TECHNICAL SPECIFICATIONS FOR PULMONOLOGY CRYO FOR THERAPEUTIC BRONCHOSCOPY WITH APC & ELECTROSURGICAL UNIT WITH ENDO CUT – COMPLETE CRYO SURGICAL WORKSTATION

- The unit must be suitable to perform endobronchial and transbronchial lung biopsies,recanalization,devitalization, foreign body removal, and blood clots extractions.
- The unit should havea modern cryo surgical unit with advanced features.
- The unit should have compatible with CO2 gas.
- The unit should havebeen supplied with one Flexible CRYO plug-and-playprobe.
- The unit should haveself-identify the instrument and set the parameters accordingly.
- The unit should have 02different effect settings with which we can create two different freezing effects for different Pulmonology/ Bronchoscope applications like CRYO Biopsy, CRYO Re-canalizations, and Tumor Debulking, Devitalization, foreign body removal, and blood clots extractions.
- The unit should have the following facilities:
- Count down, count up timers with and without alarms
- Display the number of usages of CRYO probes
- Digital display of available gas pressure of the CO2 Cylinder
- Washable Foot switches
- Reusable Cryo Probes (autoclavable up to 100 times)
- Customizable programs up to 9
- Plug& Play
- Updatable
- he offered Cryo System should be program-based, monochrome display, activation via footswitch and the minimum freezing temperature should reach within 5 seconds.
- The unit should be mounted on a mobile cart &CO_2 Cylinder (02Unit) compatible with CO_2 gas as coolant provided with a connection pipe for gas exhaust.
- The offered Cryo System should be flow controlled for operating gas pressure between 45 – 65 bars.
- The unit should have a feature to count the reprocessing cycle of the instrument.

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- The Offered System should have Effect Settings up to 2 depending on the type of instruments used with a programmable memory of up to 9 settings.
- The offered System should work on a Frequency of 50/60Hz with a line current of 0.4-0.8 Amp.
- The offered System should of dimensions of 410x130x370mm & weight of <8 kg.
- The offered Cryo System should be supplied along with various sizes of flexible Probes– reusable as well as disposable(Reusable should be recommended forlow-temperature sterilization system).
- The system should be able to connect in the future with an integrated 400 wattages RF Electro Surgical Unit, US-FDA & European Certificate marked in accordance with the medical devices directive (93/42/EEC) 4 Digit Notified, EN 60601 - 1 type CF & Class I Equipment and Electromagnetic Compatibility Certificate & ISO Certificate for electrosurgical Cut &Coag modes for the optimum effect of HF surgery & Argon plasma coagulation unit for hemostasis of bleeding tissues & devitalization of pathological tissues with non-contact technology for coagulation.
- The system should incorporate ENDO CUT mode for Therapeutic bronchoscopy that has the facility to Pre-Set the CUT Interval, CUT Duration, and amount of Coagulation between the cutting cycles.
- The ENDO CUT Mode should work on an automatic power dosage principal wherein there should be no need to Pre-Set any wattage and the system automatically and continuously adjusts the power output based on the tissue impedance and pre-set Cut Interval and Cut Duration so that only as much power is delivered as is necessary for optimal results with least thermal spread and the highest degree of safety.

- Endo cut mode I and Q - for specific bronchoscopic procedures

a. should have alternating cutting and coagulation phases
b. Maximum HF peak voltage should be 800 Volts
c. Should have at least 4 fixed pre-set reproducible hemostatic effect
d. Should have fractioned cutting with cut interval selectable in 10 steps
e. Should have cut duration selectable in 4 steps

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- Should have three different APC modes suitable for different indications

a. Precise APC – adjustment made using the effect settings

b. Pulsed APC – adjustment made using the parameter power settings

c. Forced APC – adjustment made using the parameter power settings

- Argon Plasma Coagulation System should be supplied with one APC Socket Outputs – for Filter Integrated APC Probes
- Settings for Argon Plasma Coagulation System should be controlled from the Electrosurgery System for precision APC Output.
- Argon Plasma Coagulation System should have three modes of Argon Plasma Coagulation output Forced Argon Beam Coagulation, Pulsed Argon Beam Coagulation, and Precise Argon Beam Coagulation
- APC should have adjustable Argon flow rates and Automatic monitoring of argon supply
- APC should have a facility for both manual and automatic flushing of Argon gas on the Startup of the Machine.
- Should be supplied with 02 Argon gas cylinder and Pressure reducer compatible to APC System
- Should be supplied with 1.5mm diameter flexible FiAPC probes
- The Unit should be supplied along with essential accessories from the same original equipment manufacturer, an affidavit for the same has to be submitted by the bidder, else bid will be rejected.

A) Cryo 2 Footswitch - 1 No

B) Cart which can carry cylinder – each 1 Nos

C) Gas hose to conduct gas from cylinder to unit – 1 No

D) Cryo reusable flexible probe Ø1.9mm; L 900mm - each 1 Nos

E) Cryo reusable flexible probe Ø1.9mm; L 1150mm - each 1 Nos

F) Cryo reusable flexible probe Ø2.4 mm; L 900 mm – each 1 Nos

G) Gas bottle adapter E – 1 Nos

H) Electrosurgical Unit 400 wattages, USFDA & EUCE 4 digit – 1 Nos

I) Monopolar / Two Pedal Footswitch with Remote Function – 1 No

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J) Reusable Neutral/Patient Plate of conductive silicon along with a perforated strap and fastening stud – 1 No.

K) Monopolar Cable compatible with GI Accessories – 2 Nos

L) Modular Argon Plasma Coagulator Unit with one socket Module – 1 Nos

M) Argon Gas Cylinder with Tap – 02 Nos

N) Pressure Reducer – 1 Nos

O) Filter Integrated APC Probe ø 1.5 mm, length 1.5m, Straight Firing – 1 Nos

P) Units and all the accessories should be supplied of the same make/brand

Conditions for tender:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and European CE be approved by 4 digits notified body.
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Office Memorandum dated 21, June 2022 Order No. F.4/1/2022-PPD (Pt.) dated 15.05.2020 & 28.05.2020 regarding Global Tender Enquiry Dated 21.06.2022, The revision of (a.) *Public Procurement Order No P-45021/2/2017-B-E-II Dated 15.06.2017* as amended by (b.) Order No *P-45021/2/2017 – B-E-II Dated 28.05.2018* and (c.) *order No.P-45021/2/2017-BE-II dated 29.05.2019*, herby retrained leading medical institutions for freely access the specialized medical device technology due to its unavailability with Indian manufacturers, used for the purpose of clinical research in specialized surgical procedures and their outcomes, along with treatment of patient disease. List of 371 Medical Devices / Equipment exempted from the instruction of Department of Expenditure (DOE) issued vide Oms No. F.12/17/2019-PPD dated 15.05.2020 & 28.05.2020 regarding Global Tender Enquiry.
6. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the

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mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.

7. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
8. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
9. Offered Equipment should have a strong Government Installation base.
10. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
11. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
12. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
13. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
14. Company should quote their latest model and need to provide an affidavit for the same.
15. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
16. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
17. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.

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18. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
19. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).
20. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6^{th}, 7^{th}, 8^{th}, 9^{th} and 10^{th} years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6^{th} to 10^{th} year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.

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