

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.
D- Block, Swasthya Bhawan, Tilak Marg, C-Scheme JAIPUR (Raj)



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No. F-8()RMSC/EPM/M-6/NIB-542/ 2020-21/ 405

Dated: 16/02/2021

CLARIFICATION/CORRIGENDUM/ADDENDUM

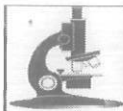
Subject: Amended Specification, Bid Condition of item 1.Laparoscope for single puncture laparoscopic sterilization with CO2 insufflators and cold light source 2. Laparoscope set for training with CO2 insufflators under No. F-8)RMSC/EPM/M-6/NIB-542/ 2020-21/237 date: 01.12.2020

In reference to subject cited above NIB-542, various representation received from the firms and issues raised by the bidder are examined by the competent authorities and technical committee. The following clarification/corrigendum/addendum is issued for inclusion in bid document of items as below:-

A-Revised Technical Specifications of 1.Laparoscope for single puncture laparoscopic sterilization with CO2 insufflators and cold light source 2. Laparoscope set for training with CO2 insufflators

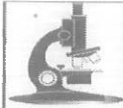
| S. No | Description | | | | | | | | | | | | |
|-------|---|------|---------------|------|---|---|---|---|---|---|---|--|---|
| 1 | <u>Revised Technical specifications of Single Puncture Laparoscope for Laparoscopic Sterilization with CO2 Insufflators and Cold Light Source.</u> | | | | | | | | | | | | |
| | <table border="1"><thead><tr><th>S.N.</th><th>Specification</th><th>Qty.</th></tr></thead><tbody><tr><td>1</td><td>Telescope: Telescope 30 degree with parallel/ straight eye piece, 10 mm diameter. Should have 6 mm instrument channel built-in ring applicator Working length of 270-275 mm/10mm 0 degree telescope. Fibre optic light transmission incorporated, should be compatible with the commonly available light cables (necessary adaptors should be provided) Can be sterilized by autoclaving, gluteraldehyde solutions and formalin chamber.</td><td>1</td></tr><tr><td>2</td><td>Trocar & Cannula: Cannula size +1 mm more than the telescope diameter; should have an automatic valve and stopcock for insufflations. (Compatible with supplied telescope). Trocar should have pyramidal tip. Tip should be sharp enough but should not injure the viscera. The length of the Trocar should be 175 mm±10 mm and the length of the cannula should be 100-110 mm. (Intra abdominal part)</td><td>2</td></tr><tr><td>3</td><td>Ring Applicator: Ring applicator for use with parallel/straight eyepiece telescope compatible with the above telescope. Capable of loading two silastic rings. The ring applicator has to be fully dismantable into different</td><td>3</td></tr></tbody></table> | S.N. | Specification | Qty. | 1 | Telescope: Telescope 30 degree with parallel/ straight eye piece, 10 mm diameter. Should have 6 mm instrument channel built-in ring applicator Working length of 270-275 mm/10mm 0 degree telescope. Fibre optic light transmission incorporated, should be compatible with the commonly available light cables (necessary adaptors should be provided) Can be sterilized by autoclaving, gluteraldehyde solutions and formalin chamber. | 1 | 2 | Trocar & Cannula: Cannula size +1 mm more than the telescope diameter; should have an automatic valve and stopcock for insufflations. (Compatible with supplied telescope). Trocar should have pyramidal tip. Tip should be sharp enough but should not injure the viscera. The length of the Trocar should be 175 mm±10 mm and the length of the cannula should be 100-110 mm. (Intra abdominal part) | 2 | 3 | Ring Applicator: Ring applicator for use with parallel/straight eyepiece telescope compatible with the above telescope. Capable of loading two silastic rings. The ring applicator has to be fully dismantable into different | 3 |
| S.N. | Specification | Qty. | | | | | | | | | | | |
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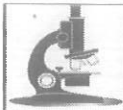
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| | parts like prone, inner tube, outer tube, knurled ring etc. | | |
| 4 | Cone: Suitable cones for loading rings to the above applicator made of Teflon / silicon / SS 317 grade | 5 | |
| 5 | Slide/guide: Suitable slide/guide for loading rings to the above applicator. | 10 | |
| 6 | Veress Needle: Veress Needle with spring loaded blunt stylet with luer lock and length of 10 cm | 3 | |
| 7 | Veress Needle : Veress Needle with spring loaded blunt stylet with luer lock and length of 15 cm | 3 | |
| 8 | Essential Spares : (i) Spare washers: Spare washers for trocar , Cannula and automatic valve (ii) Kits for cleaning: Trocar Brush, Cannula Brush, Silicon Oil 50ml, Special lubricant for stopcock & telescope lens cleaner. (iii) Spare parts: Spring of ring applicator, finger ring (thumb) for ring applicator, knurled screw for ring applicator, inner sheath of ring applicator, tension rod with grasper (prone insert) for ring applicator, adaptor for fiber optic light cable for telescope, stopcock for cannula gas inlet, spring cap for stopcock (iii) Manuals: Operational & service manuals | 10 each 2 each 2 each 1 each | |
| 9 | Supplier should provide a plastic storage brief case with foaming inside for laparoscope Telescope and all hand instruments and accessories for storage & transportation. | 1 | |
| 10 | Environment : Telescope should be specified for operation up to 45° C and 100% relative humidity | Conformity | |
| 11 | Electronic CO₂ insufflators with pin index connection. Should have an adjustable minimum flow rate of 40 ltr Per minute or more and a pressure range adjustable between 0-30 mm Hg. Pressure and flow rate should be display on the front panel Provided with silicon autoclavable tubing with luer attachment. Instrument should work on a supply of 180-240 V. with a frequency of 50 Hz single phase. Fit for purpose. The unit should be comply with relevant IEC safety standards. Automatic gas release system for constant monitoring of intra abdominal pressure and checking over pressure with automatic back release of CO ₂ gas within 5 seconds should include 1 pack/10 filter for CO ₂ gas. 1. The machine should give an audible alarm signal in case of wrongly placed veress pneumoperitonium needle and sudden block in the CO ₂ flow from machine 2. The insufflator should also give audible alarm in case of overpressure and release of it automatically 3. Both the preset value and actual value for pressure and flow should be displayed at the same time on the front panel of the machine | 1 | |
| 12 | High Pressure hose: High Pressure hose suitable to connect the insufflators with pin indexed CO ₂ cylinder. | 1 | |
| 13 | Wrench kit: Suitable for connecting the insufflators to CO ₂ cylinder | 1 | |
| 14 | Carbon Dioxide Bottle (cylinder): 5 Kg. or equivalent Capacity Carbon Dioxide bottle with pin index connection. The unit should automatically | 4 | |

