

Tender Technical Specifications for HD Laparoscopic System :

Laparoscopic Surgery Set with High Definition Camera :

1. Description of Function :

1.1. Laparoscope is used for minimally invasive surgery and comprises telescope and associated instruments and units.

2. Operational Requirements :

2.1. The set for Laparoscopic surgery should have units/groups of items/components as given below, which should be quoted individually. They could be offered bundled in a comprehensive system or separately for each individual group, which should be adaptable with all major international brands.

3. Technical Specifications :

3.1. CAMERA CONTROL UNIT & CAMERA : 1 No.

High Definition Endoscopic Camera System should have following features :

- a. Digital HD technology.
- b. Progressive scan.
- c. Consistent use of 16 : 9 format for input and output for HDTV function.
- d. CCD chip having hi-fidelity image transmission.
- e. System should have integrated Parafocal Optical Zoom (F 14-30mm, 2 X) to enhance image size.
- f. System should be able to optimize all the settings and should be ready as soon as connected to camera control unit.
- g. Camera control unit should be compatible with all camera heads i.e., Single Chip or Three Chip.
- h. Should be compatible for remote controlled operation of various features.

Technical Specifications :

- i. Image Sensor 3 x 1/3 CCD Chip.
- ii. Pixels 1920 x 1080.
- iii. AGC Microprocessor controlled.
- iv. Lens F14 - 30 mm.
- v. Video Outputs Composite to BNC, Y/C to S-VHS, RGB to D socket, HDTV/DVI-D, DV for recording.
- vi. Input Key Board for Character Generator, 5 pole DIN Socket.

3.2. MONITOR : 2 Nos. (Diagonal Screen) 32" Diagonal Screen (LED)

Two Wide Screen Monitors having the following features :

- a. HDTV Display in 16 : 10 HDTV format.
- b. LCD Crystal display. / LED
- c. Diagonal Screen. / 32" Diagonal Screen, (LED)
- d. Resolution: 1920 x 1200 pixels.
- e. SDI / HD-SDI, Composite, S-Video RGB, DVI-D and VGA input.
- f. All required cables and connectors, which should be specified.
- g. TFT screen stand/Fixtures for connecting to Pendant System / Ceiling Light Arm.

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h. Dustproof and Drip water protected.

3.3. **TELESCOPE :**

1. 5 mm & 10 mm diameter, 30-35 cm long, 30 degree angle of view, 0° degree (2 each)
2. Low risk of object burn
3. Colour coded for identification.
4. Autoclavable.
5. Fiberoptic light transmission incorporated.
6. Visiport (2 each).

3.4. **INSUFFLATOR : 1 No.**

1. Fully automatic, electronically controlled gas fill.
2. Flow rate of 30-40 litres per minute (upto 45 litres/min)
3. Optical and acoustic warning signals in case of malfunction or excessive pressure.
4. Connectible to medical gas pipeline.
5. Control by keys on front panel.
6. Clear and adjacent display of actual and present flow rate, actual and present pressure, gas consumed.
7. Facility for preheating of gas to body temperature.
8. Facility for easy evacuation of smoke and mist.
9. Memory for retention of previous pressure settings.
10. Should include pin-index connection to small / big gas cylinder with regulator, high pressure hose, mains cord, silicone tubing set, universal wrench and gas filter.

3.5. **LIGHT SOURCE : 1 Nos.**

1. LED or Xenon 300 watts.
2. Manual and automatic adjustment of light intensity.
3. Lamp life 500 hrs or more.
4. Display of lamp life/Bulb usage meter warning light.
5. Standby mode with emergency lamp with visual indicator.
6. Long (250 cm or more) fluid and fibre-optic light cable of diameter 4.8-5 min.

3.6. **SUCTION-IRRIGATION UNIT : 1 No.**

1. Pump for irrigation and suction.
2. Maximum irrigation pressure 400 mm Hg.
3. Suction pressure 0.75 bar.
4. Control from control panel and / or foot pedal.
5. Overflow protection on suction bottles.
6. Accessories should include silicone tubings, bacterial filter and bottles with cap.

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3.7. **VIDEO – CART : 1 No.**

- a. Made of Stainless Steel / Epoxy coated metal.
- b. Portable on 4 antistatic dual castors, 2 with locking brakes.
- c. Required number of shelves for housing all the units of the set.
- d. Adjustable arm for fixation to either side for fixing the TFT monitor.
- e. One drawer unit with lock and key.
- f. Cable Manager.
- g. Power box with concealed wiring for providing electrical connections of proper rating to all the units.

3.8. **IMAGE MANAGEMENT SYSTEM : 1 No.**

- a. Documentation system for digital storage of still images, video sequences and audio files.
- b. Latest processor & HDD, which should be specified.
- c. Largest possible RAM, which should be specified.
- d. Integrated DVD / CD writer with maximum speed which should be specified.
- e. Compact key board with drape.
- f. Cordless mouse.
- g. All types of connecting cables (BNC, DVI) and connectors, which should be specified.
- h. Flat screen colour monitor of 1024 x 768 resolution with all connectors and connection cables (BNC, S-VIDEO(Y/C), VGA), which should be specified.
- i. Separate mobile cart with lock and key for housing all the components of the image management system.

