A Robotic-Assisted Surgery (RAS) Review: Clinical Landscape, Commercial Arena, and Future Outlook

Full Report

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AliraHealth

HUNNIWELL LAKE VENTURES
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MassMEDIC
Massachusetts Medical Device Industry Council

Report Objectives

Source: Alira Health.

Key Questions Addressed in this Report

Clinical Landscape

- What are the **distinctions between traditional surgery and RAS** or other relevant clinical procedures?
- Which **products, technologies, and services** are employed in RAS? How are they changing the surgical workflow?
- What **procedures and techniques** use RAS the most? How is this expected to change in the next 5–10 years?

Market Landscape Demand Side

- What **key unmet needs** have historically limited the adoption of robotics? How is that changing?
- Who are the **clinical and non-clinical stakeholders** involved in the purchasing decision of a robotic surgical system? What are the **key drivers in the purchasing** decision?
- How will **reimbursement trends** impact RAS adoption now and in the future? Where applicable, do value-based contracts have an influence?

Market Landscape Supply Side

- How is the market defined? What is the **current market size** and how has it evolved in the last 5–10 years?
- What are the **key drivers and restraints**?
- Who are the **key competitors** and players in the current RAS space? What are their **key success factors** and lessons learned?
- How **does the pipeline look** and how it is expected to transform the market?
- What are the **current deals and trends**? What is the **appetite for investment in the market**?

Future Outlook

- **What functionalities do customers expect** in a RAS platform? What is required to lead the RAS market today?
- What are the **future trends in the RAS market**? Smart platforms/AI, operating systems, range of services?

Source: Alira Health.

Alira Health Methodology

Clinical primary interviews	**Over 50 qualitative interviews** across three clinical areas targeting general surgeons, urology surgeons and gynecology surgeons with minimum 10 years of experience. Interviews have been segmented on a mix of non-RAS users (30%) and RAS users (70%). Responses from more than **100 surveys** were collected from a range of surgeons across specialties.
Voice of the industry	Surveyed **global business leaders in the RAS ecosystem** about ongoing competitive trends impacting strategies, customer engagement models, success, and risk drivers.
Market analysis	**Investigated the field of application and technology** to analyze the overall RAS market.
Deals landscape	**Analyzed M&A and funding deals**, investigating competition across key geographies and the latest acquisitions by established players.

Source: Alira Health.

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Key Takeaways on RAS Current and Upcoming Landscape

Key Takeaways

Technology complexity, physician hesitancy, and high costs limit RAS adoption.

Among others, upfront costs and access are the strongest barriers to RAS adoption. These barriers differ across procedures and settings, creating an uneven level of RAS adoption across the market.

- Today, adoption is highest in well-funded providers with high surgical volumes such as academic hospitals.
- Adoption in other high-volume providers, which today remain limited by funding and access barriers, could be unlocked with more affordable business and pricing models that facilitate adoption.
- Smaller settings are often prevented from acquiring robotics platforms due to low procedural volume and the inability to overcome a steep learning curve.

Across clinical conditions, laparoscopy has the highest RAS penetration today.

- Laparoscopic adoption varies by application, due to differences in clinical fit and ergonomic and anatomic complexity.
- In the future, endoluminal, percutaneous and radiosurgery are three promising areas where robots could make the difference by increasing the accuracy and consistency during the surgical procedures.

The RAS market is projected grow from $7B in 2021 to $20B by 2030, a 13% CAGR.

- The number of deals in the RAS space has constantly grown over the last few years – large MedTech players are entering the market or strengthening their position with new acquisitions.
- At the same time, well-established players are expanding their portfolio of services and building a completely new ecosystem for RAS by acquiring AI and imaging navigation companies, among other technologies.

Source: Alira Health analysis.

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Robotic-Assisted Surgery at-a-Glance

RAS at-a-Glance

Robotic-assisted surgery provides a number of benefits to both surgeons and patients, such as improved ergonomics, precision and dexterity. On the other hand, lack of haptic feedback and learning curves remain the limitations of such technology.

Definition

- **RAS** is an advanced form of minimally invasive surgery that makes use of computer-controlled machinery to assist surgeons with tasks they could not do otherwise or improve tasks they previously performed
- **Surgical robots** empower clinicians by bringing innovative technology into the operating room to **enhance precision, accuracy, and flexibility over traditional open procedures.**
- These robots assist in a range of surgical activities, from **enhancing visualization** through **3-D cameras**, to **suturing** and **operating within complex anatomies**.
- Depending on the level of autonomy of the system, the **surgeon retains a variable amount of control on several robotic instruments**, which he/she monitors and operates via the surgeon console.

Patient Outcomes

- **RAS[1] helps to achieve better patient outcomes** by reducing scarring, pain, risk of infection and recovery time[2].
- **Fewer complications** occur during the procedure resulting in fewer patient revisits post-operatively.

Robotic-assisted Surgery

Benefits

- Minimal Invasiveness
- Visual Control
- Precision
- Tremor Elimination
- Surgeon Comfort
- Dexterity and Flexibility

Challenges

- Low Haptic Feedback
- Quality of the Internet Connection for Telesurgery
- Constant Maintenance
- Complex and Long Training

Note: [1]Robotic-Assisted Surgery; [2]Not enough studies have been conducted to be clinically proven.

Source: Alira Health analysis.

Robotic Platforms Classification by Degree of Autonomy

RAS at-a-Glance

Robots are classified based on their degree of autonomy, ranging from passive to active devices. Master-slave robots are the most established technology so far, where Intuitive Surgical's da Vinci is used to perform most robotic-assisted procedures.

Robotic Surgical System Platform Classification

Increasing Degree of Autonomy

Passive

- Passive robots **provide support actions** in surgery and **do not perform any autonomous** or active actions. Rather, they are **continuously controlled by the surgeon** at the patient's bedside and may provide visualization and hold a tool.

MONARCH

Master-Slave

- Master-slave robots are **controlled by the surgeon** who directs the interaction between the surgical (slave) robot and soft tissues using the surgeon console, and as such, can perform surgical tasks remotely.
- **The vast majority of procedures are currently performed with this technology.**

da Vinci

Semi-Active

- Semi-active robots **perform some autonomous functions** and **provide surgical assistance, based on a pre-operative plan**, the surgeon's direct oversight, and direction as to what task is to be completed.

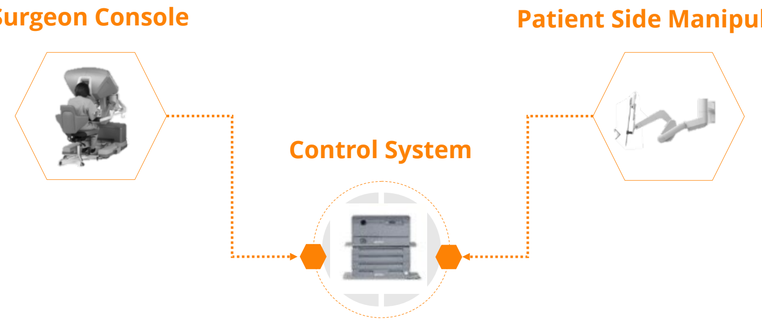
MAKO

Active

- Active robots exhibit **autonomous behaviour** and **operate without direct interaction** with the surgeon.

CyberKnife

Set-Up in a Master-Slave Robotic Surgical Operating Room



- The computerized control system acts as an **extension of the surgeon's movements into the surgical field by transmitting video images from the endoscopic camera to the stereo viewer** of the console and transmitting the surgeon's hand motions—measured by the master interfaces—to the slave manipulators.
- Since this is an electronic link, the software of **the control system can modify the signals** to filter out the surgeon's normal physiological tremor, or to scale down their motions for **enhanced precision.**
- Another feature of the master-slave systems is the ability to **mimic and enhance the degree of freedom compared to the human wrist.**

Source: Moustris *et al* (2011); Alira Health analysis.

Technology Generations Advancements

RAS at-a-Glance

Currently, endoscopic robots, such as the da Vinci, are the most common type. Further technology advancements are expected to drive expansion in novel applications, such as single-port surgery or transluminal endoscopic surgery.

Technology generations

1st Generation Stereotaxic Robots

The first surgical robot in clinical practice was the **PUMA 200**, first utilized for stereotaxic brain biopsy with the surgeon placing the arms of the robot in a position to perform its task. The robotic technology at the time **required human surgical review at the end of every step** of robotic-assisted surgery and **robots could not perform multiple sequential tasks on human subjects unsupervised**.

2nd Generation Endoscopic Robots

The introduction of the second generation of surgical robots (1998-2000) has resulted in the **greatest expansion of the concept of RAS to date**, driven by the market-need for highly precise robotic surgical systems that can augment the established MIS surgical technology by building on established stereo-endoscopic platforms, such as laparoscopy or thoracoscopy. As these **second-generation platforms are the most widespread and established platforms in current clinical use** (e.g., da Vinci), they are the platforms on to which many novel technological innovations are currently being built.

3rd Generation Bioinspired Robots

During the development and evolution of second-generation robots, MIS and endoscopic methodologies began adopting **bioinspired technologies**. In endoscopy, the **NOTES (Natural Orifice Transluminal Endoscopic Surgery) platform developed from a predilection for scarless surgery.** On the other hand, MIS surgery wanted to innovate to even less surgical exposure impact, so that **multiple MIS ports were transformed into one-port SPL (Single-port laparoscopy)**. The third generation of surgical robots has **adopted principles of biomimicry and multiple articulation technology** for multiple surgical pathologies.

Source: H. Ashrafian et al. (2017); Alira Health analysis.

Robotic Platforms' Entry Specifics to Ensure Competitive Parity

RAS at-a-Glance

In order to be competitive in the market, robotic platforms need to provide some minimum features. Among others, 3-D vision and full articulation emerge as the most relevant.

3-D Vision

Conventional **laparoscopy is limited to two-dimensional vision**. Targeting tissues requires making inferences about spatial relationships, and mini "trial" movements to confirm or refute these inferences.
In **RAS** surgery, **to create a three-dimensional or stereoscopic image, two slightly separated lenses or "chip-on-a-tip" technologies** are used.

Full Articulation

In **RAS**, the platform arms imitate the normal wrist and elbow motion, with the **capability of spinning two full revolutions.**

Image Brightness

In **RAS**, the image is sent from the endoscope tip electronically **without loss of light** by optics throughout the scope.

Ergonomics

In **RAS**, the surgeon can **choose to sit or stand comfortably at a console**. The hands are positioned in a natural forward position, and the forearms are given a rest to lean on.

Motion Scaling

In standard **laparoscopy**, distance of the tissue structure from the port site on the abdomen causes **amplification of motion at the instrument tip**. A small motion outside the body causes a relatively large motion on the inside.
In **RAS**, **motions are filtered and de-amplified up to a scale of 5 to 1.**

Visual Magnification

In RAS, images are magnified up to 10 to 15 times the actual measurement. This allows the surgeon to be more selective about the dissection of critical structures by fractions of a millimeter.

Source: RAS; M. Fujie et al. (2020); Alira Health analysis.

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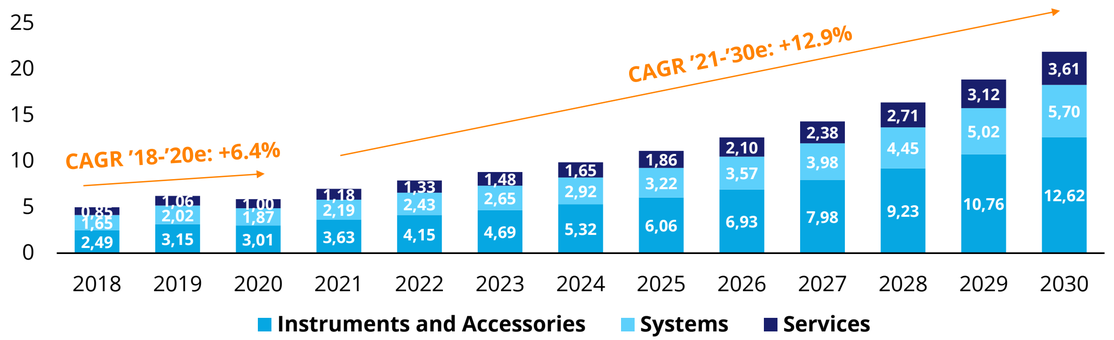
RAS Market Expecting Double-Digit Growth in Next Decade

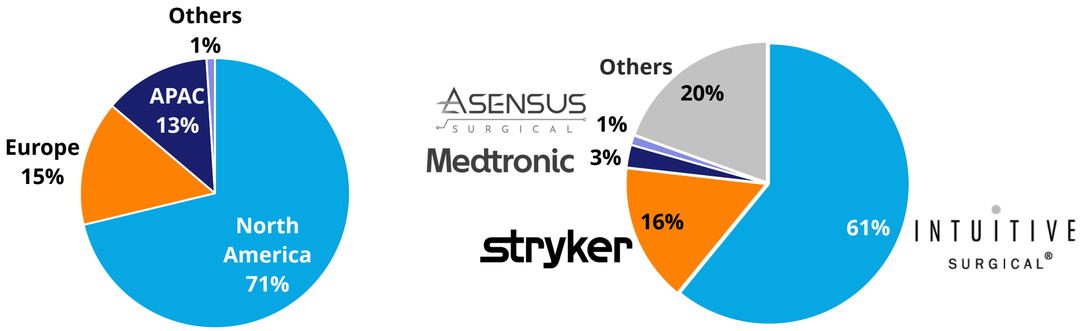
RAS Market Overview

The RAS market was valued at ~$5B in 2018, with North America being the key market where a few incumbent players hold the majority of the shares. The market is expected to grow at ~13% (CAGR '21-'30e) and to reach more than ~$22B by 2030.

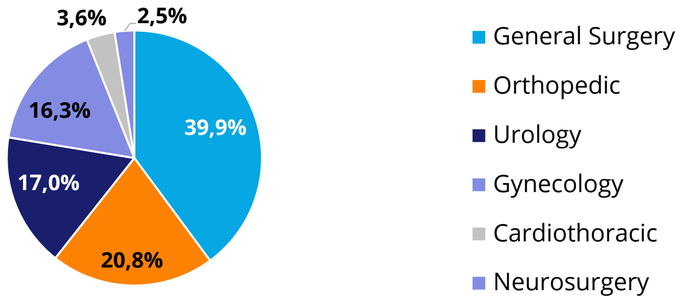
Global RAS Market Size 2018-2030 ($B)



Global RAS Market Size by Region and Key Players (2020)



Global RAS Market Size by Application (2020)



- The **global robotic surgical systems market** was valued at **$4.99B in 2018** and is expected to grow at a CAGR of ~12% from 2018 to 2030, to **reach $21.92B in 2030.**
- **General surgery is the largest segment** with **~40%** of the market and is expected to retain the largest market share in the projected forecast.
- **North America had the largest global market share** in 2020, with the **US contributing ~90%** to the North American share. The market is expected to exhibit the fastest growth is the **EU-5 market, with a CAGR of ~18%.**
- The market is an oligopoly in many segments, in which the competition is high. **Intuitive Surgical holds the majority of the market share, with 61% share,** with the second closest payer being **Stryker, holding 16%.** The **majority of companies hold less than 1%** each of the market.

Note: Market consensus on an overall expected growth rate of the RAS market between 10% to 20%.

Source: GlobalData (2020); Other Alira Health proprietary sources; Alira Health analysis.

Consumables' Growth Contributing to the Overall Market Size

RAS Market Overview

Instruments and accessories are the main sources of revenues, accounting for over 50% of the total robotic market size. By 2030, revenues coming from the system sales and services will lose another combined 6%, increasing consumables' share accordingly.

SYSTEMS

Definition

Systems are the **most complex part** of the surgical robots, including software and hardware components. They enable the surgeon to remotely use and control the robotic arms. Most systems are made of **few key components: surgeon console, robotic arms, patient cart, and vision cart**.

Components

- **Robotic Arms**
- **Surgical Console**
- **Patient Cart**
- **Vision Cart**

INSTRUMENTS AND ACCESSORIES

Definition

Instruments and accessories play an integral part of the robotic systems, including **equipment and software** that help surgeons to perform safe, precise, and accurate surgical procedures.

Components[1]

- **Scissors**
- **Dissectors**
- **Trocars**
- **Graspers and Forceps**
- **Drilling and Cutting Equipment**

SERVICES

Definition

Regular service and maintenance of the surgical robotic systems, along with an upgrade of the software, are extremely necessary in order to maintain the required operating characteristics of the system and furthermore, to ensure that the surgical procedures are performed safely and accurately.

Components[1]

- **24/7 Support**
- **Repair**
- **Installation and Maintenance**
- **Training**

Note: [1] Non-Exhaustive list.

Source: Alira Health proprietary sources; Alira Health analysis.

Share of the total market size for 2020

Share of the total market size for 2030

Access and Complexity Are Active Obstacles to Adoption

RAS Market Overview

Barriers to RAS adoption and current unmet needs can be grouped into three main categories: technology, physicians, and hospital related. The significant Total Cost of Ownership (TCO) and lack of reimbursement has the highest impact on adoption.

TECHNOLOGY

Currently, available robotic solutions are extremely **complex, have a large footprint, and have high capital equipment costs**. There is the need for more compact and affordable solutions, allowing small and medium centers to access these technologies easily, without the need of redesigning the Operating Room (OR).

- **High degree of complexity**
- **Need for more compact and mobile systems**
- **Availability of affordable robots**

PHYSICIANS

Before operating on a patient, the team must undergo **extensive training and get comfortable with the absence (or significant reduction) of tactile cues and kinesthetic signals**. During the procedure, it is also challenging for the primary surgeon at the non-sterile console to communicate with the OR Team.

- **Steep learning curve & Lack of academic training**
- **Limited clinical evidences**
- **Poor communications in the OR**
- **Lack of haptic feedback**

HOSPITAL

The **significant upfront investment, as well as the procedure cost, not usually compensated adequately by reimbursement**, limit the adoption of surgical robots in low-reimbursement procedures and small facilities.

Frequently, robotic devices are shared between departments and ORs, creating limited access (only a few days per week) and longer waiting lists for surgeons to operate.

- **High TCO (Total Cost of Ownership)**
- **Lack of reimbursement**
- **Limited availability and access**
- **Limited clinical evidences**

Impact on Adoption

TECHNOLOGY	PHYSICIANS	HOSPITAL
MODERATE	MODERATE	VERY HIGH

Source: Nodus.com; TheRobotReport.com; Interdisciplinary Discussion Chaired by Andreas Kirshniak (2018); Feussner et al. (2018); Jayne et al. (2017); BAUS (2015); Kostakis et al. (2019); Cole at al. (2018); HTA reports; Alira Health analysis.

Future Market Dynamics Guided by Emerging Trends

RAS Market Overview

Increase the adoption of advanced technology, the entrance of new players in the market and consequent price pressure, as well as the expansion of RAS clinical applications, are trends forecasted to support the expansion of the market in the near future.

Entrance of new players in the market

- **A few new companies** are expected to enter the robotic surgical systems market with their platforms
- Currently, there are over **100+ companies with products in development**, and this number is expected to grow in the coming years
- More competition is expected to **shape the market, opening space for lower-priced robotic surgical systems and/or novel business models that will increase affordability**

Expansion of RAS procedure breadth

- As new products are expected to be introduced into the market, the **procedural capabilities of these systems will increase** and therefore, a higher number of surgical interventions will be carried out with these systems across different indications.
- An **emerging market for surgical robots is minimally invasive microsurgery**, in which robots will be used to harvest nerves and place grafts with limited scarring.

Complementary use of preoperative planning

- Preoperative planning can be a **crucial step in the RAS workflow** since it allows for a reduction of risk factors and brings attention to expected complications that may occur, leading towards precision and personalized medicine.
- Surgical planning is **a growing trend**, especially in orthopedic surgery.

Shift from inpatient to outpatient settings

- Procedures have **been shifting to outpatient settings and Ambulatory Surgical Centers**[1] (ASCs), facilities with less buying power compared to hospitals.
- Features, such as **portability, modular assembly and a lower-price** may create versatility and increase opportunity.

Increased adoption of advanced technology

- **Advanced technology**, as artificial intelligence, **promotes more capabilities for surgeons;** therefore, it is expected to have a significant expansion.
- **Increased haptic feedback, artificial intelligence, augmented reality, and a reduced equipment size,** are expected to be some of the key technological trends.

Future Outlook

Entrance of new players in the market	Expansion of RAS procedure breadth	Complementary use of preoperative planning	Shift from inpatient to outpatient settings	Increased adoption of advanced technology
VERY HIGH	HIGH	HIGH	MODERATE	MODERATE

Note: [1]Specifically for the US market.

Source: Global Data (2018); Advisory Board (2019); Intuitive Surgical (2020); Alira Health analysis.

Expert Q&A: Robotic, Data, and Microsurgery

RAS Market Overview

Biography

Giuseppe Prisco
Board Member & Co-Founder

Giuseppe Maria Prisco is an experienced healthtech executive and co-founder of Medical Microinstruments (MMI) S.p.A.

Previously he was Managing Principal at Intuitive Surgical, leading development projects with yearly budgets in the $5M range for products with $~1B market potential.

He invented and brought to market the da Vinci Single Site product offering for single port surgery.

He has 15 years of experience as individual technical contributor to robotics products such as the 6 axis Adept Robot and the daVinci surgical robot. He holds 27 patents and 63 published patent applications in the fields of controls, robotics, endoscopy, and surgery.

Company Background

MMI is a privately held company dedicated to advancing the future of micro-surgery. The company was founded in 2015 by Massimiliano Simi, Giuseppe Prisco, and Hannah Teichmann committed to improving the quality of patient care by pushing the boundaries of microsurgery. **In October 2020**, **its Symani robotic system received the CE mark** for open microsurgical procedures.

Symani provides microsurgeons with the next level of motion scaling and precision in a range of open surgery procedures.