16/11/22



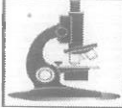
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| | display status of the CO ₂ conditioning by it electronic Bar Graph / Digital display on the front panel of the insufflator. The unit should have inbuilt pressure regulator to detect high & low pressure of CO ₂ gas automatically at the input. | | |
| 15 | Cold Light Sources: LED Light source with one / two light outlets, having power more than 100 Watts, and average LED lamp life of minimum 25000 hrs or more. Rechargeable Handy LED Back Up light source compatible with SP laparoscope is also provided. Handy LED battery light source (Rechargeable with Charger) which can be directly mounted on to the laparoscope Telescope without any delay in case of break down with Main light source type. The unit should comply with relevant IEC safety standards. | 1 | |
| | | 1 | |
| 16 | Fibre Optic Light cable: 4.5-10.0 mm in diameter. 250-300cm in length compatible with the cold light source and can be fitted the commonly available telescope (necessary adaptors may be provided) | 1 | |
| 17 | UPS : UPS-1.0 KVA with one hour backup time, good quality, ISI/CE approved | 1 | |
| 18 | Essential Parts: (i) Mains cord: Compatible with insufflators and cold light source (ii) Manuals: Operation & service manual (for insufflators & Light source) | 2 | |
| | | 1 each | |
| 19 | Formalin Chamber (for Sterilization of Laparoscope) : Dimensions of Formalin chambers 65 cm (±10cm) X 20 cm (±2cm) X 20 cm (±2cm) with three tray made of white Opaque Acrylic | 1 | |
| 20 | Tray for sterilization of Laparoscopes: Dimensions of outer sterilization box 70cm ±10cm x 20 cm ± 5cm x 15 cm ± 2 cm (Volumetric capacity 10 litre ± 2 litre) and the inner tray with holes to keep the instrument in the solution. (Which is to be kept in outer box). The material should be of S.S. material. | 2 | |
| 21 | Compatibility & Core items: The core laparoscopy items such as Telescope, Trocars & Cannula, Ring Applicator, Veress Needle, CO ₂ insufflators, Light Source and Fiber Optic light cable etc. should be from single manufacturer for system compatibility. Item like formalin chamber, cleaning kit, briefcase, tray for sterilization, ring applicator, UPS, LED monitor, etc may be from different manufacturer but should be compatible with core item. | | |
| 22 | Core items/products should be US FDA/ European CE (notified body)/BIS and comply to mentioned safety standard in specifications. | | |
| 23 | Guarantee: Three years on equipment from the date of installation. | | |
| 24 | CMC: CMC will be given @ 3 % of net rate excluding GST (as applicable). The CMC may be awarded for five years (on yearly basis) after completion of Guarantee period of three years. | | |
| 25 | Rates of Consumable/spare parts: Rates of consumable and spare parts as per requirement of the equipment should be provided by bidder in BOQ. | | |
| 26 | Installation will be done by supplier free of cost. | | |
| 27 | The service engineer should be based in Rajasthan. | | |
| 28 | Demonstration of Equipment is must for final approval. | | |
| 29 | The company should mention the make & model name/number of the quoted equipment and submit the technical brochure of the quoted model in the Technical bid along with compliance sheet as per technical specifications. | | |
| 30 | Firm should mention all the pre-installation requirements in technical bid. | | |

