

What is and how to navigate the RAS opportunity in LatAm?

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The global surgical landscape is evolving from open to Robotic-assisted surgery (RAS)

Introduction to surgical techniques

Level of technology and sophistication involved in surgical procedures



Open surgery

- **Conventional surgical method** with incisions typically 2 inches or larger
- **Surgeon has direct, unaided visualization of structures/organs**, employed in procedures like organ removal and Caesarean sections



Minimally invasive surgery (MIS)

- **Laparoscopic surgery involving small incisions with a 2D camera view of internal tissues** through a laparoscope
- **MIS is applied across multiple surgical specialties** (e.g.: OB/GYN, urologic, general surgery, vascular procedures)



Robotic-assisted surgery (RAS)

- **Robotic surgery performed using surgical robots with a camera arm and mechanical arms**; the surgeon views the internal tissues in high-magnification 3D through the camera arm
- **Primarily applied in OB/GYN, urologic, and general surgery procedures**, such as gastroenterology

Main benefits and differentiators

Compared to minimally invasive surgery:

- ✓ **Larger repairs** on tissues
- ✓ **Increased visual assessment and diagnostic** of large tissue groups
- ✓ **Enhanced insertion / removal of larger equipment** and/or tissues

Compared to open surgery:

- ✓ **Lower risk of infection** and **shorter patient recovery time**
- ✓ **Reduced procedure time**
- ✓ **Lower risk of immediate complications**
- ✓ **Better long run patient outcomes** in some procedural types (e.g., colorectal cancer)

Compared to RAS:

- ✓ **Fewer incisions** in some cases (e.g., single-site laparoscopy)

Compared to minimally invasive surgery:

- ✓ **Greater movement precision & dexterity**, allowing for procedures in low-access areas of the body
- ✓ **Greater visual magnification**
- ✓ **Easier suturing and scarring**

Such transition is driven by superior support to surgeons and clinical benefits to patients

RAS systems value proposition

Patient benefits

Shorter recovery times & less scarring



Lower risk of immediate complications



Surgeon benefits

Greater dexterity and movement precision



Greater visual magnification



- **Shorter patient recovery time and less scarring** due to the smaller incisions used, requiring less time to fully heal
- **Reduced pain and discomfort in post-operative settings**

- **Reduced risk of immediate complications**, such as infection and blood loss, due to shorter operating times
- **Shorter operating times** result in a decreased risk of complications and reduced blood loss due to smaller incisions

- **Greater dexterity and movement precision** during surgery compared to laparoscopy, which allows surgeons to reach difficult to access tissues and have greater control during wound closure, especially when performing complex procedures

- **Greater visual magnification** when compared to laparoscopic techniques, which typically magnify ~6x greater than the human eye, compared to the ~10-15x magnification achieved with a RAS camera
- This benefit is potentialized for procedures that needed to be performed in confined, difficult areas

Source: Huang et. al; Mayo Clinic, NCBI, UC Health, L.E.K. research and analysis

RAS systems can be segmented into three main categories: soft tissue, orthopedic, and other specialized systems

RAS procedures by type of surgical robot and therapeutic area

RAS systems market

Soft tissue surgical robots

General surgery

- Cholecystectomy*
- Hernia repair
- Colorectal surgery
- Bariatric surgery

Gynecology

- Hysterectomy
- Sacrocolpopexy
- Oophorectomy
- Myomectomy
- Endometriosis Resection

Urology

- Prostatectomy
- Pyeloplasty
- Nephrectomy
- Radical cystectomy

Cardiothoracic

- Thoracic Surgery
- Mitral valve repair
- Coronary art. bypass
- Lobectomy
- Cardio tissue ablation

Head and neck

- Transoral surgery
- Thyroidectomy

Focus of this report

Orthopedic surgical robots

Ortho: hip / knee

- Partial knee arthroplasty
- Total hip arthroplasty
- Total knee arthroplasty

Spine

- Thoracolumbar
- TLIF
- Pedicle screws
- Laminotomy
- Laminectomy
- Dural closure
- Facet decortic.
- CT navigation**
- ALIF^

