



Intuitive receives FDA clearance of da Vinci SP for simple prostatectomy

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SUNNYVALE, Calif., April 28, 2023 (GLOBE NEWSWIRE) -- Intuitive (NASDAQ: ISRG), a global technology leader in minimally invasive care and pioneer of robotic-assisted surgery, announced that the Food and Drug Administration recently cleared the da Vinci SP surgical system for simple prostatectomy as a representative procedure, which expands the urologic surgical procedures cleared by FDA.

Simple prostatectomy is a surgical procedure often used in patients with benign prostatic hyperplasia (BPH) or enlarged prostate. In this procedure, the surgeon removes the part of an enlarged prostate that is blocking the flow of urine.

In the same action, the FDA cleared the da Vinci SP surgical system for transvesical approach to simple and radical prostatectomy using the da Vinci SP.

In radical prostatectomy, the surgeon removes the entire prostate gland, most often for patients who have been diagnosed with prostate cancer.

"The addition of simple prostatectomy and the transvesical approach to prostatectomy to the da Vinci SP clearances expands the existing urology indication for SP," said Intuitive's Chief Medical Officer Myriam Curet, M.D.

"There is a growing body of clinical evidence on the use of the SP system, and we look forward to continuing our efforts to safely advance minimally invasive surgery," said Curet.

The da Vinci SP system provides surgeons with robotic-assisted technology designed for deep and narrow access to tissue in the body. The ability to enter the body through a single, small incision or through a natural orifice can provide a minimally invasive experience for complex procedures.

The da Vinci SP system includes three, multi-jointed, wristed instruments and a fully wristed three-dimensional (3D), high-definition (HD) camera. The instruments and the camera all emerge through a single cannula and are properly triangulated around the target anatomy at the distal tip to avoid external instrument collisions that can occur in narrow surgical workspaces.

The system enables flexible port placement and excellent internal and external range of motion (e.g., 360-degrees of anatomical access) through the single SP arm. Surgeons control the fully articulating instruments and the camera on the da Vinci SP system, which uses the same surgeon console as the da Vinci X and Xi systems.

Da Vinci SP can be used in Japan and Korea for a number of procedures across several disciplines.

The FDA has cleared SP in the U.S. for urology and transoral otolaryngology procedures, but it is not indicated for use in general laparoscopic surgery procedures.

SP is part of Intuitive's portfolio of surgical systems, now on its fourth generation of innovative technology. The da Vinci X and Xi are Intuitive's multi-port surgical systems.

About Intuitive

Intuitive (Nasdaq: ISRG), headquartered in Sunnyvale, California, is a global leader in minimally invasive care and the pioneer of robotic surgery. Our ground-breaking technologies include the da Vinci surgical system and the Ion endoluminal system. Digital intelligence allows us to unite our advanced systems, progressive learning, and value-enhancing services to 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 diseases are identified early and treated quickly, so patients can get back to what matters most. For more information, please visit: <https://www.intuitive.com/>

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Source: Intuitive Surgical, Inc.