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No. F-8() RMSC/EPM/M-2/14-15/NIB-62/76/8

Dated: 10/2/15

CLARIFICATION/CORRIGENDUM/ADDENDUM

<u>Subject:-</u> Revised technical Specifications and other terms and conditions of Bid document of Single Puncture

Laparoscope for Laparoscopic Sterilization with CO2 Insufflators and Cold Light Source under

NIB No. F-8() RMSC/EPM/M-2/14-15/NIB-62/7250 Dated: 23.12.2014

In Reference to subject cited above and NIB-62, the various representations received from the firms and issues raised by the Bidders are examined by the competent Authorities and technical committee. The following Clarification/Corrigendum/Addendum is issued for inclusion in Bid document & Technical Specification of items as below:-

01. <u>Amended Technical Specifications of Single Puncture Laparoscope for Laparoscopic Sterilization with</u> CO2 Insufflators and Cold Light Source <u>as below:</u>-

S.N.	Specification	Qty.
1	Telescope: Telescope 0 degree with parallel/straight eye piece, 10 to 12 mm diameter. Fibre optic light transmission incorporated, should be compatible with the commonly available light cables (necessary adaptors should be provided) Can be sterilized by autoclaving, gluteraldihyde solutions and formalin chamber. Should have 6 mm instrument channel built-in ring applicator Working length of 270-275 mm.	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 parts like prone, inner tube, outer tube, knurled ring etc.	3
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:	10
	(i) Spare washers: Spare washers for trocar, Cannula and automatic valve	10
	(ii) Kits for cleaning: Trocar Brush, Cannula Brush, Silicon Oil 50ml, Special lubricant for stopcock	each 2 each
	& telescope lens cleaner. (iii) Spare parts: Spring of ring applicator, finger ring (thumb) for ring applicator, knurled screw for	2 Cacii
	ring applicator, inner sheath of ring applicator, tension rod with grasper (prone insert) for ring	2 each
	applicator, adaptor for fiber optic light cable for telescope, stopcock for cannula gas inlet, spring cap for stopcock	
	(iii) Manuals: Operational & service manuals	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	Confo rmity
11	Electronic CO ₂ insufflators with pin index connection. Should have an adjustable flow rate of 0 to 20 ltr. Per minute 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. The unit should be ISI/CE marked. SECUVENT safety 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	

12	High Pressure hose: High Pressure hose suitable to connect the insufflators with pin indexed CO2 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 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.	4
15	Cold Light Sources: LED Light source with dual / two light outlets, having power of 100 Watts or more, and average LED lamp life of minimum 20000 hrs. Electrical Safety Certification IEC- 601-1.CE according to MDD and TUV certified.	1
	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
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	2
	(ii) Manuals: Operation & service manual (for insufflators & Light source)	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 $70\text{cm} \pm 10\text{cm} \times 20\text{ cm} \pm 5\text{cm} \times 15\text{ cm} \pm 2\text{ cm}$ (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, Trocar & Cannula, Ring Applicator, Veress Needle, CO ₂ insufflator, Light Source and Fiber Optic light cable etc. should be from single manufacturer for system compatibility.	
22	Core items/products should be US FDA/CE 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 - inclusive of Excise Duty & exclusive of VAT / CST et service tax (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC may be av for five years (on yearly basis) after completion of Guarantee period of three years.	c.) plus varded
25	Rates of Consumable/spare parts: Rates of consumable and spare parts as per requirement of the e	quipment
	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.	1 1
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.	

02 Instruction to bidders as follows:-

i. Section IV technical bid submission sheet (Cover-A) point no. 12 (v) is Deleted.

ii. Section III, evaluation and qualification criteria, point no. 2, clause no.8 is replaced as "Bidders shall have to submit a valid 'VAT' clearance certificate from the concerned Commercial Taxes Officer or Affidavit and the 'PAN' issued by Income Tax Department."

iii. It is also clarified that information of award of contract shall be communicated to all participating bidders on the website www.rmsc.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, 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