Clarification No. 1

Sub: Clarification to the below referred tender enquiry document.

Ref.: HITES/PCD/AIIMS-IV/36/ENDO/20-21 dated 17-09-2020

Following are the technical specification published under the above referred Tender Enquiry Document (Page no.41 to 57).

SECTION – VII TECHNICAL SPECIFICATIONS

SPECIFICATIONS - ENDOSCOPY UNIT FOR MINIMALLY INVASIVE GYNAECOLOGY DEPARTMENT OF OBS AND GYNAE, AIIMS, NAGPUR

(A.)TECHNICAL SPECIFICATION OF LAPAROSCOPY UNIT:-

1. HIGH DEFINITION MEDICAL GRADE MONITOR- for laparoscopy unit- 1 no.

Wide Screen Monitors Having the following features:

- a. HDTV Display in 16:10/16:9 HDTV format
- b. LCD/LED Crystal display
- c. 26" High Resolution HD video Medical grade monitor
- d. Resolution: 1920 x 1080 Pixels
- e. SDI/HD-SDI, Composite, S-Video RGB, DVI-D, VGA input, S-VHS-2 nos, should also have same video output
- f. All required cables and connectors, which should be specified
- g. TFT Screen stand/ fixtures for connecting to pendant system/Ceiling Light Arm
- h. Dust-proof and Drip water protected
- i. Picture in picture mode (Parallel live display of visualisation modes besides white light mode).

2. CAMERA CONTROL UNIT AND CAMERA HEAD- for laparoscopy unit- 1 no.

High definition three chip Endoscopic camera system should have following features:

a. Digital full HD technology (truly HD), should be upgradable to 3-D technology (future compatible). System should have inbuilt recording

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- (video/picture) full HD with image enhancement mode and should be controlled from camera head.
- b. Progressive Scan
- c. Camera control unit with three chip HD camera head having HD CCD chip of same aspect ratio of 16:9 and camera control unit should be able to produce following video output: DVI-D-2 nos, SDI-1 no, Composite Video
- d. Three chip camera head should produce at head itself pure digital signal with high definition video (1920*1080PI) with aspect ratio of CCD chip and video format of 16:9 or 16:10
- e. System should have integrated Optical Zoom (12-28mm, 2 Z) to enhance image size and focus lens/rings to make it fully soak-able and waterproof
- f. System should be able to optimise all the settings and should be ready as soon as connected to camera control unit.
- g. Three chip Camera control init should be compatible with all the three chip camera head and the company should provide standby facility within 48 hours of breakdown.
- h. Should be compatible for remote controlled operation of various features
- i. Camera should be suitable for both laparoscope, hysteroscope &resectoscope
- j. Should have Integrated gain, shutter, Enhancement, white balance with brightness control.
- k. All camera functions to be controlled from camera head buttons and through key board at camera control unit to make it controllable from both sterile and non-sterile zone

Technical Specification

- Image Sensor CCD Chip
- Pixels 1920 X 1080
- AGC Microprocessor controlled
- Lens F16-28mm or more
- Video Outputs composite to BNC, Y/C to S-VHS, RGB to D Socket, HDTV-DVI-D, DV for recording
- Input key board for character generator, 5 Pole din/4 pole din/touch screen

3. LED LIGHT SOURCE with fibre optic cable- for laparoscopy unit-1 no.

- a. LED 175 light source equivalent to Xenon 300 Watt.
- b. Manual and automatic adjustment of light intensity should be possible from camera head.
- c. Lamp life 30,000 hrs or more with at least two spare bulb
- d. Display of lamp life/Bulb usage meter warning light

- e. Long (250 cm or more) fluid and fibre-optic light cable of diameter 4.8-5 mm
- f. Light Weight
- g. Certified for National International safety standard normal
- h. Should be able to produce colour temperature of 6000k.

4. SUCTION-IRRIGATION UNIT-1 nos.

- a. Pump for irrigation and suction
- b. Irrigation pressure 550mm Hg or more
- c. Suction pressure 0.65 bar or more
- d. Control from control panel and/or foot pedal/mono-meter
- e. Overflow protection on suction bottles
- f. Accessories should include silicone tubings (2 nos), bacterial filter and bottles with cap
- g. Irrigation suction flow rate should not be less than 2-5 L/min.