Other specialized surgical robots

Bronchoscopy

- Bronchoscopy

Neuro

- Stereo EEG
- Cortical dysplasia
- Laser ablation
- Tuberous sclero.
- Tumor biopsy

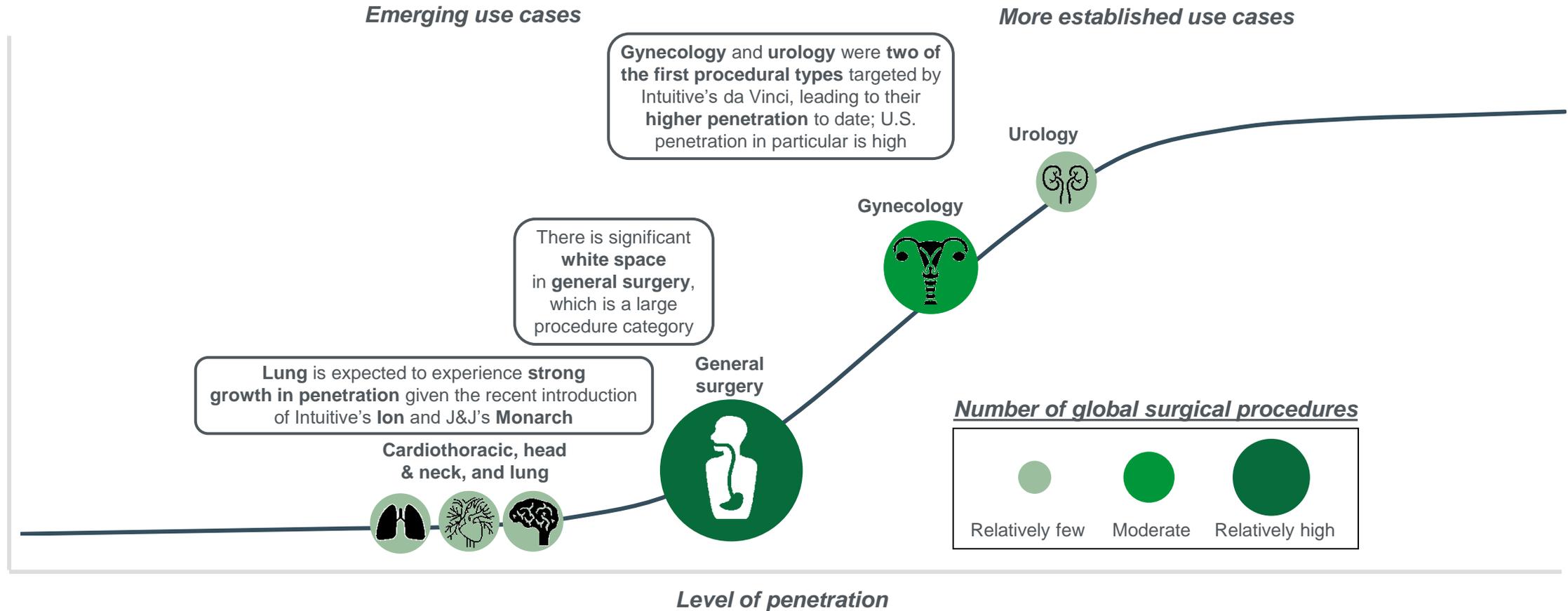
Example procedures

Note: * Gall bladder removal surgery; **CT-based spinal navigation; ^Laparoscopic and retroperitoneal
 Source: Morningstar; L.E.K. research and analysis

The adoption curve for RAS reveals significant white space in high volume procedural areas such as general surgery

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Global RAS adoption curve by surgical specialty*

