



All India Institute of Medical Sciences Jodhpur

Admn/Prop/19/2017-AIIMS.JDH

Dated: - 06th November 2017.

Subject: Purchase of Dual Console da Vinci Xi Robotic Surgery System for the department of Surgery at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Dual Console da Vinci Xi Robotic Surgery System for the department of Surgery at AIIMS, Jodhpur from M/s Intuitive Surgical, Sarl on proprietary basis. The proposal submitted by M/s Vattuti Technologies Pvt. Ltd, No. 55, Yashas Buiding, Viveswaraiah Nagar, HMT Layout, Bangalore- 560032 and PAC certification by user are attached.

The above document are being uploaded for open information to submit subjection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/19/2017-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 24th November 2017 upto 03:00 PM failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

Administrative Officer

Enclosed: Related documents enclosed.



All India Institute of Medical Sciences Jodhpur

INTUITIVE
SURGICAL®

Date: July 18, 2016

Vattikuti Technologies Pvt Ltd
No. 55, Yashas Building
Viveswaraiah Nagar, H M T Layout
Bangalore – 560032

To whom it may concern:

The *da Vinci® Xi™* Surgical System* can provide a surgeon with intuitive control, range of motion, fine tissue manipulation capability, and visualization characteristics of open surgery, while simultaneously allowing the surgeon to work through small ports and perform minimally invasive surgery.

Purchasers of the equipment use it to facilitate the pursuit of minimally invasive, cardiac, thoracic, pediatric, urologic, gynecologic and general surgery. The *da Vinci® Xi™* Surgical System is both CE marked and FDA cleared, and Intuitive Surgical, Inc. and its subsidiaries solely own all property rights in and to the System.

To the best of our knowledge, Intuitive Surgical is currently the only manufacturer of commercially available robotic surgical systems offering a suite of fully wristed 8mm instrumentation, wristed advanced energy, wristed stapling, fluorescence imaging, integrated table motion, skills simulation and robotic 4-arm multi-port and single port access, all on a single platform, capable of performing minimally invasive surgical procedures.

The *da Vinci® Xi™* Surgical System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures, thoracoscopically-assisted cardiotomy procedures, and trans-oral otolaryngology surgical procedures restricted to benign tumors and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures.

The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization.

The system is indicated for adult and pediatric use (except for trans-oral otolaryngology surgical procedures).

The *da Vinci® Xi™* Surgical System is comprised of the components listed below.

- Surgeon Console including high definition stereoscopic (3D) vision technology
- Single Patient Side Cart with Single Port, 4-arm multi-port and multi-quadrant surgical access
- Vision Cart including High Definition Stereo Endoscope 0°/30° with FireFly™ Fluorescence imaging capability and integrated ERBE electro-surgical generator

Sincerely,
Intuitive Surgical Sàrl

Signature: 
Jean-Yves Raimon (Jul 18, 2016)

Email: jean-yves.raimon@intusurg.com

Title: VP International Finance & Ops

Company: Intuitive Surgical, Sàrl

*Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System Model IS4000)



All India Institute of Medical Sciences Jodhpur

Date: October 16, 2017

The Director,
All India Institute of Medical Sciences,
Jodhpur

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Sincerely,
Intuitive Surgical Sàrl

Jean-Yves Raimon
Vice President International Finance & Operations



*Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System Model IS4000)



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da Vinci Xi
SURGICAL SYSTEM

CORE TECHNOLOGY

The *da Vinci Xi* Surgical System provides a natural extension of the surgeon's eyes and hands into the patient. As with all *da Vinci* Surgical Systems, the surgeon is always in control.

MAGNIFIED 3D HD VISION
Highly-magnified 3D HD ensures the surgeon can see the surgical site with true depth perception and crystal-clear vision.

ENDOWYST™ INSTRUMENTATION WITH INTUITIVE MOTION
Wristed instruments bend and rotate far beyond the abilities of the human hand. Tremor filtration and *intuitive* motion technologies allow the surgeon to operate with steady, natural motion.

ENHANCED ERGONOMICS
Whether it's the first or last case of the day, the ergonomically-adjustable surgeon console makes performing surgery with the *da Vinci* Surgical System feel comfortable and natural.

INTRODUCTION

At Intuitive Surgical, we are on a mission to make surgery better by providing surgeons the best products to effectively and safely perform minimally invasive surgery (MIS).

