ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-29.
STORES SECTION (DO)

Ref. No. 26/Stores (DO)/Uro/PAC/2017-18/FSC **Dated 12.10.2017**

Sub:- Purchase of Dual Console Robotic Surgical System with Accessories for the department of Urology, (AIIMS), New Delhi-110 029, on proprietary basis **Inviting comments thereon.**

******

The Institute is in the process to purchase **Dual Console Robotic Surgical System with Accessories** for the department of Urology, (AIIMS), New Delhi from **M/s. Intuitive Surgical Sarl, USA, through M/s. Vattikuti Technologies LLC, Chennai.** The PAC Certifications by M/s. Vattikuti Technologies Private Limited as well as the user department are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 15 days giving reference No. **26/Stores (DO)/Uro/PAC/2017-18/FSC.** The comments should be received in office of Stores Officer (DO), Store Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before **27.10.2107** upto **12.30 p.m.**, 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,

12/10/17

STORES OFFICER (FSC)

Encl: Related documents enclosed.

22

INTUITIVE
SURGICAL

Date: May 12, 2017

Vattikuti Technologies Pty Ltd.
55 Yashas Building. Opp to RT Nagar Police Station
Visweswariahnagar, HMT Layout
Bangalore 560032
INDIA

AND

Vattikuti's End User:
The Director
All India Institute of Medical Sciences
New Delhi

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 with up to two surgeons simultaneously using a dual console system.

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.

NOTARY GOVT. OF INDIA
L. Gopalakrishna B.A., LL.B. Bangalore City Reg. No. 6766

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

VATTIKUTI TECHNOLOGIES PVT. LTD. BANGALORE

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 electrosurgical generator**

Sincerely,
Intuitive Surgical Sàrl

Signature: Jean-Yves Raimon
Jean-Yves Raimon (May 12, 2017)

Email: jean-yves.raimon@intusurg.com

Title: VP International Finance & Ops

Company: Intuitive Surgical, Sàrl

NOTARY
L. Gopalakrishna
B.A., LL.B.
Bangalore City
Reg. No. 6765
GOVT. OF INDIA

ATTESTED
GOPALAKRISHNA, B.A., LL.B
ADVOCATE & NOTARY
GOVERNMENT OF INDIA
No 25, 3rd Cross, Lalbagh Road
BANGALORE-560 027
16 MAY 2017

VATTIKUTI TECHNOLOGIES PVT. LTD.
BANGALORE

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

TECHNICAL SPECIFICATIONS

Robotic Surgical System with Accessories

Department of Urology, AIIMS New Delhi

A DESCRIPTION

The Department of Urology, AIIMS New Delhi requires a robotic surgical system for replacement of its existing *da Vinci S*® system. The device should be capable of working as a master-slave system, translating the movements of the surgeon's hand into movements of laparoscopically introduced instruments, for performing minimally invasive surgeries in Urology. The device must faithfully reproduce the surgeon's hand movements for dissection and suturing in robot-assisted surgery.

B CAPABILITIES

1. The equipment must be capable of performing minimally invasive robot-assisted operative procedures in Urology. It should be upgradable to any new module developed by the Principal.

2. In case there are multiple versions or models of the system available in the market, the latest generation or latest later model of the system must be provided at the time of supply of the device.

C THE MAIN EQUIPMENT SHOULD COMPRISE OF THE FOLLOWING FULLY INTEGRATED SUBSYSTEMS

1. Two mutually integrated surgeon consoles which have the Master Controls that drive the slave-robotic arms. These should have integrated true High Definition, 3D display stereoscopic viewer. There should be capability to switch control from one console to another during the surgery.

2. The robotic arms mounted on a Surgical Cart wherein one camera and 3 instruments can be controlled simultaneously. The instruments should be usable with an 8mm trocar. The surgical cart should be in the form of a mobile, boom-arm, allowing any of the arms to be used for the camera. Instrument exchanges and operation of robotic arms should be through the sterile operative area.

3. A mobile vision cart must house the camera and image processing units should have an integrated, true high definition display monitor for interaction. The cart should also house an integrated electrosurgical unit capable of providing monopolar and bipolar cautery through the master-control system.