5. CO2 INSUFFLATOR-1 nos.

- a. Fully automatic, electronically controlled gas fill
- b. Flow rate of 40 litres per minute
- c. Optical and acoustic warning signals in case of malfunction or excessive pressure
- d. Connectible to medical gas pipeline
- e. Control by keys on front panel
- f. Clear and adjacent display of actual and preset flow rate, actual and preset pressure, gas consumed
- g. Facility for filtering preheating of gas to body temperature
- h. Facility for easy evacuation of smoke and mist
- i. Memory for retention of previous pressure settings
- j. Should include high pressure hose pin-index connection to small big cylinder with regulator, mains cord, silicone tubing set with luer lock, universal wrench and gas filter
- **6. IMAGE MANAGEMENT SYSTEM** (Should be from the same OEM providing laparoscopy and hysteroscopy system).
 - a. Documentation system for digital storage of still images, video sequences and audio files.
 - b. Latest processor & HDD, which should be specified. Minimum 2 TB storage memory. It should have window based operating system, minimum windows-10 with 8 GB RAM and intel i7 processor.
 - c. Integrated DVD/CD/Blue Ray disc writer with maximum speed which should be specified
 - d. Compact key board with drape/Touch screen

- e. Cordless mouse
- f. All types of connecting cables (BNC, DVI) and connectors, which should be specified
- g. With all connectors and connection cables (BNC, S-VIDEO(Y/C), VGA) Which should be specified
- h. Should have 2-4 USB connection slots for data transfer
- i. It should be medical grade with touch screen monitor
- j. Full HD recording, Medical grade computer and Monitor, Touch Screen,

7. ENDOSCOPIC TROLLEY- FOR LAPAROSCOPY UNIT- 1 NO.(SHOULD BE FROM THE SAME OEM PROVIDING LAPAROSCOPY AND HYSTEROSCOPY UNIT)

- a. Made of stainless steel/Epoxy coated metal
- b. Portable on 4 antistatic dual castors, 2 with locking brakes
- c. Central monitor holder
- d. CO2 cylinder holder
- e. Required number of shelves for housing all the units of the set
- f. Adjustable arm for fixation to either side for fixing the TFT monitor
- g. One drawer unit with lock and key
- h. Cable Manager
- i. Power box with concealed wiring for providing electrical connections of proper rating to all the units
- i. Modular in nature
- k. Should be able to add shelves and components later if required.

(B.) <u>TECHNICAL SPECIFICATIONS OF LAPAROSCOPY TELESCOPES AND HAND</u> INSTRUMENTS:-

1.) TELESCOPES

- a) 5 mm forward oblique, 30 degree 1 quantity (length = 29 cm)
- b) 10 mm forward oblique, 30 degree 1 quantity (length = 32cm)
- c) 10 mm straight forward 0 degree 1 quantity (length = 32cm)
- d) 10 mm straight forward oblique 0 to 90 degree 1 quantity (length = 32cm)
- e) All telescope should have following:
 - Low risk of object bum
 - Colour coded for identification
 - Autoclavable

- Fibre-optic light transmission incorporated
- Autoclavable tray that can hold least two telescopes

2.) HAND INSTRUMENTS & OTHER ACCESSORIES

- 1. Reusable, autoclavable, Veress Pneumo-peritoneum Needle-Spring loaded blunt stylet leur lock length 8-10cm/15cm/12cm-4 each
- 2. Reusable, autoclavable, Trocar:- 5/5.5mm-Multifunctional, insufflation stopcock and threaded sleeves, pyramidal tip, length (10.5cm), Flapper Valve-4nos
- 3. Reusable, autoclavable, Trocar:- 10/11mm & 12/13mm-Multifunctional Valve, insufflations stopcock and threaded sleeves, pyramidal tip, length (10.5cm/11) Flapper Valve-4 each
- 4. Laparoscopic autoclavable Suction and irrigation tubes-size 5mm and 10mm, length 33-36 cm, with lateral holes, with two way stopcock for single hand control, size 5mm- 2 quantity and size 10mm -2 quantity.
- 5. Three part laparoscopic autoclavable CROCE-OLMI Grasping Forceps (ATRAUMATIC, FENESTRATED, CURVED), 360 degree rotational sheath, size 5 mm, length 36 cm, long, double action jaws, ergonomic plastic handle without ratchet, with plastic finger rings with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button into three parts. Qty 2.
- 6. Three part laparoscopic autoclavable KELLY Dissecting and Grasping Forceps (ATRAUMATIC), 360 degree rotational sheath, with connector pin for unipolar coagulation, size 5 mm, length 36 cm, long, double action jaws, with ergonomic plastic handle without ratchet, with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button into three parts. Qty 2
- 7. Three part laparoscopic autoclavable BOWEL GRASPING FORCEPS (ATRAUMATIC, FENESTRATED)-360 degree rotational sheath, with connector pin for unipolar coagulation, size 5 mm, length 36 cm, long, double action jaws, with ergonomic plastic handle without ratchet, with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button into three parts. Qty 2