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| | (i) Bidders are requested to send with bid, printed descriptive literature of the quoted items. |
| | (ii) If Bidder supplied to or have rate contract of quoted items with any other Govt. institutions within one year, he may be asked to provide copies of purchase orders, invoices and rate contract. |
| 2 | Revised Technical specifications of Laparoscope Set For Training With CO2 Insufflator <u>Technical Specifications of item Laparoscope Set For Training With CO2 Insufflator</u> <u>Camera:</u> 1. It should be CMOS/3 chip full high definition digital camera head and console with HD image production. Resolution should be 1920 X 1080. 2. THE ASPECT RATION OF SENSOR SIZE AND VIDEO MONITOR SIZE SHOULD BE 16:9 OR 16:10. 3. Should be fully compatible to the color systems PAL / NTSC. 4. Resolution & progressive scan technology both on camera head & console. Multiple settings allow the user to select the preferred level of image enhancement. 5. Should have optical / digital zoom to enhance the quality of image size. 6. Should have the auto exposure system for consistent illuminable level. 7. Integrated gain / shutter / enhancement with automatic brought ness control. 8. Automatic white balance with memory functions for two settings. 9. The system should be Menu driven, thus allowing the surgeon to programe the camera head functions as per the surgical needs and requirement. Composite, S-VHS & RGB & 2 or 1 DVI, HD, SDI output compatibility. 10. The system should have facility of attaching additions video printer / recorder functions and other peripheral units. 11. Camera head fully soakable for disinfection.. 12. Universal power supply compatible with Indian Electrical System. <u>LED LIGHT SOURCE:</u> 1. LED Light should produce White Light. 2. Patient safety & added protection in OR with safe light 3. Single port universal Jaw assemble to adopt technology of fiber optic cable. LED Light source should produce luminance not less than 2000 Lumen and having LED lamp life of minimum 25000 hrs or more. <u>FIBER OPTIC LIGHT CABLE</u> Diameter size 4.8 to 5.5 mm, Length should be not less than 250 cm. <u>HIGH RESOLUTION MEDICAL GRADE VIDEO MONITOR:</u> 1. Hi definition, Maximum resolution, colored monitor, size 26 inch or more. Flat panel LED monitor , Resolution should be 1920 x1080 . THE ASPECT RATION SHOULD BE 16:9 or 16:10. 2. Color system PAL / NTSC compatible 3. S-VHS, RGB and DVI , HD SDI input and output compatibility. <u>CO2 Insufflator :</u> 1. CO2 electronic insufflator, having minimum flow rate of 40 L/M or more. 2. Unit should be easy to use clear, adjacent displays for set value and actual value allow easy |

16/4/22



monitoring of insufflation process touch keys for precise pre selection of set value optical and acoustic warning signals in the event of over inflation.

