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Robotic Surgery
Article Pack
European Debut For CMR Surgical’s Versius Surgical Robot In Two UK NHS Hospitals

Executive Summary
CMR Surgical’s Versius robotic system is now live in the UK NHS, the company announced 20 February.

CMR Surgical Ltd.’s Versius robotic system has been acquired by two NHS hospitals, the company announced 20 February.

The Western General Hospital, in Edinburgh, and the Milton Keynes University Hospital NHS Trust have become the first hospitals in the UK – and Europe – to adopt CMR’s system for minimal access surgery. The system has been used initially to perform a range of colorectal surgeries.

CMR Surgical CMO Mark Slack said this was a huge vote of confidence in the company. “The fact that the NHS believes this is suitable and affordable is a really significant milestone for us,” said Slack.

The company is now working to place the robot in other NHS hospitals, but Slack said CMR is taking a “slow and steady” approach to penetrating the market. CMR points to the possibility to purchase the robot through a Managed Equipment Service agreement, given that NHS hospitals have often found the upfront costs of surgical robotics to be prohibitive.

This year, the Cambridge, UK-based company appointed Per Vergard Nerseth as CEO, succeeding Martin Frost. (Also see “CMR Surgical Names New CEO” - Medtech Insight, 9 Dec, 2019.) Nerseth was most recently managing director and senior vice president of the industrial robotics developer, ABB Robotics. Frost remains on the CMR board as a non-executive director.

CMR Surgical is entering the robotics race at a competitive time as the big medtech giants prepare to launch rival systems. Last year, Medtronic unveiled its Hugo RAS modular robotic system for minimally invasive surgery. (Also see “Medtronic Introduces Hugo To Rival Intuitive’s Robotic Surgery System” - Medtech Insight, 25 Sep, 2019.)

“We are a smaller company, but that doesn’t mean the bigger company’s technology is better ours,” said Slack. “One of the best things about Versius is that this is the first robot in the world specifically designed from inception to do surgery,” he said.

“Most other surgical robots have been adapted from industrial robots. The design features of Versius such as being portable, give us a whole range of advantages. I believe we have a robot that can stand on its own feet – literally – and we don’t need to worry about the opposition. There’s enough space for us internationally.”

CMR estimates global annual revenues for robotic-assisted minimal access surgery at $4bn in 2020, and set to climb to $20bn by 2025.
Study Shows Rapid Adoption Of Robotic Assistance For Unproven Procedures

Executive Summary
The authors of a large cohort study of the uptake of robotic-assisted surgery in Michigan hospitals argue that the rapid adoption of robotic techniques is not supported by existing clinical evidence.

The rapid adoption of robotic-assisted surgery must be carefully monitored to ensure surgeons' enthusiasm for this technology does not compromise patient safety, according to the authors of a new study on the adoption of robotic-assisted surgery across Michigan.

Researchers at the University of Michigan, led by Kyle Sheetz, analyzed data from the Michigan Surgical Quality Collaborative, a partnership between Michigan hospitals and BlueCross/BlueShield of Michigan that covers more than 90% of all surgical procedures in that state. Results of the study are now available online at JAMA Network Open, a journal published by the American Medical Association.

“Robotic surgery is replacing conventional laparoscopic approaches for procedures that may not be complex enough to warrant the consideration of an advanced, expensive, and unproven minimally invasive platform,” the authors concluded.

“The clinical footprint for robotic surgery will continue to increase as it has for more than a decade already,” Sheetz explained. “However, accurate data on how robotic surgery is being applied in contemporary practice is lacking.” The authors explained that prior clinical studies on the adoption of robotic-assisted surgery are limited to single-center reports or claims-based analyses that may be distorted by inaccurate coding.

“This inaccuracy is problematic because it may limit our ability to understand the clinical implications of this rapid change in practice,” Sheetz explained. “It also limits the ability of policymakers and regulators to scope oversight or, more broadly, the public health implications of rapid changes in surgical practice.”

Sheetz's study cohort included 169,404 surgical procedures at 73 hospitals from January 2012 through June 2018. The researchers identified trends in robotic-assisted surgery for common procedures for which traditional laparoscopic surgery was already considered a safe and effective approach.

The study shows robotic-assisted systems were used at these hospitals in 1.8% of surgical procedures in 2012 and in 15.1% of surgical procedures in 2018. The growth in adoption of robotic-assisted surgery was faster for certain types of procedures. For example, in inguinal hernia repair, the use of robotic-assisted surgery increased from 0.7% to 28.8% between 2012 and 2018.

