Admn//Prop/10/2017-AIIMS.JDH Dated: 14th July, 2017

Subject: Purchase of Coblation System for the department of ENT at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Coblation System for the department of Nephrology at AIIMS, Jodhpur from M/s Smit & Nephew Inc., 7000 W Willam Cannon Dr Building One Austin, TX 78735, USA on proprietary basis. The proposal submitted by M/s Smit & Nephew Inc, USA and PAC certification by user are attached.

The above document are being uploaded for open information to submit subjection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/10/2017-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 14th August 2017 upto 03:00 PM failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

Administrative Officer

Enclosed: Related documents enclosed.

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

Proprietary Certificate

To Whomsoever It May Concern

Coblation® Technology is used in the ArthroCare's ENT Coblator-II System. The Coblator-II 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 manufactures 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 system is covered by US Patents.

Coblator–II is a USFDA Approved Product with 510K Certificate No_K070374.

Kulsum Master

Date: 08-Sept-2015

Kulsum Master
Sr. Mgr. Global Regulatory Services
Smith&Nephew

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The ArthroCare's SerpENT® Articulating Instruments – Thru cut Forceps and Grasping forceps (Part No's: 510-30110; 510-30210; 510-30120; 510-30220) have 240 degrees of articulation and have seven distinct locking positions for surgical ease in Maxillary and Sinus Surgeries

SerpENT® 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 manufactures such articulating instruments. A similar article is not manufactured or sold by any other firm which could be used in lieu.

SerpENT® is a USFDA Approved Product. It is a Class I product and is 510(k) exempt.

Kulsum Master

Date: 08-Sept-2015

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Proprietary Certificate

We, ArthroCare Corporation situated at 7000 West William Cannon Drive, Austin, Texas 78735-8531 USA, are exclusive manufacturer of Coblator II Device for ENT and Sports Medicine with patented plasma technology wands for various procedures.

Coblator II has a range of wands which are device specific and are designed for a specific need of the surgical procedure as listed below:

Catalog No.	Indication	Wands
EIC9820-01	Tonsillectomy Extra capsular	Excise PDW
EIC5874-01	Tonsillectomy Extra capsular	Evac 70 Xtra HP
EIC8898-01	Adenoids	Procise MAX
EIC7070-01	Routine Laryngeal Work	Procise LW
EIC7071-01	Pediatric Laryngeal Work	Procise MLW
EIC4855-01	Sleep Surgeries without Irrigation	Reflex Ultra 55
EIC4857-01	Sleep Surgeries with Irrigation	Reflex Ultra SP
EIC4845-01	Sinus Turbinate Reduction	Reflex Ultra 45
EIC4835-01	Sinus Turbinate Reduction Pediatric	Reflex Ultra PTR45
EIC8875-01	Sinus Turbinate Reduction with Suction Irrigation	Procise EZ View
EIC6895-01	Sinus Routine Work	Turbinator
EIC2000-01	Head & Neck	Head & Neck

For further information to undersigned can be contacted.

Sincerely,

Kulsum Master

Kulsum Master
Sr. Mgr. Global Regulatory Services
For and on behalf of ArthroCare Corporation

Coblation Surgery System

1. Coblation System capable of performing tissue ablation, tissue coagulation and hemostasis via Controlled, Precise Plasma Layer.
2. Should not have any need for the secondary patient grounding pad.
3. The Coblation Wand should have Multi Electrode Technology that will allow a uniform production of plasma.
4. The Coblation settings should be controlled by regulation on the generator from setting 1-9
5. The Coagulation settings should be controlled by regulation on the generator 1-5
6. The Coblation Surgery System should be digital which also covers the Coblation & Coagulation regulation.
7. The Coblation Surgery System should have facility to use a foot control or a wireless footswitch for convenience and ease of use.
8. There should be facility of separate switches at the foot control for coblation and coagulation.
9. Coblation regulation from the foot control switch is essential.
10. The Coblation Surgery System should be able to take 12 or more different types of wands for open and minimally invasive ENT procedures
11. Wands should be supplied along with the unit [Three sets of ALL the wands]
12. There must be wands which are sufficient enough for Ablation, Coagulation, and Hemostasis together with Suction & Irrigation.
13. The unit should be able to recognize the Coblation Wands and as a precaution and safety measure must automatically shift to the desired settings of Coblation and coagulation.
14. The Smart Chip Sensing system should have provision for Automatic upgrade depending upon any new wand.
15. There must be provision for sub-mucosal tissue ablation and shrinkage.
16. It should operate at 100-300V and 100-500kHz
17. There should be a saline irrigation controller with manual and auto-mode.
18. Auto-mode should allow the irrigation to act when the wand is activated.
19. 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.
20. The Unit should be US FDA & EUROPEAN CE Approved
21. The unit should have a minimum Installations base of 100 across Nation.
22. The Service Center of the Company to be located near Jodhpur
23. Price of individual wand should be quoted separately
24. Prior demo, if needed.