

Insights from the operating room: does robotics change the established protocols for developing next- generation surgical instruments?

Effective requirements capture is critical for successful product development and, traditionally, the needs of three main stakeholder groups are considered during product development, namely the patient, the provider and the payer. In the new world of robotic surgery there is effectively a fourth stakeholder – the robotic platform itself. This paper explores how increasing use of robots for intricate surgical procedures is changing the dynamics of the operating room. What is needed is targeted and organized development pathways, which take into consideration the full set of stakeholders.



1. The origins of robotic surgery – the birth of daVinci

Modern surgical robotics technologies have been on the market for nearly 20 years. Whilst forerunners existed from companies including ISS (who developed ROBODOC, now owned by Think Surgical) and Computer Motion, today's industry is often traced back to 2000 when Intuitive Surgical received FDA approval for the first commercially successful robotic system, the daVinci. Whilst Intuitive has a strong position in the surgical robotics marketplace,

competition is intense from well-established medical device corporations and robotic start-ups.

▸ [Robotic developments in the surgical space](#)

Verb Surgical (the new partnership between Johnson & Johnson and Google), as well as Medtronic (through the leveraging of Covidien surgical tools), have both promised launches of robotic platforms within the very near future. In addition, companies such as Titan

Medical and Auris Surgical are at various stages of development. There are also companies with recently approved robotic surgery platforms such as Medrobotics who has developed the Flex® Robotic System to target procedures that can be accessed through natural orifices of the body. TransEnterix is another example with its Senhance system, which touts advanced haptic feedback - seen as lacking in earlier robotic systems. The surgical robotics marketplace is now full of activity, interest and opportunity.

Not only are medical device companies showing an increased interest in surgical robotics, surgeons are

also wanting to explore the use-case for robotics in specialties that are new to robotics. Surgical robotics first found success in gynecology and urology specialties. Robotics has also found an application in orthopedic cases, as well as neurological cases, by offering benefits in positioning and stability of surgical maneuvers. Most recently, robotics has begun to enter into the general and thoracic surgery specialties. In recent years Intuitive Surgical has pushed the use of its robotics in general surgery procedures and adoption has increased. As technologies improve and new techniques are adopted by surgeons, we will see robotics entering more and more surgical specialties as is highlighted in our chart below.

