

FDA Clearance of da Vinci Surgical System for Intracardiac Surgery Now Encompasses "ASD" Closure

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SUNNYVALE, Calif.--(BUSINESS WIRE)--Jan. 30, 2003--Intuitive Surgical, Inc. (Nasdaq:ISRG), the industry leader in operative surgical robotics, today announced that it is now promoting use of its da Vinci(TM) Surgical System in the United States for performing the additional cardiac surgical procedure of Totally Endoscopic Atrial Septal Defect (ASD) Closure. On the heels of the FDA's November 2002 clearance of the da Vinci System for thoracoscopically-assisted cardiotomy procedures such as Mitral Valve Repair, the availability of this additional intracardiac surgical procedure further broadens available use of the da Vinci System, bringing significant advantages to those hospitals that invest in the da Vinci System and to their patients who benefit from robotic surgical treatment.

Didier Loulmet, M.D., Chief of The Minimally Invasive Robotic Cardiac Surgery Program at Lenox Hill Hospital, New York and Principal Investigator of Intuitive's Multi-Center ASD Clinical Trial stated: "For the first time, we will be able to offer a totally endoscopic option for performing this delicate procedure inside a patient's heart. This is particularly compelling for the young patient diagnosed with ASD who is mildly symptomatic and in search of a minimally invasive option. The patients who undergo totally endoscopic ASD closure with the da Vinci Surgical System experience less pain and easy recovery with excellent cosmetic results."

Hospitals can now use the da Vinci Surgical System to perform minimally invasive Atrial Septal Defect Closure, literally closure of a hole between internal portions of a patient's heart. "We are very pleased with this additional use of the da Vinci System," said Lonnie Smith, Intuitive's President and CEO. "Our clinical trial data have demonstrated that patients clearly benefit from minimally invasive robotic cardiac surgery. This procedure further provides significant benefits to patients, surgeons and healthcare systems."

Dr. Michael Argenziano, Assistant Professor of Surgery at the Columbia University College of Physicians and Surgeons, and Director of Minimally Invasive and Robotic Cardiac Surgery at New York-Presbyterian Hospital, performed 19 robotic ASD closures in the trial. The interim results were recently presented at the Scientific Session of the American Heart Association Meeting in November 2002. "We have demonstrated that robotic technology can be utilized to perform open heart procedures safely and effectively via a closed chest approach. Furthermore, our outcomes research suggests that patients undergoing robotic ASD closure have a superior postoperative quality of life than those undergoing other surgical approaches. Thus, this technique represents an option for patients seeking a reliable ASD closure without a sternotomy or thoracotomy and the uncertainty of transcatheter techniques."

About Intuitive Surgical's da Vinci(TM) Surgical System

First cleared by the FDA in 1997 for assisting in surgery and in July 2000 for performing actual surgery, the da Vinci Surgical System is still the only robotic system FDA-cleared to perform surgery in multiple specialty areas. Presently, the da Vinci system is FDA-cleared for laparoscopy, thoracoscopy, and thoracoscopically assisted cardiotomy procedures such as mitral valve repair and ASD closure. The System remains the only robotic surgery system ever FDA-cleared to perform any variety of cardiac surgery. The system consists of a surgeon's console, a patient-side cart, a high performance 3-D vision system and Intuitive Surgical's proprietary EndoWrist(TM) articulating instruments. By integrating computer-enhanced robotic technology with the technical skills of the surgeon, we believe that our system enables surgeons to perform better surgery in a manner never before experienced. The da Vinci Surgical System seamlessly translates the surgeon's natural hand and wrist movements on instrument controls at the console into corresponding micro-movements of instruments positioned inside the patient through small puncture incisions, or ports.

The da Vinci Surgical System is the only commercially available technology that can provide the surgeon with the intuitive control, range of motion, fine tissue manipulation capability and 3-D visualization characteristic of open surgery, while simultaneously allowing the surgeon to work through the small ports of minimally invasive surgery.

The statements contained in this release may be deemed to contain "forward-looking statements." Such statements are indicated by words or phrases such as "anticipates," "estimates," "projects," "believes," "intends," "expects" and similar words and phrases. Actual results may differ materially from those expressed or implied in any forward-looking statement as a result of certain risks and uncertainties, including, without limitation, competition and market acceptance of the Company's products, ability to obtain regulatory approvals and third-party reimbursement, ability to raise additional capital and other risks and uncertainties detailed in the companies Securities and Exchange Commission filings. Prospective investors are cautioned not to place undue reliance on such forward-looking statements.

Note to Editors: da Vinci(TM), EndoWrist(TM), Intuitive(R) and Intuitive Surgical(R) are trademarks of Intuitive Surgical, Inc.

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