



Harnessing the Benefits of Minimally Invasive Robotic Surgery for Pediatric and Adult Patients

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01 The Gold Standard of Minimally Invasive Surgery and Robotics

Minimally Invasive Surgery (MIS), also known as laparoscopic surgery, was pioneered in the 1980s and **achieved prominence in the 1990s**. Today, it is considered the “gold standard” for surgical procedures across many specialties.

In MIS, surgeons insert surgical tools through small incisions to operate on the patient, causing less tissue damage than in open surgery. In pediatric MIS, surgeons opt for smaller-diameter instruments to help minimize incision sizes for young patients, leading to **quicker recovery** and better cosmesis.

Over recent decades, MIS has been embraced by both adult and pediatric surgeons, and many have also adopted robotic surgical methods for the benefits of increased precision and dexterity. Since the first soft-tissue robotic surgery was performed over 20 years ago, **more than 12 million** robotic-assisted surgeries (RAS) have been performed. While RAS benefits are recognized across a variety of surgical specialties, limited availability of smaller-diameter robotic instruments has inhibited the use of RAS by pediatric surgeons. In fact, the lack of 3mm and 5mm instruments that are currently the gold standard for pediatric surgery has meant that traditional robotic solutions have overlooked the unique needs and importance of preserving MIS benefits for the pediatric population. The availability of only larger-sized instruments has caused surgeons to compromise Halsted's Principles, which dictate that surgery should be performed with minimal tension and gentle tissue handling. This has meant that until now, many pediatric patients have been missing out on the added benefits of RAS.

As the Asensus's **Senhance® Surgical System** is designed to preserve the benefits of MIS while advancing laparoscopic and robotic surgery, it is uniquely **qualified** to meet the needs of patients of all ages*. With smaller diameter instruments and other important design elements well-suited for pediatric surgery, Asensus can offer pediatric surgeons an opportunity to provide a new standard of surgical care.

More than 12 million

robotic-assisted surgeries (RAS) have been performed since the first soft-tissue robotic surgery was performed 20+ years ago

* Senhance is **indicated** in the U.S. for patients two years and older and 10 kg (22 pounds) and up in weight. Senhance is also indicated for general use in Japan, and in the EU for patients with a weight equal to or above 10 kg, who are suitable to be subjected to a conventional endoscopic technique.

02 A Focus on Pediatric Needs

The Senhance Surgical System helps surgeons reduce tissue trauma for patients of all sizes and ages. Asensus Surgical gives pediatric surgeons the best of both worlds: they can apply the benefits of robotics and perform more complex surgery without compromising on incision size and recovery time.

Instrument size matters for small patients

When operating on younger patients, smaller instruments are critical to reducing tissue trauma and recovery time. Smaller abdominal cavities limit port positioning and therefore require smaller tools that work in a reduced operative space. Pediatric surgeons need the least invasive instruments and scopes while maintaining high precision and stability.

Senhance enables robotic surgery for pediatric patients as young as two years old in the U.S. Its 3mm and 5mm instruments allow for smaller port size and shorter distance between ports, which are critical for smaller anatomy. RAS surgeons already using robotics for older patients can operate on a broader patient population by switching to Senhance.

Senhance enables robotic surgery for pediatric patients as young as two years old in the U.S.



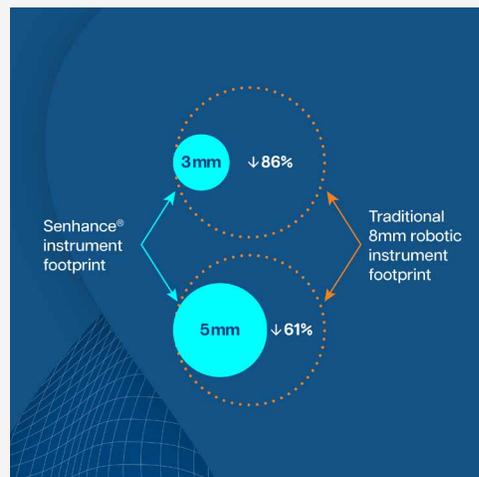
02 A Focus on Pediatric Needs

Minimizing tissue trauma

With traditional robotic surgery, larger diameter instruments necessitate larger ports and incisions compared to Asensus's 3mm and 5mm instruments. In addition, Senhance's Digital Fulcrum sets a dynamic virtual pivot that helps minimize torque at the incision site. Senhance operates within an algorithmically calculated area to help reduce damage to nearby healthy tissue and side walls.