We believe that MIS should be the standard of care in the modern day operating room and we're working hard to make that a reality.



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da Vinci^{Xi}
SURGICAL SYSTEM

THE NEXT FRONTIER FOR MIS

The *da Vinci Xi* Surgical System advances MIS for patients like never before by offering revolutionary anatomical access, crystal clear 3D HD vision and a platform built for advanced technologies. With this addition, Intuitive Surgical can now offer a full range of *da Vinci* Systems optimized for highly complex, multi-quadrant surgery to simpler, single-quadrant surgery.

REVOLUTIONARY ANATOMICAL ACCESS

CRYSTAL-CLEAR 3D HD VISUALIZATION

PLATFORM FOR ADVANCED TECHNOLOGIES



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REVOLUTIONARY ANATOMICAL ACCESS

The *da Vinci X* Surgical System combines the functionality of a boom-mounted system with the flexibility of a mobile platform. This hybrid architecture enables placement of the surgical cart at any position around the patient while allowing four-quadrant anatomical access.

PLACE PORTS WITH CONFIDENCE
The *da Vinci X* Surgical System is equipped with thin arms and instruments with long reach for a more flexible port placement.

GET STARTED WITH A PRESS OF A BUTTON
With robot sterility, the *da Vinci X* system is designed to be simple and easy to learn. With a guided walkthrough and assistance, set up is quick and precise.

TARGET ANATOMY WITH LASER PRECISION
A laser targeting system takes the guesswork out of positioning the patient cart. Once oriented, simply point the scope at the target anatomy and the system will position the foot to create an optimal configuration for the procedure.



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CRYSTAL-CLEAR 3D HD VISUALIZATION

Visualizing anatomy in highly-magnified 3D HD is a hallmark of performing surgery with the da Vinci Xi Surgical System. A new digital architecture provides the best surgical image ever developed by Intuitive Surgical.

A NEW VISION ARCHITECTURE

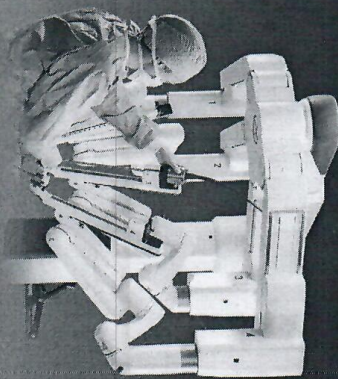
Optics mounted at the tip of the scope put the camera inside the patient, allowing the surgeon and with better see anatomical structure with better definition and more natural colors.

GREAT THINGS COME IN SMALL PACKAGES

The camera, endoscope, and handle have been integrated into one small, handheld design. No need for draping, focusing, white balance or calibration.

ONE BUTTON IMAGE CAPTURE

Just plug in a thumb drive and automatically save images with a push of a button.



SEE ANATOMY FROM A NEW PERSPECTIVE

The small scope allows in to see beyond the edge of the clear surgical lens during a procedure, providing the difference handling for visualizing the surgical site.



FIREFLY™ FLUORESCENCE IMAGING*

The da Vinci Xi Surgical System is designed to be fluorescence imaging capable. Firefly Fluorescence Imaging provides real-time visualization and assessment of vessels, bile ducts and tissue perfusion.

*Firefly Fluorescence Imaging is not currently available for the da Vinci Xi Surgical System.



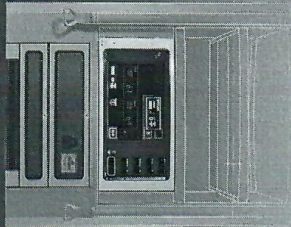
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PLATFORM FOR ADVANCED TECHNOLOGIES

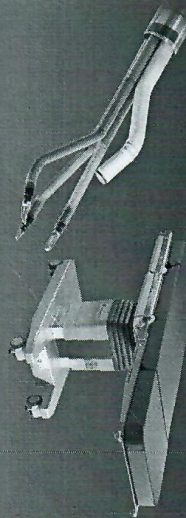
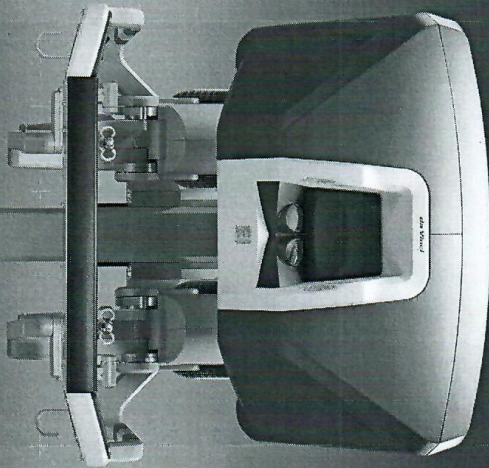
Take control of advanced and future technologies with the built-in expansion capabilities of the *da Vinci Xi* surgical console. The System is designed to seamlessly integrate future innovations, such as advanced instrumentation, software upgrades, and other advancements into one dynamic platform.