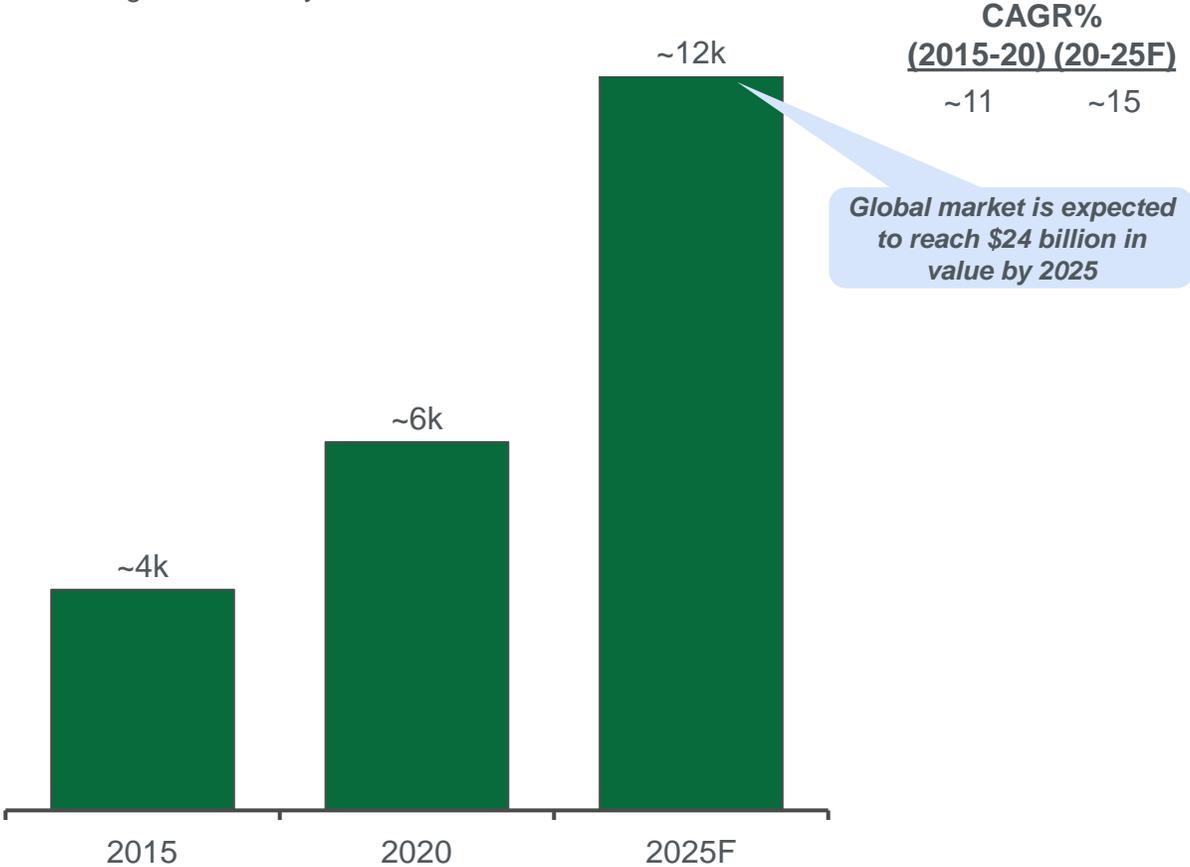


Note: *Not exhaustive as it does not include other surgical specialties such as neurosurgery, oral and maxillofacial, otolaryngology, plastic, trauma, etc.;

Source: LSI; Intuitive 10-k; Stryker 10-k; Goldman Sachs; Murphy et al; Sentara; Garas et al; Bautista et al; Spinal news; L.E.K. interviews and analysis

The global installed base of soft tissue RAS systems is expected to increase ~15% p.a. to 2025F, driven by an increase in adoption, a broader range of surgical applications, and market entrants' sales

Global soft tissue RAS systems installed base (2015-25F)
Installed surgical robotic systems



- The global soft tissue RAS system installed base was ~6k in 2020 and is projected to double its size, increasing to ~12k by 2025F
- The growth in the installed base is anticipated to result from increased penetration in general surgery due to the Da Vinci extended use program, as well as the development of new RAS technology for a wider range of surgical applications
- The installed base update is projected to support market expansion alongside the natural growth from increasing global adoption – older systems typically need replacement or upgrading with next-generation technology after ~10 years
- The intensifying competition, driven by the expiration of Intuitive's patents, is expected to stimulate both replacement and new unit sales

