CARDIO THORACIC & NEURO SCIENCES CENTRE ALL INDIA INSTITUTE OF MEDICAL SCIENCES

Dated: 03.03.2016

Subject: Purchase of Minimally Invasive Bipolar Bayonetted Self Irrigation System-Aquamantys from M/s Brainwave an authorized distributor of M/s Medtronic on proprietary basis for the department of Neurosurgery.

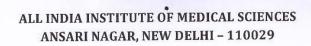
Store section is in the receipt of PAC, Specifications, Price reasonable certificate & authorization of Minimally Invasive Bipolar Bayonetted Self Irrigation System-Aquamantys from the department of Neurosurgery, with the request to purchase Minimally Invasive Bipolar Bayonetted Self Irrigation System-Aquamantys on proprietary basis from M/s Brainwave. The competent authority recommended to purchase Minimally Invasive Bipolar Bayonetted Self Irrigation System-Aquamantys as proprietary item of M/s Medtronic. The PAC submitted by the department of Neurosurgery & Proprietary certificate provided by the firm are attached & uploaded on website.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/items within 15 days from the date of issue/uploading of the notification. The comments should be sent to Asstt. Stores Officer, C.N. Centre at AIIMS on or before 18.03.2016 up to 4:30 P.M., failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on meritar

(Asstt. Stores Officer)

Encl: Related documents enclosed.

- 1. PAC Certificated enclosed.
- 2. Specifications
- 3. Price reasonable certificate
- 4. Authorization



PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE

- 1. Items/type/model No. Required along with Maintenance specification –

 MINIMALLY INVASIVE BIPOLAR BAYONETTED SELF IRRIGATION SYSTEMAQUAMANTYS
- 2. Is the item a spare part attachment Or accessory for an existing equipment- An accessory
- 3. Name of the manufactures/supplier Of the item proposed by the indenter- M/S MEDTRONIC
- 4. Are they sole manufactures/Sole distributors of the items- Yes
- 5. Is there any other item with similar/equivalent Specification available in the market to meet. The job requirement envisaged. If the answer is yes, Why the same can't be procured. Demanding officer should bring out comparative. Functional advantages/cost effectiveness of the: Yes, but the item will not be compatible with the existing microscope as told by the vendor (certificate enclosed)
- 6. What were the efforts made to locate alternative. Source of supply or use other substitutes: **Searched on internet, spoke to the vendor**
- 7. Why open/limited tender can't be resorted to, For locating alternative source- The item may be put on the AIIMS website as per AIIMS rules. If there is more than 1 bid, then an open tender may be resorted to. Please note that all items should be provided by a single vendor
- 8. Are the proprietary certify that the rates are. Reasonable or not: Certificate of reasonability may taken from the principle. Also previous purchase orders may be also looked into. The rules may be followed as suggested by AIIMS

9. Any other justification for procuring item for single - No

Officer In Change

Officer In-Charge CHANDRA Neurosurgery Store essor Countersigned ARMA

विज्ञा राज्य विकित्सा विभाग / pept. of Neurosurgery

L certify that the items at Sr. No. Above is required to be proqued on single tenden have.

are the source of supply is definitely know/the specified brand proposed was advantage in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose I this particular case. (Strike out whichever is not applicable)

डॉ० पी० एस० चन्द्रा DR. P. S. CHANDRA Professor

आचार्य | Professor

(Profon dany Henz)

Specifications for minimally invasive bipolar bayonetted self

irrigating system: Estimated cost: 25 lahs/unit;

Requirement: 2 Units

Total Cost: 50 lakhs

- 1. Should Operate in voltage of AC 230V, 20-200 watts
- Should have hemostatic mechanisms, which should reduce bleeding and reduce blood loss during and after surgery.
- 2. A combination radio-frequency energy and saline delivery controlled thermal energy to tissue must be performed in a manner that the combination allows the device temperature to stay at approximately 100°C nearly 200°C less than conventional devices, which produces a tissue hemostatic effect without the charring as associated with conventional methods.
- 3. Should be bipolar device for simultaneous delivery of radio-frequency (RF) energy with saline for hemostatic sealing of soft tissue and bone at the operative site.
- 4. Should have bayonetted construct with a handle to hold it comfortably and should be operable by a switch on the handle.
- 5. Should have Automatic settings for saline flow rate based on power setting.
- 6. Should have Ability to select 2-3 different flow rate settings saline irrigation.
- 7. Should have provision for Convenient priming mode with the priming flow rate of 25-36mL/min or less than 35-45 seconds.
- 8. Bipolar output waveform should be 370KHz
- The operating temperature of the device at the surgical site should be around 90-100 degrees Centigrade