A **15-year-old patient** needed his gallbladder removed, a procedure often done with a surgical robot. However, traditional surgical robots have attachments about 8mm in diameter—about a finger's width. Pediatric surgeon Dr. Thom Lobe at Mount Sinai Hospital in Chicago chose Senhance to conduct the procedure due to its 3mm instrument size and safety features.

“When we can use these smaller instruments, there’s very little discomfort to the patient,” said Dr. Lobe. “There’s barely even a wound to suture up at that point.”



Sensory feedback sounds the alarm

Another important dimension of minimizing tissue trauma is the use of sensory skills to make informed surgical decisions. When surgeons perform open surgery, they have the benefit of using their sense of tactile feel on tissue to gauge pressure and depth, as well as the presence of adjacent structures in the operative field. This sensory experience is significantly reduced with MIS and largely lost with the

02 A Focus on Pediatric Needs

transition to traditional RAS procedures, since the surgeon's hands and instruments are replaced with mechanical arms that have not incorporated tactile feedback.

Recognizing the role of these sensory experiences in contributing to surgical judgment, the **Senhance Surgical System** has incorporated tactile feedback, also known as haptics, to provide surgeons with a heightened sense of force and tension, which can be felt in the instrument handles, as well as providing alerts if a force threshold is reached, adding a layer of security not currently available with other robotic options. Forces on the robotic instruments are sensed and transmitted to surgeons' hands during critical tasks such as suturing. Without haptics, surgeons run a greater risk of putting undue force on tissues. This haptic feedback is especially essential for operating on small patients when the field of view is limited, as it reduces the risk of applying excessive force on tissues and causing trauma to adjacent structures.

Familiar instruments, familiar motion

Senhance's instruments mimic the laparoscopic motion surgeons are already familiar with, making the learning curve minimal. This familiarity also makes the transition between laparoscopic surgery and robotics seamless, as surgeons have the flexibility to perform portions of the surgery laparoscopically or complete the surgery end-to-end robotically. With articulation and small diameter instruments, Asensus delivers the features surgeons want with improved accuracy and access.

Compatible and cost-efficient

Asensus' instruments are reusable and compatible with standard trocars, energy modalities, and a wide array of laparoscopic cameras already available in hospitals making procedure costs with Senhance **comparable** to the cost of a standard laparoscopy. The Senhance Surgical System is designed to contribute to health system sustainability and economic goals to drive value in the OR.

Minimize learning curve for surgeons.

Senhance's instruments mimic the laparoscopic motion surgeons are already familiar with

02 A Focus on Pediatric Needs

Asensus Surgical Milestones in Pediatric Surgical Care

- **OCT 2018** – FDA 510(k) clearance for a 3mm instrument set for Senhance robot-assisted surgery device
- **FEB 2020** – CE Mark approval for pediatric indication for Senhance Surgical System; Asensus Surgical is the first to offer robotic 3mm micro laparoscopic surgery for pediatric patients
- **SEP 2020** – First pediatric surgical program in the world to utilize the Senhance Surgical System and integrate digital laparoscopy with instruments as small as 3mm into their standard of surgical care (Netherlands)
- **MAR 2023** – FDA 510(k) clearance for expanded indication to treat pediatric patients with the Senhance System; scope expands beyond the EU and Japan to the U.S.
- **JUL 2023** – Initiation of pediatric program using Senhance with leading U.S. hospital

Asensus Surgical is the first to offer robotic 3mm micro laparoscopic surgery for pediatric patients



03 Digital Surgery Designed with the Patient and Surgeon in Mind

Surgery isn't performed by robots. It's performed by people. Advancements in robotic equipment have given surgeons greater dexterity and better ergonomics, but what about predictability? Senhance is designed to enhance surgeons' extensive knowledge and capabilities for more consistent, optimal outcomes.