Symani is equipped with the NanoWrist instruments, that **enable seamless suturing under the operating microscope, thanks to their tiny 3mm diameter.**

Q&A

What are the current and future markets for RAS?

Currently the market can be divided into four main segments:

- **Laparoscopy**, which is currently the biggest market;
- **Orthopedics**, with smaller volume compared to laparoscopy but **better clinical evidence**;
- **Spinal surgery**, especially for screws positioning;
- **Specialty robots, not overlapping the classic laparoscopy** field of application, potentially covering all the possible procedures within the body (e.g., ophthalmic, vascular and bronchial applications)

In the coming years, **new key areas will be microsurgery, endoluminal, and ophthalmology.**

Which technology innovations do you expect to see in the market in the next few years?

Data and artificial intelligence will play a central role in the coming years. AI will help to analyze pre- and intra-operative data to **offer real-time insights to the surgeon on "where and how" to proceed.**

Even if there are not robust evidence of the added value yet, **procedure automation** will play an important role for high volume and low complexity procedures.

How are MMI and platform positioning in the market? Why is this positioning unique?

Symani is a **robotic system for microsurgery and supermicrosurgery** designed to operate in delicate structures. With Symani, surgeons can perform suturing, ligation, anastomoses, and coaptations on small anatomical structures such as blood vessels, nerves, and lymphatic ducts. **The system features 7-20X motion scaling with tremor filtration, combined with the use of a microscope, allows the surgeon the operate in a very natural and fluid manner.**

The platform can fully function with both traditional and digital microscope, with a **future possibility of having video enhancement** on the digital ones.

Source: Industry experts interviews.

Expert Q&A: Evolution of RAS

RAS Market Overview

Biography

Michael Pereira
Chief Strategy and Technology Officer

Michael Pereira has more than 25 years of medical device product development and manufacturing experience.
As Ximedica's Chief Strategy & Technology Officer, he helps clients shape the right mix of business, technology, and portfolio needs while working with them to create superior products.
During his career, he has been involved in the development of hundreds of medical, diagnostic, drug delivery, and consumer products in a variety of roles, including lead engineer, program manager, and head of program management and engineering.

Company Background

Ximedica is a provider of integrated product development services designed to focus on bringing medical and diagnostics technologies to market launch.

The Company offers devices and systems design and development services that utilize a human-centered, vertically integrated process creating greater efficiencies in how products are designed, approved, manufactured, and ultimately delivered and provides value to customers through decreasing development risk and expediting the time to market, enabling businesses to improve outcomes, enhance lives, and successfully advance their business strategies.

Q&A

What are the types of robots we can currently find in the market and how will the future generations of surgical robots differ?

Most of today's robots can be divided into **two main categories: generalist and indication-specific robots.**
Indication-specific robots are more flexible and do not require redesigning the OR. **The next generation will be data-based**, the acquisition and usage of data will be the real value, more than the robot itself.
A further step will be to **rethink the surgical approach based on the robot's capabilities, redefining the procedure from the ground up.**

What benefits do you think the usage of data will bring?

Data will play a central role during all processes, but it will **be key during preplanning and to assess the margin and the quality of the intervention.**
Data usage will **decrease the learning curve, enabling more surgeons to perform complex procedures** without the need of doing hundreds of them.

Do you see other possible usage of robotics in the medical/surgery ecosystem?

Once the RAS device will be fully integrated with the OR ecosystem, there **are good possibilities of using secondary/support robots.**
Nurse robots or support for the main surgeon will always become more frequent, as the **usage of robots during the sterilization and instrument position process.**

Source: Industry experts interviews.

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Takeaways on the RAS Market Overview

Key Takeaways

The adoption of robotic surgical systems provides several **benefits to both surgeons and patients**, such as improved ergonomics, and improved precision and dexterity. Companies are still working to improve the user experience for the surgeon trying to **implement the haptic feedback and reduce the learning curve.**

The current robotic systems' **classification is based on their degree of autonomy**, ranging from passive to active devices. **Master-slave robots are the most established type**, where Intuitive Surgical's da Vinci is the leader and benefits from a first-mover advantage. **In the coming years**, technology advancements are expected to drive expansion in **novel applications, such as single-port surgery or transluminal endoscopic surgery.**

The RAS market is **expected to grow at approximately 13% (CAGR '21-'30e), reaching more than $20B by 2030**. Today, **instruments and accessories** are the main sources of revenues, accounting for **over 50% of the total robotic market size**. **By 2030**, revenues coming from system sales and services will lose another combined 6%, **increasing the consumables share accordingly.**

The current **barriers** holding the adoption of robotic surgical systems can be **grouped into three main categories: technology, physicians, and hospitals.** Among physicians-related barriers, a steep learning curve, the lack of academic training, and the little clinical evidences available today are the most relevant. Overall, the high total cost of ownership and the lack of reimbursement are the main factors limiting the purchase of robotic surgical systems, especially in small and medium-sized hospitals.

The entrance of new players in the market and the adoption of advanced technology, **lowering the cost of the systems**, will further drive the expansion of RAS clinical applications and support the **expansion of the RAS market** in the future.

Source: Alira Health analysis.

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Overview of the Laparoscopic Surgical Approach

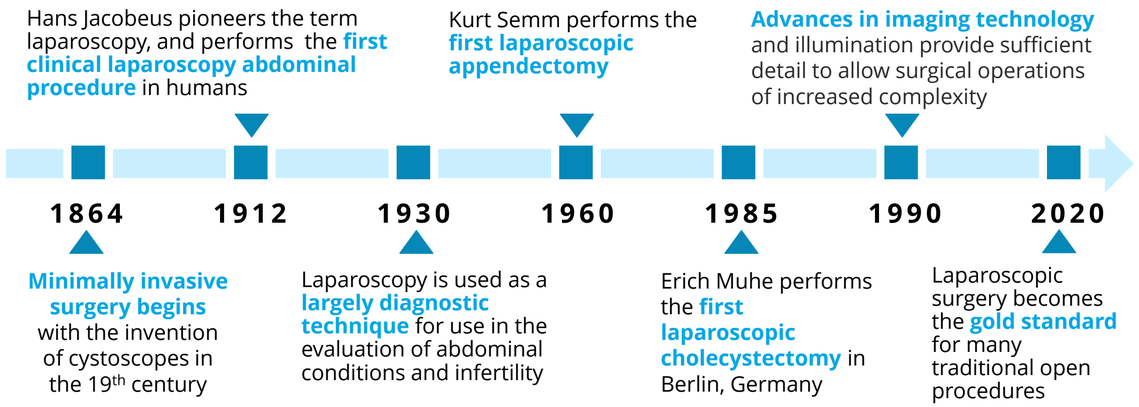
Clinical Approaches and Applications

Laparoscopic surgery allows surgeons to perform minimally invasive procedures intra-abdominally, thus reducing post-operative pain and shortening recovery time. Laparoscopy is mostly performed in general, gynecology, and urology surgery procedures.

Laparoscopic Surgery Overview

- Laparoscopy is a **minimally invasive alternative to open surgery** that enables the examination and treatment of abdominal and pelvic organs and tissues through various small incisions in the abdomen.
- During laparoscopic surgery, a **surgeon inserts a trocar**, a short, narrow tube into the abdomen, **through a small incision**. Specialized instruments and a special camera, known as the laparoscope, are then passed through the trocar, allowing the surgeon to **see the abdominal cavity in HD vision, and perform surgery.**
- **Globally**, **~15 million laparoscopic procedures are performed annually**, with 30% of those being in the United States.

History of Laparoscopic Surgery



Commonly Performed Procedures

Numerous intra-abdominal surgeries are performed laparoscopically due to decreased post-operative pain and shortened hospitalization and recovery times.

Procedure	Description
Laparoscopic Cholecystectomy	Laparoscopic cholecystectomy is the **most performed laparoscopic general surgery procedure**. Patients undergoing this procedure often have signs of **biliary tract infections, or gallstones**. Other commonly performed laparoscopic general surgeries include appendectomy, bowel resection, inguinal hernia repair, and other biliary tract and gastrointestinal procedures.
Hysterectomy	Laparoscopic-assisted **hysterectomy surgery is partially completed with a laparoscope**, and the remainder of the operation (vaginal incision, excision of cervical tissues) is **completed transvaginally**. A total laparoscopic hysterectomy is performed entirely using the laparoscope, and the surgical specimen is removed via the vagina.
Prostatectomy	Laparoscopy has become the **approach of choice for many surgical procedures on the urologic system**, including total and partial nephrectomy, and prostatectomy. Laparoscopic radical prostatectomy is a minimally invasive surgery procedure used to **remove a patient's cancerous prostate**. The surgeon makes five small incisions as opposed to one large one to perform the surgery.

Source: US National Library of Medicine (2020); American Society of Colon & Rectal Surgeons (2020); The American College of Surgeons;

RAS Shows the Highest Penetration in Laparoscopy vs. Other Approaches

Clinical Approaches and Applications

Robotic-assisted laparoscopy combines the benefits of minimally invasive surgery with the increased visualization and dexterity provided by robotic platforms. Robotic-assisted laparoscopy has the highest market penetration of all other surgical approaches.

Robotic Laparoscopic Surgery

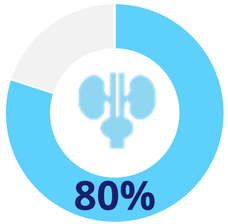
- **Robotic laparoscopic surgery is similar to traditional laparoscopic surgery** in many aspects: the surgeon makes **several small incisions** and **uses a video camera** and instruments to guide his or her work. However, while in traditional laparoscopic procedures the surgeon remains at the patient's bedside, **during robotic laparoscopic surgery, the surgeon sits at a computer console and uses hand controls to operate the surgical instruments.**
- Robotic-assisted laparoscopic procedures are **performed by an experienced laparoscopic team**, in which the surgeon watches and operates on the surgical field remotely.

Robot Technology

- The **current robots** used to perform these surgeries are either **master-slave or passive**, in which the surgeon is in direct control of the system. These systems **allow for the benefits of minimally invasive surgery, while enhancing dexterity, flexibility, and the surgeon's range of motion**.
- An advantage of robotic-assisted laparoscopy compared with traditional laparoscopic surgery is **that the instruments used in RAS are "wristed", with fully rotational capabilities,** giving the surgeon a human hand-like sensation. This in turn provides a **greater range of motion than traditional laparoscopic instruments**.
- Robotic-assisted minimally invasive surgery was first introduced to the medical device world by **Intuitive's da Vinci** robotic surgical system**. Robotic surgical systems have seen their largest use in similar indications to that of laparoscopy**, such as general surgery procedures, gynecology, and urology.

- Surgical robots aim to address the limitations of traditional laparoscopy by providing **wristed instruments** with tremor filtration.
- 3-D HD equipment allow for **higher quality visualization** and **increased access to tissues** that were not otherwise possible with traditional techniques.

- There is a **lack of haptic feedback.**
- The high **variability of abdominal surgeries** require an advanced surgical skillset.
- **There are no clinically demonstrated benefits** over traditional laparoscopy.



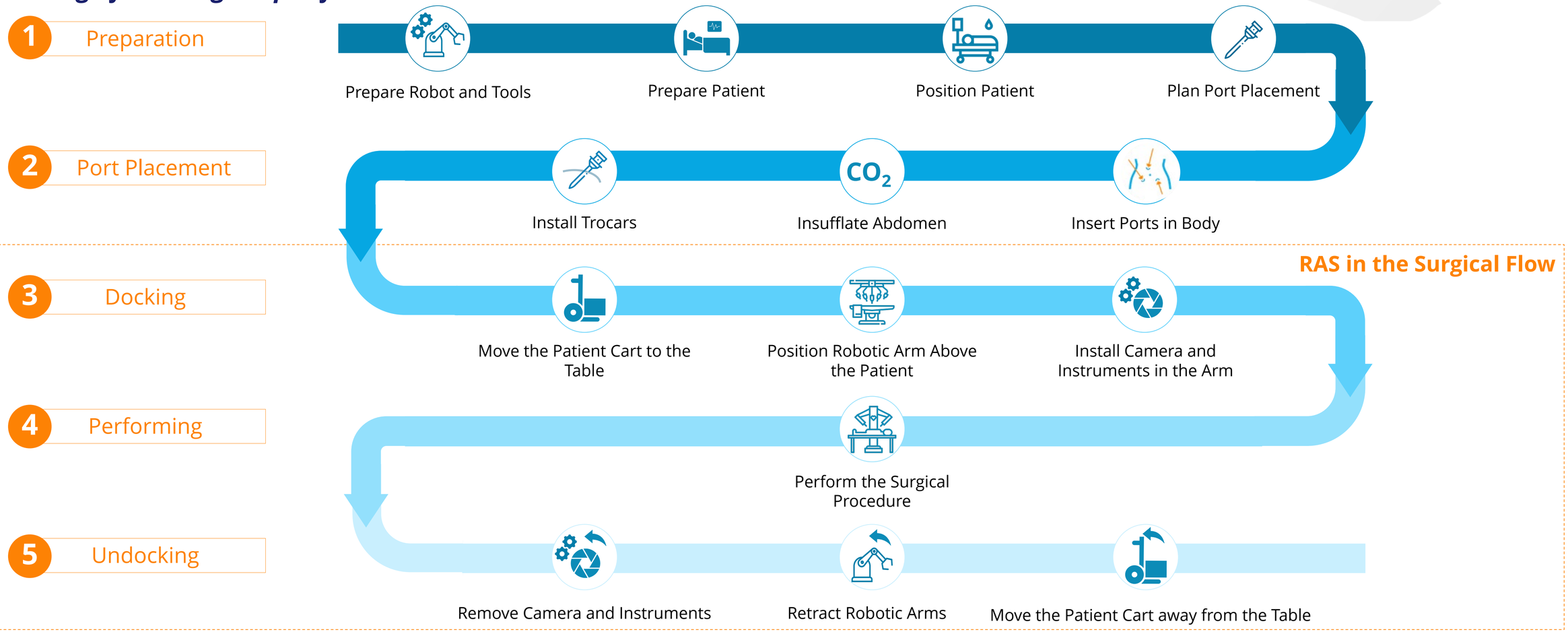
Currently, RAS penetration is highest in laparoscopic procedures due to the clinically proven benefit in **radical prostatectomy** surgery, where more than 80% of surgeries are performed using surgical robots.

Source: Wilensky (2016); Zakhari *et al* (2015); American Journal of Obstetrics and Gynecology; Alira Health analysis.

RAS Adds Two Steps to the Traditional Laparoscopy Workflow

Clinical Approaches and Applications

RAS does not overturn the traditional laparoscopy workflow, but it adds two steps related to the operation of the docking and undocking of the surgical platform.



Note: Illustrative workflow. Source: S. Cunningham et al. (2020); Alira Health analysis.

Within Laparoscopy, Single-Port Platforms are Expected to Gain Traction

Clinical Approaches and Applications

Single-port laparoscopy robots, despite their complex structural design, may be increasingly used due to low consumption of consumables and reduced patient trauma.

Multi-Port Laparoscopy Robots (MPLRs)

A multi-port surgical robot needs at least **four holes in the human body** to achieve the insertion of all instruments, including both endoscopic and robotic arms during an operation.

Advantages

- Minimal Invasiveness
- High Immersion
- High Accuracy
- Force Feedback
- Short Recovery Period

Disadvantages

- Multiple Wound Openings
- Limited Field of View
- Complex Control System
- Collides with Organ

Single-Port Laparoscopy Robots (SPLRs)

A single-hole surgical robot only **needs to open one hole in the human body** to achieve the insertion of all instruments, including both endoscopic and robotic arms, during an operation.

Advantages

- Minimal Invasiveness
- High Immersion
- High Accuracy
- Force Feedback
- Short Recovery Period
- Less Consumables
- Reduced Trauma

Disadvantages

- Multiple Wound Openings
- Limited Field of View
- Complex Control System
- Collides with Organ

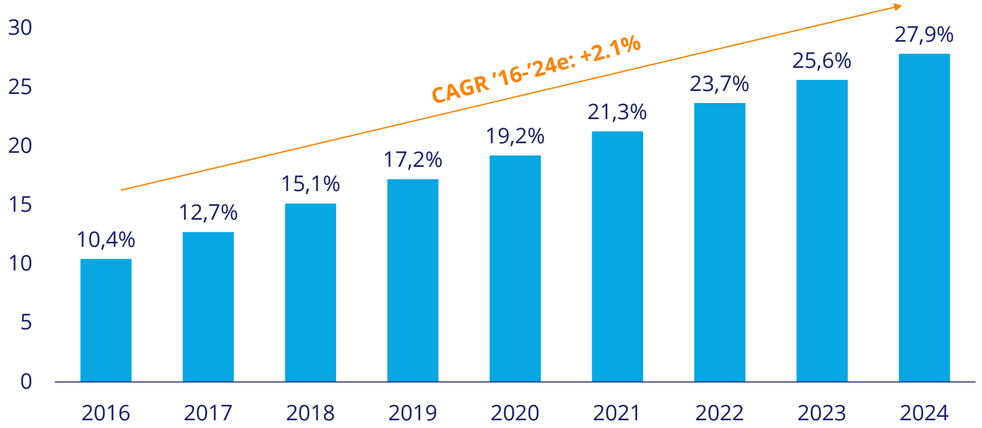
Source: M. Fujie et al.(2020); Alira Health analysis.

Adoption Rate for RAS in the Current Biggest Market: US

Clinical Approaches and Applications

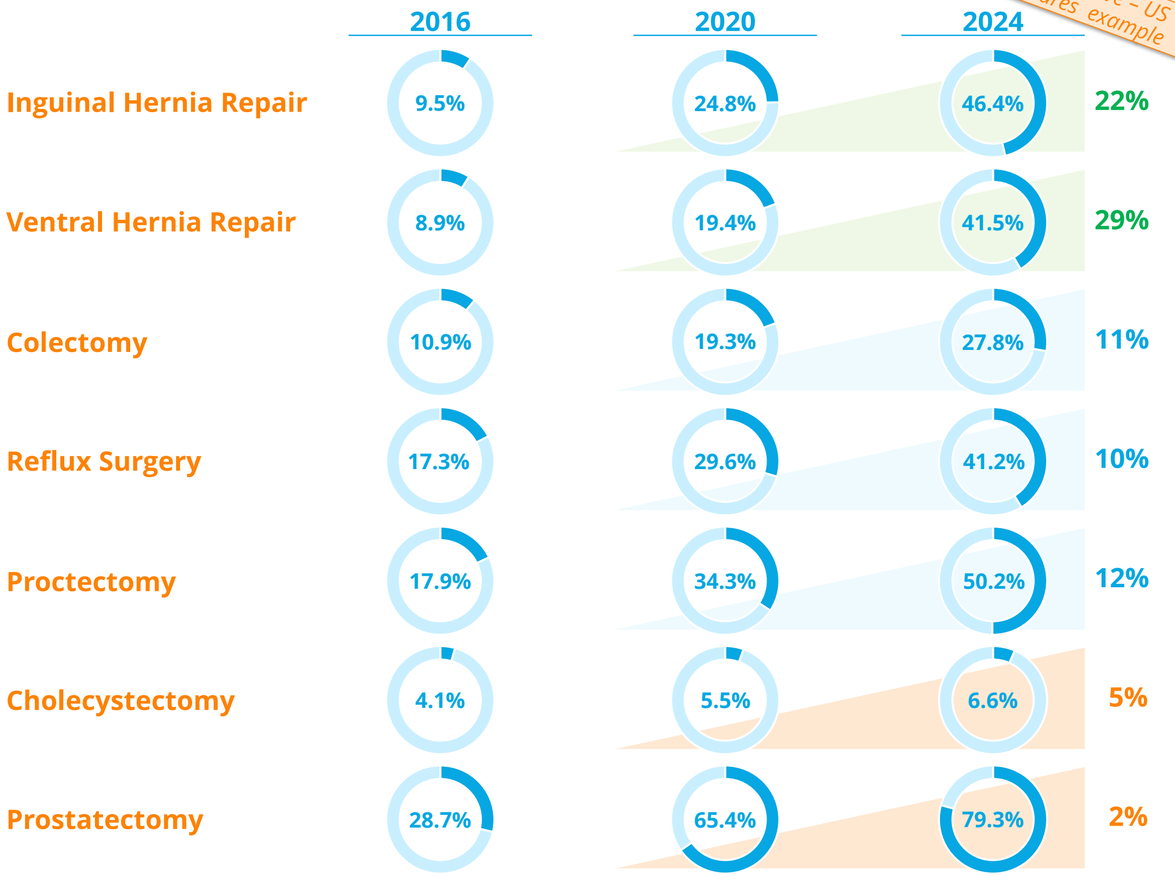
The U.S represents the biggest market for RAS with over 850k procedures performed annually. Currently, prostatectomy has the highest adoption rate followed by hernia repair, which will see the highest growth in the coming years.

