DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
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Ref. No. RMLIMS/MM(eq)/2019-20/ 5900 Date:- 19 02.2020

Notice for inviting comments/objections for purchase of Harmonic Ultrasonic Energy Device (GEN 11) and Coblator on Proprietary Basis

The Institute is in process of purchase of **Harmonic Ultrasonic Energy Device (GEN 11)** on proprietary basis submitted by the firm and user department in favour of **M/s Ethicon Endo-Surgery, LLC part of the Johnson & Johnson family of companies, USA**, wherein it has been certified and confirmed that **Harmonic Ultrasonic Energy Device (GEN 11)** is proprietary product of **M/s Ethicon Endo-Surgery, LLC part of the Johnson & Johnson family of companies, 475 Calle C, Guaynabo, Puerto Rico 00969, USA** and **Coblator** on proprietary basis submitted by the firm and user department in favour of **M/s Smith & Nephew, Inc.** wherein it has been certified and confirmed that **Coblator** is proprietary product of **M/s Smith & Nephew, Inc., 7000 W William Cannon Dr Building One Austin, TX 78735, USA**.

The above documents with specifications will be uploaded on e-tender portal i.e. **www.etender.up.nic.in** from 20.02.2020 for open information to submit online objections, comments, if any from any manufacturer regarding proprietary nature of **Harmonic Ultrasonic Energy Device (GEN 11) and Coblator** within 28.02.2020, failing which it will be presumed that any other vendor is having no comments, objections for above purchase on proprietary basis and case will be decided on merits.

The above details will also be available on our website ***www.drrmlims.ac.in*** for reference only. The objections/comments will be accepted On-Line only through above e-tender portal within above stipulated period.

Director

FORM P-3

DR. RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES,
VIBHOOTI KHAND, GOMTI NAGAR, LUCKNOW

PROPRIETARY ARTICLE CERTIFICATE

ITEM – Cobalator

It is certified that the items required should be purchased from BVM MEDITECH (P) LTD

who are the sole ~~manufacture~~ / agent ✓ of the sole manufactures M/S Smith & Nephew Healthcare Pvt. Ltd.

Similar items manufactured by other firm (s) shall not be suitable for our purpose for the following reasons :-

1. It is patented technology – Proprietary article.

Signature of indenter

Requisition No.:
Department :
Dated :

Designation & Signatures
of Head of Departments

डॉ० डी० के० सिंह
प्रोफेसर एवं विभागाध्यक्ष
न्यूरो सर्जरी विभाग
डॉ० रा०म०लो० आयुर्विज्ञान संस्थान
ओ०पी०डी०–सोमवार / शुक्रवार

N. B. :- The indenter before recording the above certificate should satisfy himself that the article is genuinely of Proprietary nature manufactured under patent laws.

Smith & Nephew, Inc.
7000 W William Cannon Dr
Building One
Austin, TX 78735
USA

1-512-391-3900
www.smith-nephew.com

We are smith&nephew

Tuesday, 28 May 2019

PROPRIETARY CERTIFICATE
TO WHOMSOEVER IT MAY CONCERN

Coblation Technology is used in the ArthroCare's ENT Coblator-II Surgical System (Model No. EC8000-01). The Coblator-II Surgical System is a Bipolar, Radiofrequency Electrosurgical system which is used to perform tissue ablation, tissue coagulation and Hemostasis via Controlled, Precise Plasma layer formation in ENT surgery.

Coblation is a registered Trademark of ArthroCare Corporation (U.S.A.) and as such the exclusive property of ArthroCare Corporation. ArthroCare is the only company which manufacturers Coblation Devices. A similar article is not manufactured or sold by any other firm which could be used in lieu.

The ArthroCare ENT Coblator-II Surgical System is covered by US Patents and is sold under EC8000-01 (120V version) and EC8001-01 (240V version)

Coblator-II Surgical System is a USFDA Approved Product with 510K Certificate No_K070374.

Coblator-II Surgical System has a range of wands which are device specific and are designed for a specific need of the surgical procedure. No other make or model provider is acceptable for the following reason:

a) Proven Quality
b) Proprietary Patents
c) Internationally recognized safety and efficacy

Catalog No	Indication	Description
EIC4835-01	Sinus Turbinate Reduction Paediatric	ReFlex Ultra PTR with Integrated Cable
EIC4845-01	Sinus Turbinate Reduction	ReFlex Ultra 45 with Integrated Cable
EIC4855-01	Sleep Surgeries without Irrigation	ReFlex Ultra 55 with Integrated Cable
EIC4857-01	Sleep Surgeries with Irrigation	ReFlex Ultra SP with Integrated Cable
EIC5874-01	Tonsillectomy Extra capsular	EVac 70 Xtra HP with Integrated Cable
EIC9820-01	Tonsillectomy Extra capsular	Excise PDW with Integrated Cable
EIC6895-01	Sinus Routine Work	Turbinator Wand
EIC7070-01	Routine Laryngeal Work	PROcise LW Wand with Integrated Cable
EIC7071-01	Paediatric Laryngeal Work	PROcise MLW with Integrated Cable
EIC8898-01	Adenoidectomy	PROcise max with Integrated Cable
EIC8875-01	Sinus Turbinate Reduction with Suction Irrigation	PROcise EZ View