3. High Pressure (HP) HOSE WITH CONNECTOR – 10 NO's WITH B TYPE REGULATOR.

4. STAND FOR KEEPING B TYPE CO2 CYLINDER OR PROVISION IN TROLLEY FOR KEEPING CYLINDER

Live Recording System – 1

1. System to be compact, easy to deploy. Portable mobile design and allows portability to any OT.
2. User – centric, simple-to-use and with preview screen interface.
3. Open architecture to give the hospital the flexibility to support any endoscopic vendor.
4. Inputs support: **DVI , S-Video, Composite, SD-SDI, HD-SDI & 3G-SDI.**
5. Video Resolution support up to 1920 x 1080 p.
6. HD – Video Bit rates upto 60 MBPS.
7. Still capture format supports JPG, BMP, PNG, DICOM.
8. The system to allow playback recorded videos on the preview screen.
9. Auto archive facility for external USB Drives, also for network drives.
10. Direct data transfer facility to devices such as USB cable/ **EXTERNAL DRIVE.**
- 11. Inbuilt HDD: Minimum 256 GB or more expandable**

Instruments:

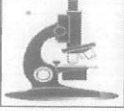
Laparoscope:

1. 10 mm 30 degree 30 – 35 cm
2. **05 -5.5 mm 30 degree 30 - 35 cm**
3. Scope should be compatible with HD camera.
4. Wide angle full screen, forward – Oblique and lateral scope.
5. Optimal centre – to – edge resolution for enhanced picture quality.
6. Fiber optic light transmission incorporated.
7. Standard ocular window for coupling the camera head.
8. Scratch resistance sapphire quoted tip lens.
9. Advanced Rod lens system for optimum brightness, contrast and definition.

Specification for Laparoscopic Hand Instruments and Accessories:

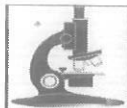
| <u>Laparoscopic Hand Instruments and Accessories</u> | | |
|---|---|------------|
| S.NO. | Product Description | Qty |
| 1 | 120 MM VERESS NEEDLE | 1 |
| 2 | 5MM ASPIRATION NEEDLE, 33 CM LO | 1 |
| 3 | 10 MM CLIP-APPLYING FORCEPS, (lc300 or LT400 COMP) | 1 |
| 4 | 5 MM, 33 cm MARYLAND DISSECTOR | 1 |
| 5 | 5MM, 33 CM SPATULA TIP ELECTROSURGICAL PROBE (3BX) | 1 |
| 6 | 5MM, 33 CM L-TIP ELECTROSURGICAL PROBE (3BX) | 1 |
| 7 | 5MM, 33CM MIXTER DISSECTOR | 1 |
| 8 | 5MM, 33CM FUNDUS GRASPER | 1 |
| 9 | 5MM, 33MM ALLIGATOR GRASPER | 1 |

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| 10 | 55MM, 33CM SINGLE ACTION ATRAUMATIC | 1 |
| 11 | 5MM, 33CM COBRA GRASPER | 1 |
| 12 | 5MM, 33CM STRONG GRASPER (FENE) | 1 |
| 13 | 5MM , 33 CM PEEK MONOPOLAR HANDL | 1 |
| 14 | 5.5 MM CANNULA, AUTOMATIC VALVE, STOPCOCK WITHOUT TROCAR | 1 |
| 15 | TROCAR, PYRAMIDAL TIP, 5.5 MM | 1 |
| 16 | 11 MM CANNULA, AUTOMATIC VALVE, STOP COCK, WITHOUT TROCAR | 1 |
| 17 | TROCAR, PYRAMIDAL TIP 11 MM | 1 |
| 18 | SUCTION IRRIGATION TRUMPET TYPE | 1 |
| 19 | 5 MM CURVED NEEDLE HOLDER | 1 |
| 20 | PADDLE BABCOCK GRASPER 33 CM | 1 |
| 21 | 5 MM, 33CM DORSEY GRASPER | 1 |
| 22 | 5MM, 33CM CURVED RIGHT NEEDLE HOLDER | 1 |
| 23 | 5MM, 33CM ENDO METZENBAUM SCISSORS (CURVED) | 1 |
| 24 | 5MM, 33CM STRAIGHT NEEDLEHOLDE | 1 |
| 25 | 5MM, 33cm, CURVED KELLY DISSECT | 1 |
| 26 | 5MM, 33cm, RIGHT ANGLE DISSECTO | 1 |
| 27 | 5MM, 33 CM ALLIS GRASPER (SINGL) | 1 |
| 28 | RATCHETED HANDLE | 1 |
| 29 | REDUCER | 1 |
| 30 | 5 MM CLIP APPLICATER | 1 |
| 31 | MYOMA SCREW | 1 |
| 32 | TENECULUM | 1 |
| 33 | PUNCH BIOPSY FORCEPS | 1 |
| 34 | SURURE PASSER NEEDLE | 1 |
| 35 | PORT CLOSURE NEEDLE | 1 |
| 36 | UTERINE MANIPULATOR (FULL CIRCLE) | 1 |
| 37 | CURVED FEN RETRACTOR (5 LEAF) | 1 |
| 38 | Core items/products should be USFDA/European CE(notified body)/BIS certified and comply to mentioned safety standards in specifications. | |
| Total | | |
| PLASTIC/METAL TRAY FROM OEM FOR STORAGE AND STERILIZATION- 2 Nos (with complete set) | | |
| Note:- Medical Grade USFDA / European CE(notified body) approved products to be quoted. | | |
| Endo Trolley: | | |
| 1. IT SHOULD BE IMPORTED MEDICAL GRADE AND FROM SAME MANUFACTURER. IT SHOULD | | |