Clinical intelligence for surgical excellence

Augmented Intelligence is the missing piece to improve reproducibility and consistency in surgery and is anticipated to provide similar value in pediatric surgery. During surgery, there are times when critical decisions need to be made. Asensus Surgical's Augmented Intelligence and machine learning will deliver data insights — in context and in real-time — before surgeons make a move. A robotic surgical platform trained with clinical insights gleaned through Augmented Intelligence will enable surgeons to elevate their laparoscopic skills and surgical capacity, limiting variability in surgical outcomes. These invaluable insights can be used in ORs across the globe to make informed decisions, navigate challenging anatomy, and reduce variability of outcomes.

In machine learning, computer models are programmed with specific algorithms to learn and recognize desired behaviors and to draw inferences from data patterns. Augmented Intelligence uses machine and deep learning, or the ability to mimic the human brain in processing data and identifying patterns, to support decision-making. This is the foundation of **Performance-Guided Surgery™** (PGS), which mitigates surgical variability by leveraging Augmented Intelligence in an assistive role to enhance, rather than replace, human intelligence.

Augmented Intelligence

- Improves reproducibility and consistency
- Delivers real-time data insights
- Limits variability in surgical outcomes

03 Digital Surgery Designed with the Patient and Surgeon in Mind

“Anyone who watches NFL football games on TV benefits from seeing the digitally produced yellow line on the field that indicates the line to gain for a first down,” said Ed Chekan, MD, F.A.C.S, Vice President of Medical Affairs and Professional Education at Asensus. “Insights from Augmented Intelligence give similar benefit of the football yellow line to surgeons while they are performing surgeries, showing them distances between anatomy, measurements on where to potentially cut or suture, and other guidelines that enhance their view of the operating area.”

As the pioneer of PGS, Asensus Surgical developed the Senhance Surgical System and the Intelligent Surgical Unit™ (ISU™) to capture, annotate, and store surgical data for future use. The ISU is the digital engine behind the Asensus Augmented Intelligence system and is the world’s first Augmented Intelligence system to be FDA-cleared, CE Marked, and approved by PMDA for use in surgery. Designed to integrate with the Senhance Surgical System, the ISU is compatible with a wide selection of laparoscopic camera platforms to deliver a greater degree of surgeon control and clinical insight. The ISU is revolutionizing surgery with a suite of digital augmentation tools designed to enhance efficiency, precision, and safety in soft-tissue surgery. By digitizing the interface between the surgeon and patient, Asensus is unlocking clinical intelligence designed to **improve outcomes**.

Performance-Guided Surgery Features



Surgeon-Controlled Camera Positioning

Eye Tracking, Follow Us, Go To, and Smart Zoom features enable surgeons to direct the camera's field of view precisely where needed and give them more control during procedures.



Enhanced Precision

Point-to-point and tissue contour measurement capabilities allow surgeons to make precise intraoperative measurements for more reproducible procedures and documentation. These tools have the potential to help standardize successful outcomes by leveraging data to interpret the surgical field and drive accurate decision-making.



Advanced Annotation

Digital tagging enables the surgeon to place a mark on an area of anatomy and provides visual instruction for enhanced communication and coordination of the surgical team.

