



## Intuitive Surgical Receives FDA Clearance for First Single-Site(R) Wristed Needle Driver for da Vinci(R) Si(R) Surgical System

September 29, 2014

SUNNYVALE, Calif., Sept. 29, 2014 (GLOBE NEWSWIRE) -- [Intuitive Surgical, Inc.](#) (Nasdaq:ISRG) today announced that it has received U.S. Food and Drug Administration (FDA) clearance for the *Single-Site* Wristed Needle Driver for use in single-incision surgery. This latest addition to the *Single-Site* suite of instruments has been cleared for use with the *da Vinci Si* Surgical System for minimally invasive removal of the uterus (hysterectomy), the ovaries and fallopian tubes for benign conditions, as well as removal of the gallbladder.

"As the first fully articulating robotic single-port instrument available on the market, this is truly a transformative technology for surgeons and patients seeking a minimally invasive option," said Dave Rosa, Executive Vice President and Chief Scientific Officer at Intuitive Surgical.

*Single-Site* Instrumentation facilitates virtually scarless surgeries through a single-incision, while providing surgeons the benefits of robotic and computer assistance. These include surgical precision, control, stability, 3D-HD visualization and an ergonomic seated position. Together, the *da Vinci* System and *Single-Site* instruments are designed to minimize instrument crowding while maximizing available working space as compared with hand-held, laparoscopic single-incision instrumentation.

"It's truly a remarkable engineering achievement to have a flexible instrument with a wristed tip that provides surgical precision," said Dwight Im, M.D., Mercy Medical Center, Baltimore, who participated in the user testing that led to FDA clearance.

The *Single-Site* Wristed Needle Driver was developed in part to facilitate suturing after removal of the uterus. It can move the instrument tip up to 45 degrees in all directions for precise needle positioning. This 5 mm instrument also features serrated jaws to facilitate needle handling.

"The debut of the wristed needle driver heralds an advancement in the evolution of the *Single-Site* platform for *da Vinci* procedures," said Devin Garza, M.D., of North Austin Medical Center, Austin, Texas, a user-testing participant. "It is likely to change the playing field with regard to the availability of this approach for benign hysterectomy procedures," Garza said.

This clearance means that the *Single-Site* Wristed Needle Driver is now available for sale in the United States. With the U.S. introduction underway, Intuitive Surgical will seek regulatory approvals to market the *Single-Site* Wristed Needle Driver for the *da Vinci Si* System around the world.

"We now have the last piece of the puzzle for *Single-Site* hysterectomy," said Thomas Payne, M.D., Texas Institute of Robotic Surgery in Austin, who was also a user-testing participant. "This technology is a true tipping point for this procedure," Payne said.

Since the *da Vinci* System was first cleared for use in gynecology in 2005, the use of minimally invasive surgery in hysterectomy has nearly doubled. *da Vinci* Surgery is currently the most common minimally invasive surgical approach used by surgeons for removal of the uterus in the United States. With the introduction of the Wristed Needle Driver, surgeons now have a new tool designed to facilitate suturing during a single-incision approach to *da Vinci* Surgery for benign hysterectomy and removal of the ovaries and fallopian tubes.

### Important Safety Information

Serious complications may occur in any surgery, including *da Vinci* Surgery, up to and including death. Risks include, but are not limited to, injury to tissues and organs and conversion to other surgical techniques. If your doctor needs to convert the surgery to another surgical technique, this could result in a longer operative time, additional time under anesthesia, additional or larger incisions and/or increased complications. Individual surgical results may vary. Patients who are not candidates for non-robotic minimally invasive surgery are also not candidates for *da Vinci* Surgery. Patients should talk to their doctors to decide if *da Vinci* Surgery is right for them. Patients and doctors should review all available information on non-surgical and surgical options in order to make an informed decision. Please also refer to [www.daVinciSurgery.com/Safety](http://www.daVinciSurgery.com/Safety) for Important Safety Information.

Potential risks of any benign hysterectomy procedure include urinary tract injury, vaginal cuff problem (separation, adhesions, granulation tissue, infection, cellulitis, hematoma), bladder injury, bowel injury, vaginal tear or laceration, vaginal shortening, voiding dysfunction and fistula formation (vesicovaginal, rectovaginal). Patients undergoing a hysterectomy for presumed benign disease who have an undiagnosed cancer may be at risk of having cancer cells spread if the uterus is cut into pieces for removal. Potential risks of any gallbladder removal procedure (cholecystectomy) include common bile duct injury, bile leak and pancreatitis.

### Indications for Use

This device is cleared for commercial distribution in the U.S. for laparoscopic cholecystectomy, and for hysterectomy and salpingo-oophorectomy for benign conditions.

The Intuitive Surgical *da Vinci Single-Site* Instruments and Accessories used with the *da Vinci Si* Surgical System (IS 3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing during single-incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the *Single-Site* Port.

The safety and effectiveness of this device for use in the performance of general laparoscopic abdominal surgery or general gynecological surgery procedures have not been established. This device is only intended to be used for single-incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and the *da Vinci Si* Surgical System (IS3000).

### *da Vinci* System Description

There are several models of the *da Vinci* Surgical System. The *da Vinci* Systems are designed to help doctors perform minimally invasive surgery. *da Vinci* Systems are not programmed to perform surgery on their own. Instead, the surgery is performed entirely by a doctor, who controls the system. *da Vinci* Systems offer doctors 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.

*Single-Site* Instruments and Accessories are compatible with the *da Vinci Si* Surgical System only.

#### **Forward-Looking Statement**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding regulatory clearances. These forward-looking statements are necessarily estimates reflecting the best judgment of our management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including those under the heading "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2013, as updated from time to time by our quarterly reports on Form 10-Q and our other filings with the Securities and Exchange Commission. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar words and expressions are intended to identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. We undertake no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

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