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Intuitive's da Vinci 5 Surgical System Receives CE Mark / Fifth-generation da Vinci surgical system approved for use in Europe across multiple procedures



Sunnyvale, California (ots) -

Intuitive, a global technology leader in minimally invasive care and the pioneer of robotic-assisted surgery, announced today that the da Vinci 5 Surgical System has received CE mark approval for adult and pediatric use in Europe for minimally invasive endoscopic procedures across abdominopelvic surgical procedures, including urologic, gynecologic and general laparoscopic surgical procedures, and thoracoscopic surgical procedures.

Da Vinci 5 is Intuitive's most advanced and integrated multiport robotic-assisted surgical system, building on the da Vinci Xi Surgical System's highly functional design.

It features more than 150 enhancements and joins a portfolio of da Vinci surgical systems that surgeons have used to treat more than 410,000 patients in Europe in 2024 and nearly 17 million patients worldwide to date.

"We are pleased that our da Vinci 5 Surgical System has received CE mark approval, marking its entry to Europe," said Intuitive Chief Executive Officer Dave Rosa.

"At Intuitive, we're focused on providing healthcare systems across Europe and around the world with thoughtful innovation that solves problems today and into the future. After over a decade of careful development, da Vinci 5 is the most advanced and integrated platform we've ever created – designed to enable better outcomes, efficiency, and insights for the future of minimally invasive care," said Rosa.

Da Vinci 5 is designed to deliver:

- **Enhanced surgical senses to support better patient outcomes**, including first-of-its-kind Force Feedback enabled technology,¹ the most realistic 3D da Vinci vision system to date², and an ergonomic, immersive surgeon console² to aid in surgeons' career longevity.
- **Operational efficiency**, through greater surgeon autonomy³ with the integration of key components that surgeons can control at their fingertips, and by streamlining workflow with an easy-to-learn system, a universal user interface for care teams, and dynamic assistance integrated into the system to automate select tasks.
- **Actionable insights** through an intelligent platform with 10,000x more computing power³ and new sensors, software, and advanced processors – providing surgeons with more useable data to help quantify, understand, and improve their surgical performance for patients.

"We believe that the operational efficiencies and actionable insights provided by da Vinci 5 will not only transform surgery but also help address critical challenges faced by healthcare systems across Europe," said Dirk Barten, Intuitive senior vice president and general manager for Europe.

“It’s exciting that surgeons and care teams across Europe will have their choice of the full portfolio of da Vinci systems, including da Vinci 5, giving greater choice and flexibility, and ultimately supporting quality care for more patients across the region,” said Barten.

In 2024, the U.S. Food and Drug Administration cleared the da Vinci 5 Surgical System for use during urology, general, gynaecology and thoracic procedures in adults.

Da Vinci 5 is the fifth generation da Vinci surgical system and the latest addition to the da Vinci family. This includes multiport systems da Vinci X and da Vinci Xi, and the single port system da Vinci SP, offering surgeons and hospitals their choice of highly capable, proven solutions from Intuitive.

2025 marks Intuitive’s 30th year developing robotic-assisted technology with the goal of improving patient outcomes, improving patient and care team experience, increasing access to minimally invasive care, and lowering the total cost to treat. In Intuitive’s first three decades, surgeons have performed nearly 17 million procedures using our technology and nearly 90,000 surgeons have been trained to use our systems worldwide.

¹Availability of Force Feedback instrumentation in Europe is subject to future regulatory approval.

²Compared to da Vinci X, Xi, and SP systems. Data on file at Intuitive.

³Compared to da Vinci Xi system. Data on file at Intuitive.

Notes to editors

About Intuitive Surgical, Inc.

Intuitive (Nasdaq: ISRG), headquartered in Sunnyvale, California, is a global leader in minimally invasive care and the pioneer of robotic-assisted surgery. Our technologies include the da Vinci surgical system and the Ion endoluminal system. By uniting advanced systems, progressive learning, and value-enhancing services, we help physicians and their teams optimize care delivery to support the best outcomes possible. At Intuitive, we envision a future of care that is less invasive and profoundly better, where disease is identified early and treated quickly, so that patients can get back to what matters most.

For more information, please visit: <https://www.intuitive.com/en-us>

About da Vinci surgical systems

There are several models of the da Vinci surgical system. The da Vinci surgical systems are designed to help surgeons perform minimally invasive surgery and offer surgeons high-definition 3D vision, a magnified view, and robotic and computer assistance. They use specialized instrumentation, including a miniaturized surgical camera and wristed instruments (i.e., scissors, scalpels, and forceps) that are designed to help with precise dissection and reconstruction deep inside the body.

About the Ion Endoluminal System

The Ion Endoluminal System (Model IF1000) assists the user in navigating a catheter and endoscopic tools in the pulmonary tract using endoscopic visualization of the tracheobronchial tree for diagnostic and therapeutic procedures. The Ion Endoluminal System enables fiducial marker placement. It does not make a diagnosis and is not for pediatric use.

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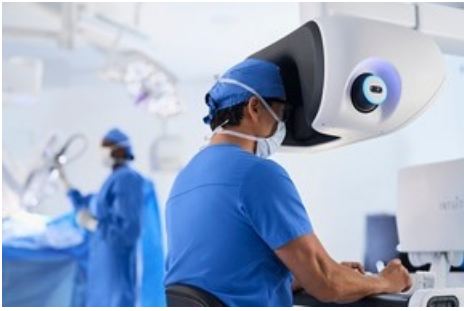
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