- 8. Three part laparoscopic autoclavable MANHES GRASPING FORCEPS (ATRAUMATIC), 360 degree rotational sheath, curved-toothed 2x4 teeth, double action jaws, rotating with connector pin for unipolar coagulation, length 33-36cm, with ergonomic plastic handle without ratchet, with larger contact area at the finger ring to avoid pressure sores, dismantling facility with the press of a button into three parts, size 5mm- 2 quantity and size 10mm -2 quantity.
- 9. Three part laparoscopic autoclavable MANHES GRASPING FORCEPS (TRAUMATIC), 360 degree rotational sheath, curved-toothed 2x4 teeth, double action jaws, rotating with connector pin for unipolar coagulation, length 33-36cm, with ergonomic plastic handle with haemostat type ratchet, with larger contact area at the finger ring to avoid pressure sores, dismantling facility with the press of a button into three parts, size 5mm- 2 quantity and size 10mm -2 quantity.
- 10. Three part laparoscopic autoclavable SCHNEIDER LYMPH NODE GRASPING FORCEPS (ATRAUMATIC), 360 degree rotational sheath, curved-toothed 2x4 teeth, double action jaws, rotating with connector pin for unipolar coagulation, length 33-36cm, with ergonomic plastic handle without ratchet, with larger contact area at the finger ring to avoid pressure sores, dismantling facility with the press of a button into three parts, size 5mm- 2 quantity and size 10mm -2 quantity.
- 11. Three part laparoscopic autoclavable CLAW grasping forceps, 360 degree rotational sheath, straight-toothed 2x3 teeth-Double action jaws, rotating with connector pin for unipolar coagulation, length 33-36cm, with ergonomic plastic handle with haemostat type ratchet, with larger contact area at the finger ring to avoid pressure sores, dismantling facility with the press of a button into three parts, size 5mm-2 quantity and size 10mm-2 quantity.
- 12. Three part laparoscopic autoclavable RIGHT ANGLED DISSECTING AND GRASPING FORCEPS- 360 degree rotational sheath, with connector pin for unipolar coagulation, size 5 mm, length 36 cm, long, double action jaws, with ergonomic plastic handle without ratchet, with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button into three parts. Qty 2.
- 13. Three part laparoscopic autoclavable BABCOCK GRASPING FORCEPS (ATRAUMATIC, FENESTRATED, WITH MULTIPLE TEETH)-360 degree rotational sheath, with connector pin for unipolar coagulation, size 5 mm, length 36 cm, long, double action jaws, with ergonomic plastic handle with haemostat style