Source: Intuitive annual reports, TransEnterix annual reports, Deutsche Bank, Morgan Stanley, JP Morgan, Ladenburg Thalmann, Guggenheim, Barclays, MedCityNews, S&P Global, General Surgery News, L.E.K. interviews and analysis

The expiration of Intuitive's first-generation patents has spurred global competition and reduced costs, potentially enabling greater access in emerging markets, as LatAm

Soft tissue RAS competitive landscape evolution



- **2000:** after its foundation in 1995, Intuitive launched the **first soft tissue RAS system** (da Vinci) **protected by patents**; by 2002, 60 da Vinci systems were sold for a total sale of \$72 million
- **2016:** Intuitive's first-generation **patents started to expire**, which included basic robotic concepts (arms and instruments remote control, and imaging functionalities) – until 2022, most first-generation patents expired; however, Intuitive kept its strategy for the following generations of RAS systems, with the fourth generation (Da Vinci Xi) protected by **at least 68 patent families**
- **2019:** launch of Senhance, a RAS platform focused on **digital laparoscopic procedures** that is currently present in 15 countries – the main differentiator is **haptic feedback** for the surgeon
- **2020:** launch of Versius, a soft tissue RAS system focused on **minimally invasive and laparoscopic procedures**; since its launch, Versius is present in more than 100 hospitals globally
- **2023:** Hugo, RAS system from Medtronic, enrolled in its **first U.S. clinical trial in December of 2022** – the soft tissues platform main differentiator is the **lower cost per surgical procedure**
- **2024:** expected launch of Ottawa, J&J RAS platform designed for applications focused on **cancer diagnosis and treatment**, including localized drug delivery to cancerous/pre-cancerous lesions
- **2025:** expected launch of Enos (Titan), a **single-arm RAS system with snake-arm instruments** targeted towards OBGYN and urology, with increased mobility and lower costs as differentiators

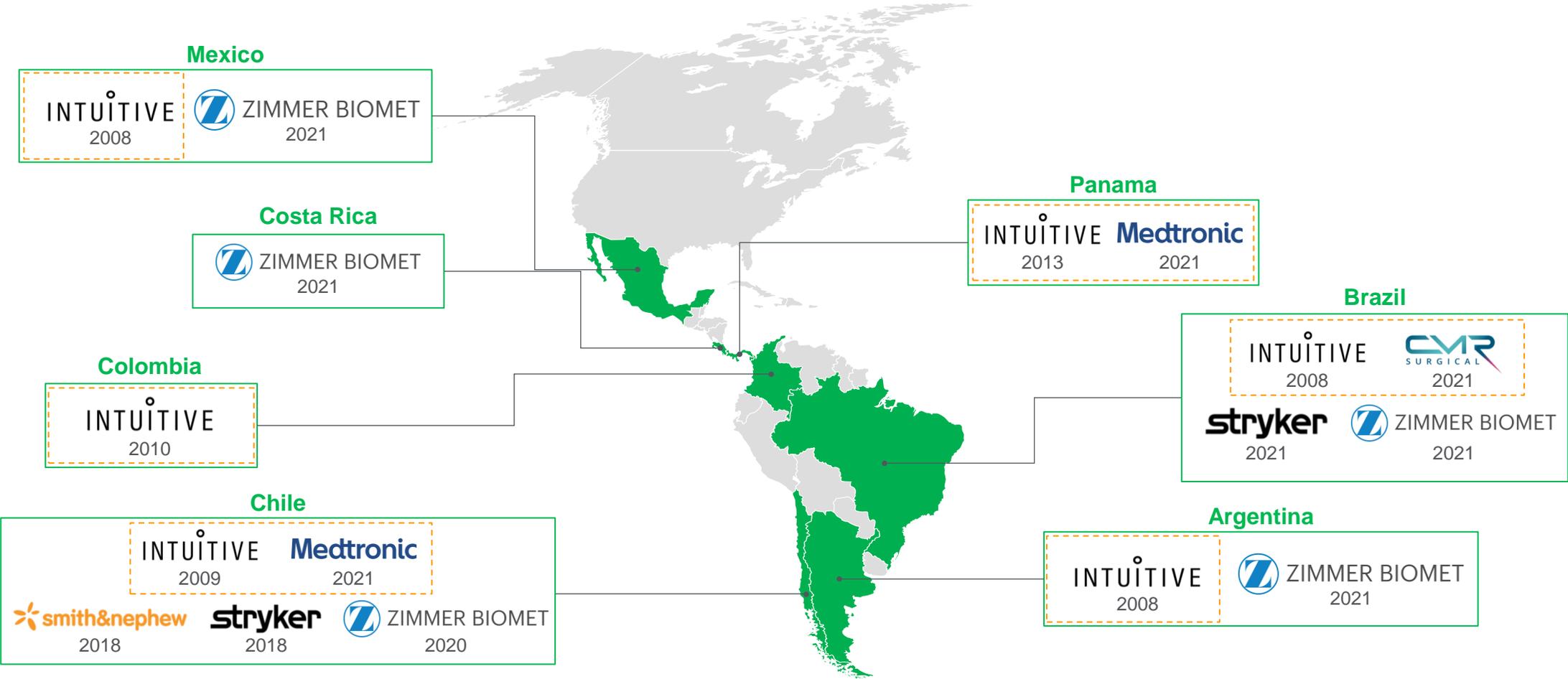
Impacts of Intuitive's patents expiration