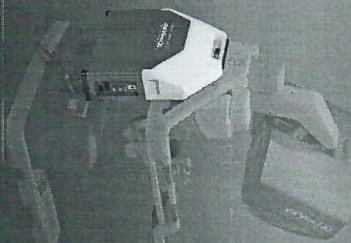
ADVANCED INSTRUMENTS WITH WRISTED MOTION*
The *da Vinci Xi* Surgical System is designed to support the EndoWrist® Stapler, articulation in stapling and the EndoWrist Vessel Sseble™ for cutting and sealing.



INTEGRATED ENERGY
The ERBE VIO d/7 serves as one integrated energy source for EndoWrist® and laparoscopic instruments. Simply set the desired tissue effect and the generator manages and minimizes more and bipolar energy delivered to the surgical site.



FUTURE INNOVATIONS**
The *da Vinci Xi* Surgical System is designed as a technology platform to support new products that enable single-port surgery and intra-operative table motion.



PRACTICE THROUGH SIMULATION
The *da Vinci Xi Skills Simulator™* allows surgeons to practice the skills required to effectively use the *da Vinci Xi* Surgical System. Skills Simulator now offers patient cart simulation capabilities designed to train the perioperative staff.

*Pending FDA clearance. Not available for sale for the *da Vinci Xi* Surgical System within the US.
**These technologies are not currently FDA 510(k) cleared for the *da Vinci Xi* Surgical System.



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1.

TECHNICAL SPECIFICATIONS FOR ROBOTIC SURGICAL SYSTEM WITH ACCESSORIES	
	DESCRIPTION The following specification is for a system capable of working in the Master slave mode with the surgeon as the Master and his hand movements are translated in to minimally invasive instruments capable of navigating inside the human body and performing manoeuvres as desired by the surgeon as per the capabilities of the instruments for performing dissection and suturing in what is come to be called as a robot assisted surgery.
	CAPABILITIES SPECIFICATION
1.	The equipment must be capable of performing minimally invasive robot assisted operative procedures in General Surgery, GI, Urology, Gynecology, Thoracic, Colorectal for benign and cancer surgeries.
2.	The Main Equipment should comprise of the following fully integrated subsystems. <ol style="list-style-type: none">1. One Surgeon's console – with Master controls and an integrated true High Definition 3D display stereo viewer. In case of expansion with an additional surgeon's console, ability to switch surgeon console from one console to the other during surgery.2. Surgical Cart with camera arm and three instrument arms.3. Vision cart containing camera, image processing units and integrated true high definition display monitor for interaction.
3.	<ol style="list-style-type: none">1. High quality Three Dimensional View of the field of operation is to be provided by the Vision system through its stereo endoscope.2. High Density Xenon/ LED light source to be provided for illumination of the surgical field with a standby lamp.3. The surgeon should be able to magnify the images with his own controls.
4.	The Stereo endoscopes should be capable to view at 0 degree and 30 degree. Capability for Real-time near-infrared guidance through visualization of injectable fluorescence dye with suitable endoscope, illuminator and camera should be available.
5.	Camera should provide high resolution images of the operative field along with perception of depth of field.
6.	Instruments to be used with the system should be able to provide surgeons with natural dexterity and a range of motion far greater than even the human hand. Such instruments are to offer a wide range of tips suitable for performing procedures for benign and onco surgeries across multiple disciplines. These Instruments shall offer Seven degrees of motion mimicking the dexterity of human Hand.