- ratchet, with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button into three parts. Qty 2.
- 14. Three part laparoscopic autoclavable MARYLAND FORCEPS- 360 degree rotational sheath, with connector pin for unipolar coagulation, size 5 mm, length 36 cm, long, double action jaws, with ergonomic plastic handle without ratchet, with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button into three parts. Oty 2.
- 15. Three part laparoscopic autoclavable TENACULUM FORCEPS- 360 degree rotational sheath, with connector pin for unipolar coagulation, length 36 cm, long, double action jaws, with ergonomic plastic handle without ratchet, with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button into three parts. Qty SHORT JAW-2nos, LONG JAW-2nos.
- 16. Three part laparoscopic autoclavable HOOK SCISSORS-360 degree rotational sheath, with connector pin for unipolar coagulation, size 5 mm, length 36 cm, long, double action jaws, with ergonomic plastic handle without ratchet, with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button into three parts. Qty 2.
- 17. Three part laparoscopic autoclavable reusable curved Rotating METZENBAUM Scissors-360 degree rotational sheath, with connector pin for unipolar coagulation, size 5 mm, length 36 cm, long, double action jaws, with ergonomic plastic handle without ratchet, with larger contact area at the finger ring to avoid pressure sores, can be dismantled with the press of a button into three parts. Qty.-size 5mm 2nos., 10mm-1nos.
- 18.**BIPOLAR COAGULATING FORCEPS** set consisting of ring handle, outer sheath, working insert-rotating, dismantling with connector pin for bipolar coagulation-Size 5mm, length 33-36cm, with jaw width of 3mm, with robust jaws- Quantity- ring handle-2nos, outer sheath 2 nos, working insert (fenestrated type-2nos, Kelly dissecting and grasping type- 2nos, curved metzenbaum scissor blades type-2nos) to be supplied with 2 high frequency bipolar cords for 5 mm instruments.
- 19. Coagulation and Dissection electrode- L-Hook shaped- Size 5mm, length 33-36 with pin for mono-polar cautery 2nos

- 20. Coagulation and Dissection electrode- Spatula shaped- Size 5mm, length 33-36 with pin for mono-polar cautery 2nos
- 21.HF Needle for splitting & coagulation, insulated, retractable, with connector pin for unipolar coagulation, size 5mm, length -31-33 cm. 2 nos.
- 22. High frequency Cord-For 5mm & 10mm hand instruments with Mono-polar Electrodes, spatula tip, needle electrode -2 each
- 23. High frequency Cord-For 5mm & 10mm hand instruments with Mono-polar Electrodes, hook tip, knife electrode -2 each
- 24. Laparoscopic Macro Needle holder -5mm, length 33-36cm, tungsten carbide insert tip, ergonomic pistol handle with disengage-able ratchet, ratchet position left, single moving jaw, jaws curved to left, 2 quantity.
- 25. Assistant needle holder-5mm diameter instrumentations with a working length of at least 33-36 cms with tungsten carbide insert tips for straight and curved needles, ergonomic pistol handle with disengage-able ratchet, ratchet position left, straight jaws with distal hole- 2 nos.
- 26.Knot pushers-Eye type, length 33-36cm, 2 each for intra and extra corporal knotting
- 27.Clip Applicator-Medium-size-Rotatable, Provision for locking the shaft conveniently, 10mm, compatible with clip LT300, 2 quoted with adequate no. Of spare clip (Minimum of 100 Clips)
- 28.Clip applicator large Rotatable, Provision for locking the shaft conveniently, 10mm, compatible with clip LT 400/LT300, 2 quoted with adequate no. Of spare clip (Minimum of 100 clips).
- 29. Fan shaped retractor-Rotating, size 5mm, length 33-36cm, dismantling facility 2nos
- 30. Hassan cone-Adaptable to 10mm/11trocar -2nos
- 31.Blunt Obturator-for 11mm port-from 10/11 mm to 5mm&5 to 3 mm -2nos
- 32. Reducer Size 5mm, length 33-36 with pin for cautery 2nos

- 33. Fascia closure instrument size 2.8mm, length 17cm 2nos
- 34. Washers-For 5&10 mm cannula and reducers 100 each
- 35. Container System: Metal & Plastic for Sterilisation and storage of telescopes, hand instruments and other accessories. Different sizes 3 nos each
- 36. Disposable extraction bags -minimum 10 Nos.
- 37.Injection and puncture cannula 5mm diameter, 33-36 cms length with luer lock 2 nos
- 38. Autoclavable laparoscopic myoma screw-33-36 cms length, Qty-5mm-2nos, 10mm-2nos.
- 39. Uterine grasping forceps, toothed jaws, with 1 large and small cone, with channel for perturbation, length 24 cm- 2 Qty.
- 40. Uterine manipulator- **Mangeshikar type** for LAVH, mobilization of uterus, identification of vaginal fornices and sealing of vagina during hysterectomy- 2 Nos.
- 41. CCL Vaginal extractor for LAVH Surgery- 2 nos.
- 42.**Electronic morcellator** with cutting sleeve and protective sleeve along with spare knife (Fully autoclavable) should be from same OEM and should be reusable. It should be European CE or USFDA approved.- 1 nos.

