

**ALL INDIA INSTITUTE OF MEDICAL SCIENCE
DR. B.R.A INSTITUTE OF ROTARY CANCER HOSPITAL
(STORE SECTION)**

Ansari Nagar, Delhi-110029

Date:- 26.09.2024

T.NO.IR-09/IRCH/SO/2024-25(CPPP)

CORRIGENDUM

Subject: Revised Tender Specifications – Reg.

With reference to tender No. IR-09/IRCH/S.O/2024-25(CPPP) (Tender ID: 2024_AIMSD_823165_1) for procurement of “Robotic Surgical System for Soft Tissue- 01 Set.” for Department of Surgical Oncology, Dr. BRAIRCH, the following amendment has been made to the existing specifications which are enclosed at Corrigendum/Addendum -1 based on the representation received from potential bidders against pre-bid meeting held on 04.09.2024.

The above is issued without prejudice to other specifications, dates and terms & conditions.

 26/9/24

**Archana Sharma
Sr. Stores Officer, DR. BRAIRCH**

ALL INDIA INSTITUTE OF MEDICAL SCIENCES
DR. B.R.A. INSTITUTE OF ROATARY CANCER HOSPITAL

Ansari Nagar, Delhi – 110091

Date: 17.09.2024

Subject: Revised Technical Specifications based on the submissions received from potential firms in the pre-bid held on 04.09.2024.

**TECHNICAL SPECIFICATIONS FOR ROBOTIC SURGICAL SYSTEM FOR SOFT TISSUE
WITH INSTRUMENTS & 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 into 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 robot-assisted surgery.

CAPABILITIES SPECIFICATION

1. The equipment must be capable of performing minimally invasive robot-assisted operative procedures in General Surgery, GI, Urology, Gynaecology, Cardiac, Thoracic, HPB, Colorectal, ENT and Paediatric surgery for benign and cancer surgeries.

2. The Main Equipment should comprise the following fully integrated subsystems.
Dual Surgeon's console – with Master controls and an integrated High-Definition 3D display immersive stereo viewer.

1. Surgical Cart with 4 universal or modular arms 8-11 mm instrument/camera arms enabling consistent 8mm port placement, rotating boom structure with a targeting laser
2. Vision cart containing the camera, image processing units and integrated true high-definition display monitor for interaction
3. System should be capable of integration with the Second Surgeon Console which provides the ability to switch surgeon console control from one console to the other in real time during surgery.
4. System should be capable for Integration of Skill Simulator with the Surgeon Console in the future with the supplied model of the robotic system to practice & enhance the surgical skills of new & existing robotic surgeons with the help of basic as well as advanced procedure simulation.
5. System should be capable of an upgrade to the Table motion feature in the future to achieve the motion of the table while the system is still docked on the patient.

	6. System should be capable enough to use Single Site instrumentations.
3.	The surgeon should be able to magnify the images with his/her own control.
4.	8mm-11mm Stereo endoscopes should be capable to view at 0 degrees and 30 degrees. Capability for Real-time near-infrared guidance with endoscope through injectable fluorescence dye
5.	Camera should provide high-resolution images of the operative field along with the perception of depth of field. Flexibility to place the endoscope in any robotic arm without the need for change in surgical port size.
6.	Instruments to be used with the system should be able to provide surgeons with natural dexterity and a range of motion equal to the human hand. Such instruments should be able to offer a wide range of tips suitable for performing procedures for benign and oncology surgeries across multiple disciplines. These Instruments shall offer Seven degrees of motion mimicking the dexterity of the human hand.
7.	The masters at the surgeon's console should be capable of translating the natural hand and wrist movements into 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 the facility for scaling of surgeon hand movements to corresponding smaller instrument tip movements. The surgeon's hand movements shall be replicated at the instrument tip after filtering tremors if any in real time.
9.	There should be the 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 sources for monopolar, bipolar cautery and Vessel Sealing, and also have the ability to use external energy sources 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 the ability for the assistants in the OR to see and communicate with the surgeon through monitor and telestration.
15.	Ability to adjust the surgeon's viewports and console to suit 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 surgeon's 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 within 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.
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 the emergency release of the robotic instruments from the surgery.
23.	System should provide the capability to conduct advanced surgical steps like stapling with the help of fully wristed robotic staplers with 120° cone of articulation, controlled directly from the Surgeon's console.
24.	System should provide the capability to conduct advanced surgical steps vessel sealing with the help of fully wristed robotic vessel sealer with 60° articulation, controlled directly from the Surgeon's console.
25.	System should have the capability, through a dedicated mobile application synced to the surgeon console to provide surgery data in the form of procedure type, operative time, instrument choreography and benchmarking of instrument usage and operative time per procedure with other surgeons.
26.	System should provide the capability to support software and hardware applications enabling live observation of surgeries between surgeons in different locations. The application should facilitate two-way audio and video communication with live access to endoscopic view of the operative field.
	OTHER REQUIREMENTS
A	TRAINING
A1	Surgeon Training
	Six surgeons nominated in a phased manner by the Institution Head shall be trained and certified by the vendor for using the system to perform robot-assisted surgeries. The duration of the training and the training method shall be as per international norms at an authorised training centre. The bidder has to arrange and provide a simulator at Dr. BRAIRCH, New Delhi for training purposes as and when with a notice of at least 15 days required by the institute till its lifecycle i.e. 10 years

	without any additional cost for a period as desired by the user and after training is completed simulator shall be returned to the bidder.
A2	OT staff training
	A set of OT Staff such as Nurses and OT 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
	The vendor should provide a list of Instruments, consumables and accessories available for the use of the system for 100 surgeries suitable for the capabilities of the system. Also, compatibility to perform all complex surgeries through instruments listed in Annexure A
C	Mandatory Terms & Conditions
1	The Vendor should have a Training Centre in India
2	The Vendor should be capable of providing the Indian proctor support if required during the initial cases/procedures at the Institution.
3	The robotic system should have USFDA/CE/CDSKO or equivalent approval (Class C for the Robotic Surgery system and B/C for instruments and accessories as per the categorization)

The following instruments and accessories are also to be provided along with the equipment.