Adoption Rate for RAS in the US Across all the Procedures



- **In the US**, during 2020, **over 850K procedures** were performed using surgical robots
- Currently, in **prostatectomy,** RAS has the **highest adoption rate, and will likely reach 80% by 2024**
- In the following years, RAS adoption in **hernia repair will experience the highest growth** across all the different types of procedures

Illustrative – US shares example



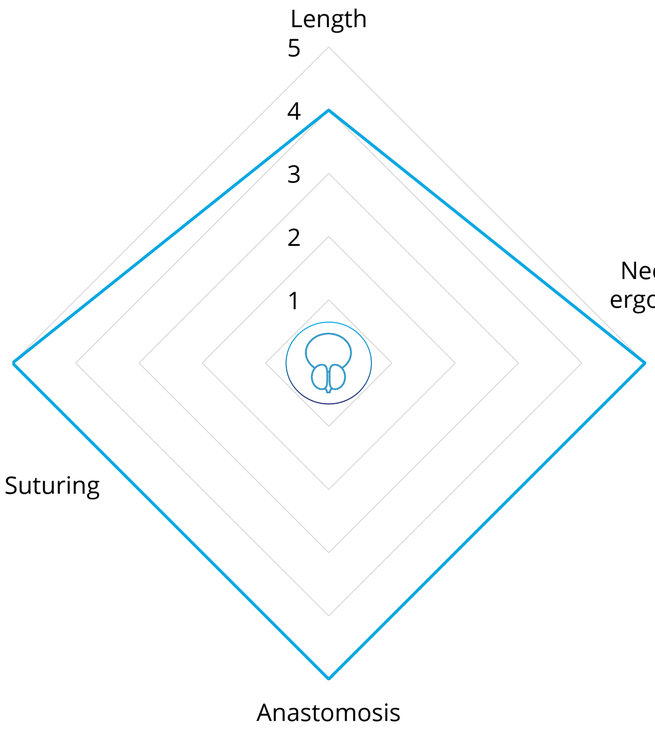
Source: K. Sheetz et al. (2020); Other Alira Health proprietary sources; Alira Health analysis.

RAS Use Case: Prostatectomy, the Highest Adoption Procedure

Clinical Approaches and Applications

Despite the lack of clinical evidence of superior clinical outcomes, RAS is widely used in prostatectomy due to the benefits it offers the surgeon during the procedure, including improved ergonomic, precision and camera control.

Clinical Use Case Assessment



Length: **Med-High**

Length of the surgical procedure goes from low (below 1h) to high (> 5 or 7 hours). The highest the length the highest the RAS fit.

Need for ergonomic: **High**

Need for ergonomic is low on simple anatomies (e.g., cholecystectomy) and high in complex and delicate ones (e.g., prostatectomy). The highest the need for ergonomic the highest the RAS fit.

Anastomosis: **Is a key step**

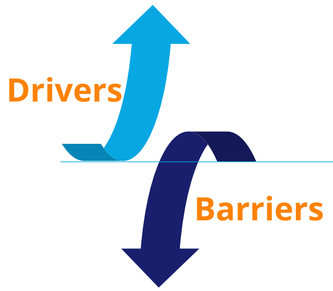
Anastomosis is one of the surgical steps where RAS can add value by bringing increased precision and accuracy. RAS has a better fit in procedures where anastomosis is a key step.

Suturing: **Is a key step**

Suturing is one of the surgical steps where RAS can add value by bringing increased precision and accuracy. RAS has a better fit in procedures where suturing is a key step.

Robotic fit score: 4.75/5

- **Ergonomic is a key unmet need in prostatectomy** due to operative times that can last from 2 to 3 hours, combined with the position that surgeon must maintain while operating on complex anatomies.
- Prostatectomies are performed deep in the pelvis and require **careful suturing in a confined space**; the difficulty is amplified when nerve-sparing procedures or anastomoses are performed. In addition, **dissection of the vascular system** surrounding the prostate is demanding and the risk of bleeding is high.
- The **tools** operate in a very narrow space and **cannot move laterally** without compromising the procedure, thus **robotic control is highly appreciated.**
- Robotic-assisted prostatectomy is the **only robotic procedure to be recognized as a differential reimbursement compared to traditional laparoscopy**, although in few geographies only.



- **Barriers to RAS adoption** in prostatectomies are also **common to other procedures** and relate to:
  - **Low procedure volumes** in smaller centers, which make it **challenging for surgeons to overcome the learning curve**
  - **High Total Cost of Ownership**, which often includes a significant upfront investment and an overall increase average cost of the procedure, especially in the case of small volumes

Note: Chart scoring goes from 1 = Low to 5 = High for each parameter. The fit score is calculated as the simple average of the scores for each criteria.

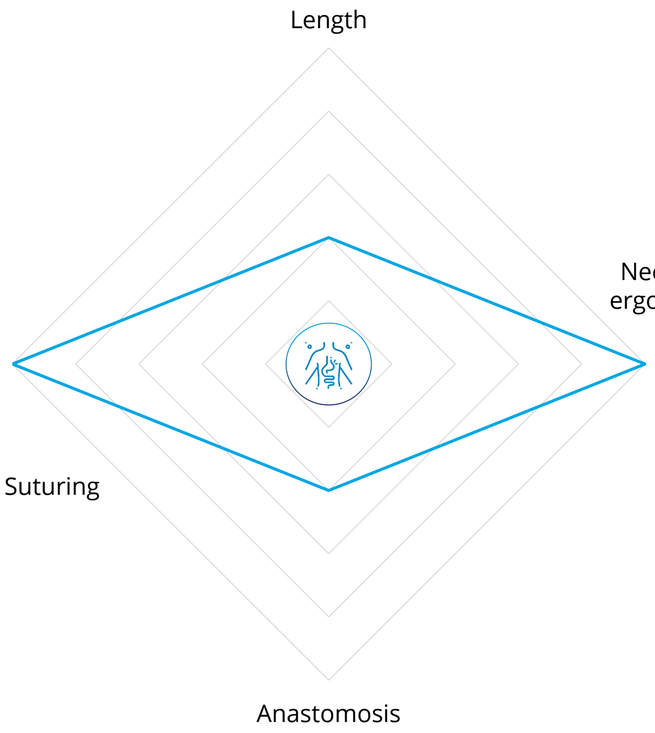
Source: Alira Health analysis based on primary interviews and internal experts.

RAS Use Case: Hernia Repair in the US, the Power of Marketing

Clinical Approaches and Applications

Obesity and a sedentary lifestyle are contributing to the growth of hernia procedures and consequently to the ones performed with RAS regardless of the low complexity, especially in the US where the RAS offering is often used a marketing lever.

Clinical Use Case Assessment



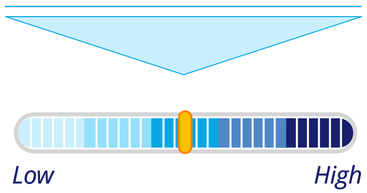
Length: Low
Length of the surgical procedure goes from low (below 1h) to high (> 5 or 7 hours). The highest the length the highest the RAS fit.

Need for ergonomic: High
Need for ergonomic is low on simple anatomies (e.g., cholecystectomy) and high in complex and delicate ones (e.g., prostatectomy). The highest the need for ergonomic the highest the RAS fit.

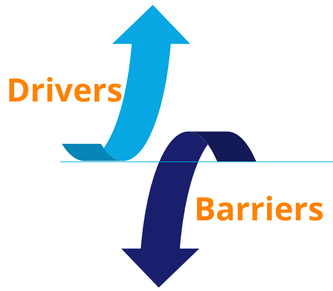
Anastomosis: Not key
Anastomosis is one of the surgical steps where RAS can add value by bringing increased precision and accuracy. RAS has a better fit in procedures where anastomosis is a key step.

Suturing: Is a key step
Suturing is one of the surgical steps where RAS can add value by bringing increased precision and accuracy. RAS has a better fit in procedures where suturing is a key step.

Robotic fit score: 3.5/5



- **The increasing prevalence of obesity, a sedentary lifestyle**, and an increasing elderly population, are factors contributing to the growth in the number of hernia procedures.
- More surgeons are **using a mesh** with the intent to decrease post-operative complications, which requires greater precision and **challenging suturing;** a robot can provide **added value by bringing increased dexterity.**
- In private hospitals in the US, the robotic-assisted hernia repair procedure is often used as a **marketing lever to bring in more patients and to exhibit the high technological level of the facility**.
- Such commercial strategies have less relevance outside of the US, especially in **European public healthcare systems, where RAS adoption in hernia procedures remains low and is not expected to increase** significantly in the future.



- The overall **level of complexity remains low compared to other procedures: most surgeons do not deem RAS necessary or useful** for most hernia repairs.
- The **inadequate reimbursement policies for RAS** and the low cost of hernia repair surgeries are **factors that are significantly limiting the use of robotic surgical systems** for hernia repair.

Note: Chart scoring goes from 1 = Low to 5 = High for each parameter. The fit score is calculated as the simple average of the scores for each criteria.

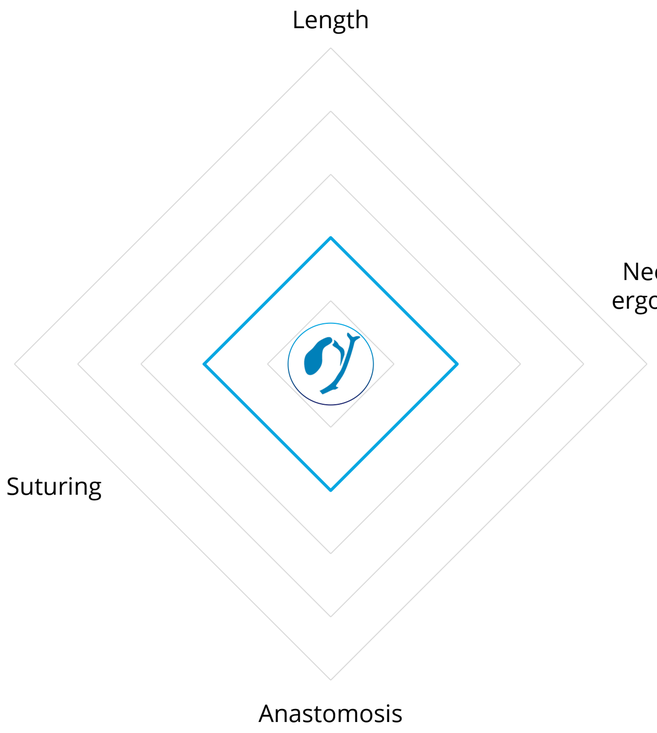
Source: Alira Health analysis based on primary interviews and internal experts.

RAS Use Case: Cholecystectomy, the Training Procedure

Clinical Approaches and Applications

Cholecystectomy is a safe, low-cost, and easy procedure with no perceived benefits coming from changing the approach from laparoscopic to robotic. Accordingly, RAS adoption is expected to remain limited to training procedures.

Clinical Use Case Assessment



Length: **Low**
Length of the surgical procedure goes from low (below 1h) to high (> 5 or 7 hours). The highest the length the highest the RAS fit.

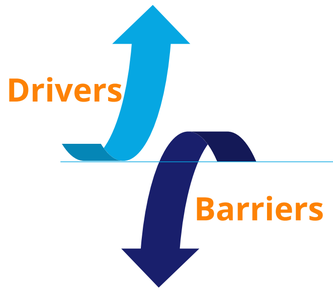
Need for ergonomic: **Low**
Need for ergonomic is low on simple anatomies (e.g., cholecystectomy) and high in complex and delicate ones (e.g., prostatectomy). The highest the need for ergonomic the highest the RAS fit.

Anastomosis: **Not key**
Anastomosis is one of the surgical steps where RAS can add value by bringing increased precision and accuracy. RAS has a better fit in procedures where anastomosis is a key step.

Suturing: **Not key**
Suturing is one of the surgical steps where RAS can add value by bringing increased precision and accuracy. RAS has a better fit in procedures where suturing is a key step.

Robotic fit score: 2/5

- Cholecystectomies are **very common and safe**. Virtually all general surgeons are trained in this procedure and accomplish them in **short operative times**.
- Being an easy and safe procedure, it is promoted as a **training procedure for surgeons untrained in RAS.**



- There are **no perceived unmet needs in terms of ergonomics, dexterity, and visualization**. It is then difficult to justify the increased cost of RAS based on the benefits for the patient or surgeon.
- Currently, nearly 90% of cholecystectomies are performed laparoscopically and the **low level of complexity cannot justify the use of RAS in this procedure**.
- Additionally, the total procedure time is almost equal for all the three possible approaches: open, laparoscopy, or RAS (1 to 2 hours).

Note: Chart scoring goes from 1 = Low to 5 = High for each parameter. The fit score is calculated as the simple average of the scores for each criteria.

Source: Alira Health analysis based on primary interviews and internal experts.

Overview of the Endoluminal Approach

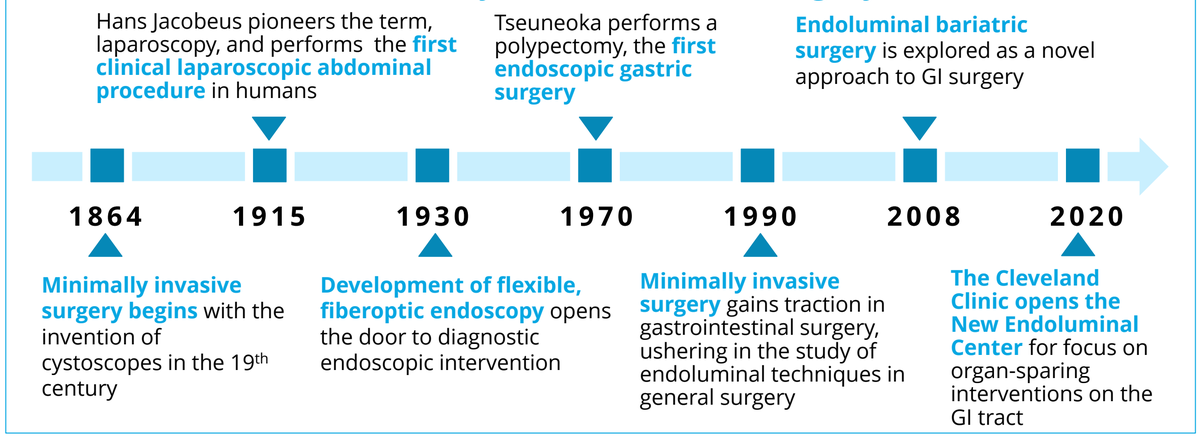
Clinical Approaches and Applications

Endoluminal surgery is a minimally invasive procedure that is conducted inside the lumen of organs, with access through the body's natural orifices. While controlling endoscopically, surgeons operate on the gastro-intestinal tract.

Endoluminal Surgery Overview

- Endoluminal surgery is a minimally invasive method to **conduct dissection, organ suturing, and organ stapling in the lumen of the gut,** as opposed to traditional endoscopic procedures, which are largely performed outside the gastrointestinal lining.
- Endoluminal surgery, completed under the control of an endoscope, has resulted from recent **advances in technology and techniques, and allows patients to keep their native organs.**
- The endoluminal technique utilizes the **natural orifice transluminal endoscopic surgery (NOTES) procedure,** which accesses the inner lumen through the body's natural openings, such as transanal and oesophageal entryways, eliminating the traditional incision and its' associated complications.

History of Endoluminal Surgery



Source: Buess *et al* (2009); Johns Hopkins (2020);

Commonly Performed Procedures

Most endoluminal procedures are **performed in the general surgery specialty**, with a **focus on intervention within the gastrointestinal tract**

Procedure	Description
Endoscopic Submucosal Resection	Endoscopic submucosal resection is a **procedure to remove deep tumors and polyps from the gastrointestinal tract**. Endoscopic mucosal resection (EMR) is performed using a long narrow tube equipped with a light video camera and surgical instruments. During EMR of the upper digestive tract, the endoscope is passed down the throat to reach an abnormality in the esophagus, stomach or upper part of the small intestine (duodenum).
Gastric Wall Excision	The **endoluminal technique is widely used for endoluminal gastric wall excision surgery**, which includes the removal of superficial gastric malignancies, benign gastric wall leiomyomas, and gastric polyps.
Roux-en-Y Gastric Bypass	Roux-en-Y gastric bypass is a type of bariatric surgery that involves creating a small pouch from the stomach and connecting the newly created pouch directly to the small intestine. Recently, **minimally invasive techniques have been employed for this type of bypass** to **reduce incision size and associated complications**.
Others	Other commonly performed endoluminal procedures include **endoscopic full thickness resection, and submucosal tunneling endoscopic resections**.

RAS Adoption in Endoluminal Surgery Remains Limited

Clinical Approaches and Applications

Robotic-assisted endoluminal surgery aims to improve precision and tissue manipulation by offering more dexterous instruments compared to traditional endoscopic methods. Adoption is limited by indirect route of access, and workspace limitations of the robot.

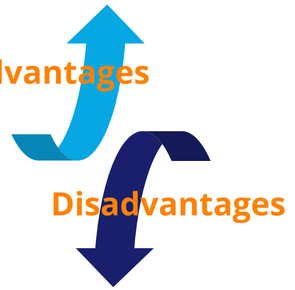
Robotic Endoluminal Surgery

- The **main goal of robotic endoluminal surgery** is to improve precision, effectiveness, safety, and reliability, in order to **enhance the interventional capabilities of endoscopists** and to augment the field of possible interventions.
- Owing to the **limitations of conventional flexible endoscopes** and the long learning curves required for some technically challenging procedures, many different types of endoscopic robotic systems have been developed.

Robot Technology

- Most commonly, robotic endoluminal surgery is performed under direct control of the surgeon, and devices used are categorized as **master-slave or passive devices**. To improve precision and visualization, robotic-assisted endoluminal surgery **operates using endoscopic control, where endoscopic devices are used within the target endoluminal organs, the gastric tract and small bowel.**
- The device **provides bimanual control**, which facilitates the use of two instruments. This system also has automatic light control and 3-dimensional visualization with improved depth of field. Available **instruments include dissection tools, graspers, electrocautery devices, and sutures.**

- Surgical robots aim to address the limitations of traditional endoluminal procedures by **providing increased dexterous instruments.**
- The RAS approach allows surgeons to **achieve complex tissue manipulation** and suturing that otherwise are very hard to achieve using manual tools.



- Surgical robots are limited in the endoluminal space due to the **inherent rigidity of the robotic arms** and **indirect routes of access** along tortuous anatomical passageways.
- Surgeons must learn the complex mapping of **joint and workspace limits of the robot** to complete surgical tasks without reaching the robot's joint limits.

Currently, adoption of robots in endoluminal surgery has been limited. However, four clinical applications have shown promise due to improved anatomy exposure:

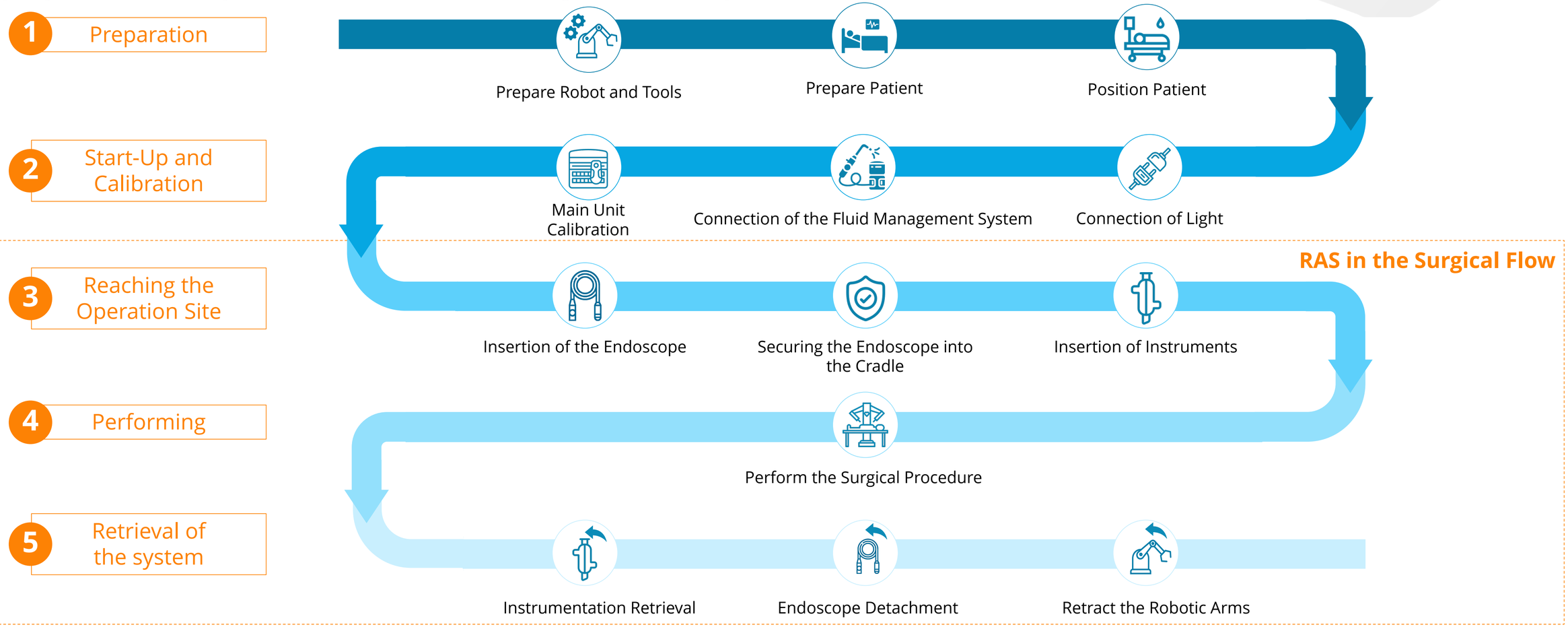
- Zenker diverticulum treatment
- Endoscopic submucosal dissection
- Full-thickness resection
- Suturing

Source: Wilensky (2016); Zakhari *et al* (2015); American Journal of Obstetrics and Gynecology; Alira Health analysis.

Endoscopic Submucosal Dissection: RAS Adds One Step to the Workflow

Clinical Approaches and Applications

Performing a robotic-assisted endoscopic submucosal dissection does not alter the traditional surgical flow since the only additional step, after an initial system calibration, is securing the endoscope into the cradle.



Note: Illustrative workflow. Source: L. Zorn et al. (2017); Alira Health analysis.

