



Subject: Regarding Procurement of “Coblation System Make: “Smith & Nephew Arthrocare, Texas, USA” on Proprietary basis –Inviting comments thereon.

The request received from Department of ENT-HNS, AIIMS Bhopal for the procurement of **“Coblation System Make: “Smith & Nephew Arthrocare, Texas, USA”** on Proprietary basis of above captioned Items having its OEM as M/s Smith & Nephew Healthcare Pvt Ltd., Mumbai, through its India Dealer M/s Jaikrit Distributors, Indore, on Proprietary basis.

The Notice is being uploaded for general information of Aspirant Manufacturer/Dealer/ Distributor to submit their objections/proposal, if any, on proprietorship of these items.

In case, the product of any Manufacturer/Authorized distributor/dealer conforms to the enclosed specifications, they may submit their proposal for the supply same item along with the following:-

- (i) Details of the required product brochure;
- (ii) Point-by-point compliance of the enclosed specifications, along with all relevant documentary evidence.

The objection/ proposal should be sent in sealed cover to, The I/c Senior Procurement cum Stores Officer, 1st Floor, Service Building-II, AIIMS, Saket Nagar, Bhopal (462020) so as to reach on or before **27/03/2023 upto 17:00 Hrs.**, failing which it will be presumed that no any other vendor is interested to offer comments/protest and case will be decided accordingly on its merit.

The reference number: Stores/2022-23/ ENT-Coblation System/2184, Date:20/03/2023, due on: 27/03/2023 should be super scribed on sealed envelope.

Yours Faithfully,

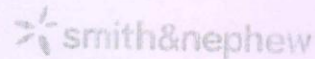
Sd/-

**I/c Senior Procurement cum Stores Officer
Central Stores,
AIIMS Bhopal**

Enclosure:

1. Proprietary Certificate – M/s Smith & Nephew Arthrocare, Texas, USA
2. Authorization Certificate – M/s Smith & Nephew Healthcare, Mumbai
3. Technical Specifications of the item
4. Schedule of Requirement

Proprietary Certificate – M/s Smith & Nephew Arthrocare, Texas, USA



25 May 2021

Proprietary Certificate

To Whom It May Concern;

Coblation Technology is used in the ArthroCare's ENT Coblator-II Surgical System (Model No. EC 8001-01). 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 such as 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 Surgical System is covered by US Patent.

Coblator II Surgical System- is a USFDA Approved Product with 510k Certificate No. K070374.

Coblator II 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 reasons:

- a) Proven Quality
- b) Proprietary Patents
- c) International 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
EIC 9820-01	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
EC8000-01		Coblator II Controller 110V

For further information, the undersigned can be contacted.

Melissa Ago

Melissa Ago
Senior Regulatory Affairs Specialist

7000 W. William Cannon Drive | Building One | Austin, Texas 78735 | phone 512.391.3900 | fax 512.391.3901 | www.arthrocare.com

Dr. Lital Mishra *Shree Lave* *Chaitanya* *Rish*

Authorization Certificate – M/s Smith & Nephew Arthrocare, Texas, USA

Smith & Nephew Healthcare Pvt. Ltd.

B-501-509, Dynasty Business Park,
Andheri-Kurla Road, Andheri (E),
Mumbai-400 059.

CIN - U 24239MH1994PTC080271

Tel: +91 22 4005 5090

Fax: +91 22 4005 5089

www.smith-nephew.com

SmithNephew

Date: 13.3.2023

To,
AIIMS Bhopal

Subject: Authorization Letter from Smith and Nephew Healthcare

Dear Sir/Madam,

On Behalf of Smith and Nephew Healthcare Pvt. Ltd. We hereby wish to inform you that **M/s. Jaikrit Distributors** having its registered office as described below is hereby authorized to deal on our behalf for the ENT range of products of Smith and Nephew in accordance with the terms of the Territory Sales Agreement executed by us and the distributor as on 31st March 2023 (TSA).