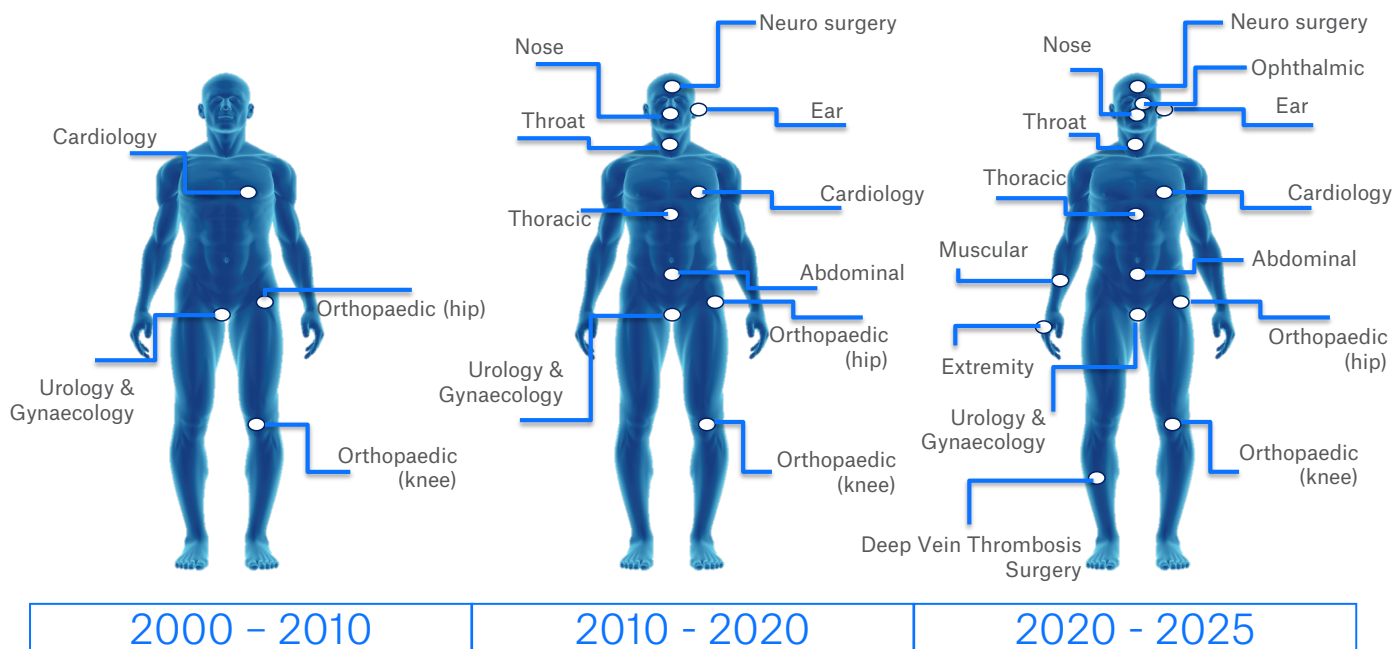


Figure 1. The predicted rise of robotic applications in surgery

→ New world dynamics of the surgical theater

Surgical robotic platforms provide enhanced dexterity and improved vision so surgeons are now able to conduct procedures with higher degrees of difficulty. Suturing and approximating tissue during surgery post dissection is a difficult task, especially with traditional laparoscopic instruments. With the da Vinci surgical robot, suturing is much easier due to the enhanced articulation and control of the instruments available to the surgeon.

New levels of accuracy and precision made possible by the use of robotic technologies have impacted the surgical approaches being used and in many cases have led to new surgical methods. An example of this is 'through the cheek' epilepsy surgery. This surgical approach requires surgeons to access the brain through the cheek bone. The challenge is that traditional straight needles and instruments have difficulty accessing the region of the brain from where the epileptic fits originate. In these instances the

surgeon also has to drill through the skull. At the University of Vanderbilt, they are developing a robotic system with a curved needle that can be guided through the cheek and have the ability to reach regions of the brain previously untouchable. This is one example of how robotic technologies can influence and improve surgical techniques and approaches.

2. Essential considerations for surgical device developers

Increasing prevalence of sophisticated robotic platforms in healthcare will require a new breed of device optimised for robotic use. It will be important to ensure that surgical accessories and other procedure-specific medical devices also meet the needs of this new world.

Traditionally it's the needs of three main stakeholder groups which must be considered when developing a new medical device – those of the patient, the provider and the payer. Each has needs and expectations of the

final device so it is vital to accurately represent these requirements and factor them in early on to ensure successful product development and final design.

In the new world of robotic surgery there is effectively a fourth stakeholder - the robotic platform itself. Product development must give due consideration to compatibility with robotic design and function. As medical product portfolios evolve they must complement robotic surgery and not inhibit performance.



3. Five steps to effective surgical device design

Step 1. Ethnographic approaches: How do you refine your research goals to maximise your chances of developing commercially-successful products?

Ethnography and Voice of the Customer (VoC) research is an excellent way to elicit the full range of stakeholder requirements for any new medical device development as they provide extensive contextual experience directly from within the operating room. Successful Voice of the Customer research projects depend on understanding several key factors: the setting (in this case likely to be the operating room); current products, approaches and technologies being used; who the stakeholders are and, finally, how the outcomes of the Voice of Customer work will be used and fed into the product development process. Real-world Voice of Customer research and wider stakeholder insight programs undertaken by bio-medically qualified engineers are vital in helping to capture all crucial project requirements at the outset and in helping to prioritize product features.

Step 2. Fully understanding the setting where the device will be used: What is the difference between traditional laparoscopic or open surgery rooms and robotically-optimized surgical theaters?

Ethnography is about studying people in context, whether directly or through observation. . The location of individuals during a robotic surgery and the movement of staff throughout the robotic case may differ compared to traditional surgery. These differences can lead to changes in procedure, steps and timing. Surgeons are often not operating from within the sterile field, they are now, most commonly, working from behind a seated robotic console from where they control robotic arms and view the surgical site in 3DHD. They are, however, often scrubbed in and patient-side at first, to assist in selecting the initial incision site and robotic port placements. The surgeon (or assistant) may need to scrub back in at the close of the procedure to suture up each of the robotic port incisions and apply a local anaesthetic to each incision.

In a robotic surgery setting there will be several other healthcare professionals, including an anaesthesiologist, a rotating nurse and two additional nurses, situated within the surgical field next to the patient. The rotating nurse will be responsible for several activities including the robot-specific activity of docking the robotic surgery platform to the patient bed. Attaching and situating the robot next to the patient is guided by the surgeon and is one of the first steps in a robotic case. The nurses within the surgical field may have varying levels of responsibility, depending on how that individual surgeon or hospital conducts robotic operations. The main assist, or PA, in the sterile field is responsible for the introduction of tools and robotic devices into the body cavity during surgery and may also control a laparoscopic grasper through an additional incision or 'assist port'. This 'assist port' may be used in certain procedures to provide support and tension to tissue, when needed, and assist in the manipulation of products within the body.