Overview of the Endovascular Approach

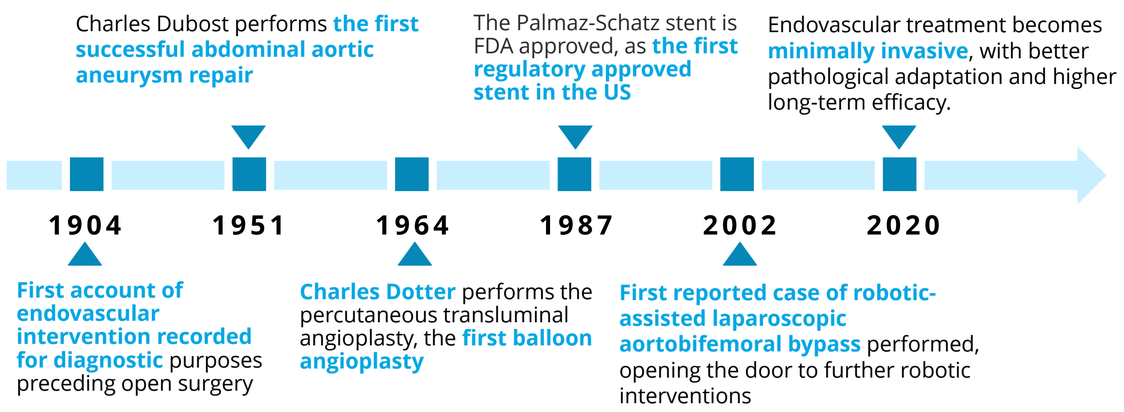
Clinical Approaches and Applications

Endovascular surgery is a minimally invasive technique for the treatment of blood vessel disorders from inside the vessel wall. A catheter is placed and threaded through small incision sites, allowing for significantly less scarring than traditional open procedures.

Endovascular Surgery Overview

- Endovascular surgery is a minimally invasive technique designed to treat blood vessel disorders from inside the vessel, using balloons, stents, or other devices.
- During endovascular surgery, a **surgeon inserts a catheter**, a long, narrow, flexible tube, through **two incisions made at each of the patient's hips, or in the abdomen**. Through the catheter, the surgeon inserts specialized devices such as an endovascular graft, along with a camera, to visualize and operate on the patient's vasculature.
- Common procedures include aortic aneurysm repair and splenic and renal artery aneurysm reconstruction.

History of Endovascular Surgery



Commonly Performed Procedures

The most commonly performed endovascular procedures all follow the same initial approach: a small incision is made through which the surgeon inserts a catheter to thread to the site of occlusion

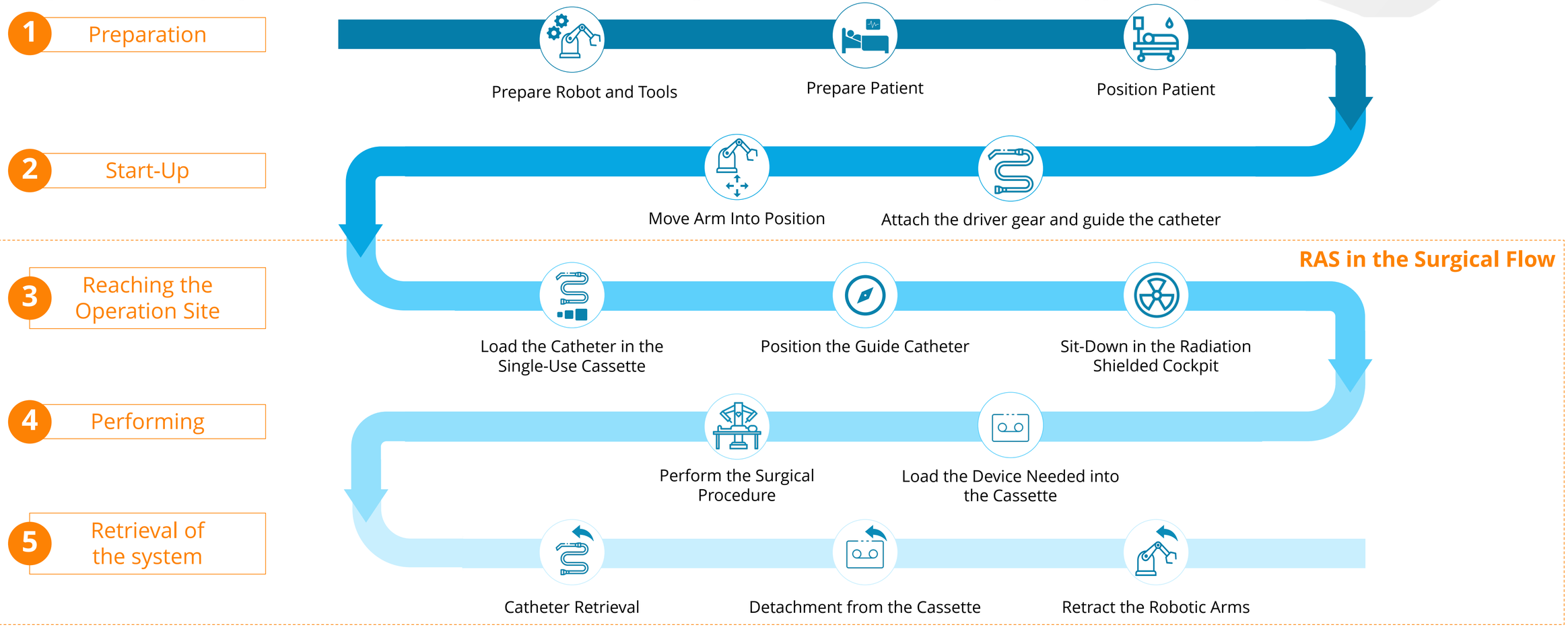
Procedure	Description
Aortic Aneurysm Repair	Endovascular aneurysm repair is a minimally invasive technique to support an aortic aneurysm. In the procedure, the doctor makes a small incision in the groin, inserts a stent graft through a catheter, and threads it up to the heart. At the aneurysm, the doctor places the stent and graft to support the aneurysm.
Percutaneous Endovascular Balloon Angioplasty	Percutaneous transluminal angioplasty is a minimally invasive procedure used to open a blocked artery, which is usually caused by peripheral artery disease. During surgery, the surgeon makes an incision in the thigh, threading a guide wire up through the femoral artery. At the occlusion, the surgeon deploys a balloon, to flatten the plaque blockage, and opens the artery.
Carotid Artery Stent Angioplasty	Carotid artery angioplasty with stenting is a minimally invasive procedure in which a very small hollow tube or catheter is advanced from a blood vessel in the groin to the carotid arteries located in the neck. Once the catheter is in place, a balloon may be inflated to open the artery and a stent is placed.

Source: US National Library of Medicine (2020); Johns Hopkins (2020); The American College of Surgeons; Society for Vascular Surgery; Alira Health analysis.

Robotic Assisted Percutaneous Endovascular Balloon Angioplasty Workflow

Clinical Approaches and Applications

While reducing the ionizing dose for the surgeon, performing a robotic-assisted angioplasty requires quite a few steps before the actual procedure is performed. The cassette loading and the guide catheter positioning are key factors for the procedure's success.



Note: Illustrative workflow. Source: L. Zorn et al. (2017); Alira Health analysis.

Expert Q&A: Robotic Endovascular Surgery

Clinical Approaches and Applications

Biography

Tal Wenderow
Venture Partner

Tal Wenderow is a Healthtech executive with a proven track record in building and scaling innovative & disruptive companies that change the way we deliver healthcare.

Mr. Wenderow is currently a Venture Partner at Genesis MedTech. A global medical company, where he is leading Genesis' M&A and Investments activities.

Previously Mr. Wenderow was the President & CEO of Vocalis Health, a vocal biomarkers company, developing voice-enabled AI solutions to create proprietary vocal biomarkers for personalized healthcare screening and continuous remote monitoring of health by using a simple voice sample.

Prior to Vocalis Health Mr. Wenderow co-founded Corindus Vascular Robotics [NYSE:CVRS], acquired by Siemens Healthineers in 2019 for ~$1.1B; In his last position he served as the Executive Vice President of International & Business Development responsible for global sales and business partnerships of Corindus.

Mr. Wenderow is also a member of the Board of Directors of Microbot Medical Inc. [NASDAQ: MBOT].

Mr. Wenderow holds a Bachelor of Science, Summa Cum Laude, in Mechanical Engineering from Technion in Israel and completed the Executive Program for Life Sciences at the Merage Foundation, Merage Business School, University of California, Irvine, CA, and has numerous patents issued based on his inventions.

Q&A

What are the advantages of using robotics in endovascular procedures and what benefits could the usage of AI and big data bring?

AI and imaging fusion enabled by the robot can streamline and automate steps that the physician cannot do by hand or that he can do but not in a concise and repeatable manner, no matter the skills of the physicians.
All these improvements will help the physician to **make better decisions and planning optimized and personalized to the patient and by that enhancing clinical outcome while** reducing the total procedure.

What is one of the biggest challenge for robotic companies and how they are facing it?

One of the **biggest challenges** today, even for some big companies, is to **continuously placing new systems each quarter especially with high capital cost.**
Today, more companies are optimizing robots for a single or a few procedures, while reducing the footprint and the cost. This strategy will make robots **more affordable and will increase the adoption by potential buyers**.

Which key incremental or disruptive innovations do you expect to see in the market in the next few years?

A move to **more accessible robots without compromising their performance**.
Platforms will become smaller as the technology miniaturization process goes further.
The possibility of **perfectly matching a robotic system** with a device will also help to reduce the footprint, **ideally having a robotic system with the tool built-in.**

Source: Industry experts interviews.

Overview of the Percutaneous Approach

Clinical Approaches and Applications

Percutaneous surgery is defined by the entry, using a needle-puncture, of instrumentation through the skin to reach the site procedure. Robotic percutaneous surgery improves precision and helps surgeons to accurately insert the needle into the skin.

Percutaneous Surgery Overview

- In surgery, a **percutaneous procedure** is any medical procedure defined by an **entry, using a needle-puncture or minor incision, with an instrument through the skin or mucous membrane and any other body layers necessary to reach the site of procedure**.
- Advantages of a percutaneous procedure include **lower complication rates and faster recovery times**. On the other hand, potential disadvantages are related to the **need for specific equipment and an extensive learning curve** for surgeons and their team.

Commonly Performed Procedures

Procedure	Description
Percutaneous Nephrostomy	**Percutaneous nephrostolithotomy** (PN) is the passing of a special medical instrument through the skin into the kidney, with the objective of removing kidney stones. Despite it being a basic urological procedure, it **remains technically challenging to insert it in the right way and in the right place**. PN is used most often for larger stones or when other procedures, such as extracorporeal shock wave lithotripsy or uteroscopy, are unsuccessful or not possible.
Percutaneous Coronary Interventions (PCI)[1]	**PCI is done via a percutaneous femoral, radial, or brachial artery puncture**. A guiding catheter is inserted into a large peripheral artery and threaded to the appropriate coronary ostium. **A balloon-tipped catheter, guided by fluoroscopy or intravascular ultrasonography, is aligned within the stenosis**, then inflated to disrupt the atherosclerotic plaque and dilate the artery. Angiography is repeated after the procedure to document any changes. **The procedure is commonly done in two or three vessels as needed.**

Robotic Percutaneous Surgery

- The **main goal of robotic percutaneous surgery** is to improve precision, effectiveness, safety, and reliability, in order to enhance the interventional capabilities of the surgeon and **accurately position and insert a needle percutaneously into the skin**.
- Over the last years, different technologies were designed and developed where the robotic surgical system provides an extra hand for the surgeon and contributes towards load sharing and enhancement of the accuracy for targeting and puncturing the percutaneous access.
- **Potential future development** of the technology entails the ability to **operate fully in remote**, thus making percutaneous surgeries accessible in remote and underprivileged locations.

Advantages

- Shorten the learning curve for robotic-assisted percutaneous access procedures
- Ability to move the catheter a millimeter at a time and to turn into any direction with precision, achieving great accuracy
- Less radiation exposure for the physician during the procedure

Disadvantages

- Lack of compatibility of robotic platforms with many devices and strategies in the standard procedure's toolkit
- Inability to manipulate multiple devices (wires, balloons, stents) simultaneously in PCI

Note: [1]Percutaneous approach since it is a non-surgical procedure.

Source: CMS; National Library of Medicine; Journal of the American Heart Association (2019); International Conference on Intelligent Robots and Systems (2018); Alira Health analysis.

Expert Q&A: Robotic Percutaneous Surgery

Executive Summary

Biography

Harel Gadot
Executive Chairman & President

Harel Gadot is a seasoned healthcare executive and entrepreneur. He is the founder of XACT Robotics, the world's first and only hands-free robotic system, and serves as its executive chairman and president.

He is the founder and Company Group Chairman of MEDX Ventures Group, a unique investment and management firm, as well as the founder and Chairman of MEDX Xelerator, an Israel based MedTech incubator.

Co-Founder of Microbot Medical, he serves as its CEO, President & Chairman, leading it from inception through its successful listing. He has served as a Worldwide Group Marketing Director at J&J (Ethicon Inc.), overseeing the company's global strategic marketing.

Company Background

XACT Robotics is a privately held company focused on advancing the field of radiology by improving targeting accuracy, efficiency, and consistency in percutaneous radiology procedures. The company was founded in 2013 by Harel Gadot, whose vision reimagined how image-guided percutaneous procedures are performed. In July 2020, its **XACT ACE™ Robotic System was cleared to market in the U.S**. for computed tomography (CT)-guided percutaneous procedures.

XACT ACE™ Robotic System is the world's first and only hands-free robotic system that combines advanced image-based procedure planning and navigation with **robotic instrument insertion and non-linear steering capabilities**.

Q&A

Which key incremental or disruptive innovations do you expect to see in the robotic market in the next few years?

Currently, the surgical robotic systems on the market are defined as robotic assisted system that rely on the **technical skills of the surgeon to perform the procedure,** and hence are limited by the variability in those skills.

In the future, robotic systems will allow **physicians to focus on their intellect skills as they view pre and intra operative images, plan and monitor the surgery**, while the robot itself will perform the surgery. This new approach will increase accuracy, efficiency and truly democratize procedures.

What are the benefits of percutaneous RAS?

During percutaneous procedures, the user needs to overcome multiple challenges, from soft tissue, flexible instruments, awake and breathing patients, and more. Navigation systems or robotic assisted systems only solve some of those challenges as the insertion is still done by the user. Therefore, a truly hands-free robotic system that take away those variables can allow for **more physicians to treat more patients earlier, with better accuracy and efficiency of the procedure.** It also allow for more efficiency in healthcare resources including the setting (inpatient, outpatient, and ambulatory centers) and the use of mid-levels for certain procedures.

How are XACT and its platform are positioned in the RAS market? Why is this positioning unique?

XACT is the first and only FDA-cleared robotic system for percutaneous approach that performs the insertion of the instruments hands-free, which in return takes away the variability in user's skills. **It is also the only** robotic system that combines advanced image-based procedure planning and monitoring with **robotic instrument insertion and non-linear steering capabilities.** Its unparalleled accuracy has the potential to treat patients earlier, and its one–insertion to target capability makes the procedure predictable and efficient. **It requires minimal learning curve, and with a size of a tablet it is truly mobile system.**

Source: Industry experts interviews.

Overview of the Radiosurgery Approach

Clinical Approaches and Applications

Radiosurgery is a very precise form of therapeutic radiology used to treat cancerous tissues. Robotic-assisted radiosurgery enables access to previously unreachable tumors, delivering precise and accurate ionizing radiation and achieving faster and safer treatments.

Radiosurgery Overview

- **Radiosurgery**, also called stereotactic radiosurgery, is a very **precise form of therapeutic radiology.**
- It is called "surgery" because it is a 1-session radiation therapy treatment that creates a similar result as an actual surgical procedure. Its procedure is **based on focused beams of radiation** (gamma rays, X-rays, or protons) **used to treat cancerous tissues without a surgical incision or opening.**

Commonly Performed Procedures

- There are three types of radiosurgery. Each type uses different equipment and radiation sources.

Types	Description
Gamma Knife	This system uses cobalt as a source of gamma rays. **Is mainly used to treat small- to medium-sized lesions**, usually in the brain. Many beams of gamma radiation join to focus on the lesion under treatment, providing a very intense dose of radiation in a safe manner. The treatment generally involves four steps: head frame placement, tumor location imaging, radiation dose planning, radiation treatment.
Linear accelerator system	This system uses high-energy X-rays to **treat large tumors or other lesions outside of the brain**. In addition to not using radioactive material to produce the radiation, the machine is around the patient during treatment and thus able to treat larger tumors and larger affected areas than the Gamma rays.
Proton beam therapy	Proton beam therapy is a type of particle beam radiation therapy. Rather than using rays of radiation, such as gamma rays or X-rays, particle beam therapy uses particles, such as protons or neutrons. **Proton beam therapy is the most widely-used type of particle beam therapy and is useful in treating tumors or lesions that are small and/or have an irregular shape.**

Source: John Hopkins; Mayo Clinic; Coste-Manière, E., *et all, (2005)*,Alira Health analysis.

Robotic Radiosurgery

- The **key to the activation and utilization** of any robot in radiosurgery is **accuracy in imaging.**
- The robotic-assisted radiosurgery combines i) a compact X-band linear accelerator, ii) is connected to a six-degree of freedom robotic arm capable of freely moving in 3-D space, and iii) guided by real-time images of the internal and external anatomy of the patient.
- The design development of innovative, target-tracking technologies has extended clinical applications of radiosurgery to tumors and lesions within soft tissues which are affected by respiratory motion. Recently, radiosurgery can be applied to the whole body.

- Increased precision and accuracy in the delivery of ionizing radiation
- Elimination of morbidity and mortality associated with general anesthesia
- Flexibility for patients to be treated in ambulatory environments with their associated economic and clinical benefits

- Integration of the overall treatment workflow due to the increased complexity of the clinical requirements for robotic-assisted radiosurgery

RAS Maturity and Outlook Vary across different Robotic Surgical Approaches

Clinical Approaches and Applications

Among the five different types of surgical robotic approaches, the laparoscopic approach has the highest penetration, which is expected to solidify in the next 5 years. RAS adoption is expected to grow in other segments, mainly endovascular and radiosurgery.

Illustrative

	Laparoscopic	Endoluminal	Endovascular	Percutaneous	Radiosurgery
Description	A procedure to access the inside of the abdomen and pelvis without having to make large incisions in the skin	The procedure is performed in a hollow organ, using typical surgical techniques	A less invasive procedure used to treat problems affecting the blood vessels	A procedure where access to inner organs or other tissues is done via needle-puncture of the skin	A procedure where radiation is used to precisely destruct selected areas of tissue using ionizing radiation
Robotic Surgical systems	Da Vinci, Senhance, Versius, Avatera, Hugo[1] & Ottava[1]	Ion	Corindus CorPath, Robocath Stereotaxis	XACT ACE	Cyberknife
Current level of RAS penetration	HIGH	LOW	MEDIUM	LOW	LOW
Expected level of RAS penetration in next 5 years	VERY HIGH	MEDIUM	HIGH	MEDIUM	HIGH
Rationale	Increase adoption, driven by **a new business model, making the system more affordable, thus more accessible**	Technical constraints for NOTES[2]. **Fully functional devices are expected in 3 to 4 years**	**Small-scale untethered robots should mitigate** and tackle the **many drawbacks** that physicians experience today	**Few systems are expected to reach the market** due to the extensive trajectory of certification and approval that requires a guarantee of safety in all circumstances	A higher adoption rate of stereotactic radiosurgery (SRS) and a significant **increase in the number of pinpoint beams**

Note: [1]Pipeline; [2]Natural Orifice Transluminal Endoscopic Surgery.

Source: Company websites; Primary interviews; Alira Health analysis

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Procurement Often Initiated by Clinical, Decided by Business Stakeholders

Customer Overview and Segmentation

The procurement process is usually initiated by clinical stakeholders; however, non-clinical stakeholders guide it in the later stages and are the ultimate decision makers. In the negotiation process, the vendor assists in providing data for different use cases.

	Robotic Purchase Proposal	Purchase Evaluation	Post-Sales Support
Activities	Initiation of the robotic system purchase is driven by the **head of surgery, a specialized or experienced surgeon or clinical team**.	After the request is initiated, an **internal committee of up to 15 stakeholders** is formed where a robotic proposal prospectus is reviewed. The prospectus is weighted and **analyzed on clinical and economic criteria** delineated below.	**Installation, training and maintenance support** is provided to the facility by the manufacturer. **Post-sales support** is one of the **key criterion** on which the purchase decision is taken.
Decision makers[1]	**Non- Clinical Stakeholders**: Board Members/ C-level Executive **Clinical Stakeholders**: Head of Surgery, Surgeon	**Clinical Stakeholders**: Board Members/ C-level Executive, Head of Surgery, Specialized Surgeon **Non- Clinical Stakeholders**: Purchase Manager, Supply Chain, Finance Staff	**Clinical Stakeholders**: Head of Surgery, Surgeon **Non- Clinical Stakeholders**: Purchase Manager
Evidence presented / Material required	**Information required to generate interest** from the hospital management includes the following: ▪ **Cost analysis** ▪ Increase in **Patient Quality of Life (QoL)** ▪ Decrease in **Hospital Length of Stay (LoS)** ▪ Perceived innovation level of the system ▪ Surgical volume and procedures that can be performed ▪ **Safety Profile** ▪ Ability to attract reputed surgeons	**Information that is evaluated by the Internal Committee** includes the following: ▪ Product Trial / Comparison with other competitive products in terms of clinical outcomes, precision and ease of use for surgeons. ▪ **Cost analysis / HEOR[2]** outcomes ▪ **Safety and efficacy data** (recovery time, LoS, EBL, QoL) ▪ Source of funding – Local government, hospital budget or third party ▪ Compatibility with third-party instruments ▪ **Contractual Terms** – Purchase model: upfront investment, pay-per-use, etc. – Pricing: Volume, rebates, etc. – Maintenance, servicing and upgrades	Basic **requirements that are expected in terms of post-sales support** include the following: ▪ Surgical robot **installation and trainings** ▪ Frequent initial visits, including surgical supervision ▪ **Frequent maintenance** and service visits ▪ Technical upgrades, when available ▪ 24-hour service in case of a breakdown or problem ▪ Follow-up meetings ▪ **Training of new staff**

Note: [1]The decision makers vary by name and position in different geographies; [2]Health economics and outcomes research; The above flow is illustrative and not inclusive of countries specificities.