The study also found that the use of robotic-assisted surgery jumped an average of 8.8% in the first four years after hospitals began performing robotic-assisted surgery. This trend was associated with a decrease in the average percentage of surgeries performed laparoscopically at those hospitals – from 53.2%
to 51.3%. In the years covered by the study, the hospitals’ use of laparoscopic surgery increased by an average of 1.3% per year up to the time they began a robotic-assisted surgery program.

After they started a robotic-assisted surgery program, the hospitals’ use of laparoscopic surgery fell by 0.3% per year. This trend in favor of more robotic-assisted procedures at the expense of laparoscopic procedures was seen in all the different types of procedures analyzed in the study.

The authors conceded that the generalizability of their study may be limited because it only included hospitals in Michigan, but pointed out that the results of the study “are consistent across multiple different procedures, which also suggests that these trends are independent of unique clinical domains or disease processes.”

The safety and effectiveness of robotic-assisted surgery has not been established for mastectomy procedures or the prevention or treatment of cancer, according to a safety communication issued by the US Food and Drug Administration in February 2019. (Also see “FDA Urges Caution On Surgical Robots For Off-Label Women’s Cancer Treatments” - Medtech Insight, 28 Feb, 2019.)

Randomized clinical trials have failed to demonstrate the benefits of robotic surgery over other approaches for treating rectal cancer or cervical cancer and observational studies have failed to show that robotic assistance improves outcomes in inguinal hernia repair, kidney resections, colectomy or cholecystectomy.

Despite the paucity of evidence for many types of robotic-assisted surgery, the global market for robotic-assisted surgery systems is expected to grow to $9.7bn in 2023, according to a recent analysis by Informa’s Meddevicetracker.

Intuitive Surgical Inc. dominates the global market for robotic-assisted surgery systems with a 81% market share. In 2019, about 1.2 million procedures were performed with Intuitive’s da Vinci system. About 5,500 da Vinci systems are installed worldwide and da Vinci system placements grew by 21% in 2019, Intuitive CEO Gary Guthart said on 14 January at the JP Morgan Health Care Conference in San Francisco.

Sheetz concluded, “The discrepancy between the ongoing rapid adoption of robotic surgery and unclear clinical benefit highlights why accurate information on how it is being applied in contemporary surgical practice is necessary.”

Sheetz cited a 2016 study of 1,370 US hospitals showing patients are far more likely to receive robotic-assisted surgery than conventional laparoscopic surgery, if the hospital is operating in a competitive health-care market.

“These data are complementary to ours and suggest that the greatest forces driving robotic surgery adoption may be the technological imperative and economic pressures experienced by hospitals in certain health-care markets,” the authors concluded.

The authors call on the US Centers for Medicare and Medicaid Services to work with the FDA to create a coverage with evidence development policy that would restrict Medicare coverage of robotic-assisted procedures to centers that submit clinical data on these procedures to a national registry.

“Use of [coverage with evidence development] would facilitate greater understanding of how robotic procedures are being used in real world
practice [and] allow hospitals, which provide credentials to perform robotic surgery, to better understand where sufficient evidence suggests plausible benefit,” Sheetz argued. “At present, surgeons are largely able to use robotic surgery for any procedure at their professional discretion, [but] this discretionary use may place patients at risk for poor outcomes. Facilitating transparency around the allocation of robotic surgery would allow patients to make better collaborative decisions with their surgeons.”
Intuitive Surgical Opens New UK/Ireland HQ In Oxfordshire

Executive Summary
Surgical robotics giant Intuitive Surgical has opened a new UK and Ireland headquarters and training suite in Oxford. The California company expects the new facility to help expand business across the region.

Intuitive Surgical Inc. has landed its first UK headquarters and training suite in Oxford in a bid to penetrate the UK and Ireland markets further.

The Sunnyvale, California-based company first introduced da Vinci robotic surgical systems in the UK in 2000 and has placed more than 85 da Vinci surgical systems across UK and Ireland hospitals, with plans to expand its presence further. The new center in Oxford will offer training and education programs to improve the company’s links with UK and Ireland health services.

Last year, Intuitive appointed Phil Bradshaw as its first General Manager in the United Kingdom and Ireland. Joining from Medtronic’s integrated health solutions division, Bradshaw previously held a senior position in Stryker UK’s neurosurgery division. Speaking to Medtech Insight at the opening of the facility, Bradshaw said the new center would help robotic-assisted surgery become a standard option for UK and Irish surgeons.

“The vision of the new HQ is to create a home and a training center for Intuitive to work with the next generation of surgeons. We will be introducing resident courses, introductory courses to robotic-assisted surgery and nursing courses. Robotic assisted surgery is a ‘team sport’ and I think it’s important that nurses are engaged and trained as well. So, we are ramping up operations to seriously capture the next generation.”