10. Should deliver controlled thermal energy to tissue, to provide hemostatic sealing without the charring effect on tissue.

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- 11. Bipolar sealer should have RF power & saline flow activation button on the hand piece itself.
- 12. There should be option of Bipolar Sealer with an adjustable sheath at the distal portion of the shaft.
- 13. Should have an option for One single hand piece which can manage both cut muscle and epidural bleeding to optimize speed and continuity of surgical cases
- 14. Options of different bipolar sets should be available i.e a 2-prong bi-polar, a single prong bi-polar.
- 15. Prices of all parts should be quoted separately and mentioned clearly
- 16. Costs of all accessories should mentioned clearly.
- 17. Cost of 15 hand pieces per equipment (i.e total 45 hand pieces) should be provided along with the equipment
- 18. Should be USFDA and/or CE Europe approved

19. OTHERS Terms & cardition Has

1	Warranty: 5 years onsite comprehensive including spares + 5 years AMC
2	The cost of all spares should be quoted upfront and should be valid for 10 years
3	In no case the instrument should remain in non-working conditionfor more than 7 days, beyond
4	The vendor should have a good service and application back up along with instruments to provide an effective trouble shooting and support (response time < 24 hours)
5	All technical bids comparative statement to the tender specifications must be enclosed along with
6	If the company quotes false information regarding technical specifications, the committee will then have the right to reject this company and also black list the company.
7	Undertaking from the specification committee stating that the specifications are broad based, general in respect to the requirement of instrument and not made to suit any particular firm or broad
8	The cost of all consumable, spare parts and accessories should be provided upfront and should be valid for 5 years.
9	Warranty: 5 years onsite comprehensive including spares + 5 years AMC

Prof BS Sharma

Prof SS Kale

Prof P Sarat Chandra (Stores in charge)

Prof Manmohan singh

Profo Ashish Suri

Prof Rajender Kumar

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India Medironic Pvt. Ltm. CIN: U33110MH 1937 1241, Solifaire Corporate Paris Andheri-Ghafkapar Link Road Andheri (East)

Mumbai - 400 093, India Tele.: 91-22-33074701 Fax: 91-22-33074704

21 December 2015

To The Director All India Institute of Medical Sciences Ansari Nagar New Delhi-110 029

Dear Sir.

This is to declare that Medtronic "Aquamantys System", consisting of the Aquamantys pump generator (the "Generator") and the Aquamantys bipolar sealers (the "Disposables"), features Medtronic Advanced Energy LLC's ("MAE") proprietary Transcollation technology. This technology integrates RF energy and saline in a controlled relationship that permits hemostatic sealing and coagulation of soft tissue planes and bone. Transcollation technology allows tissue planes to be treated with a "painting" motion in addition to traditional spot sealing. The one (1) to two (2) millimeter depth of effect assures hemostatic sealing without the resultant charring typically associated with electro surgery.

Aquamantys products and Transcollation technology is the subject of numerous U.S. patent applications and/or patents. The Generator is covered by the following U.S. patents: U.S. Patent Nos. 6,702,810; 7,811,282; 7,815,634; and additional pending patent applications. The Aquamantys pump generator is not compatible with any bipolar sealers other than MAE's Aquamantys Disposables. The Disposables are covered by one or more of the following U.S. patents: U.S. Patent Nos. 7,645,277; 7,651,494, and additional pending patent applications. MAE's Aquamantys Disposables are not compatible with any generator other than MAE's

As such, at this time it is believed that patent protection provides for the exclusive availability and/or use of the Aquamantys System for surgical applications and treatments promoted by