Source: Factors Associated With Hospital Decisions To Purchase Robotic Surgical Systems; Society for Medical Decision Making; Primary research; Alira Health analysis.

Procurement Criteria Importance Differs by Stakeholder

Customer Overview and Segmentation

The willingness to adopt of clinical and non-clinical stakeholders is driven by criteria related to the platform's performance and its cost-effectiveness, the latter being the most impactful on the purchase decision and creating disparity in adoption across settings.

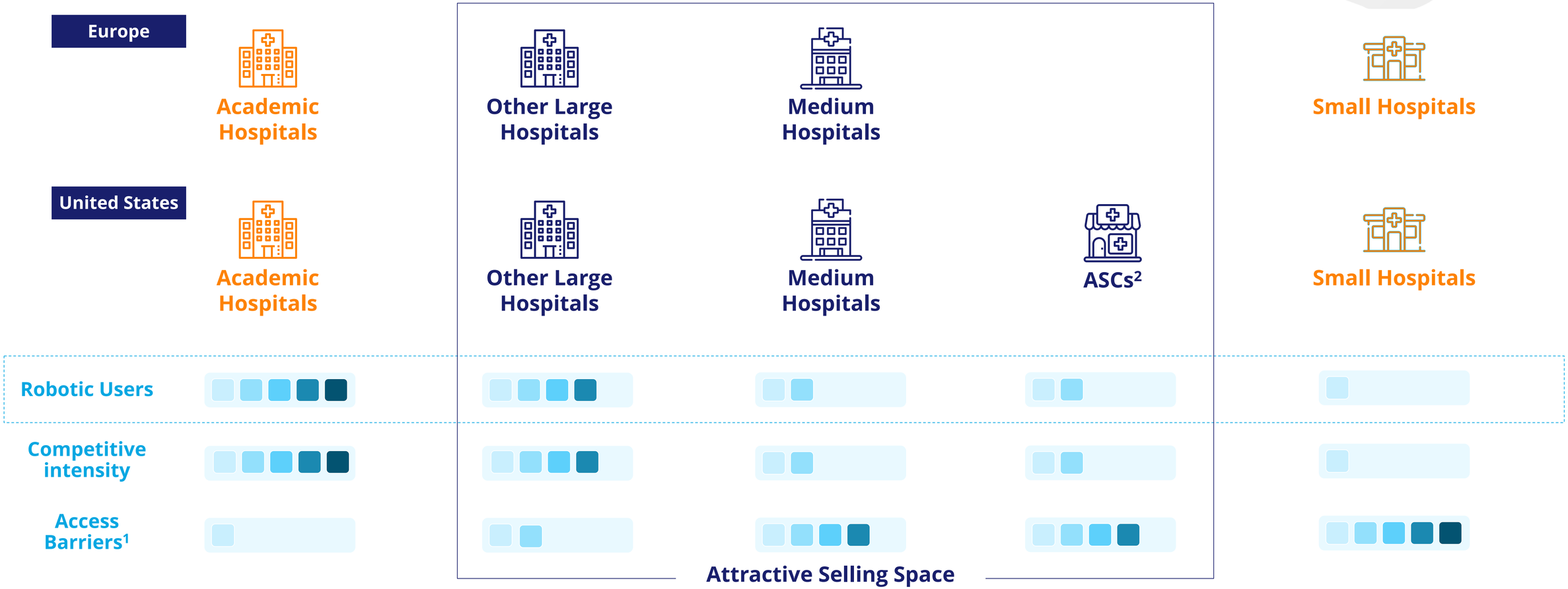
		Relevance for Clinical Stakeholders	Relevance for Non-Clinical Stakeholders
	Safety and clinical data: Safety and efficacy of a surgical approach/device over the others in terms of better patient outcomes.		
	Improved ergonomics, dexterity and precision: The magnitude in which different surgical approaches/devices meet current open unmet needs.		
Setting-dependent	**Impact on the surgical flow, logistics and learning curve:** The impact in terms of OR logistics, changes in the surgical flow, and the expected learning curve of one approach/device over the others.		
Setting-dependent	**Cost effectiveness:** The financial impact and return on investment of one approach/device over the others, keeping in consideration the price of the consumables.		
Setting-dependent	**Other commercial considerations:** Among others, the possible return in terms of marketing and ability to attract reputed surgeons.		

Source: Factors Associated With Hospital Decisions To Purchase Robotic Surgical Systems; Society for Medical Decision Making; Primary interviews; Alira Health analysis.

Appraisal of Such Criteria Across Settings Leads to Differential Adoption

Customer Overview and Segmentation

Across the US and EU, the highest adoption of RAS emerges in academic hospitals and other large accounts such as tertiary centers. Adoption is still low or null in medium-sized accounts and outpatient facilities due to strong access barriers.



Note: Large/medium/small hospitals are classified based on the number of beds. Thresholds are country dependent. [1]Including budgetary and logistic barriers; [2]Specific to the US market landscape.

Source: Primary interviews; Alira Health analysis.

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Takeaways on the RAS Clinical Landscape and RAS Adoption

Key Takeaways

Across clinical approaches, **RAS has the highest penetration in laparoscopy** . The current level of technology offers two types of approaches: **multi-port and single-port**, with each one having its own advantages. However, multi-port remains predominant today and is expected to further solidify in the future.

RAS penetration is differential across different laparoscopic procedures: due to the clinical benefits for the patients, today, over 80% of radical prostatectomy are performed using surgical robots, while almost **70% of all prostatectomies are conducted robotically**. Usage of **RAS in hernia repair is also growing, especially in the US** where obesity and a sedentary life are expected to increase the procedure volume in the coming years. **Penetration remains limited in cholecystectomy**, while it is expected to **grow at market pace in other procedures,** such as pancreatectomy, bariatric, etc.

Looking at other surgical approaches, endoluminal, percutaneous and radiosurgery are three promising areas of applications where **robots could make the difference by increasing the accuracy and consistency during surgical procedures**. There are robotic platforms already on the market and many others are coming, taking advantage of the latest technology innovation and usage of artificial intelligence.

Adoption is also differential across settings, where different appraisals of procurement criteria by clinical and non-clinical stakeholders drives **higher adoption in academic settings and larger hospitals**, while in smaller settings and/or outpatients centers, RAS usage remains extremely limited today. Specifically, the **procurement process is initiated by clinical stakeholders,** but **non-clinical stakeholders will be the ultimate decision makers**, **driven mainly by economic and access-related considerations**.

Source: Alira Health analysis.

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Regulatory Review in RAS

Regulatory and Market Access

In the US, the FDA classifies robotically-assisted surgical devices according to the risks they pose for patients. More products are expected to be in Class III as the systems will get more autonomous.

Regulatory Landscape

- Medical equipment is **classified by the FDA based on the risk it poses to patients during use**, which determines the type of premarket submission/application and the regulatory requirements **for the submission** to the FDA.
- Based on the characteristics and design of the system, the **510(k) and De Novo are the two different pathways** to clearance. For the De Novo pathway, detailed information on the training platform and clinical cases are required.

Most **Class I** devices are exempt from Premarket Notification 510(k)

Most **Class II** devices require Premarket Notification 510(k)

Most **Class III** devices require submission of a Premarket Approval Application

Regulatory Control

Master -slave

Passive

Semi-Active

Class II

- **The robotic surgical system** is one type of computer-assisted surgical system, which enable the surgeon to use computer and software technology to control and move surgical instruments for a variety of surgical procedures.
- **Robotic surgical systems are currently regulated as Class II 510(k) devices**, under the Endoscope and Accessories regulation for the FDA. This regulation **requires the manufacturer to provide the FDA** with evidence of safety and effectiveness of their device.
- **Originally, robotic surgical systems were found substantially equivalent to laparoscope holding devices**. Therefore, they have been cleared for **general surgical indications** with premarket testing, demonstrating the capability of performing representative tasks or procedures.
- In this context, such general claims for device use in a specialty have typically been assessed for only one or a few procedures within a specialty.

Active /AI

Class III

- **Class III devices are classified based on the risks posed by the device** and the inability of general and special controls to provide reasonable assurance of the safety and effectiveness of the device.
- With the **increasing advancements in robots leading to greater autonomy and higher degrees of freedom**, it is highly probable that in the coming years robots will have limited surgeon control and maximum autonomy. This will lead **these systems to fall under the Class III device category, which is the highest risk class of devices.**
- A Premarket Approval Application, required for Class III devices, is the **most stringent type of device marketing application** required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device, **based on extensive bench, animal and clinical testing.**

Source: FDA; Global Data; Alira Health analysis.

Regulatory Review in RAS

Regulatory and Market Access

In Europe, manufacturers of medium and high-risk devices can place the CE mark on the device once the regulatory authorities have assessed the required documentation. Based on the device risk-classification, different requirements and procedures apply.

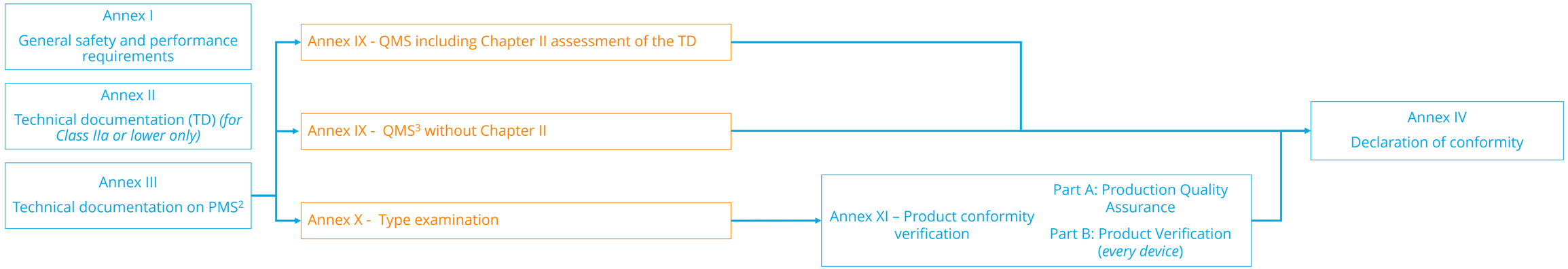
Regulatory Landscape

- According **to EU Medical Device Regulation (MDR 2017/745)**, **most robotic surgical systems are classified as Class IIb medical device and must be labeled with a CE mark after an appropriate Conformity Assessment (CA) procedure**, which determines whether a medical device complies with the requirements in the MDR[1]. In annex IX to XI, the MDR specifies the current conformity assessment procedures.
- **The CA** involves an **audit of the manufacturer's quality system** and, depending on the type of device, a **review of technical documentation** from the manufacturer on the **safety and performance of the device**. If the device's class requires the **involvement of a Notified Body** (EU competent Health Authorities for MD), the medical device manufacturer may apply for the procedure to the notified body of its choice. During the procedure, the notified body will review all information from the manufacturer and all data which is necessary to perform the procedure.

CE

The **CE mark confirms** that a device **complies with the relevant General Safety and Performance Requirements (GSPRs)**. They must be supported by compliance with relevant standards, relevant scientific literature, studies performed with the devices, data from clinical evaluation, and the results and conclusions of performed clinical investigations, among others.

Conformity Assessment Procedures under MDR



Note: [1]Medical Devices Regulation; [2]Post-Market Surveillance; [3]Quality Management System.

Source: FDA; Global Data; Thema website; Alira Health analysis.

Reimbursement Overview

Regulatory and Market Access

As of today, neither the US or EU5 have a standardized or a differentiated reimbursement pathway for robotic-assisted surgery procedures, hampering a wider implementation of this technology.

- Reimbursement approval is based upon consideration of primary procedures such as minimally invasive laparoscopic surgeries.
- When covered by private insurers, it consistently increases the insurance premium. In 2007, the AMA[1] CPT Editorial Panel determined that there was no need for a new CPT code or unique modifier for surgical procedures performed using robotic assistance, thus, the CPT code that accurately describes the basic surgical procedure should be used.
- Nonetheless, in 2016, the CMS[2] increased the reimbursement rates to 82% for most minimally invasive outpatient procedures for example, in gynaecologic surgery.

- The NHS[3], following advice from the NICE[4] and physician groups, set medical device reimbursement, considering both the effectiveness of devices against currently reimbursed treatments, as well as the cost of the device against the long-term cost savings associated with improved outcomes.
- **The UK has a specific reimbursement for RAS Prostatectomy.**
- Since the healthcare system is government-funded, **the cost of acquisition is crucial, nonetheless, budgets for robotics are gradually increasing**, even if not fast enough to sustain the higher increase in patients treated with the technology.

- **Robotic-assisted procedures are reimbursed via the same DRGs[5] as open and laparoscopic procedures, except for hysterectomy, total fundoplication, cholecystectomy and wedge resection of the liver**, for which the open and robotic-assisted procedures are grouped into different DRGs with a higher tariff.
- In the case of not listed innovative procedures, reimbursement of inpatient hospital services can be provided via NUB[6] charges. The NUB process enables participating German hospitals to receive full reimbursement plus a supplemental payment when using groundbreaking medical technologies.

- Reimbursement prices are set according to the medical and economic benefits of each device and, whenever possible, determined in comparison to available similar equipment.
- **No specific code currently exists for robotic-assisted surgery.**
- The **use of robotic assistance during surgery is not tracked in the billing circuits**, either when the procedure is coded or when the hospital stay is billed, which prevents any precise accounting of this activity.

- The reimbursement for each procedure is DRG-based and region dependent. The DRG is usually not sufficient to cover the procedural cost of the technology. As such, each hospital computes the minimum number of procedures needed for the technology to be considered as profitable.
- In **Italy, some regions**, such as Veneto, Toscana and Lombardia, may **provide an additional reimbursement on top of the DRG if the surgery is performed with the use of robotic systems**.

Both the **US and EU5 do not differentiate reimbursement of procedures based on the approach, namely traditional or robotic-assisted**. Nonetheless, especially **in Europe, different mechanisms to alleviate the lack of specific reimbursement codes may exist**.

Note: [1]American Medical Association; [2]Center for Medicare & Medicaid Services; [3]National Health Service; [4]National Institute for Health and Care Excellence; [5]Diagnosis Related Groups; [6]Neue Untersuchungs- und Behandlungsmethoden (New diagnostic and therapeutic methods).
Source: FDA; EMA; Alira Health analysis.

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The Competitive Landscape is Vast…

Competitive Landscape at-a-Glance

The current marketed competitive landscape appears crowded, with over 35 marketed robots and 100+ currently in the pipeline, covering different clinical applications.

Key Robotic Surgical Products Competitive Landscape[1]

Pipeline

- Ottava
- ENOS
- Vicarious System
- Virtuoso
- C2MR Platform
- Acusurgical Platform
- Xsurgical System
- ActivEdge
- HUGO
- MIRA
- ANSUR
- Liberty
- Remebot
- Edge Medical System
- Hinotori
- Epione
- Carlo
- Bitrack
- Galen Platform

Marketed

- Da Vinci
- Mako
- Mazor X
- VELYS
- Cirq
- ROSA ONE
- CorPath GRX
- Versius
- Avatera
- Navio
- Flex
- ExelsiusGPS
- Ion
- Hominis
- Pulse
- R-One
- MONARCH
- Gamma Knife
- ACE
- Artas
- CyberKnife
- OMNIBotics
- AMIGO
- Symani
- NeuroBlate
- Yomi
- Preceyes System
- Senhance
- TSolution One
- AquaBeam
- Dexter
- Soteria Medical BV
- Neuromate System
- Fusion Robotics System
- ISR'obot Mona Lisa
- Stereotaxis System

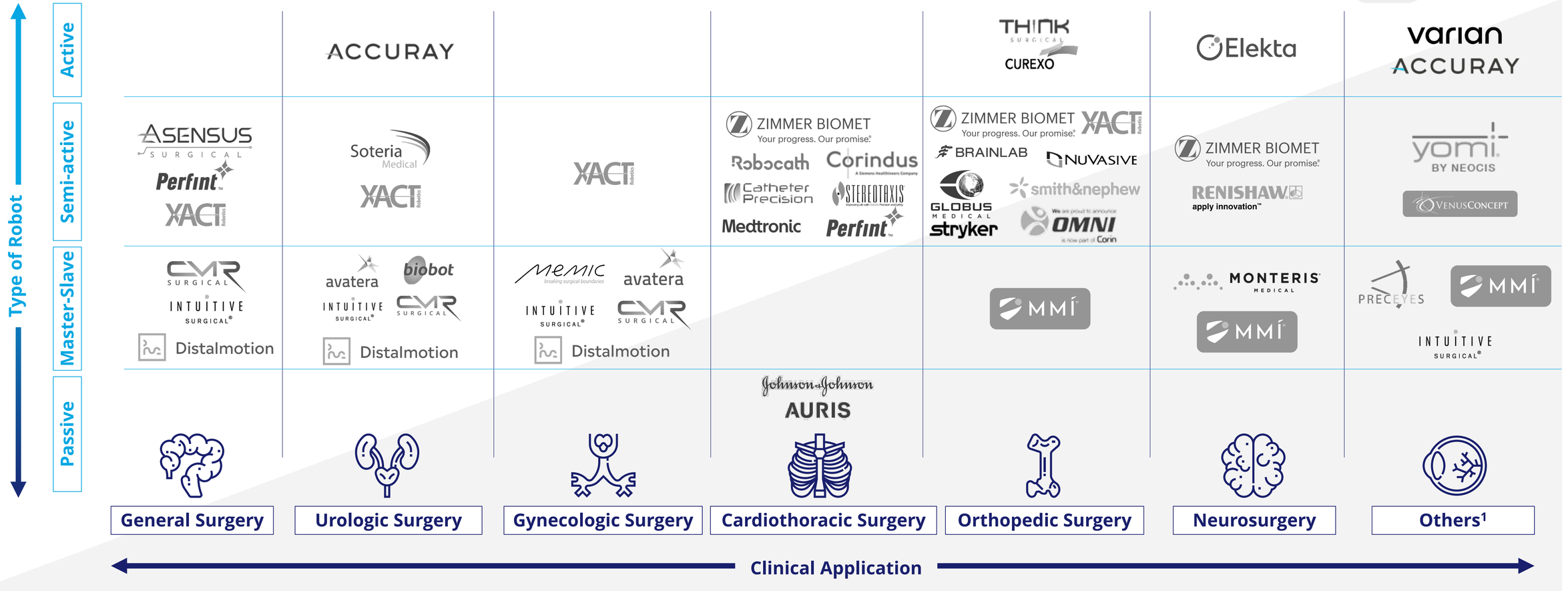
Note: [1] The list is non-exhaustive, over 150 companies are present nowadays in the robotic competitive landscape (marketed or pipeline), a more complete list can be found in the appendix.

Source: Company Websites; Alira Health analysis.

...Across Clinical Applications and Robot Type

Competitive Landscape at-a-Glance

The majority of general, urologic, and gynecologic surgeries still employ master-slave following the path started by Intuitive Surgery in the field. However, in other surgical areas, more products are moving into a semi-active or active level of autonomy.



Note: [1]ENT surgery, Dental surgery, Eye surgery and Hair surgery, Radiosurgery; The list is non-exhaustive (over 150 companies are present nowadays in the robotic competitive landscape) and includes both commercial and pipeline platforms. A more complete list can be found in the appendix.
Source: Alira Health analysis.

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Intuitive Surgical

Company Profiles

Intuitive Surgical is the leader in the RAS market, owning 61% of the overall RAS market. Systems can either be sold as capital sale or under operating lease agreements, but the majority of the revenue is derived from instrument and accessory sales.

Intuitive Surgical at-a-Glance

Main Product

da Vinci Si HD SURGICAL SYSTEM

The da Vinci Surgical System provides surgeons with remote access to an operation through a console to control the patient cart, holding the camera and robotic arms as instruments

Master-Slave

Key Highlights

- Revenues in 2019: **$4.4B**, +20% vs. 2018
- Installed base of da **Vinci systems:** +12% vs. 2018
- **Direct sales force** in the US, part of the EU (excluding Spain, Portugal, Italy, Greece and most East countries[2]), China, Japan, South Korea, India, and Taiwan
- The direct sales force is divided into capital sales and clinical teams

Clinical Applications

- General Surgery
- Gynecological Surgery
- Urological Surgery

Technique

- Laparoscopy

Key Selling Proposition Points

Versatility
Performs four functions without exchanging instruments

Visualization
Multi-armed device allows for continuous visibility without exchanging instruments

Speed
Fast seal time, lower than three seconds

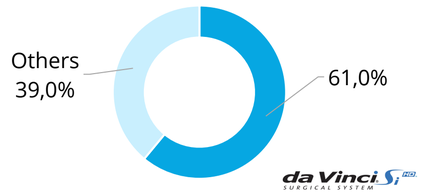
Control
Articulated wrist and slimmer jaw profile

Deep Dive

Current Value Proposition

The da Vinci System has pioneered **new capabilities in the operating room, transforming minimally invasive surgery** without exchanging instruments **by improving outcomes and cost of care** through enhanced AI and a connected ecosystem

Overall Share in Robot Surgery Market (2020)



Sales and Business Model

- In 2017, **52%** of revenues was derived from **instruments and accessories, 29%** from robot **systems**, and **19%** from **service.**
- **Instruments and accessories** are reusable for up to 10 times.
- **33%** of systems are under **usage-based arrangements and operating leases.**
- **Intuitive provides robotic training programs** to increase safety and market adoption.

Future Plan

- **Drive adoption** in **European and Asian markets** and **maintain the leading position** in the US.
- **Increase surgeon adoption** by building education through robotic training programs and providing better financial options.