Intuitive’s new facility at the Oxford Science Park is close to the offices of several other UK medtech companies, including Sensyne Health and Oxford Nanopore. Sebastian Johnson, Head of Innovation & Inward Investment at Oxfordshire Local Enterprise Partnership (OxLEP), said the close links to Oxford’s tech ecosystem could spur further innovation.

“We will be encouraging Intuitive to be working with other organizations across Oxford to collaborate and look at any opportunities to really develop other stuff. We want to support them to grow their operation here,” Johnson told Medtech Insight. “It’s great to work with Intuitive here in Oxford and fits with our drive to be a global innovation ecosystem. The kind of innovative business that Intuitive is fits perfectly with our existing ecosystem and is exactly the type of business we want to attract to Oxfordshire.”

OxLEP focuses on developing Oxfordshire’s economy by fostering relationships between businesses, academia and the public sector. “We’ve got it all here in Oxford, but if we’re serious about our mission, we need to be attracting companies from the US and globally into Oxford,” added Johnson. “Intuitive joining us is a great case study to share, both nationally and internationally, of that pull of Oxford.”
J&J Takes Full Ownership Of Verb Surgical, Verily Breaks Off Robotics Partnership

Executive Summary
Johnson & Johnson is acquiring the remaining stake in Verb Surgical from Verily following a four-year partnership. The transaction is expected to close in the first half of 2020.

Johnson & Johnson is acquiring full ownership of Verb Surgical, buying out the share held by Alphabet’s Verily Life Sciences LLC, after a four-year collaboration to develop a digital surgery platform.

J&J announced on 20 December its plans to acquire the remaining stake from Verily and move the robotic surgery platform to market alone. Verily CEO Andrew Conrad said he was “excited for the future of Verb in Johnson & Johnson’s hands following a successful partnership.” Financial terms of the deal were not disclosed.

J&J’s Ethicon and Verily founded Verb Surgical in 2015 as a joint-venture to develop robotics and machine learning tools for “democratizing” surgery. Since then, J&J has pursued an aggressive robotic surgery strategy. In 2018, its DePuy Synthes orthopedic division acquired Orthotaxy, a French developer of software-based surgical technologies (Also see “J&J Adds To Robotic Focus With French Firm Acquisition” - Medtech Insight, 22 Feb, 2018.) and earlier this year, it picked up Auris Health, Inc. for $3.4bn in cash, plus milestones payments of up to $2.4bn. Auris has the FDA-cleared Monarch platform, which is expected to rival Intuitive Surgical’s robotic-assisted bronchoscope device, Ion, awaiting FDA clearance. (Also see “Johnson & Johnson Diversifies Robotic Efforts With Auris Health Acquisition” - Medtech Insight, 13 Feb, 2019.)

Verb’s surgical system is expected to launch on the market in 2020 and will compete with established market leader Intuitive Surgical Inc. (Also see “Exec Chat: Intuitive Surgical CEO Gary Guthart On Expansion, Innovation And Competition” - Medtech Insight, 8 Oct, 2019.) In a report earlier this year, Wells Fargo analyst Larry Biegelsen said surgeons who have tried Verb’s platform describe it as “impressive,” and very different from the da Vinci Xi. “It appears that the platform will be smaller, more versatile and may offer a lower-cost solution to customers,” Biegelsen wrote. (Also see “SAGES 2019: Spotlighting Competitive Robotic Systems And Procedures” - Medtech Insight, 3 Apr, 2019.)

The global market for robotic surgery systems is expected to rise at a compound annual growth rate of 16%, reaching about $9.7bn in 2023, driven by patient demand for minimally invasive surgery, expanded indications and continued innovation by companies, according to “Robotically Assisted Surgical Devices,” a new analysis by Informa’s Meddevicetracker.

The space is becoming increasingly competitive, with a series of new entrants expected to launch systems in the new few years including Hugo, the eagerly-anticipated robot from Medtronic. MT125674 In Europe, German company Avatera Medical is entering the European market with a new, CE-marked system and UK robotics firm CMR Surgical is preparing to launch Versius system in 2020.
Medtronic Adds UK-Based Digital Surgery To Support Robotic Surgery

Executive Summary
Digital Surgery, a London-based developer of surgical artificial intelligence, analytics, digital education and training solutions, will join Medtronic’s surgical robotics business within its minimally invasive therapies group.

Medtronic PLC is acquiring Digital Surgery to augment its developing robotic-assisted surgery technology, the company announced on 13 February.