43. Morcellator Accessories

- a. Electronic Drive unit with motor for use with morcellator -1 no.
- b. Morcellator tube serrated edge -1 no
- c. Atraumatic trocar sleeve with pyramidal trocar 12 mm- 1 no
- d. Claw forceps insert 2 x 3 teeth- 1 no
- e. Insulated sheath- 1 no
- f. Laparoscopic Bag- 10 no
- g. Insulated handle with HF connection rotating with ratchet- 1 no
- h. High frequency mono-polar cables for above auxiliary instruments.- 1 no
- i. High frequency bipolar cables for above auxiliary instruments.- 1 no
- 43. Cleaning Accessories
 - a. Cotton carrier with thread- 1 no

- b. Cotton carrier with "U shaped handle- 1 no
- c. Cleaning brush- 1 no
- d. Brush for cleaning jaws 1 no
- e. Oil dropper 1 no
- f. Wadding silver polish- 1 no
- g. Special lubricating oil minimum 10 bottles of 50ml

44. Specifications of **Ring Applicator**

The following item is required with the laparoscopic surgery set for performing family planning surgeries:

- a. **Telescope** -1 nos- Telescope 0 degree with parallel eye piece,10 to 11mm diameter Fibre optic light transmission incorporated; should be compatible with the commonly available light cables (necessary adaptors Should be provided) can be sterilised by autoclaving, cidex solutions And Formalin Chamber. Should have in built 6mm instrument channel for ring applicator as well as CO2 gas insufflations channel. Working length of 270-275 mm.
- b. **Trocar & Cannula** 2 nos- Cannula Size+1mm more than the telescope diameter, Multifunctional Valve and automatic Valve to prevent damage of sharp Instruments and optical tip Lens while passing through the Cannula Valve. It should have stopcock for CO2 insufflation. (**Trocar**: should have pyramidical tip with fine hole for gas outlet. The Working length should be 8.5 to 10.5 CM.).
- c. **Ring Applicator** 2nos- for use with parallel eyepiece telescope compatible with the above telescope, capable of loading two silastic rings. Firing of silicon ring to position 1 where one ring is loaded and firing of two rings simultaneously at position 2. The Ring applicator has to be fully dismantable into different parts like, Prone, inner tube, Outer tube, Thomb, Knurled ring etc to make it Sterilization and service friendly.
- d. **Cone** 5 nos-Suitable cones for loading rings to the above applicator.
- e. **Slide/Guide**—10 nos-Suitable slides/guide for loading ring to the above applicator.

Note: Insulated outer sheath for all forceps and scissors.

(D.) TECHNICAL SPECIFICATION FOR HYSTEROSCOPE & RESECTOSCOPE UNIT.

1. <u>HIGH DEFINITION MEDICAL GRADE MONITOR-for hysteroscopy unit-</u>
1 no.

Wide Screen Monitors Having the following features:

- a. HDTV Display in 16:10/16:9 HDTV format
- b. LCD/LED Crystal display
- c. 26" High Resolution HD video Medical grade monitor
- d. Resolution: 1920 x 1080 Pixels
- e. SDI/HD-SDI, Composite, S-Video RGB, DVI-D, VGA input, S-VHS-2 nos, should also have same video output
- f. All required cables and connectors, which should be specified
- g. TFT Screen stand/ fixtures for connecting to pendant system/Ceiling Light Arm
- h. Dust-proof and Drip water protected

2. CAMERA CONTROL UNIT AND CAMERA HEAD-for hysteroscopy unit-1 no.

High definition three chip Endoscopic camera system should have following features:

- a. Digital full HD technology (truly HD), should be upgradable to 3-D technology (future compatible). System should have inbuilt recording (video/picture) full HD with image enhancement mode and should be controlled from camera head.
- b. Progressive Scan
- c. Camera control unit with three chip HD camera head having HD CCD chip of same aspect ratio of 16:9 and camera control unit should be able to produce following video output: DVI-D-2 nos, SDI-1 no, Composite Video
- d. Three chip camera head should produce at head itself pure digital signal with high definition video (1920*1080PI) with aspect ratio of CCD chip and video format of 16:9 or 16:10
- e. System should have integrated Optical Zoom (12-28mm, 2 Z) to enhance image size and focus lens/rings to make it fully soak-able and waterproof
- f. System should be able to optimise all the settings and should be ready as soon as connected to camera control unit.
- g. Three chip Camera control init should be compatible with all the three chip camera head and the company should provide standby facility within 48 hours of breakdown.
- h. Should be compatible for remote controlled operation of various features
- i. Camera should be suitable for both laparoscope, hysteroscope &resectoscope
- j. Should have Integrated gain, shutter, Enhancement, white balance with brightness control.

k. All camera functions to be controlled from camera head buttons and through key board at camera control unit to make it controllable from both sterile and non-sterile zone

Technical Specification

- Image Sensor CCD Chip
- Pixels 1920 X 1080
- AGC Microprocessor controlled
- Lens F16-28mm or more
- Video Outputs composite to BNC, Y/C to S-VHS, RGB to D Socket, HDTV-DVI-D, DV for recording
- Input key board for character generator, 5 Pole din/4 pole din/touch screen

3. LED LIGHT SOURCE with fibre optic cable-for hysteroscopy unit- 1 no.

- a. LED 175 light source equivalent to Xenon 300 Watt.
- b. Manual and automatic adjustment of light intensity should be possible from camera head.
- c. Lamp life 30,000 hrs or more with at least two spare bulb
- d. Display of lamp life/Bulb usage meter warning light
- e. Long (250 cm or more) fluid and fibre-optic light cable of diameter 4.8-5 mm
- f. Light Weight
- g. Certified for National International safety standard normal
- h. Should be able to produce colour temperature of 6000k.

4. HYSTEROPUMP/HYSTEROMAT- 1 no.

- a. Irrigation system for use in hysteroscopy
- b. Irrigation function is performed by electric pump
- c. Maximum parameters for hysteroscopy are automatically set
- d. Precise pre-setting of volume and pressure of suction and irrigation parameters via touch keys
- e. Adjacent display scales for set values and actual value to ensure safe monitoring.
- f. To be used with pressure regulated from 35 to 150mm of Hg or more, and flow rate regulated from 0-500ml/min. Power supply 100-240 VAC, 50/60 Hz, Mains cord
- g. Connecting cable 100 cm, one pedal foot switch/Touch screen.
- h. Hysteroscopic tubing set
- i. Irrigation tube
- j. Bottle 1 L or more, sterilisable with bottle stand and bottle stand holder

- k. Silicon Tubing Set for suction, sterilisable.
- 1. Hysteromat should be from same manufacturer as of Hysteroscope

5. HYSTEROSCOPE TELESCOPES STANDARD -

- **a.** Operating and Compact-Hysteroscope, Forward-Oblique Telescope 30 degree, enlarged view, diameter 4.0 mm, length 30 cm, autoclavable, fibre optic light transmission incorporated with angle light guide adaptor-1 no.
- b. Forward-Oblique Telescope 30 degree, enlarged view, diameter 4.0 mm, length 30 cm, autoclavable, fibre optic light transmission incorporated 1 no.
- **6.** <u>Diagnostic Hysteroscope Sheath</u> with obturator 5mm diameter for the above 4 mm Hysteroscope telescopes (item 6), with luer lock adapter. 1 no.
- **7.** Operative Hysteroscope Sheath with obturator, continuous irrigation outer and inner sheath for the above 4 mm hysteroscope telescope (item 6) with channel for semi-rigid 5/8 fr size instruments. Should have facility for self-closing sealing system for precise irrigation.