Note: [1]Software as a Service; [2]Distributors are present in those countries; Profile based on publicly available data.

Source: Company website and investors' reports; Global Data (2020); Alira Health analysis.

Legend: Hardware Sales — Capital Sales; Instruments and Accessories Sales; Operating Leases | Service Sales — SAAS[1]; Training and Maintenance

Stryker

Company Profiles

Stryker holds 79% of the orthopedic market. The Mako Surgical system is a semi-active robot that provides pre-operative planning and intra-operative navigation for both knee and hip replacement surgeries using haptic technology for accuracy control.

Stryker at-a-Glance

Main Product

MAKO

The Mako Smart Robotics consists of a robotic arm, 3-D CT-based planning, AccuStop haptics, and data analytics to improve outcomes

Semi-Active

Key Highlights

- **Revenues in 2018** in North America: **$26.6M**
- Stryker holds **79% of the robotic orthopedic market**
- Stryker has a **large global footprint and reports that 860 Mako robots are installed worldwide**, including more than 700 in the US.

Clinical Applications

Orthopedic Surgery

Key Selling Proposition Points

Planning
3-D surgical plan is created from CT imaging

Accuracy
Target area is reached by AccuStop haptic technology

Navigation
Patient registration software detects patient anatomy to follow pre-operative plans

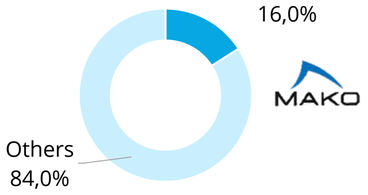
Patient outcome
Insightful data analytics lowers risk factors

Deep Dive

Current Value Proposition

The Mako System provide surgeons with **intra-operative haptic guidance for bone preparation and implant placement and** personalizes a patient's surgical experience based on a specific diagnosis and anatomy.

Overall Share in the RAS Market (2020)



Sales and Business Model

- The Mako System is sold as a **capital sale.**
- Reusable mechanical **instrument** sales for implant placement and **single-use implants** are sold in addition to the system.

Future Plan

- Stryker is **developing Mako's application** in hip surgery, data analytics, and cloud-based data acquisition.
- The focus is **to increase penetration** in the US.

Note: Profile based on publicly available data.

Source: Company website and investors' reports; Global Data (2020) Alira Health analysis.

Legend: Capital Sales | Hardware Sales: Instruments and Accessories Sales; Operating Leases | Service Sales: SAAS[1]; Training and Maintenance

Medtronic

Company Profiles

Medtronic is the leader in the spinal segment, holding 75% of the market share. Its robot, Mazor X, brings augmented precision, navigation, visibility, and guidance factors to the Operating Room.

Medtronic at-a-Glance

Main Product

MAZOR X

The Mazor X System incorporates advanced technologies into spinal surgery, including real-time vision, pre- and intra-operative planning, optimal implant trajectory and navigation, and 3-D analytics

Semi-Active

Key Highlights

- In 2020 the spinal surgical robot market was of **$333M**, with a **'20-'23 CAGR of 14.2%**
- Medtronic holds **75% of the US and EU robotic spinal surgery market share**
- Mixed sales force formed by direct heads and distributors in the US, Western Europe, Japan, and China

Clinical Applications

Orthopedic Surgery

Key Selling Proposition Points

Visibility
Real-time visibility of the implant relative to the pre-operative plan

Predictability
AI algorithms plan implant trajectories, and 3-D analytics allow for procedural pre-planning

Precision
Closed connection of the robotic arm for mechanical stability and surgery precision

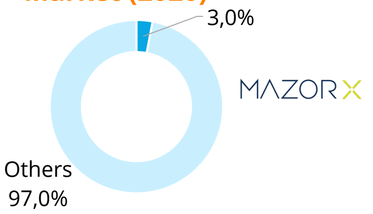
Guidance
Patient registration software identifies specific patient anatomy, guiding surgeons to the target area

Deep Dive

Current Value Proposition

The Mazor X Stealth system fully-integrates procedural solutions for planning, execution, and conformation of surgeries.
AI software is applied to spinal implants to provide navigation, and intra-operative imaging.

Overall Share in Robot Surgery Market (2020)



Sales and Business Model

- In 2019, **80%** of the Mazor X systems were sold to customers, combining Mazor X and **spinal implant.**
- Mazor X Stealth is only compatible with Medtronic **instruments and accessories.**
- Repairs, support, planned maintenance inspections, and software updates are **maintained by Medtronic technicians** as a part of the overall contract.

Future Plan

- **Increase** Medtronic's **spinal and neurosurgery penetration in the US.**
- Gain **market access** and accumulate clinical data for the **Hugo Robotic system,** a developing soft robotic system.

Note: Profile based on publicly available data.

Source: Company website and investors' reports; Global Data (2020), Alira Health analysis.

Legend: Capital Sales | Instruments and Accessories Sales | Operating Leases | SAAS[1] | Training and Maintenance

Hardware Sales | Service Sales

Smith & Nephew

Company Profiles

Smith & Nephew is a market leader in the robotic orthopedic joint surgery space. A large portion of the system's revenues is attributed to instrument and accessory sales, as they are compatible with many external orthopedic systems.

Smith & Nephew at-a-Glance

Main Product

CORI

The Cori System is a handheld robotic device that uses advanced intelligence platforms to support system components

Semi-Active

Key Highlights

- Revenues in 2019: **$5,138M**, +4.8% vs. 2018
- Orthopedic revenues in 2019: **$3,758M** +4.4% vs. 2018
- Direct sales in **the US, Asia Pacific, and Europe**
- **Largest market reported in China**, second largest is the US

Clinical Applications

Orthopedic Surgery

Key Selling Proposition Points

Speed
Automatic registration from smart mapping reduces procedure time

Enhanced Workflow
Landmark capturing reduces time-consuming data collection

Accuracy
Clinically proven for implant placement, alignment, and bone resection

Smart Mapping
Image-free, real-time landmark collection and point mapping

Deep Dive

Current Value Proposition

Smith & Nephew's robotic specialties are **orthopedic surgical** systems and equipment.

Using **image-free pre-operative 3-D modeling** and **smart mapping,** procedures are performed **with augmented precision.**

Sales and Business Model

- CORI surgical systems are sold as **capital sales** to hospitals and orthopedic facilities.
- Smith & Nephew sells **disposable instruments and accessories** that are compatible with other orthopedic systems.

Future Plan

- Focus on **innovation and development** of new R&D programs to advance existing system

Note: Profile based on publicly available data.

Source: Company website and investors' reports; Alira Health analysis.

Legend: Hardware Sales: Capital Sales; Instruments and Accessories Sales; Operating Leases. Service Sales: SAAS[1]; Training and Maintenance

Zimmer Biomet

Company Profiles

Zimmer Biomet developed three robotic-assisted devices: ROSA knee system, ROSA ONE Brain, and WalterLorenz. These devices apply to hip and knee replacement surgery, neurosurgery and spine surgery, and are leased out to hospitals through operating agreements.

Zimmer Biomet at-a-Glance

Main Product

ROSA

The ROSA System consists of a robotic arm, optical tracking system, and software system that work to select intraoperative parameters and preoperative planning

Semi-Active

Key Highlights

- Knee and hip surgery product revenues for **2019: $4.745M**
- Spinal surgery products for **2019: $747M**
- Direct sales to the Americas and EMEA (Europe, Middle East, Africa), as well as Asia- Pacific

Clinical Applications

Orthopedic Surgery

Neurosurgery

Key Selling Proposition Points

Planning
Precise bone resection based on plan

Efficiency
X-ray and pre planned 3-D bone modeling imaging

Data Driven
Intelligence platform to connect pre-, intra-, and post operative data

Accuracy
Personalized care based on patient anatomy using dynamic tracking and real-time data

Deep Dive

Current Value Proposition

The ROSA Knee system assists with **total knee replacement, bone resection, and implant.**

The ROSA ONE Brain is a robotic assistant in that **plans and performs complex minimally invasive neurosurgery.**

Sales and Business Model

- Zimmer Biomet provides two options for a device purchase, one being a **cash capital purchase, and the other being reoccurring payments with operating agreements to lease** the ROSA Knee, ROSA ONE Brain, WalterLorenz systems.
- **Instruments and accessories** are reusable for a certain number of procedures with proper sterilization.

Future Plan

- **The WalterLorenz system is expected to expand geographically** and **increase penetration** because of forecasted **broaden application use.**

Note: Profile based on publicly available data.

Source: Company website and investors' reports; Alira Health analysis.

Legend: Capital Sales; Instruments and Accessories Sales; Operating Leases; SAAS[1]; Training and Maintenance

Hardware Sales | Service Sales

Globus Medical

Company Profiles

ExcelciusGPS, Globus Medical's robotic navigation system, combines a rigid robotic arm with an intuitive navigation system to assist in spinal surgery. The ExcelciusGPS system is sold to hospitals as a capital sale, and integrates with Globus implants and instruments.

Globus Medical at-a-Glance

Main Product

ExcelsiusGPS™
REVOLUTIONARY ROBOTIC NAVIGATION

Globus Medical's system incorporates a rigid robotic arm, smart navigation software, and a navigation console monitor compatible with any imaging system

Semi-Active

Key Highlights

- Revenues in 2019: **$785.4M,** +10.2% vs. 2018. This increase is attributed to a higher demand for ExcelsiusGPS
- **Direct sales force and distributors are primarily located in the US**
- ExcelciusGPS received the **CE mark** of approval for sales in the EU

Clinical Applications

Orthopedic Surgery

Key Selling Proposition Points

Navigation
AI machine learning navigates the surgeon using patient registration from preoperative images

Radiation Reduction
Shorter procedure time reduces the number of fluoroscopic images

Accuracy
Screw placement precision results from accurate identification of the target area

Target Identification
MRI guidance and solid fluid transmission articulation to identify the target

Deep Dive

Current Value Proposition

The Excelsius GPS system combines a rigid **robotic arm and full navigation capabilities** into one adaptable platform for **accurate alignment in spinal surgery**.

Sales and Business Model

- The ExcelciusGPS system is sold to hospitals as a **capital sale** and integrates with **Globus implants and instruments.**
- **Operating leases** are offered for both **short-term and long-term agreements**.
- **Compatible with a hospital's pre-existing image modalities,** such as pre-operative CT, intraoperative CT, and fluoroscopy.

Future Plan

- **Increase** the number of **direct and distributor sales representatives in the US.**
- **Expand the worldwide footprint** into ~50 countries outside of the US.

Note: Profile based on publicly available data.

Source: Company website and investors' reports; Alira Health analysis.

Legend: Capital Sales | Hardware Sales: Instruments and Accessories Sales, Operating Leases | Service Sales: SAAS[1], Training and Maintenance

Asensus Surgical

Company Profiles

Asensus Surgical is a semi-active laparoscopy system able to increase control and comfort for the surgeon and reduce surgical variability. Asensus Surgical's sales model encompasses renting and reusable instruments to improve cost-effectiveness.

Asensus Surgical at-a-Glance

Main Product

Senhance®

Senhance uses eye-tracking camera control, 3-D HD visualization, a robotic arm with haptic feedback, and an ergonomic console

Semi-Active

Key Highlights

- **Revenues in 2019 based on the Senhance System**: **$10M** +20% vs. 2018
- A direct sales force in the US and part of the EU
- Operating lease agreements are available in Germany and Japan

Clinical Applications

General Surgery

Technique

Laparoscopy

Key Selling Proposition Points

Cost-Effectiveness
Reusable instruments leverage existing hospital visualization systems

Control
Eye tracking capabilities allowing the surgeon to control the endoscope with eye movements

Feedback
Haptic control of instruments thanks to force-sensing on multiple degrees of motion

Deep Dive

Current Value Proposition

The Senahnce System digitizes the interface between the surgeon and the patient to increase control and comfort for the surgeon and to reduce variability in laparoscopic surgery.

The Senahnce System is the first platform to offer 3 mm instruments, the smallest instruments available in the world on a robotic surgical platform.

Sales and Business Model

- **Operating lease agreements** provide hospitals with a system **rental option that is more cost-effective** compared to the current standard of care.
- **Reusable instruments and accessories** are also available for purchase.

Future Plan

- **Increase the amount of Senhance System** foundational sites that profit from operating lease agreements and **expand geographically** to the EMEA and Asia.
- In **March 2021**, Asensus Surgical received an **additional FDA clearance** for the Senhance Surgical System which allows for indication **expansion in general surgery in the United States.**

Note: Profile based on publicly available data.

Source: Company website and investors' reports; Alira Health analysis.

Legend: Capital Sales | Hardware Sales: Instruments and Accessories Sales; Operating Leases | Service Sales: SAAS[1]; Training and Maintenance

Corindus

Company Profiles

Corindus Vascular's CorPath GRX system is a robot-assistant for cardiovascular interventional procedures. The system assists procedures using guidance control and TechnIQ software to automatically rotate the guidewire upon retraction.

Corindus at-a-Glance

Main Product

CorPath GRX

The CorPath GRX System is comprised of active guide management technology, TechnIQ smart procedural automation, and a radiation shield to protect surgeons from exposure

Semi-Active

Key Highlights

- Revenues: **$10.8M** in 2018, +12% vs. 2017
- **Direct sales and approval in the US**
- Acquired by **Siemens Healthineers** in 2019

Clinical Applications

Cardiothoracic Surgery

Technique

Endovascular

Key Selling Proposition Points

Precision

Sub-millimeter measurement and movement to position stents

Radiation protection

Radiation shield for surgeons reduces risk

Control

TechnIQ automatically rotates the guidewire upon joystick retraction

Deep Dive

Current Value Proposition

Robotic-assisted intervention enables **precise measurement of anatomy and device positioning** with the added benefit of **radiation protection** from a physician shield.

TechnIQ is a smart AI-based software to retract the guidewire through the body to eliminate procedure risks.

Sales and Business Model

- Most sales come from the **CorPATH GRX system.**
- A small percentage of the revenues is acquired by **consumable cassettes and drape sales.**
- Provides **training and maintenance** services**.**

Future Plan

- **Expand** medical education and **training** programs to support physicians, staff, and hospital partners.

Note: Profile based on publicly available data.

Source: Company website and investors' reports; Alira Health analysis.

Legend: Hardware Sales — Capital Sales; Instruments and Accessories Sales; Operating Leases | Service Sales — SAAS[1]; Training and Maintenance

CMR Surgical

Company Profiles

CMR Surgical is the UK's leading surgical robotics company that developed the Versius Laparoscopic Robotic System. The company is currently targeting in Europe, the Middle East, Asia and India. It received $600M funding in June 2021 and is evaluated at $3B.

CMR Surgical at-a-Glance

Main Product

versius®

The Versius Surgical System comprises a surgeon console, modular light-weight robotic arms and a range of wristed 5 mm instruments.

Master-Slave

Key Highlights

- The company raised $600M in series D funding in June 2021 and has **total disclosed funding of $986M.**
- The company is at a **$3B valuation**
- CMR currently employs approximately **700 people** and plans to grow its workforce to **2,000 in the next 4 years.**

Clinical Applications

- General Surgery
- Gynecological Surgery
- Urological Surgery

Technique

- Laparoscopy

Key Selling Proposition Points

Visualization
3D HD immersive vision provides precision, dexterity, and depth perception

Precision
V-wrist Technology mimics the human arm, allowing for greater precision and control

Mobility
Possibility to use 2 to 4 arms in combination with multiple control consoles

Ergonomic
A small and transportable system footprint and a comfortable surgeon console

Deep Dive

Current Value Proposition

The system claims to overcome obstacles to widespread adoption of robotic minimal access surgery, namely **robot size, instrument size, versatility, port placement, cost and ease of use**, allowing the **system to be highly utilized and ultimately cost-comparable to manual laparoscopic surgery**

Sales and Business Model

- **Versius Connect delivers data driven insights from a surgeon's clinical practice**. The **Versius Connect app** allows surgeons to record and "claim" every Versius procedure they perform, whether in the training environment or during live surgery.
- With "**hospital dashboards"**, it provides **insights on system utilization**, as well as predicting and scheduling planned maintenance to maximize utilization.

Future Plan

- Increase **presence in Asia and the Middle East** as a result of a partnership with **Gulf Drug,** a medical equipment supplier in the United Arab Emirates.

Note: [1]Software as a Service; Profile based on publicly available data.

Source: Company website and investors' reports; Global Data (2020) Alira Health analysis.

Legend: Hardware Sales — Capital Sales; Instruments and Accessories Sales; Operating Leases | Service Sales — SAAS[1]; Training and Maintenance

Avatera Medical

Company Profiles

Avatera Medical is a German company that developed a single patient cart with a four-arm robotic surgical system. It is currently conducting clinical trials and the system is expected to reduce the TCO for HC institutions, thus making robotics more accessible.

Avatera Medical at-a-Glance

Main Product

avatera

The Avatera Surgical System comprises a single patient cart with four robot arms and a surgeon console

Master-Slave

Key Highlights

- Avatera Medical received a **financing commitment** for an additional **EUR 100M** in 2020.
- Avatera received the **CE mark in Q4 2019. The company planned to perform a couple of hundred surgeries** before commercialisation.
- Avatera Medical started clinical trials in Germany and Southern Europe to acclimate surgeons to receive their feedback.

Clinical Applications

- Gynecological Surgery
- Urological Surgery

Technique

- Laparoscopy

Key Selling Proposition Points

Compact
Saves space with only two main components: a surgical robot and a control unit

Minimally Invasive
5-mm diameter instruments provide the seven degrees of freedom

Single-use products
Eliminates risk of cross-contamination

Economic Efficiency
The cost is almost half of Da Vinci's top range model to attract medium-sized to large hospitals

Deep Dive

Current Value Proposition

The Avatera System was **developed based on the current standards** in robotic-assisted surgery and was **optimized in close cooperation with future users,** including surgeons and surgical teams **in terms of cost, quality, comfort and reliability.**

Sales and Business Model

No publicly available data

Future Plan

- Plans to sell **250 systems annually in the first three years** of commercialisation in Germany and the rest of Europe.
- The next target geographies are **Russia, India, the Middle East and China.** In a further stage, market entry in the US is planned.

Note: [1]Software as a Service; Profile based on publicly available data.

Source: Company website and investors' reports; Global Data (2020) Alira Health analysis.

Legend: Hardware Sales: Capital Sales; Instruments and Accessories Sales; Operating Leases. Service Sales: SAAS[1]; Training and Maintenance

MMI Micro

Company Profiles

MMI Micro developed a master-slave robotic system called the Symani Surgical System for microsurgery applications. The system has obtained the CE mark of approval and plans for FDA approval for US commercialization in the future.

MMI Micro at-a-Glance

Main Product

Symani

The Symani System incorporates NanoWrist micro instruments, tremor filtration, a 3-D visualization system, and an ergonomic surgeon

Master-Slave

Key Highlights

- **CE mark of approval** allows for direct sales in Europe
- Headquarters **based in Italy**

Clinical Applications

- Orthopedic Surgery
- Neurosurgery

Technique

- Microsurgery

Key Selling Proposition Points

Precision
NanoWrist instruments provide submillimeter precision and micromovement

Motion Control
The system provides motion scaling and tremor reduction

Dexterity
The surgeon can access anatomies that are difficult to reach using wristed instruments

Control
Instruments can target anatomy provided by seven degrees of freedom

Deep Dive

Current Value Proposition

The Symani Surgical System was developed **specifically for microsurgery procedures** designed to **improve a surgeon's ability to access and suture small, delicate anatomy.**

Sales and Business Model

- **Sales of capital equipment and proprietary disposable instruments** account for most of the system-based revenues.

Future Plan

- In the future, MMI Micro will **apply for FDA approval** for US commercialization.

Note: Profile based on publicly available data.

Source: Company website and investors' reports; Alira Health analysis.

Legend: Capital Sales; Instruments and Accessories Sales; Operating Leases; Hardware Sales; SAAS[1]; Training and Maintenance; Service Sales

Johnson & Johnson

Company Profiles

Johnson & Johnson entered the robotic-assisted surgery space with two acquisitions for completely different applications. In the addition to the two already FDA-cleared surgical platforms, J&J is working on a third robotic platform for general surgery.

Johnson & Johnson at-a-Glance

Main Product

VELYS™ Digital Surgery — Semi-Active

The VELYS robotic-assisted platform is a table-mounted solution, helping to execute accurate bony cuts.

MONARCH — Passive

The Monarch Platform is a robotic endoscope that uses an intuitive controller interface to navigate the surgical field

Key Highlights

- **Johnson & Johnson** and DePuy Synthes **acquired** the VELYS system **from its developer, Orthotaxy, in 2018**
- **In 2019** Ethicon, part of the **Johnson & Johnson** Medical Devices Companies, **acquired Auris Health,** a robotic endoscopy medical company

Clinical Applications

VELYS

Orthopedic Surgery

MONARCH by Auris Health

Cardiothoracic Surgery[1]

MONARC Technique

Endoluminal

Key Selling Proposition Points for MONARCH

Interface
Instinctive interface to navigate the endoscope to the periphery of the lung

Technology
Innovative telescoping design allows for greater reach, vision and control

Platform
Designed for mobility and upgradeability for future clinical applications

Deep Dive

Current Value Proposition

VELYS

The **VELYS** Robotic-Assisted Solution **simplifies knee replacement surgery** by providing valuable insights, versatile execution, and verified performance to deliver efficiency for surgeons and to optimize patient outcomes. The **VELYS** Robotic-Assisted Solution delivers a **reduced footprint** compared to other knee replacement surgical robots.

MONARCH

The Monarch Platform is a **bronchoscope device** that reaches deeper into the lung than traditional devices. Physicians can use the **scope** with both direct vision and software guidance to **hard-to-reach areas of the lung.**

Sales and Business Model

VELYS

Not publicly available data

MONARCH

- The Monarch system is sold as a **capital sale** directly to hospitals or with an **operational service agreement** based on the use of the device.
- Reusable **instruments and accessories** require sterilization between procedures.