3.9. **CARBON DIOXIDE CYLINDER : 1 No.**

Two B – Type cylinders with required regulators and connecting pipe to the insufflator.

3.10. **SUITABLE CAUTERY SYSTEM CAPABLE OF BIPOLAR AND MONOPOLAR COAGULATION AND CUTTING : 1 No.**

HAND INSTRUMENTS & OTHER ACCESSORIES :

Sl. No. :	Instrument :	Specifications :	Quantity :
1.	Reusable Veress 10 & 13 cm Pneumoperitoneum Needle.	Spring loaded blunt stylet luer lock length 10 / 15 cm.	01 Each.
2.	Reusable Trocar : 5 mm.	Multifunctional valve, insufflation stopcock and threaded sleeves, pyramidal tip, length (10.5 cm).	01 No.
3.	Reusable Trocar : 10 / 11mm & 12 mm.	Multifunctional valve, insufflation stopcock and threaded sleeves, pyramidal tip, length (10.5 cm).	01 No. Each.
4.	Safety Trocar with Port.	10 mm length approx 10.5 mm.	01 No.
5.	Spare Sealing Trocar Caps for Trocar.	5 – 6 mm.	01 No.

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Sl. No. :	Instrument :	Specifications :	Quantity :
6.	Spare Sealing Trocar Caps for Trocar.	10 – 11 mm.	01 No.
7.	Reducer Sleeve.	10 / 11 mm to 5 / 4 mm.	01 No.
8.	Reducer Sleeve.	12 mm to 6 / 5 mm.	01 No.
9.	Suction and Irrigation Cannula.	Size 5 mm, length 36 cm, used with suction and irrigation handle.	01 No.
10.	Grasping Forceps – Toothed 2 x 4 Teeth.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
11.	Grasping Forceps – Toothed 2 x 3 Teeth.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
12.	Maryland Forceps.	Double action jaws , rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility.	01 No.
13.	Grasping Forceps – Atraumatic.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
14.	Grasping Forceps – Allis.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility	01 No.
15.	Grasping Forceps – Rt Angled.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
16.	Grasping Forceps – Mixer.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
17.	Grasping Forceps – Plain Dissection & Grasping.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
18.	Grasping Forceps – Babcock.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
19.	Fan Shaped Retractor.	Rotating, size 5 mm, length 33 - 36 cm, dismantling facility.	01 No.

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Sl. No. :	Instrument :	Specifications :	Quantity :
20.	Nathanson Liver Retractor.	Set of four sizes (45, 55, 78, 95 mm), sandblasted to eliminate light reflection.	01 No.
21.	Hook Scissors.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
22.	Micro Scissors.	Single / Double action jaws, size 5 mm, length 33 – 36 cm.	01 No.
23.	Laparoscopic Knife.	5 mm, 30 – 36 cm length.	01 No.
24.	Rotating Metzenbaum Scissors.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
25.	Bipolar Coagulating Forceps.	Size 5 mm, length 33 – 36 cm fenestrated.	01 No.
26.	Bipolar Coagulating Forceps.	Size 5 mm, length 36 cm, 3 mm width of jaws.	01 No.
27.	Maryland Bipolar.	Double action jaws, rotating with connector pin for bipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
28.	CO2 Connector.	Compatible with CO2 "B" type cylinder.	01 No.
29.	High Frequency Cord.	For 5 mm & 10 mm hand instruments with monopolar electrodes, spatula tip.	01 No.
30.	High Frequency Cord.	For 5 mm & 10 mm hand instruments with monopolar electrodes, hook tip.	01 No.
31.	Knot Pushers.	Eye type, length 33 – 36 cm.	01 No.
32.	Needle Holder Coaxial Type.	Size 5 mm, tungsten tip, straight handle with ratchet, single moving jaw, length 33 – 36 cm.	01 No.
33.	Assistant Needle Holder.	Size 5 mm, tungsten tip, straight handle with ratchet, single moving jaw, length 33 – 36 cm.	01 No.
34.	Clip Applicator – Medium Large.	Rotatable, provision for locking the shaft conveniently, 10 mm, compatible with clip LT 300.	01 No.
35.	Clip Applicator – Large.	Rotatable, provision for locking the shaft conveniently, 10 mm, compatible with clip LT 400.	01 No.
36.	Grasping Forceps – Toothed 2x3 Teeth.	Double action jaws, rotating with connector pin for unipolar coagulation, size 10 mm, length 33 – 36 cm, dismantling facility.	01 No.
37.	Grasping Forceps – Toothed 2x4 Teeth.	Double action jaws, rotating with connector pin for unipolar coagulation, size 10 mm, length 33 – 36 cm, dismantling facility.	01 No.