8. ACCESSORIES

Hysteroscopy flexible / semi rigid instruments which should be adaptable to above sheath (item C), 5/8 fr. Diameter-

- a. Foreign body grasping forceps.- 2 nos.
- b. Scissors-Scissors semi rigid, blunt tips, 5 Fr., length 33-36cm, single action jaws- 2nos
- c. Scissors semi rigid, pointed jaws,5 Fr., length 33-36cm, single action jaws, semi-rigid 2 nos
- d. Biopsy and grasping forceps Biopsy and Grasping Forceps semi rigid, 5 Fr., length 33-36cm, double action jaws 2 nos
- e. Punch forceps Punch through cutting semi rigid 5Fr, length 33-36 -2 nos
- f. Tenaculum grasping forceps, semi rigid, size 5Fr, length 33-36cm 2 nos
- g. Needle electrode and ball electrode-Unipolar high frequency cords-1 no.
- h. Bipolar vaporising electrode -- 1 no.
- i. Myoma fixation screw- 2 nos.
- j. Palpation probe- 2 nos.
- k. Polypectomy loop- 2 nos.

9. RESECTOSCOPE FOR TCRE BI-POLAR SET

- **a.** Forward-Oblique Telescope 12°, enlarged view, diameter 4 mm, length 30 cm, autoclavable, fibre-optic light transmission incorporated, with angle light guide adaptor- 1 no.
- **b.** BIPOLAR WORKING ELEMENT SET BIPOLAR Working element to be used with 26FR Resectoscope sheath: Motion by means of a spring. The thumb support is movable. Return of the loop is controlled by thumb and in rest position the electrode should rest inside the operating sheath, to be used with 4 mm hysteroscopy telescope. Should work in saline 01 no
- **c.** BIPOLAR CUTTING LOOP –BIPOLAR cutting loop 24 Fr should work in saline 06 nos
- **d.** BIPOLAR CUTTING LOOP SMALL Cutting Loop 24Fr, bipolar, small should work in saline 06 nos
- **e.** BIPOLAR ELECTRODE POINTED –Coagulating electrode 24Fr, bipolar, pointed should work in saline 06 nos
- **f.** BIPOLAR ELECTRODE BALL END Coagulating Electrode 24Fr, bipolar, ball end should work in saline -06 nos
- **g.** BIPOLAR LOOP STRAIGHT cutting Loop 24Fr, bipolar, straight should work in saline 06 nos
- **h.** RESECTOSCOPE SHEATH FOR BiPOLAR Continuous Flow resectoscope Sheath 26 Fr., for Bi-Polar including connection tubes for in-and outflow, 2 LUER-lock adaptors, diameter 8mm, oblique beak, rotating inner tube, with ceramic insulation, for use with working element should work in saline 01 nos
- **i.** OBTURATOR Obturator, for use with the Resectoscope sheath 2 nos
- **j.** FIBRE OPTIC CABLE Fibre Optic Light Cable, diameter 3.5 mm, length minimum 300 cm 2 nos
- **k.** All Possible accessories of the equipments should be quoted. The specific accessory and its quantity will be decided on the basis of actual requirement.
- **1.** The codes and rates of all relevant individual accessories should be quoted separately with clear mention of period of validity of rates
- **10.** Endoscopic trolley-for hysteroscopy unit- 1 no. (Should be from the same OEM providing laparoscopy and hysteroscopy system).
 - a. Made of stainless steel/Epoxy coated metal
 - b. Portable on 4 antistatic dual castors, 2 with locking brakes
 - c. Central monitor holder
 - d. CO2 cylinder holder

- e. Required number of shelves for housing all the units of the set
- f. Adjustable arm for fixation to either side for fixing the TFT monitor
- g. One drawer unit with lock and key
- h. Cable Manager
- i. Power box with concealed wiring for providing electrical connections of proper rating to all the units
- j. Modular in nature
- k. Should be able to add shelves and components later if required.

E.) ELECTROCAUTERY COMPATIBLE WITH LAPAROSCOPE,

HYSTEROSCOPE And resectoscope

- a. Should have unipolar cutting and coagulation as well as bipolar cutting and coagulation modes and have the facility of blending cutting and coagulation in different ratios and degree soft, standard and / or forced coagulation and spray coagulation
- b. Arc controlled cutting with a pre selectable power of 200 watts in both unipolar and bipolar mode.
- c. Arc controlled coagulation with a pre selectable power of 120 watts in both unipolar and bipolar modes.
- d. Auto stop function with automatic power off on completion of coagulation process.
- e. Automatic start function for bi-polar coagulation. Should be operable both in hand and foot mode and should have hand control switch on the handle of the electrode. Bipolar application with irrigation with sodium chloride
- f. Endoscopy mode with reduced voltage out put for use with fine endoscopic electrodes. (micro-function)