Future Plan

Johnson & Johnson is developing Ottava, its general surgical robotics platform. The Ottava System will employ Ethicon instrumentation (**up to six robotic arms**) with advanced visualization, machine learning, and a connected ecosystem.

Note: [1] Peripheral Bronchoscopy; Profile based on publicly available data.

Source: Company website and investors' reports; Alira Health analysis.

Legend: Hardware Sales — Capital Sales; Instruments and Accessories Sales; Operating Leases | Service Sales — SAAS[1]; Training and Maintenance

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Key SoR[1] Span from Capital Sales to Consumables and Services

Current and Upcoming Sales and Business Models

Currently, companies in the RAS market position themselves with diverse sales and business models comprising revenues from hardware sales, service sales, or a mix of both.

Hardware Sales → **Service Sales**

System-Related Revenues

In the most classic model, the **full robotic system,** including robotic arms, monitors, and surgeon console, **is sold as an upfront purchase.**

Instruments and Accessories Revenues

Instruments and accessories are either disposable after a single-use or reusable with sterilization for a certain number of uses, examples include ofendoscopes, sterile drapes, forceps, scissors, and cautery tools.

SAAS

Additional software, such as an AI algorithm, **can be sold independently from the robotic system**.
When the purchase of a robot is completed, the **software to guarantee the functionality of the system, is provided with the platform** itself.

Training

In the **first years** of the contract, training sessions for surgeons and OR staff are **usually included in the package. For following years, training sessions need to be negotiated** with the companies or certified training robotic centers across the US and EU.

Post-Sales Services

Often, in a sales package, vendors include **3 to 5 years for maintenance, servicing, upgrades and 24-hour service** in case of a breakdown or problem.

Today's Contribution to Total Revenues by SoR

HIGH	VERY HIGH	LOW	MEDIUM-LOW	MEDIUM-LOW

Note: [1]Source of Revenues.

Source: Publicly available company information; Alira Health analysis.

Sales Models are Becoming More Flexible, Addressing Access Barriers

Current and Upcoming Sales and Business Models

Upfront costs being one of the key barriers to adoption, players in the robotic markets are shifting towards flexible sales models, such as leasing, renting or pay-per-use. More competitive business models are expected to emerge in the coming years.

Capital Sales Model

The entire robotic platform is **purchased upfront by the hospital**. **Additional sources of income** for the company are the sales of proprietary/custom made consumables. This option requires a **significant initial economic effort from the hospital**, a very uncommon possibility for small and medium facilities.

Pay-per-Use Model

There is **no initial cost for the platform.** The company receives **payment based on the number of procedures performed, which is agreed to upfront**. The average cost per procedure is **defined during the negotiation process** and platform **consumables and services can be included** in the total cost. This solution could be a great option especially for a medium or small medical center with low procedural volumes.

Operating Lease / Rental Model

Through a lease/rental option, the **upfront cost for the purchase of a platform is zero**. Along with the lease/rental fees, the hospital is often required to purchase the consumables from the vendor for the duration of the contract.

Upcoming Disruptive Models

Minimal or no cost related to the purchase of the platform. Instead, the **entire business model could revolve around consumables and/or software**.

Source: Companies' websites; Alira Health analysis.

Sales Model: Intuitive & Galen Robotics

Current and Upcoming Sales and Business Models

Moving from traditional capital sales models, innovative companies in the robotic space have begun offering multiple and more flexible options to ease integration into already existing workflows, and to lower investment costs for hospitals.

Intuitive Surgical's Business and Sales Model

- **Intuitive Surgical has remained a leader in the RAS market** since the release of the da Vinci surgical system in 1999.
- In **2010**, the company's revenues totaled **$1.4 billion**. In **2019**, Intuitive Surgical generated revenues close to **$4.5 billion**.
- While approximately 30% of their revenue is attributed to capital equipment sales, **more than half of their revenues can be attributed to the sale of instruments and accessories**.

- In the coming years, a key to the company's recurring revenue growth will be customers opting **to lease systems rather than purchase them**. Currently, ~**33%** of systems are under **usage-based arrangements and operating leases**, which is expected to remain a growing trend among robotic surgical system customers.
- Leveraging a first-mover advantage, Intuitive Surgical supported its innovative sales model with the **development of a comprehensive training program** for its systems.

Galen Robotics Business and Sales Model

- Founded in 2016, Galen Robotics represents a **new competitor in the neurosurgical robotics market**. Currently in clinical development, Galen is working to **create a single-platform solution** to aid in neurosurgery and ENT procedures.
- With minimal disturbance to existing workflows, Galen offers their **software platform as a service for integration,** with a wide range of standard surgical tools.

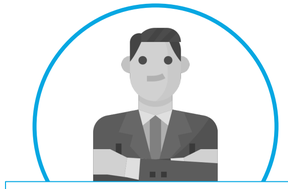
- The microsurgical robotic platform is a small **cooperative robotic motor system**, through which the surgeon inserts his/her instruments.
- Known as a pioneer in the "**digital surgery as a service,**" Galen's device will be capable of **delivering cloud-based big data analytics** and machine learning to assist future surgeons in identifying the best steps in performing delicate surgeries and **offering augmentative assistance during procedures.**

- Expansion into **alternative sales forms,** such as instruments and accessory sales that are compatible with a range of systems, offering software as a service, and development of new software technology compatible with existing robots can **boost market adoption due to increased affordability of systems and ease of integration** into already existing hospital platforms.
- With the forecasted market expansion ahead, **different sales and business models,** such as renting or multidisciplinary devices, **are expected to hit the market.**

Source: Intuitive Surgical (2020); Forbes Business Insights (2019); Galen Robotics (2020); Alira Health analysis.

A Structured S&M[1] Effort Is Required to Support a Successful Business Model

Current and Upcoming Sales and Business Models



Account Managers

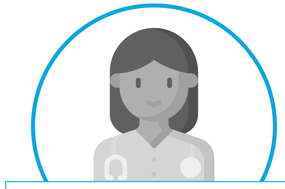
Account Managers are the key stakeholders in the context of **client engagement and closing of a first-sale**. They should **have financial, strategic and selling capabilities, as well as deep product knowledge.**

Clinical Specialist

Clinical Specialists are **key stakeholders when it comes to penetration of existing accounts.** They spend the majority of their time on-site, engaging clinical call-points and fueling sales growth within existing accounts. They also provide guidance on the utilization of installed systems.

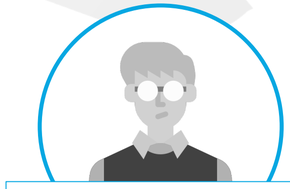
Field Engineer

Field Engineers are involved in the selling process after the PO[2] closing to support the software installation. Afterwards, they regularly visit the account every quarter to take care of recurrent updates.



Proctor

Proctors are **independent contractors** who support the account as part of the training process. They **deliver system training sessions to surgical teams as well as provide product knowledge** support to teams during proctored cases.



Customer Service

Customer Service Representatives support the end-to-end sales process, offering 24/7 support to clients by directly answering their questions or triaging them to field engineers.

Key Roles

- **Lead generation**
- **Account engagement**
- **Continuous surgeon engagement to upsell**
- **Set-up, testing, software installment**
- **On-site support in case of hardware/software issues or updates**
- **Training sessions for surgical teams, and proctored cases**
- **Product information, purchase support**
- **Product-related questions and triaging**

Note: [1]Sales & Marketing; [2]Purchase Order.

Source: Primary interviews; Alira Health analysis.

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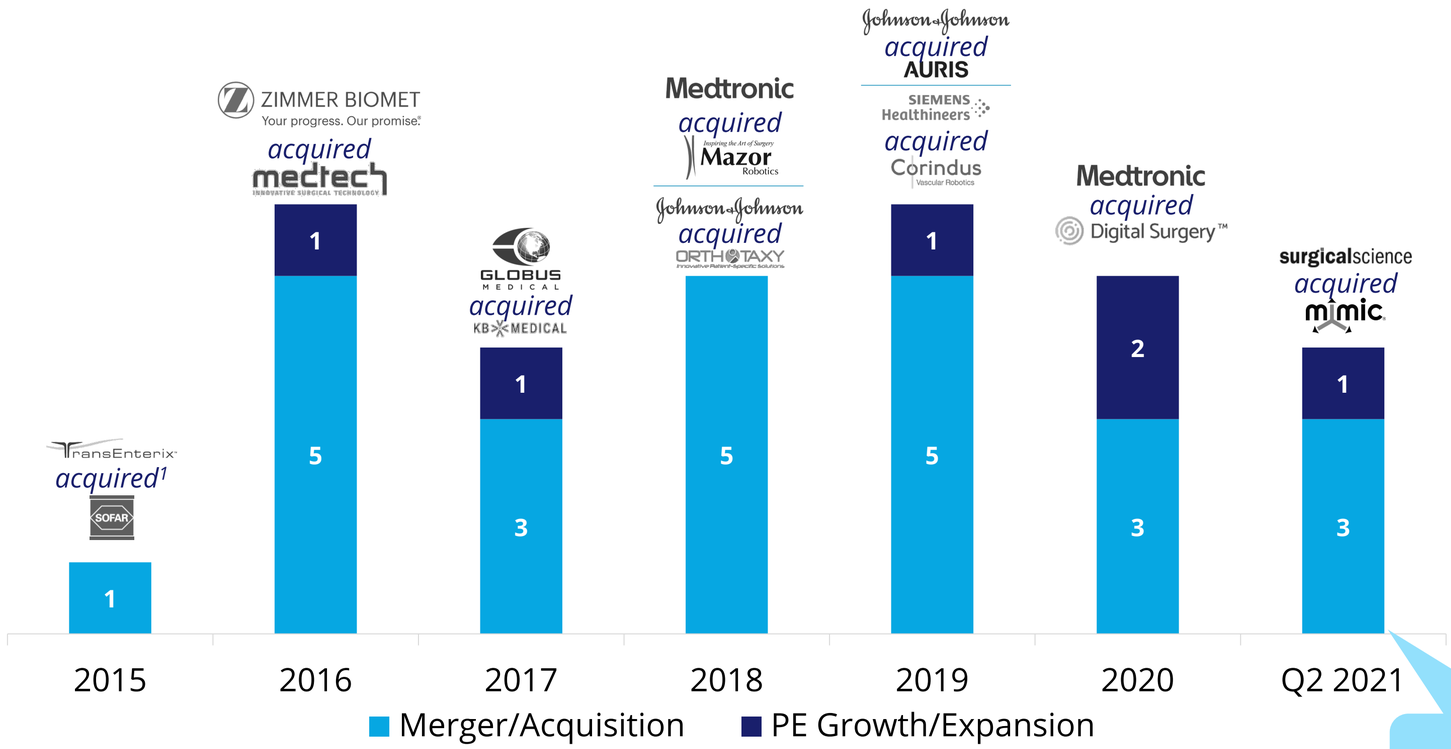
The M&A Activity is Led by Large Groups to Accelerate Market Entry

Deal Flow Analysis

Over the past years, large MedTech companies have been trying to enter the market or strengthen their positioning in the RAS space through new acquisitions.

Number of RAS M&A and PE expansion deals

2015 to Q2 2021



SPAC deal: D8 Holdings' acquisition of Vicarious Surgical

Key Highlights

Established firms and larger groups in the surgical medical devices and operating room space **have been acquiring new technologies to compete with Intuitive Surgical's first-mover advantage:**

- Between 2018 and 2019, **Johnson & Johnson acquired Orthotaxy and Auris Health ($5.8B)** to enter into the field of orthopedics and endoluminal surgeries.
- **Medtronic** entered the RAS market in 2018, **acquiring Mazor Robotics ($1.7B),** and strengthening its position by broadening the offered services and its ecosystem with the recent **acquisition of Digital Surgery**, a company specialized in surgical artificial intelligence (AI), data and analytics.
- In 2019, **Siemens Healthineers bought Corindus** for **$1.1B** and is now working on building a complete robotic-assisted ecosystem combining the CorPath GRX from Corindus and its imaging abilities.
- In 2019**, Stryker bought Mobius** Imaging and its subsidiary, Cardan Robotics, for **$500M**.

Note: [1]Asset deals: TransEnterix (now Asensus Surgical) acquired SOFAR's surgical robotics division.

Source: Pitchbook; Alira Health analysis.

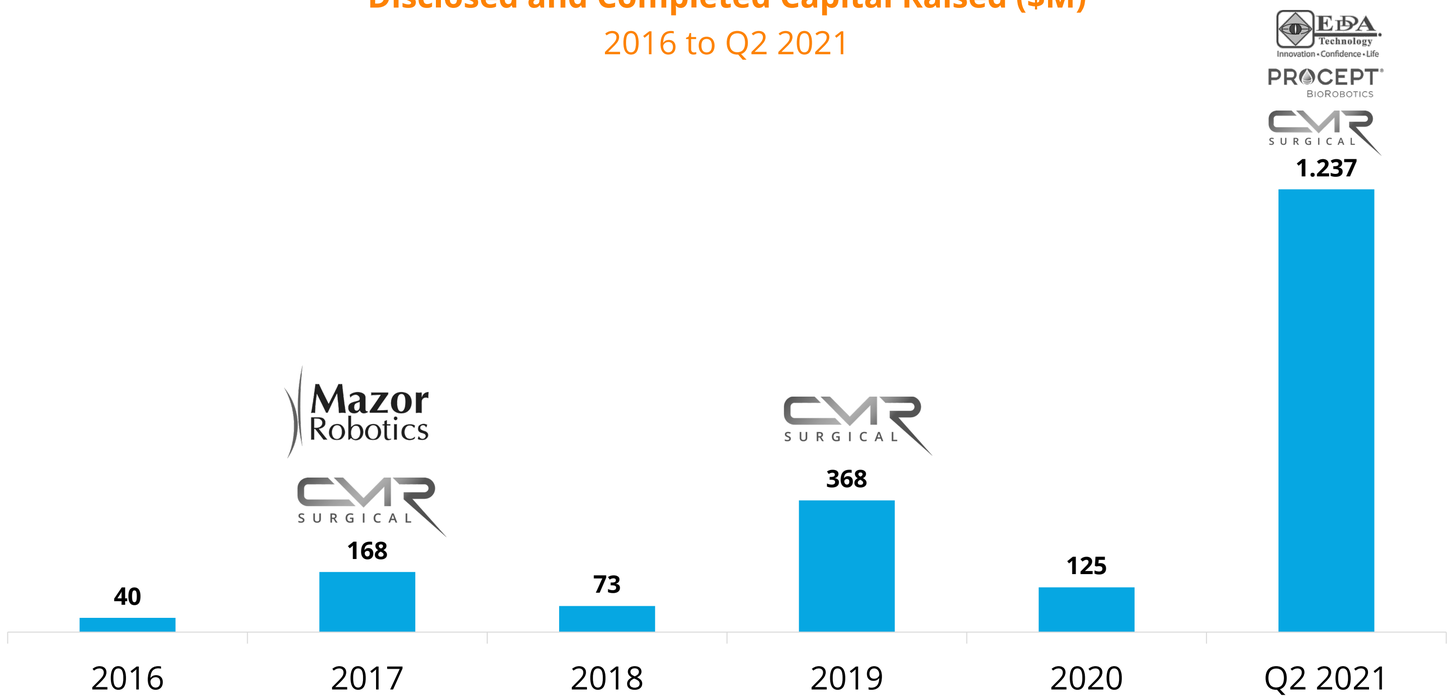
With More Than $1B of Capital Raised, 2021 Has Been an Unprecedented Year

Deal Flow Analysis

The last four years have shown an uneven activity from venture funds in the RAS space. In 2021, CMR raised $600M and, up to the end of Q2, there has been more than $1.2B from venture funds.

Disclosed and Completed Capital Raised ($M)

2016 to Q2 2021



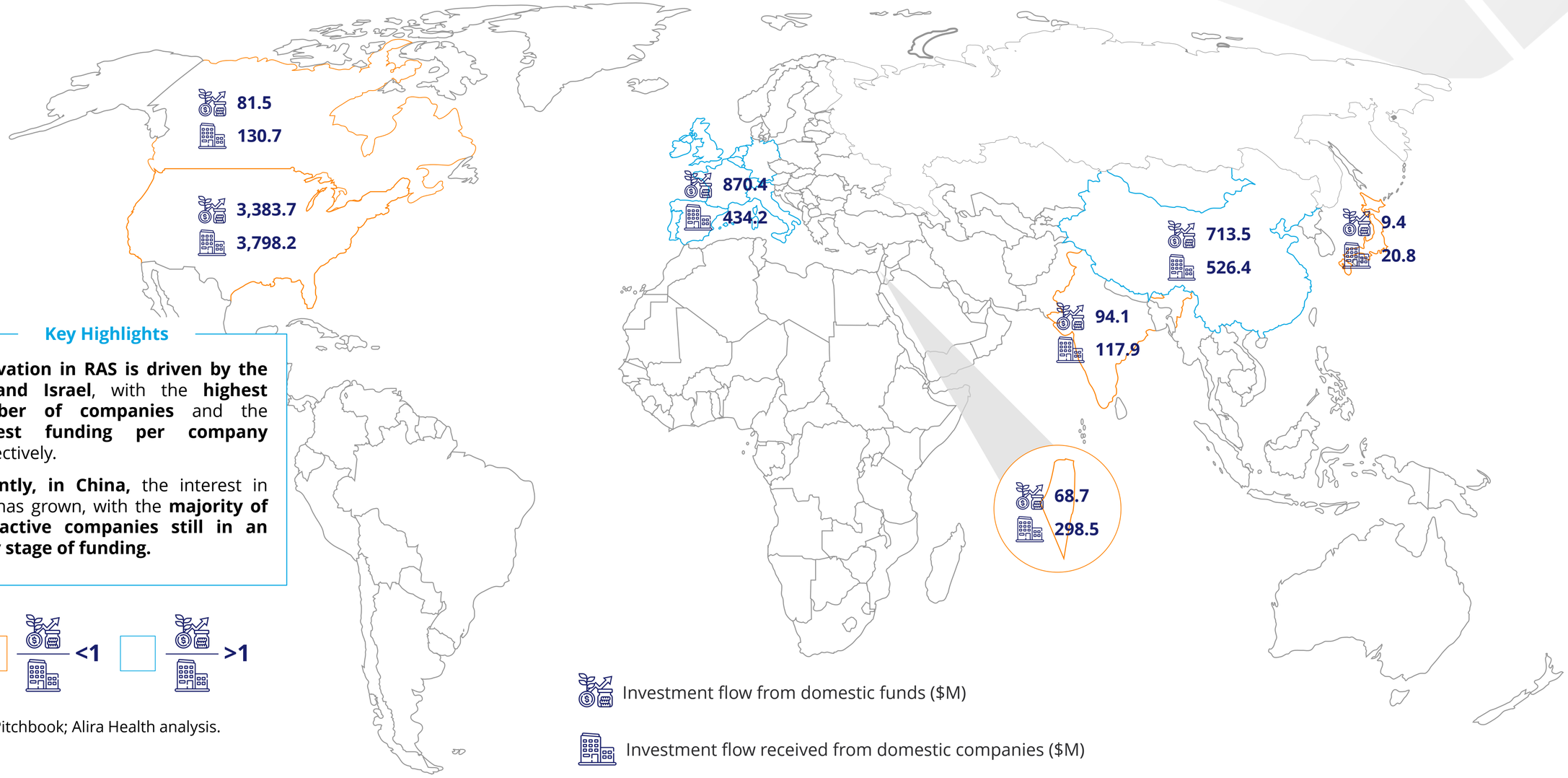
Key Highlights

- The high-paced growth of RAS and the increase in the number of start-ups, has been **attracting funds from venture capitals.**
- **2021 has been exceptional,** with more than $1B of funds raised:
  - **CMR Surgical raised $600M** (laparoscopic robotic surgical system)
  - **EDDA Technology raised $150M** (intraoperative navigation robots)
  - **PROCEPT BioRobotics raised $85M** (ultrasound-guided surgical robot)
- Apart from institutional funds, **Intuitive Surgical also launched a $100M venture-capital fund in 2020** to invest in start-ups working on minimally-invasive surgery.

Source: Marketline database-updated as of 16th July 2021; Public disclosures; Alira Health analysis.

Since 2019, Key Economies Have Invested in RAS

Deal Flow Analysis



Key Highlights

- **Innovation in RAS is driven by the US and Israel**, with the **highest number of companies** and the **highest funding per company** respectively.
- **Recently, in China,** the interest in RAS has grown, with the **majority of the active companies still in an early stage of funding.**

<1 >1

Investment flow from domestic funds ($M)

Investment flow received from domestic companies ($M)

Source: Pitchbook; Alira Health analysis.

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Takeaways from the RAS Commercial Landscape

Key Takeaways

The approval process (FDA clear or CE mark) for RAS platforms follows a different **pathway based on the field of application and level of innovation** (AI or not) of the platform. The **reimbursement is different across countries**, in many of which there is no specific code for RAS.

Currently, there are more than 35 robots on the market for different types of surgical applications and **more than 150 currently being developed** by companies and start-ups, the majority at an early stage of funding. The pipeline analysis shows a **strong interest in the development of procedure-specific robots,** with the idea of **making more affordable and compact solutions without compromising performance**.

Most of the revenue from current system sales, apart from the system itself, **is coming from consumables and new additional software** for video enhancement and real-time analysis. Another portion of the revenue is represented by training sessions and post-service sales.

Aware that upfront costs are one of the key barriers to adoption, players in the **robotic markets are shifting towards flexible pricing models, such as leasing, renting, or pay-per-use**. More competitive, and potentially disruptive, business models are expected to emerge in the coming years.

The number of deals in the RAS space has constantly grown over the last few years, while **large MedTech companies are trying to enter the market or strengthen their position with new acquisitions**. Well-established players are expanding their portfolio of services and are building up a completely **new ecosystem for RAS by acquiring companies of AI and imaging navigation**.