For Further information to undersigned can be contracted

Kulsum Master
Kulsum Master
Director, Regulatory Affairs
Smith & Nephew

(Dr. Deepak Kr. Singh)
Prof. Jr. Grade & HOD
Deptt of Neurosurgery
Dr RML's MS. UKO

Technical Specification of Coblator with accessories

- Coblation System capable of performing tissue ablation, tissue coagulation and hemostasis via Controlled, Precise Plasma Layer.
- Should not have any need for the secondary patient grounding pad.
- The Coblation Wand should have Multi Electrode Technology that will allow a uniform production of **plasma.**
- The Coblation settings should be controlled by regulation on the generator from setting 1-9
- The Coagulation settings should be controlled by regulation on the generator
- The Coblation Surgery System should be digital which also covers the Coblation & Coagulation regulation.
- The Coblation Surgery System should have facility to use a foot control or a wireless footswitch for convenience and ease of use.
- The footswitch should have the facility to control the Ablation settings from sterile (Surgeon's) field only.
- There should be facility of separate switches at the foot control for coblation and coagulation.
- Coblation regulation from the foot control switch is essential.
- The Coblation Surgery System should be able to take 11 or more different types of wands for open and minimally invasive ENT procedures
- There must be wands which are sufficient enough for Ablation, Coagulation, and Hemostasis together with Suction & Irrigation.
- There must be provision for sub-mucosal tissue ablation and shrinkage.
- Provision & reach for laryngeal, head & neck surgeries must be there.
- It should operate at 100-300V and 100-500kHz
- There should be a saline irrigation controller with manual and auto-mode.
- Auto-mode should allow the irrigation to act when the wand is activated.
- There shouldn't be any separate power requirements for the Saline Flow Controller rather, it should derive power and run in synchronization with Coblation Surgery System Plasma Generator.
- The Flow controller should have dual operational mode, i.e. Auto & Manual Mode and should self-calibrate before operation.

- <u>It should be US FDA & CE Approved</u>
- Satisfactory Performance report from minimum 10 Govt. Institutes.
- The Service Center of the Company to be located in India.

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Coblation WANDS

- The wand/s should be based and designed for Coblation Surgery System technology for Nuro ENT Head & Neck applications.
- ENT application wand/s should have capability of producing **plasma** in presence of saline medium.
- The wand/s should be available in multi electrode technology for the even formation of plasma for volumetric tissue removal.
- There must be dedicated wand each for tonsil, adenoid, sinus surgery, larynx, turbinate, soft palate, Head & Neck, etc. applications.
- The wand should be recognized by the Coblation Surgery System and as a precaution and safety measure must automatically shift to the desired settings of Coblation and coagulation.
- Depending upon the various applications there should be options of suction and non-suction wands with-in roughly 13 different types of wands for ENT Head & Neck, etc. applications.
- Depending upon the various applications there should be options of irrigation and non-irrigation wands with-in roughly 11 different types of wands for ENT Head & Neck etc. applications.
- There must be wand which is capable of sub-mucosal tissue ablation together with irrigation, suction, coagulation with good hemostasis.
- The wands should be capable of providing Coblation, coagulation, irrigation and suction functionalities with good hemostasis.
- There should be wands capable of both volumetric tissue removal as well as tissue shrinkage
- There must be dedicated wands for laryngeal applications with a long length ranging from at-least 16.50CM to 19.00CM to maintain access & surgical precision through laryngoscope.
- The laryngeal wands must be available for Bulk Tissue Removal as well as precise cutting and dissection of the laryngeal legions.
- Dedicated Head & Neck Dissection wand is must for surgeries of thyroid, parotid etc.

- It should be US FDA & CE Approved
- Satisfactory Performance report from minimum 10 Govt. Institutes.
- The Service Center of the Company to be located in India.

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Endoscopy Neuro Skull base access wands
Triple–wire active electrode configuration removes tissue for both tonsillectomy and adenoidectomy • Integrated saline and suction ports allow for quick and easy operating room setup • 6 inch, malleable shaft allows improved access to the during adenoidectomy
• Enhanced flat electrode configuration for fast tissue ablation, suction and bendable shaft • Unique saline delivery system ensures sufficient saline delivery to the tip of electrode regardless of Wand orientation
• Active electrode coupled with saline delivery produces plasma field within turbinate , 2.9mm diameter shaft with angled tip allows insertion into hypertrophic turbinates • Depth markers indicate depth of Wand within turbinate ,Longitudinal line allows for easy recognition of Wand orientation • Shorter, smaller diameter provides easy access and reduces visual obstruction in smaller anatomy • With a slightly longer shaft length and integrated markers ,wand is suited for the reduction of larger turbinates • Treat both anterior and posterior portion of turbinate. Tip diameter 1.3 mm & 1.7 mm, length of electrode 10.5mm & 10.0mm, • Distance from tip to bend 42.6mm & 56.1mm
The Wand small diameter device. Integrated ablation, suction, and bipolar hemostasis designed to enhance precision and visibility during sinus surgery.
• Electrode configuration to enhance COBLATION-CHANNELING◊ for immediate tissue removal combined with thermal lesion creation ,55 degree bend in Wand shaft follows the curvature of the soft palate • Retractable saline delivery sheath eliminates need for saline gel typically used with other Wands, Electrode configuration to enhance COBLATION-CHANNELING for immediate tissue removal combined with thermal lesion creation.

Signature of Committee members:-

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