4. A skills simulator must be provided for training and skills enhancement of robotic surgeons. It should be preloaded with all software currently available for training on urological robotic surgeries.

D VISION SYSTEM

1. The vision system must provide true high definition, high quality three dimensional view of the field of surgery through a stereo endoscope.

2. The camera should provide high resolution images of the operative field along with perception of depth of field.

3. An LED light source must be provided, housed in the vision cart, for providing illumination of the surgical field. A spare lamp/bulb for standby must be provided.

4. The master console must allow the surgeon to change magnification of images through the console.

5. The stereo endoscopes should be capable to viewing at 0 degree and 30 degree angles.

6. The system must be capable of real-time near-infrared guidance through visualization of injected fluorescence dye without any change in equipment during surgery. The images so received must be displayed on the main surgeon's console.

7. The surgeon console must be capable of receiving and displaying images from an intra-operative ultrasound machine in separate windows from the main vision.

8. It should be possible to adjust the surgeon's view ports and console to suit individual comfort and ergonomics.

E OTHERS

1. Instruments to be used with the system should be introduced through 8mm or smaller diameter ports and be able to provide surgeons with natural dexterity and a range of motion similar to the human hand. The large variety of instruments should be available capable of grasping, dissection, retracting, incising, coagulating etc for use in surgeries for benign and malignant conditions. These instruments must offer 7 degrees of motion mimicking the dexterity of human hand.

2. The masters at the surgeon's console should be capable of translating the natural hand and wrist movements into corresponding precise and scaled movements of the instruments and camera attached to the surgical cart arms, minimising fatigue. Such movements of the instrument tips must replicate the experience of open surgery.

3. 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.

4. The system should perform self-checks to provide safety during usage.

5. The system should have built-in energy source for monopolar and bipolar cautery and also have ability to use external energy source of at least one compatible model for emergency use.

6. There should be features to provide ability for the assistants in the OR to see and communicate with the surgeon.

7. There should be provision to replicate the surgeon's view to at least 2 external video sources with sufficient ports for recording and archiving of all surgeries in hospital information systems.

8. Adequate safety features must be provided to prevent inadvertent movements of the surgeon causing movements of the instruments.

9. The sub systems should be easily movable within the OR. If wheels are used there should be features to lock the wheel to prevent movements.

10. The system must have all software required to support all disciplines of surgery which is possible by the system under the control of the surgeon.

11. The system must have features for emergency release of the robotic instruments from the surgery. 2 sets of all instruments required for ensuring emergency release must be provided.

12. Training specifically for the use of this model must be provided to at least 4 surgeons and sufficient numbers of OT staff, within the hospital complex at the site of installation.

13. Service engineers and or trainers must make sufficient visits to ensure training on-site. A service technician/engineer must be allocated to provide ongoing service and training at the installation site and to ensure continual functioning of the device without error. Physical presence of the Clinical Team person should be ensured during each procedure in the operating room in the interest of Patient safety.

14. Instruments essential for performing at least 300 urological procedures as per list below must be provided. The list of instruments to be provided is given in annexure 1. However, if these are insufficient to perform 300 surgeries as listed below, the vendor must quote instruments that are sufficient to perform at least 300 surgeries.

    Radical prostatectomy: 75

    Radical cystectomy: 25

Pyeloplasty: 100

Partial nephrectomy: 100

15. It is expected that the specifications mentioned in this document will be sufficient to procure all equipments required to make the device fully functional and for all its features to be fully utilized. However, the vendor must specify any additional equipment that may be required for the use of the robotic surgery system and provide the cost of such equipment in the tender. It will be responsibility of the vendor to ensure that the supplied equipment is complete and can be utilized to its full capability. The vendor may visit the site of installation to satisfy themselves of the conditions available.

16. All equipment must be capable of working on 230 V AC, +/- 5%, 50 Hz Power supply.

The system shall be capable of working between 22 and 30 Deg C air-conditioned environment.

17. A minimum set of Emergency spares that may be required for immediate replacement during procedures must be provided. A set of reusable accessories required for common procedures shall also be proposed.