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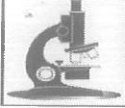


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| <p>HAVE 4 SHELF AND 1 LOCKABLE DRAWER . with proper Wheel locking system .</p> <p>2. It should have extendible arm for monitor mount it should have isolation transference should have extendible video arm to mount Medical grade LED monitor.</p> <p>3. Instrument trolley should have attachment of UPS system of around 30 minutes back up should be provided with the set.</p> <p>4.Should be supplied with UPS of Suitable capacity as per demand of quoted items.</p> |
| <p>Guarantee: Guarantee for 3 years from the date of installation.</p> |
| <p>5. CMC: CMC will be given @ 2% (of net rate-inclusive of Taxes etc.) plus service tax (as applicable) The CMC will be awarded for five years (on yearly basis) after Guarantee period of three years.</p> |
| <p>The entire system should be ICG Compatible.</p> |
| <ul style="list-style-type: none"> • Laparoscopic set with attached instrumentation should be US FDA / European CE (notified body) certification will be must. • Rates of Laparoscopic Hand Instruments and Accessories must be quoted separately in the online BOQ and a separate pdf with rates must be attached with online BOQ. |
| <p>6.Product should have IEC safety standards wherever listed</p> |
| <p>The core items of laparoscopy set like camera system, LED light source, CO2 insulator, video monitor, Telescope, instrument trolley and Fiber optic light cable should be from same manufacturer for system compatibility for optimal performance of system as whole & the rest items should be either be from same manufacturer or marketed by same company & agreement shall be submitted between both the companies while submitting the bid.</p> |
| <p>Installation will be done by supplier free of cost.</p> |
| <p>The service engineer should be based in Rajasthan.</p> |
| <p>Demonstration of Equipment is must for final approval.</p> |
| <p>The company should mention the make & model name/number of the quoted equipment and submit the technical brochure of the quoted model in the Technical bid along with compliance sheet as per technical specifications.</p> |
| <p>Firm should mention all the pre-installation requirements in technical bid.</p> |
| <p>(i) Bidders are requested to send with bid, printed descriptive literature of the quoted items.</p> |
| <p>(ii) If Bidder supplied to or have rate contract of quoted items with any other Govt. institutions within one year, he may be asked to provide copies of purchase orders, invoices and rate contract.</p> |

B-Revised Bid Condition:-

| S.N. | Existing bid condition/Clause/Term | Revised Bid Condition |
|------|------------------------------------|---|
| 1 | --- | 1. वित्त विभाग (G&T) की अधिसूचना दिनांक 01.01.2021 एवं वित्त विभाग (G&T) राज.सरकार के आदेश F.2(1)FD/G&T-SPFC/2017 dated 15.01.2021 के अनुसार जारी नियम/संशोधन इस निविदा पर प्रभावी होंगे। |

1/1/21



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| 2. | | 2.वित्त विभाग (G&T) की अधिसूचना दिनांक 18. 12.2020 एवं वित्त विभाग (G&T) राज.सरकार के आदेश F.2(1)FD/G&T-SPFC/2017 dated 23.12.2020 के अनुसार जारी नियम/संशोधन अनुसार बिड़ सिक्यूरिटी राशि प्राप्त नही करने एवं इसके स्थान पर बिड़ सिक्यूरिटी के संबंध में घोषणा पत्र (Declarations) प्राप्त करने का प्रावधान हेतु संशोधन इस निविदा पर प्रभावी होंगे। Declaration की प्रति सलग्न है। उक्त Declaration Rs.50/- के Non-Judicial Stamp Paper पर Notarized कराना है। |
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It is also clarified that information of award of contract shall be communicated to all participating bidders on the website www.rmssc.nic.in and sppp.raj.nic.in. Please note that individual bidder will not be intimated.”

Note:- Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-V, Schedule of Supply, and Point no. 3) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

This bears the approval of M.D., RMSCL, Jaipur.


Executive Director (EPM)
RMSCL, Jaipur