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Sr.No.	Instrument:	Specifications ;	Quantity
3.	Suction Irrigation Cannula	10 mm	01 No.
39.	Babcock Grasper.	Double action jaws, rotating with connector pin for unipolar coagulation, size 5 mm, length 33 – 36 cm, dismantling facility.	01 No.
40.	Stone Extractor	10 m single / double action Jaws.	01 No.
41.	Hassan Cone.	Adaptable to 10 mm trocar.	01 No.
42.	Bowel Grasper.	10 mm fenestrated, rotatable.	01 No.
43.	Blunt Obturator	For 11 mm port.	01 No.
44.	L – Hook.	Size 5 mm, length 33 – 36 cm with pin for cautery. Well insulated hook with small un-insulated working part.	01 No.
45.	Spatula.	Size 5 mm, length 33 – 36 cm with pin for cautery.	01 No.
46.	Fascia Closure Instrument.	Size 2.8 mm, length 17 cm.	01 No.
47.	Washers.	For 5 & 10 mm cannula and reducers.	01 No. Each
48.	Container Systems : Metal & Plastic.	For sterilization and storage of telescopes, hand instruments and other accessories, Different sizes.	01 No.
49.	Endobag		200 Nos.
50.	J-shaped hook with porcelain base		01 No.

4. System Configuration Accessories, Spares and Consumables :

- 4.1. System as specified.
- 4.2. **ACCESSORIES** : All possible accessories of the equipment should be quoted. The specific accessory and its quantity will be decided on the basis of actual requirement.
- 4.3. The system should be capable of accepting standard accessories of major international brands, which should be specified and for which suitable adaptor, if required, is to be provided.
- 4.4. All the items should be from one single manufacturer.

5. Environmental Factors :

- 5.1. The unit shall be capable of being stored continuously in ambient temperature of 0 – 50 deg.C and relative humidity of 15 – 90%.
- 5.2. The unit shall be capable of operating continuously in ambient temperature of 10 – 40 deg.C and relative humidity of 15 – 90%.

6. Power Supply :

- 6.1. Power input to be 220 – 240 VAC, 50 Hz fitted with Indian power-plug.
- 6.2. Electronic Voltage corrector / stabilizer of appropriate ratings for power supply to the whole set meeting BIS Standards / Specifications, (Input 160 – 260 V and output 220 – 240 V and 50 Hz).
- 6.3. Optional UPS of adequate rating for power supply to the system for 60 minutes.

7. Standards, Safety:

- 7.1. Should be FDA, CE, UL *optional Rsh* of BIS approved product. (BIS - mandatory) *Rsh*
- 7.2. Manufacturer and Supplier should have ISO certification for quality standards.

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- 7.3. Electrical safety conforms to standards for electrical safety IEC 60601-1 General Requirements (or equivalent BIS Standard).
- 7.4. Shall meet internationally recognized standard for Electro Magnetic Compatibility (EMC) for electro medical equipment : IEC-60601-1-2 : latest edition Or Equivalent BIS) or should comply with 89 / 366 / EEC; EMC – directive as amended.
- 7.5. Certified to be compliant with IEC 60601-2-2 Medical Electrical Equipment Part 2-2 : Particular requirements for the safety of equipment mentioned above – wherever applicable.

8. Training :

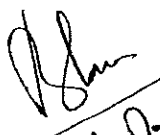
- 8.1. Comprehensive training for staff of user department and support services till familiarity with the system.


9. Warranty & Service :

- 9.1. Comprehensive warranty for 5 years and 5 years Comprehensive Maintenance Service after warranty. The cost of CMC must be quoted in the price bid.
- 9.2. Percentage of uptime guarantee of the equipment during warranty and CMC period for which commitment is to be given must be specified with acceptance of applicable penalty clauses in case of failure to do so.
- 9.3. After sales service must be provided in the city of installation. In situations requiring service / repair of the unit outside the city of installation, the expenditure on account of this will have to be borne by the supplier.


10. Documentation :

- 10.1. Product Literature in original along with that of accessories and indigenous components if any. Photocopies / computer generated copies are not acceptable.
- 10.2. Statement of compliance with tender specifications with clear and unambiguous links to relevant portions of product literature / authentic document, which should be highlighted. Alternatives provided for noncompliant specifications with justification must be described in detail with supporting literature.
- 10.3. Certificate of compliance with standards and approvals stated above.
- 10.4. Certificate of manufacturer/principal regarding authorization of service facility provided by the supplier.
- 10.5. List of Equipment available in the Service Centre for providing calibration and routine Preventive Maintenance Support as per manufacturer documentation in service / technical manual.
- 10.6. List of important spare parts and accessories, which are required for maintenance and repair, with their part number and costing.
- 10.7. Terms and conditions of warranty and CMC including schedules of visit by service personnel with check list of services to be carried out.
- 10.8. Commitment for supply of log book with check list for daily, weekly, monthly and quarterly preventive maintenance with contact details of service personnel along with the equipment. The job description of the hospital technician and company service engineer should be clearly spelt out in the log book.
- 10.9. List of users of quoted model with performance certificate from major hospitals.


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