## SPECIFICATION FOR DUAL ACTION LITHOTRIPSY (ULTRASONIC AND MECHANICAL)

The Dual Action Lithotripsy System must have the followings:

- 1. Should have a single generator for both ultrasonic and low-frequency mechanical energy integrated into the same machine.
- 2. The system should be able to deliver these energies by the same probes and handpieces.
- 3. The system should have a Surgeon Controlled/Hand Activation Transducer & Suction.
- 4. The system should be equipped with Surgeon Control and have a probe of 3.76 mm probe size providing the largest inner lumen for stone fragments evacuation
- 5. The unit should be supplied with the following probes: 3.4 MM-1 No, 3.76mm-2No's, 1.83mm-1nos, 1.50 mm-2No's.9 mm-1 no.
- 6. The system should simultaneously produce (at the probe tip)- Constant Ultrasonic Wave energy & Intermittent Shockwave (ballistic/mechanical) Energy-high-rate of occurrence-300 x per second/300 Hz Delivered via a Revolutionary Single Probe with a Large Inner Lumen.
- 7. The system must Fragment and aspirate all stone sizes, shapes and compositions at a faster speed with a significant reduction in procedure time to benefit the patients, physician and hospital.
- 8. The system must be Compatible with standard Steam Autoclaving, Sterrad and Sterrad NX cycles
- 9. The System must be used for fragmentation of urinary tract calculi in the kidney, ureter and bladder.
- 10. The system should have integration of both ultrasonic +high frequency bursts of mechanical wave energies, delivered simultaneously from a single probe with shock pulse technology and suction control.
- 11. The system should effectively fragment and pulverizes stones of various shape, size and composition.
- 12. The system must have increased speed and performance while generating a lower pitched noise level (less irritating to users).
- 13. The system should be of Auto tunning quipped- a true "plug & play system".

Prof. Avinash Agrawal Head, Departy

- 14. The systems should have a user-friendly Torque wrench design-reduces the force required to assemble the probe onto the transducer.
- 15. The system should have a single Handpiece design.
- 16. The system should also have activation which eliminates the need for the footswitch.
- 17. The system should have Ergonomic Placements of Buttons that allows for physician control for all procedures (PCNL,mPCNL, URS, Bladder).
- 18. The system should have a transducer with Surgeon Controlled Suction and Integrated Hand Activation.
- 19. Generator Specifications. The voltage of 90-264 VAC. Frequency of 50/60 Hz.

## 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/ or 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. 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 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.
- 6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.

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- 7. 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.
- 8. Offered Equipment should have a strong Government Installation base.
- 9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
- 10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
- 11. 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.
- 12. 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.
- 13. Company should quote their latest model and need to provide an affidavit for the same.
- 14. 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.
- 15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India-2017.
- 16. 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.
- 17. 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.

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- 18. 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).
- 19. 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<sup>th</sup>, 7<sup>th</sup>, 8<sup>th</sup>, 9<sup>th</sup> and 10<sup>th</sup> 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<sup>th</sup> to 10<sup>th</sup> 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.

Prof. Aymash Agrawal

Mo. Dec., IFCCM, FICCM, FIACCM, FCCP (USA)

Head, Department of Critical care,

King George's Medical University, UP, Lk

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