Digital Surgery has developed an “ecosystem of products” called Touch Surgery, which includes mobile-based education and training products as well as artificial intelligence (AI) technology to guide surgery and instrumentation, according to Medtronic. Touch Surgery provides insight into procedure time, cost and processes to improve surgical care.

“Joining Medtronic creates an incredible opportunity to realize the promise of reducing unwarranted variability in surgery,” Digital Surgery CEO Jean Nehme said. “We have always believed in computational power and data as two central drivers of consistency and quality in surgery, [but] within surgery it is almost absent. By joining forces with Medtronic, we will finally apply computing and AI to surgery on a meaningful scale.”

The London, UK-based Digital Surgery team will help Medtronic’s robotic-assisted surgery group develop its soft tissue robotic-assisted surgery capabilities, Medtronic said.

In September, Medtronic announced plans for its Hugo RAS robotic minimally invasive surgery system, which it hopes will compete with Intuitive Surgical Inc.’s da Vinci soft-tissue robotic surgery system. Medtronic expects Hugo RAS to earn a CE mark in late 2020 or early 2021 and expects the US Food and Drug Administration to clear it by late 2021. Medtronic also markets the Mazor robotic system for spine surgery. (Also see “Medtronic Introduces Hugo To Rival Intuitive’s Robotic Surgery System” - Medtech Insight, 25 Sep, 2019.)

Digital Surgery will become part of Medtronic’s minimally invasive therapies group, but will maintain its headquarters in London, Medtronic said. Nehme and the company’s other co-founder, Andre Chow, will remain with Digital Surgery following Medtronic’s acquisition.

Terms of the deal are not disclosed, but Medtronic said the cost will be immaterial to Medtronic’s fiscal 2020 adjusted earnings per share while also meeting Medtronic’s long-term criteria for acquisitions.
Medtronic Introduces Hugo To Rival Intuitive’s Robotic Surgery System

Executive Summary
The company unveiled its new modular robotic surgery system for minimally invasive surgery at a special event in Hartford, CT. Medtronic expects the new system to earn a CE mark by early 2021 and FDA approval by the end of 2021.

Medtronic PLC announced plans for its Hugo RAS robotic minimally invasive surgery system, which will compete with Intuitive Surgical Inc.’s da Vinci robotic surgery system.

At its Robotic-Assisted Surgery Investor Update in Hartford, CT, on 24 September, the company announced plans to launch Hugo RAS outside of Europe and the US in the next few months. The company did not disclose where it will initially launch Hugo RAS, but several analysts who were at the meeting in Hartford have suggested the first cases with Hugo RAS will be in India, where Intuitive Surgical does not have a major presence.

At the event, Bob White, president of Medtronic’s minimally invasive therapies group, said the company hopes to earn a CE mark for the system in late 2020 or early 2021 and expects the US Food and Drug Administration to clear Hugo RAS around September 2021.

“This will be a meaningful contributor to us,” White said. “We absolutely believe in the value of the platform.” The company expects Hugo RAS to contribute less than 50 basis points, or less than 0.5%, to the minimally invasive surgery group’s revenues in fiscal 2021, growing to 250 basis points by fiscal 2023.

Medtronic markets the Mazor robotic system for spine surgery, but Hugo RAS represents Medtronic’s first effort to compete directly with Intuitive Surgical’s da Vinci robotic surgery system for market share in general, urology, gynecology, thoracic, colorectal and bariatric robotic-assisted surgical procedures. (Also see “Brain Therapies Leads Medtronic’s Growth In First Quarter Of Fiscal 2020” - Medtech Insight, 21 Aug, 2019.)

Traditional minimally invasive surgery accounts for about 30% to 35% of all surgeries and represents a $9bn market and the market for robotic minimally invasive surgery systems is growing close to 20% annually and is worth about $4bn, according to Medtronic. Only about 10% of surgeries in the US and fewer than 2% of surgeries worldwide are performed with robotic assistance, according to the company. About 39,000 surgeons have been trained to use robotic surgical tools and more than 5,000 robotic surgery systems have been installed worldwide. But each of those systems is used, on average, just once a day.

White said the biggest barrier to convincing more hospitals to buy robotic surgery equipment is not the total upfront price of the equipment, but the high cost per procedure. Medtronic believes designing Hugo RAS to be flexible and mobile will make it easier for hospitals to use it more often, keeping the per-procedure costs down. This will improve the value to the hospital and third-party payers while allowing more patients to safely undergo minimally invasive procedures instead of open surgery.

Hugo RAS includes a universal tower, a surgeon control console, and up to four independent
carts that carry the robotic arms that control the surgical tools.