Step 3. Understanding the current approaches and technologies used: What is the current gold standard? What products are care providers using to treat patients and why are they selecting them?

Robotic platforms are constantly improving such that surgery is becoming less invasive, port sizes are getting smaller and companies are exploring technologies that may remove the need for an incision altogether. The desire to make surgery easier and minimise the chance of complications is at the heart of the growth in robotic technologies. It is also fundamental to any new product introduction that manufacturers are able to demonstrate to regulators and other stakeholders the effectiveness of their offering compared to currently available tools and techniques.

Step 4. Identifying and understanding the needs of all stakeholders: Who are the involved stakeholders in robotic surgery? How do they interact?

The added dimension of the robot as interface between surgeon and patient complicates the OR stakeholder interactions, but also opens up opportunity. Regardless of whether it is open, traditional laparoscopic or robotic, surgical goals are similar. You want to access the surgical site in question, perform the necessary steps to treat the problem in a minimally-intrusive manner, close up the access wound sites and prepare the patient for post-operative recovery. In each scenario you have a surgeon, an anaesthesiologist, several nurses and support staff. However, the presence of a robot adds an important new dimension - there are nuances to the workflow, staffing and training that may impact associated product needs. Meanwhile, the surgeon is remote from the patient and the robot is now patient-side. This may become a consideration to aspects such as tool exchange and introduction or response to complications which, in the extreme, may require converting to an open approach.

An exciting aspect of the new robotically-assisted OR is not just accommodating these practical differences, but capitalising on the new capabilities the robot can provide. Improved stability, dexterity, ease of access to otherwise awkward locations all have the potential to open up new procedural techniques and there would undoubtedly be consequences to the ancillary products that are needed in these cases.

Step 5. Understanding that you are developing against a moving target: How do you ensure that your project will still be relevant when it delivers?

The operative care environment can be a busy place. When it comes to providing care, there are numerous products available and, across providers and geographies, different policies in place. Combine with this, the pace of innovation and resulting surgical approaches emerging, it becomes increasingly important to clearly define the scope for any new research or development project and fully understand how the results will be employed for next-generation builds. Next-generation robotic platforms are likely to include machine learning and advanced intra-operative imaging capabilities allowing surgeons to detect risks and change surgical approaches in real time.

There are tools that can be used to combine contextual research with future market trends to help build a picture of the unmet needs of that future world. In a dynamic area such as this, adopting these kinds of techniques will help ensure current innovation efforts will address those future requirements.

4. A new horizon for medtech development

In summary, surgical robotics is here to stay and usage will continue to expand as the technology advances and surgeon adoption of these systems increases. All companies developing surgical products should consider the impact of robotics on their marketplace and the compatibility of their devices with robotic procedures. Surgical robotics should not be seen as a threat to the next generation of surgical devices, since the use of next generation devices alongside robots opens up new possibilities for improved approaches. However, targeted and organized development

pathways, which take into consideration the full set of stakeholders via VoC research programs, will be needed. Through optimising their products for use alongside surgical robots, many surgical device companies can contribute to the advances enabled by robotics.

How Sagentia can help

Sagentia's VoC research programs take a rigorous and detailed approach aimed at identifying specific user needs, including a thorough analysis of the considerations mentioned in this article. The needs are often not directly articulated and are teased out through a combination of observational research and probing interviews to generate insights. Each new insight is valuable and we use analysis methodologies which provide full traceability of user requirements back to the primary data. This also helps us to segment and prioritise the data using strategic development criteria. Our VoC research programs allow new product developments to be grounded on a rigorous and insightful analysis of stakeholder needs.

About Sagentia

Sagentia is a global science, product and technology development company. Our mission is to help companies maximise the value of their investments in R&D. We partner with clients in the consumer, industrial, medical and oil & gas sectors to help them understand the technology and market landscape, decide their future strategy, solve the complex science and technology challenges and deliver commercially successful products.

Sagentia employs over 150 scientists, engineers and market experts and is a Science Group company. Science Group provides independent advisory and leading-edge product development services focused on science and technology initiatives. It has six offices globally, two UK-based dedicated R&D innovation centres and more than 350 employees. Other Science Group companies include OTM Consulting, Oakland Innovation and Leatherhead Food Research.