Innovation in RAS is driven by the US and Israel, with the highest number of companies and the highest funding per company, respectively. Recently, in **China, interest in RAS has grown, with most of the active companies still in an early stage of funding**.

Source: Alira Health analysis.

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Staying Ahead of the Curve: Technology Trends

Future Robotic Outlook

The implementation of artificial intelligence, augmented reality, miniaturization of systems, and tele-surgery are technology trends that are expected to impact the market and further facilitate the adoption and capabilities of robotic surgical systems.

Artificial Intelligence

- The **combination of artificial intelligence and RAS** allow for the development of future autonomous robots
- **Rather than replacing** human surgeons, it will **assist surgeons by performing tedious subtasks,** such as suturing and debridement to improve consistency and reduce fatigue
- Platforms are **trained using several cognitive learning algorithms** and can perform a surgery supported by a variety of sensors

Augmented Reality

- The development of augmented reality devices in surgery has **allowed physicians to incorporate data visualization into diagnostic and treatment procedures** to improve work efficiency, intra-operative visualization, and to enhance surgical training
- The future of RAS will **combine elements of augmented reality, haptic feedback, and robotic manipulators** to **enhance** the next-generation of **surgical systems**

Miniaturization

- There has been a push to reduce the of RAS footprint
- A **smaller footprint would require less space in the OR, potentially increasing the adoption** in medium and small facilities
- New materials and technologies are being explored to widen the application field

Tele-Surgery

- Surgical robots have allowed for the exploration of tele-surgery
- Advancements in the world of tele-surgery have been **focused on decreasing latency time, the time delay in the transfer of auditory, visual, and tactile feedback between the two locations**, utilizing 5G signaling

Future Outlook

VERY HIGH	HIGH	HIGH	MODERATE	MODERATE

Source: Company websites; M. Bhandari et al.(2020); Intuitive Surgical (2020); Alira Health analysis.

Artificial Intelligence: How it Works

Future Robotic Outlook

AI-controlled robots can mimic human behaviors. Robots are trained using several cognitive learning algorithms and can perform surgery supported by a variety of sensors that provide real-time multimodal sensory data.

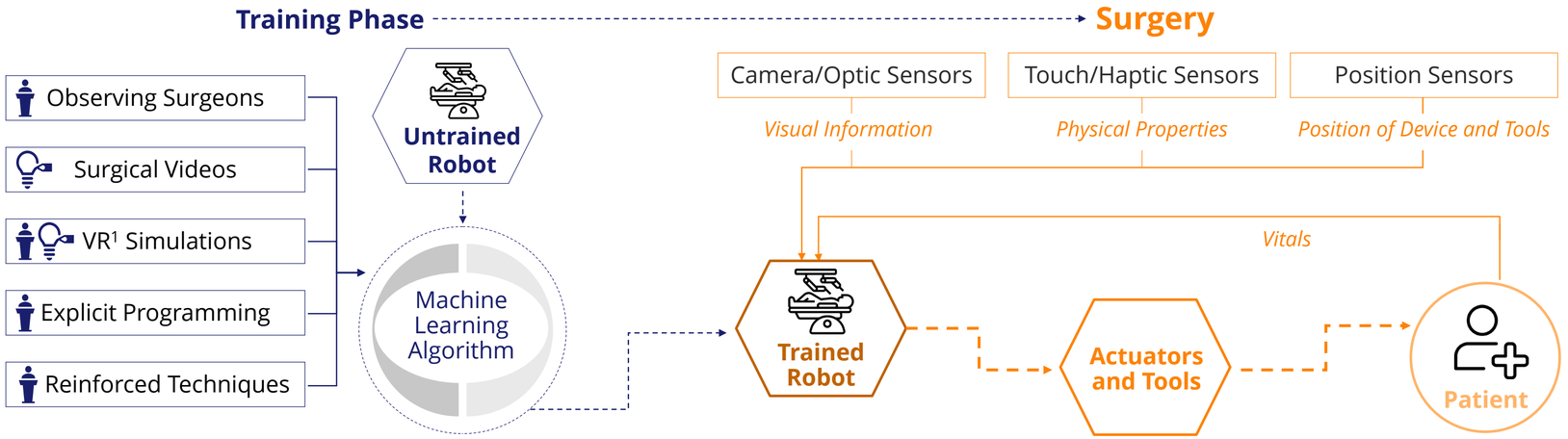
Artificial Intelligence

- The combination of **AI and RAS allow for the development of future autonomous robots** that will have the ability to "see," "think," and "act" without human intervention to safely and effectively achieve a predetermined surgical goal
- Three parameters define the task of an autonomous surgical robot: **mission complexity**, **environmental difficulty**, and **human independence** (autonomy degree)
- **Autonomy** is defined as the ability to perform intended tasks based on current state and sensing without human intervention

Artificial Intelligence in RAS

- The surgical robot is controlled by AI algorithms and input received from an **array of visual and haptic sensors** providing a real-time stream of multimodal sensory data
- The robot's processors and algorithms integrate the data sources as well as environmental data, e.g., patient vitals, to produce the surgical output via the robot's actuators
- **These physical outputs allow the robot to achieve its surgical goal** within its environment, which is subsequently physically modified by its actions. The robot's sensory apparatus monitors all subsequent changes in real time, to modify its future actions

Simplification of process to train and perform a RAS using AI



- The types of **machine learning** (ML) relevant **to train autonomous surgical devices** can be divided into **unsupervised and supervised** learnings and can be applied to continuous or categorical data sources
- Some ML techniques are rooted in **traditional statistical principles** (e.g., regression), whereas **others involve decision mathematics and computer science principles**. **Reinforcement learning** is rooted in psychological principles, where the agent (robot) performs its actions within its environment to achieve an end goal. Each action that brings it closer to its goal yields a **positive reward** (and vice versa).

Note: [1]Virtual Reality.

Source: Annals of Surgery: Artificial Intelligence and the Future of Surgical Robotics (2019); Alira Health.

Augmented Reality: How it Works

Future Robotic Outlook

The future of robotics will aim to combine elements of AR with robotic manipulators, enabling remote operation by providing surgeons with enhanced vision and navigation capabilities.

Augmented Reality

- **AR enhances the vision or perception of the user** by overlaying and combining a rendering of information to their field of view
- The development of **AR devices in surgery has allowed physicians to incorporate data visualization into diagnostic and treatment procedures**, improving work efficiency, intra-operative visualization, and enhancing surgical training
- In challenging operations that require speed and dexterity, such as neurosurgical and cardiothoracic procedures, **AR allows the surgeon to maintain attention on the surgical field while simultaneously viewing patient scans**

Augmented Reality in RAS

- The **future of RAS** will combine elements of augmented reality, haptic feedback, and robotic manipulators, to enhance the next generation of surgical systems
- These capabilities will **allow any surgeon**, located away from the operating table, **to view the operating field directly from the point of view of the robotic arm**, with an AR overlay displaying patient scans and a pre-determined operative plan

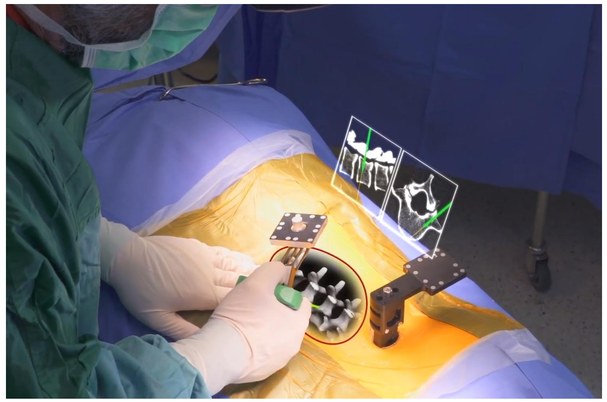
AR Component Overview

Pre-Operative Planning

A combination of a patient's pre-operative CT and MRI scans along with the pre-determined surgical plan are integrated at the registration center to form a 3-D anatomical model.

Main Visual Source

Intra-operatively, data from the main visual source is sent to the registration center to be used as the base image for rendering. The main visual source in robot-assisted procedures is often the stereo laparoscopic device, attached to one of the robotic arms.



Computer Processing

The projection of AR is made possible by combining data from projectors, cameras, trackers, and other specialized equipment.

A registration process is needed to properly adjust the augmentation inputs with respect to the main visual field to create cohesive image.

AR Projection

Through a variety of mediums, such as an electronic monitor, a projector, or virtual reality glasses, the AR interface is presented to the surgeon, giving them a view of the surgical field with the AR image overlayed on top.

Source: Lee *et al* (2020); Madhavan *et al* (2017); Qian *et al* (2020), Hunniwell Ventures Material.

Miniaturization: How it Works

Future Robotic Outlook

Miniaturization allows the surgeon to navigate in smaller spaces and reduce the number of incisions compared to other surgical technologies. Manufacturing complexity, cost, and surgery integration are some of current limitations of this technology.

Miniaturization

- The constant **push to reduce the footprint of RAS,** including the number and size of incisions as well as the financial and physical impact of the surgical system have been leading companies to focus on robotic miniaturization
- **Strong materials**, **small power source**, **precision manufacturing**, **small internal electronics, and visualization systems** allow for the development of this technology
- As with other new technologies, **a few limitations are impacting adoption**: Smaller devices generally cannot apply as much force as large ones. As well, have a more limited range of motion and visibility when compared to open surgeries

Miniaturization in RAS

- The continuous shrinking of devices leads to the **exploration of new materials and technologies**. Today, two technologies are quickly emerging: **magnetic and fluid devices** and **soft robotics.**
- The success of these technologies means the adoption of those in applications that cable-driven devices cannot currently be used. Nevertheless, limitations such as manufacturing complexity, cost, and easy integration with surgery environment still exist.

Miniaturization Sub-Technologies

Concentric Tube Robots

The robots articulate through a series of concentrically–nested curved tubes that can individually rotate to move the end to a certain position. Generally, they are smaller than tendon-driven devices but less dexterous. *(C)*

Cable-drive Serpentine Backbone Robots

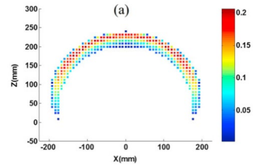
Such robots are cable-driven with a jointed backbone that contains a series of wrist–like joints that can be manipulated with cables to move to a certain position. Used in the current SoC, it's lightweight, can exert large forces, and has a fast response. However, it has a complex structure and is only capable of moving in one direction (no compression). (B)

Cable-driven Continuum Backbone Robots

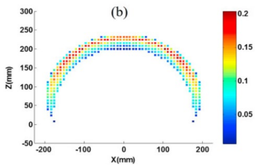
The robot's material allows memory shape and features surgical arms that are made of soft materials containing microchannels that can be filled with fluid or air to shape the arms. The robot can be single (one continuous, flexible backbone) or have multiple backbones connecting a series of discs to one another, which are moved by manipulating cables attached to them. *(A)*

Untethered Mobility Robots

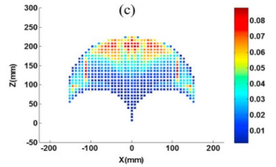
These devices can move in three different ways: natural motion, moving with the body, such as peristalsis or blood flow; electro/magnet actuation, where a magnetic/electromagnetic force is applied externally; or mechanical actuation, where the device contains "legs" or other mechanism that allows its movement in the body without being tethered.



(A) cable-driven continuum backbone



(B) cable-driven serpentine backbone



(C) concentric tube robots

Both cable driven robots have similar dexterities, while the concentric tube robot has a substantially different dexterity.

Source: Badal, Justin, Canvasser, Noah (2019); Hunniwell Ventures Material.

Tele-Surgery: How it Works

Future Robotic Outlook

Tele-surgery utilizes surgical robots to allow surgeons to perform surgery remotely. Operating through a closed-loop system, the surgeon manipulates the master console, transmitting information to the teleoperator machine and back.

Tele-Surgery Overview

- Tele-surgery uses **wireless networks and robotic technology**, giving surgeons the ability to **operate on a patient remotely**
- The world's **first successful tele-surgery was completed in 2001**, using the ZEUS surgical robotic system manufactured by Intuitive Surgical, during a laparoscopic cholecystectomy
- Since then, several tele-surgical procedures have been performed. However, **adoption has been limited due to the lack of a reliable network connection**, as well as the lack of RAS technology in many institutions

Tele-Surgery Advancements

- Major advancements have **decrease latency time**, which is the time delay in the transfer of auditory, visual, and tactile feedback between the two locations. Generally, latency has fallen below 200 milliseconds, however, **variable latency still proves to be a challenge**, especially considering the different types of sensory modality being transmitted. The **implementation of 5G signaling will aim to eliminate this data lag**
- Conventional tele-surgery modalities have a **lack of haptic information**, causing the operator to receive visual feedback only. Coupled with the **lack of depth perception** due to a flat monitor, **visualization improvements** are necessary for the implementation of tele-surgery systems

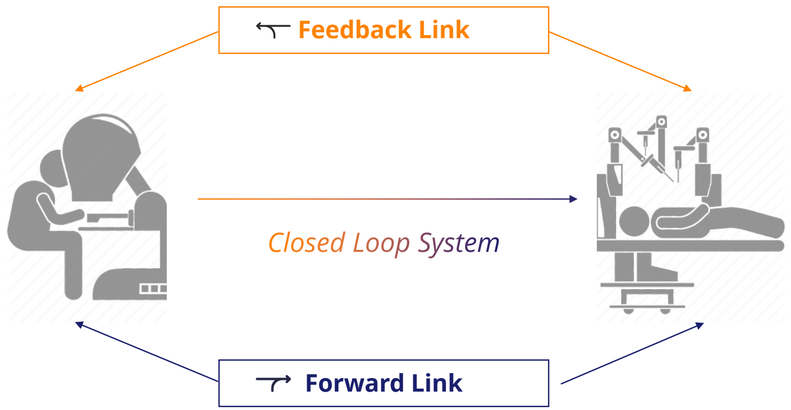
Tele-Surgery Technology

Master Console

At the master console, the surgeon directs the surgical robot using manipulation commands, the robotic controller, and audio and eye-tracking commands.

Forward Link

The forward link transports real-time manipulation commands from the master console to control the motions and rotation of robotic arms, along with voice stream from the surgeon to communicate with the remote surgical team at patient bedside.



Feedback Link

The feedback link transports real-time multi-modal sensory feedback from the teleoperator, including a 3-D video stream, force feedback, tissue mechanical properties, and a patient's physiological data, e.g., blood pressure and heart rate, along with a voice stream from the assistant nurses, anesthesiologists, and other collaborating surgeons from the patient's bedside.

Teleoperator

At the patient's bedside, the surgical robot executes the task as dictated by the surgeon located at the master-slave console.

Source: Zhang *et al* (2018); Acemoglu *et al* (2020); Alira Health analysis.

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David Uffer has over 25 years of management experience in the medical device, products and clinical diagnostics fields. He has led strategy development, strategic planning and business development activities in these fields for mid and large cap public companies. David has executed deals ranging from M&A, licensing, and distribution to co-development for companies such as Medtronic (legacy Covidien) in their respiratory and medical products business, as well as Hologic in women's health and Boston Scientific in interventional medicine and surgery. He has held management roles at Integra Lifesciences and Abbott Labs. David has a BA from Clark University, Worcester, MA and an MBA from Thunderbird, School of Global Management, Glendale, AZ.

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Piergiulio Lauriano, MBA, is a strategist and innovator who combines a passion for business and finance with a hands-on technology background. His early career included management consulting in the US and Italy where he specialized in healthcare, advising on corporate strategy and restructuring, organic growth, portfolio innovation and M&A. He has gained considerable market experience at Alira Health across several domains including: surgery comprising MIS and robotics, patient monitoring, oncology, addiction, diabetes, orthopedics, cell therapies, plasma derivatives, infection prevention and control, consumer health, and Woundcare. Piergiulio holds an MBA from the IE Business School, an MSc in Managerial Engineering from École Centrale de Nantes and an MSc in Robotics and Computer Engineering from the University of Genova.

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Raquel Ribeiro joined Alira Health as an Analyst in July 2020 and is currently pursuing her MBA at the ESADE Business School. She has a Master in Pharmaceutical Sciences and 6+ years’ experience in the healthcare industry. Her professional experience in healthcare began in the Export Department of a Portuguese healthcare company where she held the position of Logistic and Supply Chain Manager, working with emergent markets in Africa, especially Angola. She then moved and joined Boots Norway where she took a leadership and management role in a pharmacy, developing her customer-driven mindset. Finally, she pursued additional learning experiences in healthcare by completing a Career Accelerator Program in Healthcare at ESADE and by being the President of the ESADE MBA Healthcare Club.

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Amanda Celia graduated from The University of Rhode Island with a Bachelor's of Science in Biomedical Engineering with minor in Mathematics. She then began her role at Alira Health as a MedTech Intern. Her interest in medical robotics began with an academic study involving lower-limb prosthetics, balance detection, and feedback systems. She now continues her career with automated instrumentation in Massachusetts General Hospital's Neurology Department.

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A (Non-Exhaustive) List of RAS Vendors (1/2)

A

Acrobot

AcuSurgical

Aopeng Medical

Aptorum Group

Ark-la-tex Urology

ARTHROBOT

Asensus Surgical

A-Traction

Augusta Arthritis Center

Auris

Avatera

AVRA Medical Robotics

B

Bingshuo Biomedical

Borns Robot

Bota systems

Bradford Md

Brainlab (Orthopaedic Joint Reconstruction Business)

Bridger Orthopedic

C

CAScination

China Joint Venture (Ally Bridge Group & LifeTech Scientific Corporation & Quantum Surgical)

ClipTip Medical

ColubrisMX

Cv RAS

Cyberdontics

D

Delreysinus

Dex Surgical

DEXSONO MEDICAL

Diggs Realty

Distalmotion

Drgholami

E

Echopoint

EdgeMedical

EndoControl

EndoMaster Pte Ltd

Excelsius Surgical

F

Forcen

ForSight Robotics

FreeHand

Freehold Surgical

Fusion Robotics

G

Galen Robotics

Garrison Women's Health Center

Greystone OB/Gyn

H

Hamesh Medical

Hanjani Md

HealthCare Global Enterprises

Hehua Ruibo

Hutchinson Technology (Medical Business)

I

Imorphics

Infinite Mind

Injeq

InnovoTone

Insight Medbotics

Insight Medical Systems

Instrumen

INTEGRIS

International Centre for RAS

K

K & B Surgical Center

Kezhixing Robotics

L

LapTics

Lightpoint Medical

Liuyedao Robots

M

Mazor Robotics

Medical Surgery Technologies

Medineering

Medsys

MedTech (surgical robots)

A (Non-Exhaustive) List of RAS Vendors (2/2)

MeereCompany Inc.
Melzi
Memic Innovative Surgery Ltd.
Microbot Medical Inc.
MicroPort Medical Robots
MicroSure

N

NDR Medical Technology
Neocis
NeuroArm Surgical
Neurowired
NISI
nView medical

O

Origami Surgical
Osso VR
oVio Technologies

P

Palliare
Partners In Urology
Praxicut
Precision Robotics
ProPep Surgical
Proprio
Prosurgics

Q

Quantum Surgical

R

Remebot
Restoration Robotics
Revolve Surgical
Riverfield
Rob Surgical
ROBO Medical
Robossis
Roboticscalifornia
Ronovo Surgical
Rossum Robot

S

Schaerer Mayfield NeuroMate
Shuchuang Robotics
SHURUI
Simulated Surgical Systems
Sina Robotics
Sinovation
Smart Touch
SolitonReach
Sucabot MedTech
Surgica Robotica

T

Think Surgical
TINAVI Medical Technologies
Titan Medical
Trios Health
Trocar Sweep

U

Unison Surgicals Company
Urology Associates
Uticaobgyn

V

Vascular Specialist-e Tx
Vicarious Surgical

X

XACT Robotics

Z

ZhiGuangKeJi

Abbreviations

- 3-D – 3 Dimensional
- 5G – Fifth Generation
- AI – Artificial Intelligence
- AMA – American Medical Association
- ANT – Automated Needle Training
- APAC – Asia Pacific
- AR – Augmented Reality
- ASC – Ambulatory Surgical Center
- CAGR – Compounded Annual Growth Rate
- CEO – Chief Executing Officer
- CE – Conformitè Europëenne
- CMS – Center for Medicare & Medicaid Services
- CPT – Current Procedural Terminology
- CT – Computed Tomography
- DRG – Diagnostic Related Groups
- ENT – Ear Nose Throat
- EU-5 – European Union 5 (UK, Italy, France, Spain, Portugal)
- EU – European Union
- FDA – Food and Drug Administration
- GI – Gastrointestinal
- HEOR – Health Economics and Outcomes Research
- HD – High Definition
- LoS – Length of Stay
- M&A – Mergers and acquisitions
- MDR – Medical Devices Regulation
- MIS – Minimally Invasive Surgery
- MPLR – Multi-Port Laparoscopy Robots
- MRI – Magnetic Resonance Imaging
- NHS – National health Service
- NICE – National Institute for Health and Care Excellence
- NOTES – Natural Orifice Transluminal Endoscopic Surgery
- NUB – Neue Untersuchungs- und Behandlungsmethoden
- OR – Operating Room
- PCI –Percutaneous Coronary Interventions
- PMS – Post Market Surveillance
- PN –Percutaneous nephrostolithotomy
- PO – Purchase Order
- R&D – Research and Development
- RAS – Robotic-assisted surgery
- S&M – Sales and Marketing
- SoC – Standard of Care
- S0R – Source of Revenue
- SPL – Single-port Laparoscopy
- SPLR – Single-Port Laparoscopy Robots
- TCO – Total Cost of Ownership
- UK – United Kingdom
- US – United States of America
- QMS – Quality Management System
- QoL – Quality of Life

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