Handwritten signatures and initials:
A. Chakrabarti
Jain
Chauhan
Raut
Chandel
Gupta
Bhatnagar



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7.	The masters at the surgeon's console should be capable of translating the natural hand and wrist movements in to corresponding precise and scaled movements to the instruments and camera attached to the surgical cart arms minimising fatigue. Such movements of the instrument tips shall replicate the experience of open surgery.
8.	There should be facility for scaling of surgeon hand movements to corresponding smaller instrument tip movements. The surgeons hand movements shall be replicated at the instrument tip after filtering tremors if any in real time.
9.	There should be facility for learning hand – eye coordination movements by a Simulator subsystem.
10.	The system should perform self-checks to provide safety during usage.
11.	The system should have built in energy source for monopolar and bipolar cautery as well have ability to use external energy source of at least one compatible model for emergency use.
12.	Ability to change instruments during surgery safely with proper guidance should be in built.
13.	Should provide the flexibility to place scope in any one of the surgical arms during the procedure.
14.	Features to provide ability for the assistants in the OR to see and communicate with the surgeon through monitor and telestration.
15.	Ability to adjust the surgeons view ports and console to suite individual comfort and ergonomics should be available.
16.	Ability to enable the surgeon to view two additional video sources from other medical systems with compatible video sources.
17.	While the robotic arms shall be operated by sterile persons the vision system and surgeons console shall be non-sterile are in the Operating room.
18.	Adequate safety features to prevent inadvertent movements of the surgeon affecting the instruments shall be available.
19.	The sub systems shall be easily movable with in the OR. If wheels are used there should be features to lock the wheel to prevent movements.
20.	The system shall provide video output suitable for connecting to external devices such as recorders and additional video monitors.

(A)
07/08/2017

Jain

Khawade
Pruthi

Choudhary
Gupta

Bhargava



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21.	The system shall have all software required to support all disciplines of surgery which is possible by the system under the control of the surgeon.
22.	System shall have features for emergency release of the robotic instruments from the surgery.
23.	Insufflation system with capability to maintain constant Pneumo- peritoneum pressure , and smoke evacuation suitable for easy performance of onco surgery shall be provided as a stand -alone equipment with initial lot of consumables if any.
24.	Air seal with consumables for 200 cycles, this also includes warranty/ CMC of the system for 5 years.
25.	Skill simulator with warranty/CMC for 5 years.
26.	Medical grade HD recorder device with warranty/CMC for 5 years.
27.	Compatible plasma sterilizer device for scopes and instruments with warranty/CMC for 5 years.
28.	The robotic surgery shall be used for Urologic procedures, Head and Neck procedures, Gynecologic procedures, Bariatric procedures, Pediatric procedures and CTVS procedures. It is expected that the demand shall be in the proportion of 40%, 30%, 15%, 5%, 5% and 5% respectively. The starter kit should contain the instruments for 200 procedures so that these cases can be performed.
OTHER REQUIREMENTS	
A	TRAINING
A1	Surgeon Training
	A set of surgeons who will eventually use the robotic surgery system shall be trained by the vendor for using the system to perform robot assisted surgeries particularly oncology procedures in the abdomen and pelvic areas and thoracic areas. The duration of the training and the training method shall be described.
A2	OT staff training
	A set of OT Staff such as Nurses and OT technicians and Biomedical staff shall be trained by the vendor for handling the system covering powering on, moving and positioning the system and observing the system for right function and errors if any etc. The training method and duration shall be outlined by the vendor. There may be multiple batches of OT staff required to be trained over a period of time.
B	INSTRUMENTS, CONSUMABLES & ACCESSORIES

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T/02/1501/70

Shiv

Chauhan
Pruthi

Choudhary

Gandhi

Sharma



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4.

	The vendor should provide a list of Instruments, consumables and accessories available for the use of the system for benign and cancer surgeries suitable for the capabilities of the system
C	SPECIAL ADDITIONAL EQUIPMENTS
	Vendor to specify any special additional equipment that may be required for the use of the robotic surgery system such as special cleaning and sterilisation equipment and UPS with adequate back up capacity.
D	ENVIRONMENT AND POWER
	All equipment shall be capable of working on 230 V AC, +/- 5%, 50 Hz Power supply. The system shall be capable of working between 22 to 30 Deg C air-conditioned environment.
E	SPARES and ACCESSORIES
	A minimum set of Emergency spares that may be required for immediate replacement during procedures. A set of Reusable accessories required for common procedures shall also be proposed.

(A)
07/05/12
DR ANUP KUMAR
PROF & HOD
Urology & Renal Transplant
VMHC & SJH
C Expert from DGHS
Ministry of Health & Family Welfare
Govt of India

Yash
2/9/12

Chauhan
2/9/12

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