Hugo RAS’s universal tower contains 2D and 3D visualization technology created by Storz and Medtronic’s FT10 generator that powers the system’s surgical tools. Megan Rosengarten, the general manager of the surgical robotics business within Medtronic’s minimally invasive surgery group, explained that the Storz visualization components, the generator and all the software needed to run them are designed to be “upgradeable” as technology improves.

Hospital administrators have repeatedly told Medtronic that they are afraid of investing millions of dollars in a technology that could be obsolete in a year.

“We took that in, and said, ‘How are we going to build a system that we can then commit to being able to upgrade in the field or the hospital when technology advances, so that you’re not required to replace your entire system?,’’ she said. “[This approach is] increasing the return on investment in robotics for our customers.”

The control console has an “open design” rather than forcing the operator to be confined in a small space with a “periscope view” that isolates them from the patient and the rest of the staff in the operating room. “What we heard [from surgeons] is, ‘It’s very important for me to not be isolated from my patient and what’s going on there. It’s very important for me to feel connected to the overall staff and the activities going on and the environment,’” she explained. The console was also designed to reduce strain on the operator’s back and neck.

The carts that hold the robotic arms are mobile so they can move between operating rooms or moved out of an operating room to quickly make room for surgery that does not require the robotic system, Rosengarten said. This mobility will make it easier for surgical teams to schedule multiple robotic surgeries in a row, because they will be able to prepare one operating room for a surgery while the robotic arms are still being used in a different room, and then move the robotic arms to the room that is already prepared and start the next surgery quickly, she explained.

“[Hospitals] can buy the laparoscopic tower and they can move that into every single one of their ORs and they can buy a fleet of robotic arms that can be shared across those operating rooms,” Rosengarten said.

Analysts Expect Hugo To Succeed, But Want More Information

In a 24 September analyst note, Deutsche Bank’s Pito Chickering wrote, “The modular design is in our view one of the more compelling attributes of Hugo.” Chickering added that Medtronic’s “strong established presence in minimally invasive surgery will be instrumental in Medtronic making inroads in the robotic surgery space.

“The company’s unwillingness to provide much in the way of specifics here was frustrating, albeit not surprising given the competitive considerations,” Chickering said. He pointed out that some analysts expected Medtronic would sell Hugo RAS at below cost, at least initially, and generate revenue entirely from per-procedure costs. “But the clear message today was that this will not be the strategy,” Chickering said. “The bottom line goal will be to enable robotic surgery procedures at cost parity with simple laparoscopy – but how this will be achieved remains a key open question for us coming out of the meeting given the huge capital expenditure involved.”
Hugo RAS will compete with Intuitive Surgical’s da Vinci robotic surgery system, which has an almost 20-year head start in the market with more than 5,000 systems already installed. Chickering also pointed out that Intuitive also has a “huge advantage” in informatics and analytics from the data it has collected from the surgeries performed with the da Vinci so far. But “the global surgery market is massive and minimally invasive surgery/robotics penetration remains very low, thus leaving ample room for multiple players,” he said. (Also see “Market Intel: Rivals Catching Up To Intuitive Surgical In Fast-Growing, Fast-Innovating Robotic-Assisted Devices Market” - Medtech Insight, 10 Nov, 2017.)

On 24 September, Jefferies analyst Raj Denhoy wrote that Medtronic’s projections for Hugo RAS’ revenue contributions amount to about $40m, $115m and $200m of incremental revenue over the next three years, which would contribute about 0.25% to Medtronic’s overall revenue during this early phase of the market launch. “While some conservatism is clearly baked-in, the initial targets appear modest,” especially relative to the $5bn in revenue Intuitive is forecasting for 2022. (Also see “International Demand For Robotic Surgery Drives Intuitive Surgical’s Revenues Up 21% in Q2” - Medtech Insight, 19 Jul, 2019.) “Despite this modest early look, we still see robotics as having blockbuster ($1bn-plus) potential over time as the launch evolves.”

In a 24 September note, Wells Fargo analyst Larry Biegelsen said he expects that the specific surgical instruments for Hugo RAS will be more durable than comparable instruments for da Vinci, which will help make Hugo RAS cost-effective.

“It is worth noting that approximately 70% of Intuitive Surgical’s revenues are generated from recurring revenues, including over 50% from instruments and accessories,” Biegelsen wrote. “The company’s response will have to be closely monitored, especially if Medtronic is able to successfully drive instrument usage higher and cost lower.”

He expects the initial adopters of Hugo RAS to be mostly academic centers and community hospitals with the company focusing initially on colorectal surgery and prostatectomy surgeries.