- 1 Increased competition**
 - As first-generation patents have expired, other companies have been able to develop and market their RAS systems, leading to an increase competition in the RAS market
- 2 Innovation and technological advancements**
 - Expiration led to the introduction of more advanced and sophisticated technologies, both from Intuitive and new entrants, with a focus on creating innovative systems eligible for patents
- 3 Cost reduction**
 - Increased availability of RAS systems and competition has led to cost reductions, broadening robotic surgery accessibility to hospitals and ultimately benefitting patients
- 4 Broader range of surgical applications**
 - Expiration motivated the development of RAS systems for various surgical specialties beyond what da Vinci initially focused on (i.e., orthopedics, neurosurgery, and other specialized fields)

Source: Global Health Intelligence, National Library of Medicine, Canadian Healthcare Technology, L.E.K. research and analysis

Indeed, surgical robot market in Latin America gained traction over the last few years; Chile and Brazil have the highest diversity of players and were prioritized by almost all manufacturers

RAS landscape in Latin America



Source: Global Health Intelligence, National Library of Medicine, Canadian Healthcare Technology, L.E.K. research and analysis

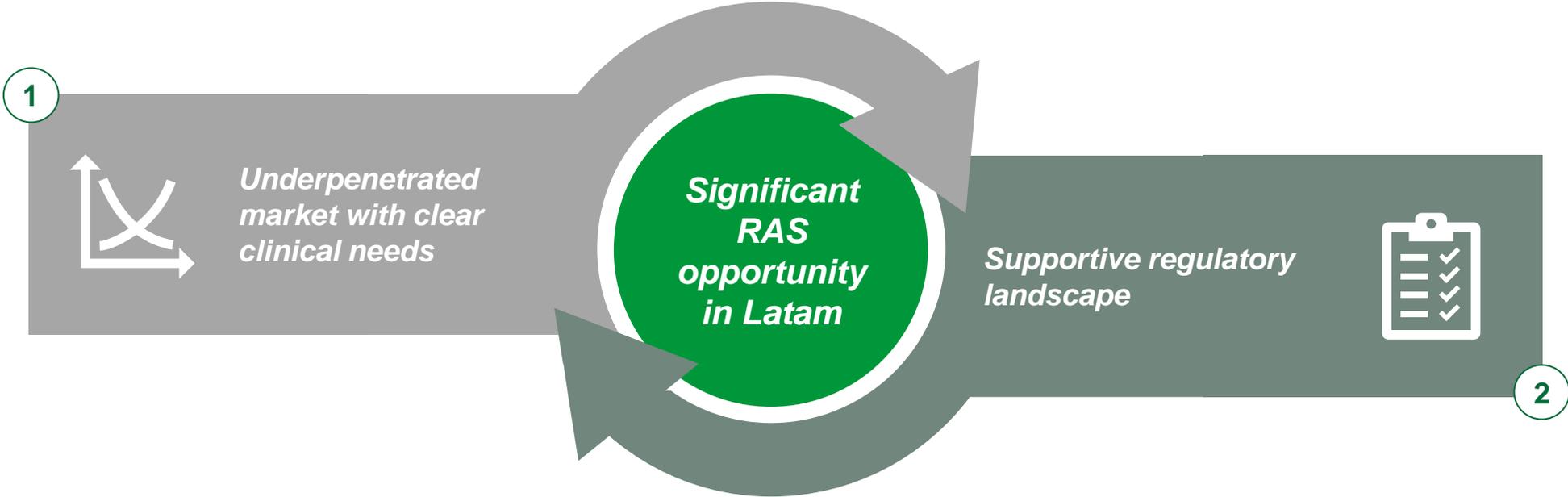
In soft tissue, Intuitive leads the market, and CMR and Medtronic have just started to operate; in orthopedics, Zimmer is key player, followed by Stryker and Smith

