAS market, which is divided into three segments -- instruments and accessories, RAS systems and services – is expected to rise from $3bn in 2016 to $5.3bn by 2021, a CAGR of 11.7%. (See Figure 1.)

In 2016, instruments and accessories accounted for 52% of global sales. This segment is expected to see the second-highest growth from $1.6bn in 2016 to $2.9bn by 2021, a CAGR of 13%, driven by rising procedure volumes and higher cost of advanced instruments.

Meanwhile, sales of RAS systems in 2016 accounted for 29% of the total market share. Robot sales are hampered in large part by high acquisition costs, which range from $400,000 to $2.5m. Over the forecast period, sales of RAS systems are expected to see the slowest growth from $892m in 2016 to $1.1bn by 2021, a CAGR of 5%.

The rising installations of RAS systems, however, will translate directly to higher services revenue, generated from maintenance and repair contracts. While the services segment accounted for the smallest market share in 2016 at 19%, it is expected to see the biggest growth, rising from $581.5 in 2016 to $1.3bn by 2021, a CAGR of 16.8%.

Figure 1

Robotically Assisted Surgical Devices, Global Market Forecast ($m), By Revenue Segment, 2016-2021

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Figures for RAS systems revenue include both leased and purchased systems. Totals may not sum due to rounding

"Robotically Assisted Surgical Devices Market," Meddevicetracker

Competitive Landscape

da Vinci

Intuitive continues to lead the global market for RAS systems with an 88.8% market share and about $2.7bn in sales of its da Vinci systems, instruments and accessories and services in 2016.

In 2016, about 563,000 procedures were done in the US with the da Vinci, with an estimated 44% involving gynecology procedures, 33% general surgery and 19% urology. Outside of the US, about

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190,000 procedures were performed with the da Vinci systems, predominantly in urology. (See Table 1.)

Table 1

Intuitive Surgical's *da Vinci* Surgery Systems Procedure Volumes, By Clinical Application And Geographic Area, 2016

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General surgery includes bariatric, colorecal, cholecystectomy, hernia repair procedures. Most procedures outside of the US were in urology.

Intuitive Surgical, 2016

The company says that more than four million minimally invasive surgeries have been performed with the da Vinci systems since 2000. In the Q3 2017 earnings call in October, Calvin Darling, senior director of Intuitive, said the company is increasing its estimate for 2017 from an estimated 14% to 15% above the approximately 753,000 procedures done in 2016 to a new range of 15% to 16%. In Q3, the company placed 169 systems vs. 134 systems in the same quarter in 2016.

The company's devices are used in all top-ranking US hospitals for applications predominantly in cancer, urology and gynecology. To increase MIS penetration, Intuitive and other manufacturers target specific procedures, geographies and physician specialties where MIS penetration is low and robotics could enable greater open-to-MIS conversion.

Intuitive's president and CEO, Gary Guthart, told investors during the Q3 earnings call that worldwide procedure growth was 15% in Q3 2017 compared to Q3 2016.

"As we have described on prior calls, we expect growth in general surgery and countries outside the United States to continue to lead performance while procedure growth in mature categories in the United States temper," Guthart said. He added that during the last quarter, Intuitive saw strength in general surgery in the US with moderate growth in the mature areas of urology and gynecology.

"Drivers of growth include US inguinal and ventral hernia repair, colon and rectal surgery and thoracic surgery as well as urology and gynecology procedures outside the United States," he said. "Procedure performance in Asia showed continued strength with solid growth in China, Japan and Korea. Overall European procedure growth moderated slightly from its first half of

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2017 performance with trends varying by country."

The company is now on its fourth-generation system: the *da Vinci Surgical System Xi* has advanced instruments and accessories that target more complex procedures. The lower-priced models include the *daVinci X*, released in April 2017 as a valuable-based, upgradeable system, the three-arm *daVinci Si-e*, the refurbished *da Vinci Si* and Single-site instruments.