Name of the Distributor: M/S JAIKRIT DISTRIBUTORS

Address: Shop No / Plot no : 176, Scheme No. 114,
Part 2, Anand Niketan, Indore
Phone No: 9302118612
Email ID: jaikritdistributors@gmail.com

The Scope of dealing includes quoting rates, negotiating, accepting, and servicing orders on our behalf with hospitals as per the Territory defined in the TSA.

This authorization is valid unless and until it is revoked by Smith and Nephew in writing or up until March 31st, 2024, whichever is earlier. Should you have any further queries please contact Mr. Shah, Falgun (Area Sales Manager at +91- +91 9724331569 or Email Falgun.Shah@smith-nephew.com)

Thanking you and assuring you our best services all the times.

Yours' Sincerely
For Smith and Nephew Healthcare Pvt. Ltd

Bandhana



Ms. Bandhana Kachroo
Business Unit Manager South Asia - ENT

Technical Specifications of the item

4

Coblation specifications:

- Coblation system capable of performing tissue ablation, tissue shrinkage and haemostasis via controlled, precise plasma layer
- Should not have any need for the secondary patient grounding pad
- Coblation wand should have bi-polar multi-electrode technology that will allow a uniform production of plasma
- The plasma formed should be with the help of external saline delivery mechanism rather than relying on interstitial fluids to ensure consistent plasma formation
- Should be controlled by regulation on the generator from setting 1-9
- Should be digital settings which also covers the coblation and coagulation regulation
- Should have facility to use a foot control for convenience and ease of use
- Should be facility of separate switches at the foot control for coblation and coagulation
- Regulation of Coblation settings from the foot control pedal is essential
- Should have wands which have ablation, coagulation and hemostasis together with suction and irrigation
- Should be able to take 13 or more different types of wands for ENT procedures such as:
 - Tonsillectomy – should be compatible for dissection as well as volumetric reduction of tonsil tissue
 - Adenoidectomy – should be a separate wand than tonsil wand with large flat screen surface area and large suction port
 - Sinus surgery – should be a separate wand with thinner shaft diameter for nasal surgery
 - Laryngeal surgeries – should also have a separate wand with a fine single 2mm loop electrode on one side of the wand for fine dissection work and a second wand with a large flat screen electrode for bulk removal of tissue in the larynx. Wand lengths should be atleast 19.5cm and 16cm respectively for easy reach
 - Turbinate surgeries: two separate wands for turbinate shrinkage and submucosal turbinate resection. For submucosal turbinate resection wand the electrode should be opposite the saline delivery port to ensure smooth functioning in an enclosed area. It should also have suction and irrigation facilities.
 - UPPP and other OSA related surgeries – should have a wand with a needle like tip for cutting and channelling and also a saline delivery sheath to help plasma formation for easy cutting effect
- Should be able to recognise the coblation wands as a precaution and safety measure must automatically shift to the default settings of coblation and coagulation
- The smart chip sensing system should have provision for automatic upgrade depending upon any new wand
- Must be provision for sub-mucosal tissue ablation and shrinkage
- Should be with a saline irrigation controller with manual and auto-mode
- Auto-mode should allow the irrigation to flow when the footpedal is activated and stop the flow when footpedal is idle
- Shouldn't be any separate power requirements for the saline flow controller, it should derive power and run in synchronization with coblation surgery system plasma generator.
- Should be US FDA & CE approved.
- There should be a service centre in India for convenience

Y. Ad
Y. Ad (Hka) Mision)

Shale Kade

Shale Kade

Shale Kade

Schedule of Requirement:-

S.No	Particular's	Quantity	Manufacturer
1	Coblation System for ENT Surgery	01 Nos.	M/s Smith & Nephew Arthrocare, Texas, USA, through its Indian Dealer M/s Smith & Nephew Healthcare Pvt Ltd. through its Local Dealer M/s Jaikrit Distributors, Indore.

**** Note: Please don't quote the prices of the above schedule requirement**