	Manufacturer	Product ¹	Countries with presence						
									
Soft tissue RAS	INTUITIVE	<i>da Vinci</i> SURGICAL SYSTEM	✓	✓	✓	✓		✓	✓
		versius [®]		✓	✓				
	Medtronic	Hugo™ RAS		✓	✓				✓
Orthopedic RAS	stryker			✓	✓				
		NAVIO [◇]			✓				
	 ZIMMER BIOMET	ROSA Knee System	✓	✓	✓		✓		✓

Note: 1) Cyberknife device not included given distinct medical applications
 Source: Global Health Intelligence, L.E.K. research and analysis

✓ Presence but no sales to the moment

Moving forward, there is significant potential for RAS in the region given significant low penetration and supportive regulatory landscape



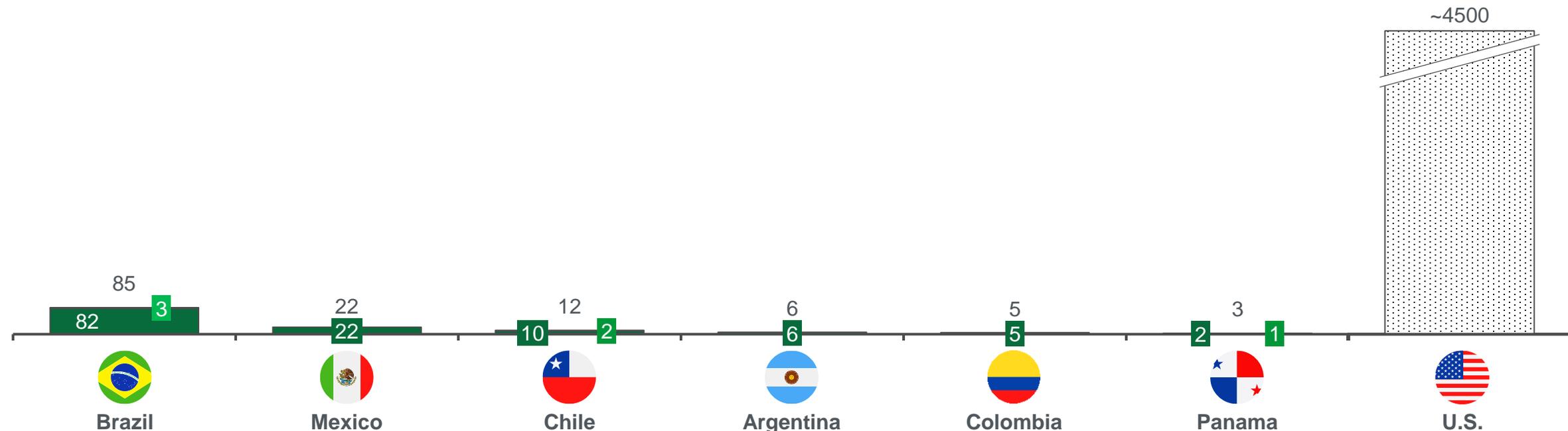
Source: L.E.K. research and analysis