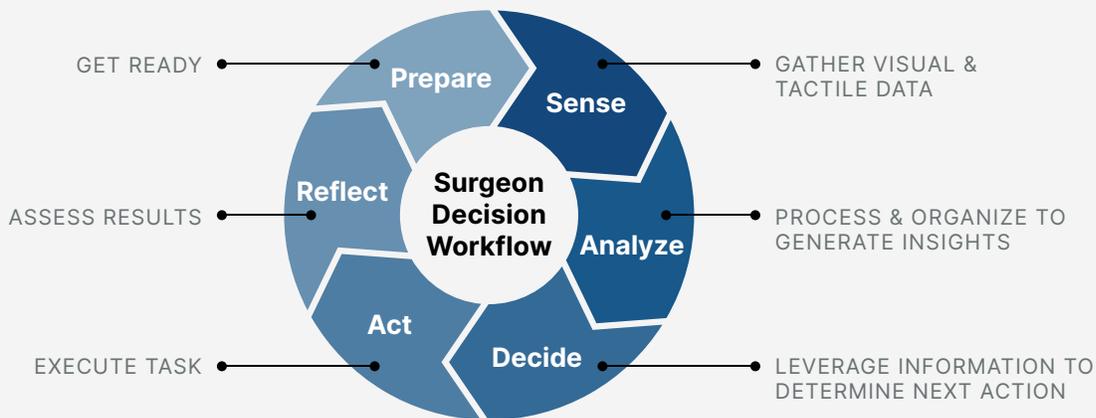
These capabilities

enable real-time data-driven decision-making on precise manipulation and incisions.

PGS aims to:

- Enhance the entire Surgical Decision Chain
- Enrich collaboration across surgical staff
- Bridge the surgeon-patient gap to produce consistently superior outcomes

Surgical Decision Chain



03 Digital Surgery Designed with the Patient and Surgeon in Mind

Better comfort, better care

The OR is a mentally and physically taxing work environment for surgeons. Fatigue, limited line of sight, and physical discomfort may reduce surgical accuracy and precision. These challenges can also lead to surgeons burning out and leaving the profession, contributing to a **significant shortage of active surgeons** today in the U.S. To improve outcomes and enable surgeons to stay in the field long-term, there is a critical need for better surgical ergonomics.

Asensus Surgical is committed to improving the surgical experience for all. With other surgical robots, surgeons may work for hours with limited movement and limited field of vision. With Senhance's ergonomic design and open console, surgeons can sit comfortably in a natural, upright position with a clear line of sight to the patient and the rest of the OR. Eye tracking control allows surgeons to instantly pan out, zoom in, and view any area of the surgical field. A clutch pedal allows the surgeon to pause instrument movement and reposition to a more comfortable and ergonomic operating position at any time. The system is designed to ease fatigue to improve outcomes, increase efficiency, and provide career-extending surgeon comfort.

Senhance's ergonomic design and open console allows surgeons to sit comfortably in a natural, upright position



04 Enhanced by Technology, Powered by People

Asensus Surgical is a **global team** of experienced engineers, software developers, and physician partners working together to improve the tools and techniques currently available to surgeons. The Asensus team looks through a clinical lens and partners with hospitals to learn how technology impacts surgeons, administrators, and patients.

Pediatric surgery has long been an **underserved specialty** due to its lower case volume and unique challenges. Asensus is passionate about serving pediatrics and providing comprehensive programs that improve outcomes for patients and surgical teams. Asensus Surgical technology is therefore collaborating with the pediatric community to take a holistic programmatic approach to serving their needs, so that surgeons, their surgical teams, and their patients can benefit from the latest advancements in robotic and digital surgery.

A community of minds is better than one, so Asensus developed the TRUST collaborative research network in which surgeons can connect with each other, discuss complex cases they have undertaken with Senhance, and share feedback on the technology. Asensus also offers education materials for patients and their families so that both the surgeon and the patient can go into the OR with increased confidence in an optimal outcome.

Recognizing that innovations can make surgery better for surgeons, allied health professionals, and patients, Asensus is committed to taking a collaborative approach to achieving a new standard of care in ORs across the world.

Asensus developed the TRUST collaborative research network in which surgeons

- can connect with each other
- discuss complex cases they have undertaken with Senhance
- share feedback on the technology

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04

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3D Measuring

Allows surgeons to measure and digitally tag a patient's anatomy with precision. This capability is extremely useful and may help drive consistency and efficiency.

Articulation

The ability for an instrument to flex at the tip. These instruments allow the surgeon to “reach around the corner” or dissect around difficult anatomy during demanding procedures.