In closing, please note that the patents identified herein should not be considered exhaustive as to all patents which may pertain to MAE's products and use thereof. Also, MAE's beliefs of patent protection should not be construed as legal advice, and you may wish to have such

for and on behalf of India Medtronic Pvt. Ltd

Kaustav Das

Regional Manager I Surgical Technologies

Cell: +91-9971133599



Medtronic Advanced Energy, LLC 180 International Drive Portsmouth, NH 03801 www.medtronic.com/advancedence

December 20, 2012

I hereby affirm, to the best of my knowledge that Medtronic Advanced Energy LLC holds proprietary rights in radiofrequency with saline (Transcollation Technology) surgical technology on the basis of the following patents which Medtronic Advanced Energy either owns or has exclusively licensed the patents from the owners. The patents cover Medtronic Advanced Energy Aquamantys product portfolio.

6,558,385 7,445,617 7,537,595 7,604,635 7,645,277 7,651,494 7,727,232 7,811,282 7,909,820

Best Regards,

Janet Kwiatkowski Regulatory Affairs Manager Medtronic Advanced Energy



15 September, 2014.

India Medtronic Pvt. Ltd. 1241, Solitaire Corporate Park Andheri-Ghatkopar Link Road, Andheri (East) Mumbai – 400 093, India.

Tele.: 91-22-33074701 Fax: 91-22-33074704

TO WHOM IT MAY CONCERN

We India Medtronic Private Limited situated at 1241, Solitaire Corporate Park, Building No.12, 4th Floor Andheri-Ghatkopar Link Road, Andheri (East) Mumbai – 400 093, India who are a fully owned subsidiary of Medtronic Inc., 7000 Central Avenue NE, Minneapolis MN 55432, USA hereby declare that M/s Brainwave Medical Technologies Pvt. Ltd. having office at Office No.4, 1^{5t} Floor, CSC, B. Block, Yojana Vihar, New Delhi - 110092 are, at the date hereof, and until 29 April, 2016 authorized Distributors of India Medtronic Private Limited for the resale of following products in northern part of India and as stipulated in the Distributor Agreement.

Medtronic Neuro-Technology

- Midas Rex Craneotome High Speed Drill systems, accessories and consumables
- P.S. Medical Neurosurgery Products
- Medtronic Advanced Energy Products

Medtronic ENT

Medtronic Xomed ENT products – Equipments and consumables

Medtronic Navigation

 Medtronic Image Guided Navigation System, Accessories and Consumables,

Medtronic Neuromodulation

Medtronic Core Neuro Products,

As a company policy, all our agreements with independent distributors are renewed every two years. Further, we wish to confirm to you that in case the distributor agreement with M/s. Brainwave Medical Technologies Pvt. Ltd. is not extended for any reason whatsoever, India Medtronic Pvt. Ltd undertakes to meet the servicing, importing, honoring guarantee / warranty and product quality related legal obligations incumbent on reputable suppliers with respect to supplies made.

We further certify the technical adequacy and expertise of the above products offered by us to M/s. Brainwave Medical Technologies Pvt. Ltd. and we will provide them with back up support for supplies, spare parts and technical updates.

For India Medtronic Private Limited

Yours faithfully, For India Medtronic Pvt. Ltd

> Abhijeet Patwari 2014.09.15 17:08:42 +05'30'

Abhijeet Patwari Director – Surgical Technologies & Neuromodulation South Asia

Brainwave Medical Technologies Pvt. Ltd

Office No. 04, 1st Floor ,C.S.C. B.Block, Yojana Vihar Delhi-110092, Ph.+911122164460, Fax:- 22164463 Email:- brainwavemt@gmail.com

Brainwave

Date: 12.02.2016

PRICE REASONABILITY CERTIFICATE

This is to certify that we have offered the maximum possible price to you in our Performa Invoice No. BMTPL/NT/201516/15-16 dated 12.02.2016 for Rs. 2,178,960.00

We would like to certify that the quoted price are the reasonable and we have not sold the same configuration of the system to any other customer lesser than the price offered to All India Institute of Medical Sciences, Delhi in this Financial Year.

For and on Behalf of Brainwave medical Technologies Pvt. Ltd

Authorized Signato