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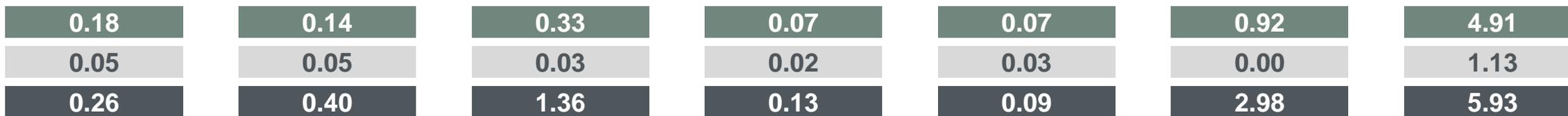
Comparison of RAS adoption in Latin America vis-à-vis mature markets indicates clear white space for growth across markets

Number of surgical robots¹ in Latin America, per country (2022)
Units

■ Da Vinci ■ Versius ■ Hugo



Surgical robots' coverage per thousand of beds (2020)



Note: 1) Only considering soft tissue RAS devices
Source: Global Health Intelligence; L.E.K. research and analysis

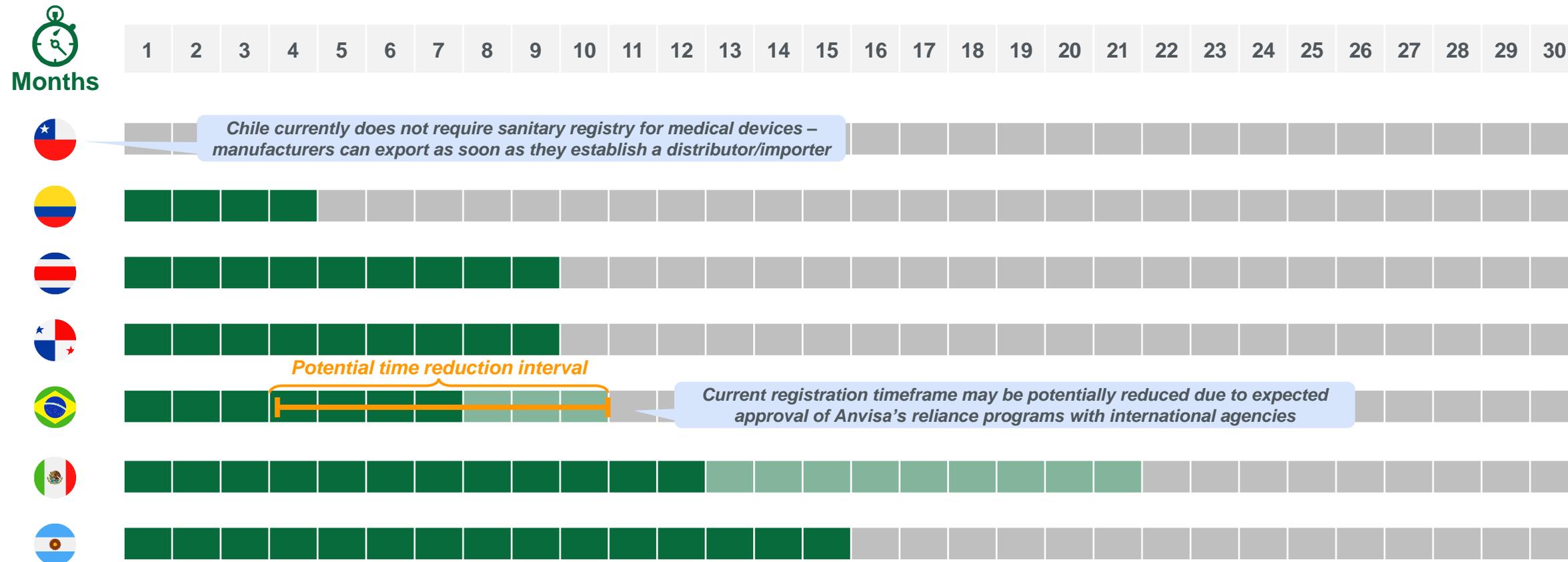
Key: **Total** **Public** **Private**



2

Regulatory landscape is supportive of novel technologies, not demanding clinical trials by specialty, allowing for fast market entry