A potential game changer, according to industry insiders, could be the *da Vinci Sp* (single-port), which is expected to complete patient enrollment in surgery for clinical trials taking place in the US and Asia this quarter. Cases in Asia include transoral, urologic and colorectal surgery while those in the US focus on transoral surgery.

Guthart said during the earnings call that Intuitive plans to file for 510(K) for the da Vinci Sp by year-end with follow-on submissions for more indications thereafter.

Catherine Mohr, Intuitive's vice president of strategy, told *Medtech Insight* what's exciting to her is that the Sp platform allows surgeons to do things they can't do with triangulation.

"This is where you start thinking about transoral and transanal, because you can come in through a natural orifice (such as the mouth) without having to stretch them out very wide to be able to get all the way down into the throat." In traditional surgery, surgeons often need to split open the neck.

She expects the instrument will have far-reaching applications.

"We're going for initial approvals in areas where we're kind of more experienced ... but in the long run, I see a whole new set of different kinds of surgeries that are going to be enabled, because you can bring the instruments in in parallel," Mohr said. "It will be a long process to develop those procedures, to make sure that they're safe and effective, and to figure out how do we teach surgeons how to do a surgery they don't have an analog for."

Exec Chat: An Inside Look At Intuitive Surgical

By Marion Webb and Ferdous Al-Faruque

10 Nov 2017

Medtech Insight recently caught up with a top executive at robotic surgery leader Intuitive Surgical at the Exponential Medicine Conference in San Diego. Check out our podcast interview with VP of Strategy, Catherine Mohr, about future plans at her company and much more.

Read the full article here

But that's just one of many projects. Intuitive also recently made its way into early-stage lung cancer detection when it teamed up with China's *Fosun Pharma Kite Biotechnology Co. Ltd.* to

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develop a flexible robotic catheter that can navigate into the cavernous regions of the lungs.



Singularity University

As Intuitive continues to innovate, it's also facing rising competition ((Also see "*Intuitive Still Dominates, But New Robotic Surgery Players Could Speed Penetration*" - Medtech Insight, 4 Aug, 2015.),.

Jennifer Grasso, director of Robotics and Emerging Technologies at Zimmer Biomet Spine, told *Medtech Insight* about 100 ROSA robots are currently used at sites in Europe, the Middle East, Asia Pacific and North America; six of these robots with spine applications are located in France, Germany, Belgium and Australia.

The vast majority of procedures have been brain-oriented. Asked about the marketing strategy for rolling out the combined ROSA spine and brain system in the US, Grasso said Zimmer Biomet will leverage its existing 50 "brain-install bases" in the US, mainly pediatric and academic hospitals, and other key sites. She said the company will swap out existing brain units with the combined brain/spine robots at institutions that have an interest in upgrading their robots.

Grasso declined to give an exact number for its spinal procedures. However, Zimmer Biomet will have a long way to go to catch up to Mazor, whose systems have been used in more than 24,000 cases worldwide.

"We've been working to combine the platforms for spine and brain together onto one platform, so we slowed the roll-out (in the US) until we can provide that," she explained. In other countries where ROSA Brain is also marketed, the company will look at "procedure volume" to decide whether to swap out systems, she added. "It will be something that we will provide as an option," she said.

Among the newcomers in this space is Globus Medical's Excelsius GPS guidance and positioning robot, which was FDA-approved in August 2017 after receiving CE-mark approval in January 2017.

Asked what makes Zimmer Biomet's ROSA spine system different from others currently on the market, Grasso said they are very similar.

"There are some differences in imaging, compatibility, but for the most part they are very similar in providing an accurate trajectory for pedicle screw placement," she said.

Ronnie Mimran, a neurosurgeon with the Pacific Brain and Spine Medical Group in Danville,

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California agreed with Grasso.

Mimran said he's familiar with Zimmer Biomet's ROSA Spine and Globus Medical's Excelsius, but adopted the Mazor X for spinal surgeries eight months ago in his practice.