Augmented Intelligence

The use of technology to enhance human intelligence rather than replace it.

Digital Laparoscopy

Digital laparoscopy elevates surgery for surgeons during the operation by providing Augmented Intelligence capabilities to help enhance decision-making. It allows surgeons to sit in a comfortable console with digital capabilities elevating their performance, which may alleviate both physical and mental tolls an operation can take on the body.

Digital Tagging

With digital tags, surgeons can mark off areas of anatomy to pay attention to. It goes hand-in-hand with anatomical measuring capabilities.

Eye Tracking

The latest camera control technologies. Surgeons can set their camera view to follow wherever their eyes point.

Haptic Feedback

Haptic feedback heightens the surgeon's sensing of pressure or tension with sensations in the handles and alerts if a pressure threshold is reached.

Intelligent Surgical Unit™ (ISU™)

The ISU is the digital engine behind the Asensus Augmented Intelligence system, empowering surgeons to operate like never before with the first Augmented Intelligence platform to be FDA cleared, CE Marked, and approved by PMDA for use in robotic surgery. It allows surgeons to gain real-time visual guidance and access to revolutionary digital tools to promote confidence during challenging procedures.

Laparoscopy

Laparoscopy is a type of surgical procedure that allows a surgeon to access the inside of the abdomen and pelvis without having to make large incisions in the skin. This procedure is also known as minimally invasive surgery (MIS).

Machine Learning

The use and development of computer systems that can learn and adapt without following explicit instructions by using algorithms and statistical models to analyze and draw inferences from data patterns.

Minimally Invasive Surgery

See Laparoscopy.

Open Console

An open console enables the surgeon to have full visibility of the entire operating room and clear communication with the staff. The place where the surgeon views the inside of the patient on a screen while comfortably seated.

Performance-Guided Surgery™ (PGS)

A form of computer-assisted surgery that digitizes the interface between the surgeon and patient and assists the surgeon when performing demanding procedures. Performance-Guided Surgery aims to

06 Glossary

combine Senhance robotic manipulation capabilities, clinical guidance during surgery, and surgery data collection and storage in the cloud for future use and future surgeries to enable consistently superior outcomes for a new standard of surgery.

Real-Time Insights

Augmented Intelligence aims to enable the surgeon to access surgical data while performing the procedure.

Robotic-Assisted Surgery (RAS)

Usually associated with MIS, robotic-assisted surgery allows doctors to perform many types of complex procedures with more precision, flexibility and control than is possible with conventional techniques.

Senhance® Surgical System

As the first digital laparoscopic platform on the market, the Senhance Surgical System provides surgeons with an unprecedented level of control. It offers hospitals a value-driven healthcare model that delivers surgical best practices with a focus on optimal patient outcomes. Standard reusable instruments and an open-platform architecture strategy also offer cost optimization and comfort.

07 Background on Asensus Surgical

Asensus Surgical, Inc. and our amazing 200+ team members in 12 countries are committed to developing technology that helps surgeons deliver life-changing patient care with better outcomes for all.

For so long, the industry has focused on incremental advancements in robotic equipment; innovations that bring speed, dexterity, and a clear view of what's in front of us to do surgery. Augmented Intelligence goes further by giving surgeons a sense of what's around the corner. And as a surgeon builds on their digital legacy, our technology only gets smarter, ensuring that every surgery that follows will be, too.

Asensus Surgical is revolutionizing surgery with the first intra-operative Augmented Intelligence technology approved for use in operating rooms around the world. Recognized as an award-winning leader in digital technology, Asensus is committed to making surgery more accessible and predictable while delivering consistently superior outcomes. The company's novel approach to digitizing laparoscopy has led to system placements globally. Led by engineers, medical professionals, and industry luminaries, Asensus is powered by human ingenuity and driven by collaboration. To learn more about the Senhance® Surgical System and the new LUNA™ System, visit www.asensus.com.

Please visit www.asensus.com/indications-for-use or contact your local representative for information about your area.



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PPT-001-00224.001

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