RAS devices expected approval times¹ in Latin America



Note: 1) expected times are the medians of intervals for each country
Source: L.E.K. research and analysis

Caption: ■ Potential harmonization time reduction

However, there are multiple barriers that need to be circumvented to unlock full value of RAS systems in the region, especially training, limited insurance coverage, and capital limitations

Potential adoption barriers for RAS systems



Surgeon training requires a significant amount of time and money to obtain certification, which represents a bottleneck for meeting patient demand

Insurance coverage is still limited in many countries, leading to a higher share of co-payments for RAS procedures compared to other surgical techniques, restricting the ability of patients to pay out-of-pocket

The need for proctoring in training poses a challenge for manufacturers, especially for new entrants, which hinders the growth of a qualified physicians' network

Despite cost reductions in recent years, RAS systems still present a financial challenge in terms of equipment purchase and covering maintenance and training costs, particularly for smaller institutions

Distinct healthcare systems and requirements (i.e., fundraising, regional autonomy, regulatory scenario) often act as barriers for manufacturers, often requiring a long lead time before operations can commence

Integrating RAS systems into existing hospital infrastructure can be challenging since they require specialized operating rooms, staff, and maintenance, which may not be readily available within healthcare providers

Source: L.E.K. interviews, research and analysis

Moreover, OEMs need to consider specific market dynamics to successfully enter the market

Market entry considerations for Latin America



1. Competition

- **Competition level is increasing across most Latin America countries**, especially in Chile and Brazil, where CMR Surgical and Medtronic are adopting more aggressive commercial strategies, including leasing and trial agreements
 - New entrants must adjust their go-to-market strategies to compensate for the head start that faster competitors already have



2. Positioning

- **A lower pricing strategy combined with an attractive value proposition**, such as extended warranty coverage and efficient customer support, may help reduce the reimbursement gap and tap into previously untapped markets
 - Intuitive is well-established and dominates the premium hospitals segment; however, “tier 2” customers are underserved, representing a potential opportunity



3. Distribution

- **Use of distributors may be challenging as competitors are establishing/using their own operations** in Latin America as an alternative to tackle the training, proctoring, and integration barriers
 - Manufacturers are not solely depending on commercial partners to access Latin American markets – companies are making direct investments in the region to overcome adoption barriers and enhance their competitiveness



4. Insurers

- **Many insurance providers usually do not offer reimbursement for minimally invasive and robotic procedures** – patients face high co-payment rates, making out-of-pocket expenses more relevant in the RAS market
 - Manufacturers must consider cost reduction strategies as a crucial factor to improve access; lower cost alternatives could enable higher access to RAS, as it is likely to result in lower out-of-pocket expenses

Source: L.E.K. interviews, research and analysis

L.E.K. has deep expertise in the RAS and LatAm markets to help create a winning launch strategy

DIRECTIONAL, NON-EXHAUSTIVE

How L.E.K. can help



Perform a detailed internal diagnostic

Evaluate company's data, including historical performance, governance, portfolio, go-to-market strategy, and growth opportunities



Assess the RAS landscape in desired geographies

Characterize healthcare systems and market dynamics, including healthcare indicators, reimbursement landscape, and trends



Estimate market size, including growth and forecast

Develop a market sizing and forecast model, including historical and projected growth, and relevant breakdown (region, procedure etc.)



Map the competitive environment and dynamics

List competitors in market, including potential strategies, market feedback, strengths, weaknesses, and differentiation opportunities



Analyze customer profiles, preferences and KPCs

Assess providers profiles (hospital, ASC etc.) and patient preferences, including key purchase criteria, awareness, and adoption drivers



Develop a comprehensive go-to-market strategy

Define the GTM model (direct, distributor), including optimal route-to-market strategies and required capabilities (marketing, sales etc.)



Identify key launch success factors (LSFs)

List key launch success factors and associated deliverables by workstream and launching dimension (e.g.: market, product etc.)



Develop a financial business case

Forecast key financial metrics (revenue, costs, ROI, payback etc.) and estimate upfront investments and launch-related costs

Connect with us to learn more!



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