Ronnie Mimran

"For most types of procedures, they are very comparable in terms of what they can accomplish," Mimran told *Medtech Insight*. "The Mazor has the largest breadth of experience, however the Excelsius incorporates a navigation system, which gives us more features. You don't have that incorporated in the Mazor system, but the Mazor system is compatible with existing navigation systems."

Asked about his wish list for improvements, Mimran said that he'd like to see the development of more end effectors.

"Right now, the robots are good for trajectory guides for drilling and placing screws for other implants, but I'd like to see different end effectors that allow us to do more than that – drill, cut bone, perhaps a camera that can see around corners that we can't currently see."

Charla Fischer, a spine surgeon at NYU Longone Orthopedic Hospital, said she had an opportunity to test the Globus system and prefers it over current robotic systems available, citing ease of use and built-in navigation system.

"It combines the aspects of a robot, meaning it's got a mechanical arm that guides you, and it also has navigation, so on a monitor you can see in real time where your instruments are going in the spine," Fischer told *Medtech Insight*.

For brain surgeries, Mimran acquired a surgical robot developed by Toronto-based startup Synaptive Medical Inc. He considers this robot a real "paradigm shift."

The *Brightmatter technology* includes surgical planning and navigation, robotic digital microscopy and informatics. The information platform won *FDA* approval in early 2016, according to the company website.

Synaptive Medical's Brightmatter for brain surgery

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"The Synaptive robot is different than the other types of robots," he said. "It helps surgeons visualize the anatomy better and allows for smaller incisions and smaller approaches, less tissue disruption and on the surgeon's side, less fatigue and easier visualization."

When it comes to robotic surgery for neurosurgeons, he said, "in the spine, the robot is sort of an incremental step forward, but in brain surgery, the Synaptive robot is a big step forward."

In the orthopedics space, robotic systems offer orthopedic surgeons better dexterity, efficiency in hand-eye coordination, ergonomic positioning and improved visualization with aid of computed tomography (CT) scans, preoperative plans and simulation software.

Several of the major companies have robots on the market, including Stryker's MAKO, which has a total knee application for use in conjunction with Stryker's Triathlon Knee (FDA-approved in 2015), and the widely used partial knee and hip replacements. In the third quarter of 2017, Stryker sold 33 Mako robots, up from 30 robots in 3Q 2016. Since the commercial launch of the Mako total knee application this March, around 9,400 procedures have been performed worldwide *(Also see "Latest Mako Tech Fleshes Out Stryker's Robotic Joint Replacement Line But Cost Critics Still There*" - Medtech Insight, 20 Mar, 2017.).

Stryker may soon face competition from Zimmer Biomet, which plans to launch a robot based on the ROSA technology for total knee replacement during the second half of 2018.

Smith & Nephew markets the *NAVIO surgical guidance* and positioning robot, developed by *Blue Belt Technologies Inc.*, for total hip arthroplasty and partial and total knee arthroplasty (Also see "*Blue Belt Robotic Surgery Buy Is A 'Must-Have,' Says Smith & Nephew*" - Medtech Insight, 30 Oct, 2015.). Think Surgical markets the T*Solution One Surgical System* for total hip arthroplasty.

Among the emerging products in this space are Swiss-based AOT AG's CARLO, which uses laser, robotics and navigation systems for osteotomy and the University of Calgary's *neuroArm 2*, which is controlled by a surgeon from a computer workstation and works in conjunction with an intra-operative MRI.

Head, Neck, ENT

In the head, neck/ear, nose and throat segment, three companies have robotic-assisted systems on the market. They are Intuitive's da Vinci, Medrobotics' Flex Robotic System, which was CE

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marked in March 2014 and FDA-approved in July 2015 for transoral applications, and Renishaw, which markets the *Neuromate* stereotactic robot for electrode implantation, which is approved in the US and Europe.

Cardiovascular

In the cardiovascular segment, several companies are on the market with robotic-assisted technologies that aim to provide surgeons with better control and precision while shielding them from radiation.

Auris Surgical Robots, which bought Hansen Medical in July 2016, gained rights to two catheter guidance and positioning robots: The *Sensei X2*, which is sold in Europe and the US since October 2014 and the *Magellan*, which became available in the US in 2012 and is also sold in Europe.

Catheter Precision (formerly Catheter Robotics) markets the *Amigo Remote Catheter System*, used for guidance and positioning of a catheter in electrophysiology procedures (EP) such as atrial fibrillation. The Amigo received the CE mark in 2010 and FDA (510K) clearance in August 2012.

Corindus Vascular Robotics' *CorPath System* was the first RAS system approved for use in PCI. The next-generation *CorPath GRX* debuted in the US in January 2017. Corindus seeks an indication approval for peripheral vascular procedures and believes the technology has applications in neurointerventional and more complex cardiac interventions such as structural heart applications.

Stereotaxis sells its *Niobe ES Magnetic Navigation* system for managing arrhythmia and coronary artery disease in major markets including Canada, China, Japan, Europe and the US.

Among the emerging technologies is the MRI-guided robotic intravascular catheter system for pulmonary vein isolation ablation to treat atrial fibrillation in development by Case Western Reserve University.

Thoracic

The market opportunity in thoracic surgery for minimally-invasive surgeries is significant and the proliferation of low-dose computed tomography (CT) scanning and other advanced diagnostics are expected to increase the potential population as more people are diagnosed in earlier, more treatable stages of disease.

Market leader Intuitive estimated that the market opportunity in thoracic is around 100,000 potential procedures, with the biggest opportunity being in minimally-invasive treatment of

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lung cancer.

Intuitive executives said last year that the company wants to expand into the thoracic surgery market and did so with the launch of the da *Vinci XiEndo Wrist* Stapler 30 and *XiSingle-Site* instrument and accessory kit, which received FDA 510(K) clearance in March 2016. The stapler is also indicated for use in gynecology, urology and general surgery.

According to *Meddevicetracker*, over the long term, the biggest market opportunity could be in countries where smoking rates are high, such as in Europe and Asia. *Intuitive* presented favorable first results of the flexible robotic catheter it developed with China's Fosun Pharma at the CHEST Annual Meeting this month, suggesting that the system is safe and a feasible approach to sample lung tissue.

Auris Surgical Robotics received FDA approval in May 2016 for the *Auris Robotic Endoscopy System*, a patient-side system that is intended to provide bronchoscopic visualization of the patient's airways.

Also competing with Intuitive in this market segment is TransEnterix's Senhance system.

Both Medtronic and Verb Surgical, which is Johnson & Johnson Medical Inc.'s joint robotic surgical project with Google's *Verily Life Sciences LLC*, are also expected to rival Intuitive with their respective technologies in development. Verb Surgical's robot, which has thoracic, colorectal and oncology applications, is designed to be smaller, smarter and less costly with machine learning and advanced visualization components. It is expected to hit the market in 2020.

Limiters

Cost

The high cost of owning and operating robotic systems continues to represent a major barrier to entry, especially for smaller, low-volume hospitals.

Zarnegar said most major hospitals in the US already have adopted surgical robots and Weill Cornell Medical Center has six systems.

"It's used by select robotics specialists from different divisions," Zarnegar said. "I think when you do that, then there is an overwhelming advantage of the robotic technology, so I think that's where it starts paying off. It's all based on the number of cases and if you can maximize case utilization, then the original cost kind of evens out."

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Mimran said for some health systems it makes sense, for others it may not.

"That's the same type of question every hospital and every spine surgeon needs to evaluate when it comes to a capital purchase and every institution and surgeon is different."

Fischer agrees that the high cost of installing a robotic system puts a damper on wider adoption of RAS, but she finds that in spine surgeries robots offer multiple advantages for patients, surgeons and hospitals.

"I think in general you're going to have fewer complications, overall less radiation to the surgical team and the patient, and shorter length of stay (hospitalization) because more surgeons will feel more comfortable doing more things minimally invasive and with that patients will have faster recovery."