g. Should be compatible with under water operative procedures

- h. It should have neutral electrode monitoring though a patient contact system.
- i. It should have automatic high frequency power cut off by autocoagulation stop and autostart facility
- j. The unit should have the facility of self-testing for trouble shooting
- k. Visual and acoustic signs of HF activation by different coloured indicators and different acoustic tones for cutting and coagulation
- 1. Unit should have safety monitoring circuit in event of malfunction for output monitoring. Neutral electrode connection. Automatic self test and automatic power cut off in event of malfunction. Ground leakage current (LF/HF) HF application time
- m. Power supply 230VAC, 50/60 Hz.

- n. The unit should be supplied with all standard accessories such as electrode, foot switch, Twin earth pad, bipolar forceps with Cord, Electrode Handle with switches, neutral plate, ball electrodes, Loop electrodes, variable output power for all types of currents
- o. Trolley should be provided for electrocautery.
- p. Cautery system should be upgradable for vessel sealing device

(F). MISCELLANEOUS ITEMS:-

1.) Sterilisation/Disinfection Tray:

- a. Disinfection/Sterilization tray with sieve, tray to lift size: 27"X5"X5" (LXBXD) -04 nos
- b. Suitable autoclavable plastic tray double tray for sterilization and storage for hand instruments of minimum 20 hand instruments preferably from OEM -04 nos

2.) Formalin Chamber (Imported/Indian make)

Formalin Chamber made of virgin Acrylic 4.5mm thickness; size: 26"X8"X8" (LXBXH) with three tray, for sterilising the laparoscope& Hysterescope-04 nos

(G.) ENVIRONMENTAL FACTORS

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

(H.) POWER SUPPLY

- 1. Power input to be 220-240VAC, 50Hz fitted with Indian power-plug
- 2. UPS for all systems of adequate rating for power supply to the system for 60 minutes.

(I.) STANDARDS & SAFETY

- 1. Should be USFDA or European CE approved product
- 2. Electrical safety conforms to standards for electrical safety IEC 60601-1 General requirements (or equivalent BIS Standard)
- 3. Shall meet internationally recognised 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
- 4. Certified to be complaint with IEC 60601-2-2 Medical Electrical Equipment part 2-2: Particular requirements for the safety of equipment mentioned above-wherever applicable

(J.) TRAINING

- 1. Comprehensive training for staff of user department and support services till familiarity with the system.
- 2. Training of two faculties form each consignee to be provided

(K.) DOCUMENTATION

- 1. Product Literature in original along with that of accessories and indigenous components if any photocopies/computer generated copies are not acceptable
- 2. Statement of compliance with tender specification with clear and unambiguous links to relevant portions of product literature/authentic document, which should be highlighted. Alternatives provide for noncompliant specification with justification must be described in details with supporting literature
- 3. Certificate of Compliance with standards and approvals stated above
- 4. Certificate of manufacturer/principal regarding authorisation of service facility provided by the supplier
- 5. List of important spare parts and accessories, which are required for maintenance and repair, with their part number and costing.
- 6. 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 should be clearly spelt out in the log book.

(L.) PLEASE NOTE:-

1.The **laparoscopy unit** (HD Medical grade monitor, Camera Control Unit and Camera head, LED Light source, Fibre optic cable, Suction irrigation Unit, Insufflators, Image management system, Endoscopic trolley, Telescopes, Hand Instruments, Morcellator, Ring applicator) **and Hysteroscopy unit** (HD

Medical grade monitor, Camera Control Unit and Camera head, LED Light source, Fibre optic cable, Hysteropump/Hysteromat, Telescope, accessories, Resectoscope set and Endoscopic trolley) should be from same manufacturer for system compatibility and service, with USFDA or European CE approved.

- 2. There should be a separate light source, camera control unit, camera head along with a separate high definition medical grade monitor, endoscopy trolley for the Hysteroscope-Resectoscope unit. All from same manufacturer providing the laparoscopy unit for compatibility.
- 3. The electro cautery should be compatible with the principal system and it should be USFDA or European CE approved.

All other contents of the Tender enquiry including terms & conditions remain unaltered.

Note:

I. Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids