



Notice Inviting e-Tender

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Supply and Commissioning of Bone Splitting & Bone Decompression system for BIN -Annex
of IPGME&R-SSKM Hospital
(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-317/2023

Dated-19.06.2023

Amendment-III

Revised Technical Specification

Specification for Bone Splitting, & bone decompression system using ultrasonic energy in neurosurgery

SYSTEM ; The system is intended to for use in surgical procedures, for bone cutting & bone ablation in neurosurgery, the system should be capable of fragmentation emulsification and aspiration of soft and hard tissue, if desirable, in neurosurgery. The system should work on piezoelectric **/magnetorestrictive** technology.

HAND PIECE;

1. The angled hand piece, with frequency of **23-36** KHz, when used with appropriate ultrasonic tip is intended for use for bone cutting & bone ablation in neurosurgery. The system should also be capable of fragmentation, emulsification, and aspiration of soft and hard tissue, if, desirable, in neurosurgery.
2. The universal handpiece should be light weight, sterilizable with flash autoclave, plasma sterilization or ETO.
3. Hand piece should have integrated **inside -out** irrigation.

4. Tips / Blades of hand piece must be changeable in the sterile field & should be capable of being used for longer time. The material of the tips should be Titanium. The mass of any hand piece should not exceed 120 gms, length of 5-6 inch.
5. The system should be provided with frequency of 23-25 KHz Universal Angled Hand Piece with attached cord length of 4 meters or more – 2 Nos

OR

The system should be provided with frequency of 23-25 KHz Universal Angled Hand Piece with attached cord length of 4 meters or more – 1 No & Universal Angled hand piece with frequency of 34-36 KHz with attached cord length of 4 meters or more – 1 No

The system should be provided with common ultrasonic titanium tips to be used by both the hand piece ;

- a. Two side Serrated knife tip, length 11 to 11.2 ± 2 cm, cutting length 12.3 to 12.5 ± 2 mm, cutting width 0.7 to 0.9 ± 2 mm – 5nos.
- b. 360 –degree serrated tip, that will help in fine bone drilling, length 9.9 to 10 ± 2 cm, cutting length 2.5 to 2.7 ± 2 mm, cutting width of 3 to 3.12 ± 2 mm – 5 nos.
- c. Micro claw open angle tip, that will help for bone ablation, length 10 to 10.2 ± 2 cm cutting length of 1 to 1.2 ± 2 mm, cutting width of 2 to 2.2 ± 2 mm – 5 nos.
- d. Straight Micro diameter tip, that will help in excising tumor at finer angles, length 12.2 to 12.4 ± 2 cm. Outer diameter 1.76 to 1.78 ± 2 mm , inner diameter 1.36 to 1.38 ± 2 mm – 5 nos.
- e. Straight large diameter tip, length 11.6 to 11.8 ± 2 cm. Outer diameter 2.46 to 2.48 ± 2 mm , inner diameter 1.91 to 1.93 ± 2 mm – 5 nos.
- f. Straight Superlong tip, for better access to deep seated structures, length 19 to 20 cm, outer diameter 1.91 to 1.93 ± 2 mm, inner diameter 1.49 to 1.51 ± 2 mm – 5 nos.
- g. Large diameter “v” shaped tip, for hand tissue, length 11.6 to 11.8 ± 2 cm, outer diameter 2.45 to 2.47 ± 2 mm, inner diameter 1.99 to 2.01 ± 2 mm – 5 nos.

MAIN CONSOLE :

- a. The console should allow operation using Push Button & should provide visual parameters 7 status annunciators.
- b. Should display the suction level as a percentage to indicate the suction at the tip of the handpiece. The same can be controlled by the increase & decrease button.
- c. Should display ultrasonic vibration level value as a percentage to indicate the motion at the tip of the handpiece. The same can be controlled by the increase & decrease button.
- d. Should display the rate of irrigation flow delivered to the tip of the handpiece in millimetres per minute.
- e. The system should be equipped with suction/ irrigation buttons between standard & synchronized mode.

- f. The system should be equipped with annunciators like irrigation, annunciator, ultrasonic power annunciator, overload annunciator & frequency annunciator.
- g. **IRRIGATION & STERILIZATION**; the system should have facility for outside in irrigation in the hand pieces. The hand piece and its cables should be autoclavable. The system should have roller pump irrigation range of 3 to 40 ml/min.

FOOTSWITCH: Universal single pas footswitch provided should control the US power, suction & irrigation. The cord length should be 11-12 feet.

SAFETY ALARMS: the system should be with different alarms to indicate malfunction, overload etc.

ASPIRATION: the system should have Aspiration / Vacuum range of 0 to 0.6 bar.

Output Power: Continuous operation (when activated) upto – 100 watt, Power Source – 230 AC +/-10% / 50 Hz. +/-5%

Suction type: Diaphargm pump with Pressure – 0-500 mm of Hg.

Irrigation Type : Roller pump with flow rate of 3 to 4 ml per minute.

TROLLEY : Trolley for the machine is to be provided from the same manufacturer .

Safety Certifications: UL 60601-1, IEC 60601-1-2, CSA No: 601.1-M90.

The system should be supplied with the following accessories:

1. Universal Step Torque Wrench 7 mm – 1 no, universal sterilization tray 7 mm – 1 no, Disposable canister – 24 nos., Disposable tubing set – 20nos.

ADDITIONAL REQUIREMENTS

Service & Support:

Details of fully equipped Service center in West Bengal of the manufacturer or its 100% subsidy in India should be declared by the original manufacturer or its 100% subsidy in India.

OEM Warranty certificates must be submitted by Successful Bidder at the time of delivery of Goods.

Dedicated /toll Free Telephone No. for Service Support: BIDDER/OEM must have Dedicated/toll Free Telephone No. for Service Support.

The system should be USFDA / CE / BIS approved to achieve highest standard of quality.