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According to Intuitive, in 2016, the average sales price of an Intuitive Surgical da Vinci system declined from $1.54m in 2015 to $1.52m. Per-procedure costs for the da Vinci ranged from $700

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to $3,500, and system maintenance expenses ranged from $80,000 to $170,000 per year.

Although more systems are available at different price points, Intuitive customers continue to purchase the da Vinci Xi system over the less expensive and less capable Si models by a factor of about three to one, according to *Meddevicetracker*. *Meddevicetraker* expects that the level of growth in the RAS systems market is expected to be constrained due to rising sales of lower-priced systems.

These include Medrobotics' Flex Robotic System for head and neck and colorectal surgery and Titan Medical's SPORT product for general abdominal, gynecologic, and urologic indications, which may be launched by 2021.

Table 2

Average Sales Price Of Selected Robotically Assisted Surgical Devices, 2017

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"Robotically Assisted Surgical Devices Market," Meddevicetracker

But Mohr isn't convinced that surgical robots that are going to be commercialized will be less expensive than the da Vinci systems.

"I think they may discover they're very surprised at how much it actually costs them to run and support a robot program," she told *Medtech Insight*. She said when hospitals evaluate whether to invest in a robot, it's less about cost and more about value. "Does it bring enough value to justify the cost," she said. The move toward value-based and outcomes-based health care in Europe and the US will work well for Intuitive, she said.

"I think they may discover they're very surprised at how much it actually costs them to run and support a robot program," said Catherine Mohr. She said when hospitals evaluate whether to invest in a robot, it's less about cost and more about value. "Does it bring enough value to justify the cost," she said.

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Though, some industry insiders say that the jury is still out whether robotic surgery uniformly leads to better outcomes with studies offering varying conclusions.

During the Q3 2017 earnings call Patrick Clingan, Intuitive's VP of finance and sales operations, pointed to a recent economic analysis that studied the impact of da Vinci hysterectomy in Denmark, published in the Journal of Robotic Surgery. Comparing cost of care from the previous year to year following a hysterectomy for benign and malignant conditions in more than 7,600 hysterectomy patients across open, laparoscopic and da Vinci Surgery, the authors found in comparison to open and laparoscopic surgeries the da Vinci was less costly for benign procedures and more expensive for less complex malignant procedures. The authors concluded that "the use of robotic technology for hysterectomy is potentially cost saving from a broad health care prospective."

Another study published in the *Journal of the American Medical Association* in 2013 found that robot-assisted hysterectomy had similar complication rates as laparoscopic hysterectomy, but cost nearly $2,200 more per procedure.

While reimbursement rates for patients in the US tend to be the same whether they opt for robotic surgery or not, proponents of robotic systems say hospitals save money when they factor in shorter length of stay and lower complication rates for patients. But more peer-reviewed data is needed to show superior outcomes with RAS systems compared to open surgery or MIS.

Learning curve is often cited as another issue. But Mohr said it has a "fuzzy definition."

"What a lot of people talk about when it comes to learning curve is how many cases does it take them to get back to the same time that they were doing it before, but if you were to think about learning curve in terms of how many cases do you need to do before you've got better outcomes or before you've got fewer complications, the learning curves are actually very short," she said. Getting to the point when a surgeon feels confident or comfortable doing a robotic procedure can also vary and then there is the issue of complexity of a surgery.

> ***"When I think about the role that robotics is playing … it's not just the robot as a set of manipulators," Mohr said. "It's a platform onto which we can bring a lot of other technologies."***

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Robotic surgery is undoubtedly the future. With increased demand by patients and expanded indications and technological advancements, more hospitals and ambulatory centers will adopt RAS. In the future, RAS systems will play a greater role in workflow and supply chain management of operating rooms with systems analyzing how much time a surgery will take, what instruments and implants are required and preorder supplies.

At Intuitive, Mohr will push for continued innovation.

"When I think about the role that robotics is playing ... it's not just the robot as a set of manipulators," she said. "It's a platform onto which we can bring a lot of other technologies."

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