Instruments		
Sr. No.	Description	Total Number of Uses (at Least)
1.	Large Needle Driver	30
2.	Large Suturecut Needle Driver	30
3.	Fenestrated Bipolar Forceps	28
4.	Monopolar Curved Scissors	50
5.	Tip Cover Accessories for Monopolar Scissors	5
6.	Cadiere Forceps	18
7.	Force Bipolar	12
8.	Maryland Bipolar Forceps	14
9.	Prograsp Forceps	18
10.	Harmonic Ace Curved Shears	1
11.	Vessel Sealer Extend	1
12.	Large clip applier (Closure)	100
13.	Wristed Robotic Stapler 45 Curve-tip instrument	1
14.	Wristed Robotic Stapler 45 instrument	1
15.	Wristed Robotic Stapler 45 Blue reload	1

16.	Wristed Robotic Stapler 45 green reload	1
17.	Wristed Robotic Stapler 45 black reload	1
18.	Wristed Robotic Stapler 60 instrument	1
19.	Wristed Robotic Stapler 60 Blue reload	1
20.	Wristed Robotic Stapler 60 Green Reload	1
21.	Wristed Robotic Stapler 60 Black Reload	1

Accessories

Sr. No.	Description	Number of Uses (At Least)
1.	12-8 mm reducer	1
2.	12 mm cannula seal	3
3.	5-8 mm Universal Seal	16
4.	Instrument Arm Drape	10
5.	Column Drape	2
6.	8 mm Bladeless Obturator	3
7.	8 mm bladeless obturator long	1
8.	12 mm stapler bladeless obturator	1
9.	12 mm stapler cannula	1
10.	8 mm Cannula	4
11.	Energy Activation Cable, Ethicon, Gen 11	1
12.	8 mm blunt obturator	1
13.	8 mm cannula long	4
14.	8mm blunt obturator long	1

List of accessories and accessories which are required to be quoted by the bidder for fixation of price

Annexure A

Sr. No.	Instruments	Number of Uses in One Unit	Unit Price (Excl. GST)	GST %
1.	Monopolar Curved Shears			
2.	Maryland Bipolar Forceps			
3.	Bipolar Fenestrated grasper			
4.	Dual grip bipolar forceps			
5.	Vessel Sealer			
6.	Harmonic ACE(Ultrasonic) Curved Shears			
7.	Medium-Large Clip Applier			
8.	Large Clip Applier			
9.	Large Needle Driver			
10.	Extra Large needle driver			
11.	Medium Clip applier			
12.	Toothed Grasper			



13.	Permanent Cautery Hook			
14.	Secure Cadere Forceps			
15.	Robotic Arm Drape			
16.	Upper Arm cart sterile drape/Column Drape			
17.	Black Diamond micro forceps			
18.	DeBakey forceps			
19.	Resano forceps			
20.	Atrial Retractor Short Right			
21.	Dual Blade Retractor			
22.	Cardiac Probe Grasper			
23.	Potts Scissors			
24.	Round Tip Scissors			
25.	Tenaculum Forceps			
26.	Small Grasping Retractor			
27.	Tip-Up Fenestrated Grasper			
28.	Permanent Cautery Spatula			
29.	Micro Bipolar Forceps			
30.	Cobra Grasper			
31.	5 mm - 8 mm Cannula Seal			
32.	8 mm Cannula			
33.	8 mm Cannula, Long			
34.	8 mm Blunt Obturator			
35.	8 mm Blunt Obturator, Long			
36.	8 mm Bladeless Obturator			
37.	8 mm Bladeless Obturator, Long			
38.	Tip Cover Accessory			
39.	Energy Activation Cable			
40.	Energy Activation Cable			
41.	Monopolar Energy Instrument Cord			
42.	Bipolar Energy Instrument Cord			
Staplers & Accessories				
1.	12mm stapler cannula			
2.	12mm stapler cannula Long			
3.	12mm stapler blunt obturator			
4.	12mm stapler blunt obturator Long			
5.	12mm stapler bladeless obturator			
6.	12mm stapler bladeless obturator Long			
7.	12mm stapler cannula seal			
8.	12-8mm reducer			
9.	Wristed Robotic Stapler 60 instrument			
10.	Wristed Robotic Stapler 60 White reload			
11.	Wristed Robotic Stapler 60 Blue reload			
12.	Wristed Robotic Stapler 60 Green reload			
13.	Wristed Robotic Stapler 45 instrument			

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14.	Wristed Robotic Stapler 45 White reload			
15.	Wristed Robotic Stapler 45 Blue reload			
16.	Wristed Robotic Stapler 45 Green reload			
17.	Wristed Robotic Stapler 45 instrument (Curved Tip)			

Note: In addition to the above, if any other instruments or accessories are required for the operation of the equipment apart from the above, the price of the same should also be quoted along with the above otherwise it will be assumed that the bidder will provide the same free of cost.


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