18. The vision cart must also contain a video-recording device capable of recording all procedures performed with capability of external transfer of recorded data. The device must have sufficient capacity of continuous recording of 4 hour long procedures.

19. Continuous smoke evacuating, gas insufflation system with all disposables, instruments and accessories required for the conduct of 300 surgical procedures must be quoted. The device must be capable of providing high-flow insufflation (upto 30L/min), LCD display for set and current pressure, flow rate, gas consumption; constant measurement of intra-abdominal gas pressure, internal venting system for safety.

20. If additional equipment is required for sterilization of instruments or for power back-up such as UPS, this must be quoted in the tender.

21. All equipment quoted must carry a full comprehensive 5-year warranty and rates for extension from 6^{th} to 10^{th} year must be provided.

22. All equipment quoted must be the latest model available in the market.

ANNEXURE-1

S.No.	Instrument	Number of uses
A	**LIMITED USE INSTRUMENTS**	
1.	Large Needle Driver	600
2.	Prograsp Forceps	200
3.	Maryland Bipolar Forceps	300
4.	Hot shears (Monopolar curved scissors with its accessories/tip cover)	300
5.	Large clip applier	600
6.	Small Clip applier	100
7.	Ultrasonic curved shears	50
8.	Vessel Sealer	50
B	**DISPOSABLE INSTRUMENTS/ ACCESSORIES**	
9.	Arm Drapes	300 for each arm
10.	Column Drape	300
11.	5-8mm Cannula Seal	300
12.	8mm Bladeless Obturator	12
13.	8mm Bladeless Obturator Long	8
14.	8mm Bladeless Obturator, optical	12
15.	8mm Bladeless Obturator Long, optical	8
C	**REUSABLE EQUIPMENT**	
16.	Monopolar Energy Instrument Cord	15
17.	Bipolar Energy Instrument Cord	15
18.	8mm Cannula	4
19.	8mm Cannula. Long	4
20.	8mm Blunt Obturator	2
21.	8mm Blunt Obturator, Long	2
22.	Instrument Release Kit	2
23.	Energy Activation Cable, Ethicon	2

(73)

ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI – 110 029

PROPRIETORY/SPECIFIC BRAND GOODS CERTIFICATE

1.	Item/Type/Model No. required along with specification	**Robotic Surgical System with Accessories**
2.	Is the item a spare part attachment or accessory for an existing equipment	**No**
3.	Name of the manufacturers/Supplier of the item proposed by the indenter.	**M/s Intuitive Surgical Sarl, Switzerland/ M/s Vattikuti Technologies Pty. Ltd., India**
4.	Are they sole manufacturers/sold distributors of the item	**Yes**
5.	Is there any other item with similar/equivalent specification available in the market to meet the job requirement envisaged. If the answer is yes, why the same can't be procured. Demanding Officer should bring out comparative functional advantage/cost effectiveness of the recommended item from these offered by other.	**No**
6.	What were the efforts made to locate alternative source of supply of use other substitutes.	**Internet/ No other alternative source for supply of other substitutes**
7.	Why open/limited tender can't be resorted to, for locating alternative source.	**These are proprietary items of M/s Intuitive Surgical Sarl, Switzerland**
8.	Are the proprietary items certifying that the rates are reasonable or not.	**Rates certificate from the firm is enclosed**
9.	Any other justification for procuring item from single source.	**Only single Manufacturer**

The above mentioned information is provided by the firm.

Signature of Indenter
(Demanding Officer)

DR. RISHI NAYYAR
Assistant/Assistant Professor
Deptt. of Urology

(Counter Signed)
Head of the Department

आचार्य एवं अध्यक्ष/Professor & Head
मूत्रविज्ञान विभाग/Deptt. of Urology
अखिल भारतीय आयुर्विज्ञान संस्थान
All India Institute of Medical Sciences
अंसारी नगर, नई दिल्ली/Ansari Nagar, New Delhi-29, INDIA

I certify that the item at Sr. No.1 above is required to be procured on single tender basis as the source of supply is definitely known/the specified brand proposed was advantages in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

(Strike our whichever is not applicable)