

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-29.
STORES SECTION (DO)**

Ref. No. 27/Stores (DO)/Uro/PAC/2017-18/FSC

Dated 12.10.2017

Sub:- Purchase of Combined Single Generator for Ultrasonic Cutting & Coagulation Device with advanced Radio-Frequency energy for the department of Urology, (AIIMS), New Delhi-110 029, on proprietary basis Inviting comments thereon.

The Institute is in the process to purchase **Combined Single Generator for Ultrasonic Cutting & Coagulation Device with advanced Radio-Frequency energy** for the department of Urology, (AIIMS), New Delhi from **M/s. Ethicon Endo-Surgery (Part of M/s Johnson & Johnson), LLC, USA, through M/s. Oriental Surgical Works, New Delhi.** The PAC Certifications by M/s. Ethicon Endo-Surgery (Johnson & Johnson) as well as the user department are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 15 days giving reference No. **27/Stores (DO)/Uro/PAC/2017-18/FSC.** The comments should be received in office of Stores Officer (DO), Store Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before **27.10.2107** upto **12.30 p.m.**, failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,


STORES OFFICER (FSC)

Encl: Related documents enclosed.



Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, Puerto Rico 00969
USA

To Whom It May Concern:

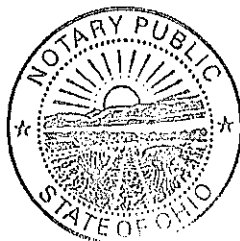
We, the undersigned, Ethicon Endo-Surgery, LLC, a Johnson & Johnson Company, a duly established and existing Company located at 475 Calle C, Guaynabo, Puerto Rico 00969, USA declare that Ethicon Endo-Surgery Generator G11, product code GEN11 is manufactured only for Ethicon Endo-Surgery, LLC and is covered by the following patent numbers:

Product Code	Product Description	Patent No	Country
GEN11	Ethicon Endo-Surgery Generator G11	8546996 6678621 D695407 D696631 6908472 8253303 8512365	UNITED STATES OF AMERICA

On Behalf of Ethicon Endo-Surgery, LLC


Brian Ruble
Group Manager, Regulatory Affairs

12/1/2011
Date



Mary Galeano
61 DEC 2014
MARY GALEANO
Notary Public, State of Ohio
My Commission Expires
October 19, 2018

Date - 03/05/2017

TO WHOMSOEVER IT MAY CONCERN

PROPRIETARY ARTICLE CERTIFICATE

This is to certify that the below mentioned items are our proprietary item manufactured by Ethicon Endo-Surgery, a Johnson & Johnson company.

1. **(GEN11):** Combined Generator for Harmonic & Enseal with a universal connector, touchscreen display with the option of software upgrades available via USB memory stick.
2. **(CRT11):** Cart for Combined Generator for Harmonic & Enseal GEN11.
3. **(FSW11):** Footswitch for Harmonic & Enseal for Combined Generator GEN11.
4. **(HGA11):** Harmonic connector & **(EGA11):** Enseal Connector for Combined Generator GEN11 for Harmonic & Enseal.
5. **(Product code:- HP054):** Transducer/hand piece for ultrasonically activated cutting and coagulating device, compatible with GEN11.
6. **(Product code:- HPBLUE):** Transducer/hand piece for ultrasonically activated cutting and coagulating device, compatible with GEN11.
7. **(Product code :- NSLG2C35A):** Hand Activated 5 mm diameter G2 tissue sealer Articulating curved jaw, 35 cm long with a 110 degrees articulating joint (55 degrees each direction) & 360 degrees rotation knob, capable of sealing blood vessels up to 7mm in diameter, articulation wheel to help lock in desired angle of approach, Ergonomic handle compatible with the combined Generator GEN11.
8. **(Product code :- NSLG2S25):** The Hand Activated G2 tissue sealer straight - 5.5 mm diameter, 25 cm long, capable of sealing blood vessels up to 7mm in diameter, Ergonomic handle compatible with Combined Generator GEN11.
9. **(Product code :- HAR9F):** Hand activated curved taper tip coagulating shear with adaptive tissue technology, 240 degree hand activation buttons, 9 cm length, 16.2 mm active cutting length capable of sealing blood vessels up to 5mm in diameter, with ergonomic symmetrical finger ring grip compatible with GEN11.

Plot No. 118 P, Sector 44, Gurgaon 122 002, India T: +91 124 4647000 F: +91 124 4647009
Registered Office : Johnson & Johnson Private Limited, L.B.S. Marg, Mulund (W), Mumbai 400 080.

T: +91-22-2564 4441 F: +91-22-2564 3410
Web: www.jnjindia.com CIN: U33110MH1957PTC010928

Total Number required: 01

A. Generator:-

1. System should be a single generator with Single footswitch that provides Ultrasonic energy and Advanced RF energy technology for soft tissue dissection and vessel sealing.
2. Should have the ability to select hand switch or footswitch activation or both for Ultrasonic and advanced RF energy instruments and the ability to change selection during use can seal and transect vessel upto 7mm with system feedback mechanism for better patient safety.
3. Should have very minimal lateral thermal with spread not more than 1mm.
4. RF energy instruments compatible with generator should have controlled gap mechanism for uniform compression across the instrument jaw for better sealing and transection of vessels and tissue bundles upto 7mm simultaneously.
5. Should have standby mode to ensure safety.
6. Should be able to power ultrasonic energy instruments with 55.5 KHz frequency.
7. Should be compatible for RF energy and ultrasonic energy instruments for open and laparoscopic surgery.
8. Should be able to power energy instruments with microprocessor controlled bipolar electrosurgical radiofrequency technology with a quasi-sinusoidal forced impedance output
9. Should be equipped with smart advanced RF energy technology to measure the tissue Impedance and control the power delivery and that can simultaneously seal and transect vessels up to 7mm, large tissue pedicles and vascular bundles.
10. Should be compatible with articulating RF energy instruments with articulation of 55 degree either side and total of 110 degree of articulation with 360 shaft rotation and can simultaneously seal and transect vessels up to 7mm, large tissue pedicles and vascular bundles with system feedback.
11. Should provide temperature controlled energy delivery which should maintain tissue temperature approximately at 100 degree Celsius and hand instruments that provide tissue / vessel seal strength to withstand bursting pressure of 7 times the systolic pressure.
12. Should be compatible with ultrasonic energy instruments which can simultaneously seal and transect vessels upto 7mm, large tissue pedicles and vascular bundles with ultrasonic energy only with system feedback.
13. All hand probes for open and lap procedures should be able to simultaneously cut and Coagulate tissues and also works separately Curved Blade and Dissecting Hook having telescoping shaft (10cm-14cm) with integrated hand activation control buttons.
14. Should have the ability for software updates via USB memory stick.
15. Should conform to the following international standards EN (IEC) 60601-1, EN (IEC) 60601-1-2, EN (IEC) 60601-2-2, EN (IEC) 60601-1-8 & System should be European CE and US FDA approved.

approved.

16. Should provide Class 1 protection against electric shock.
17. Should come equipped with system diagnostics and troubleshooting guide to pin point any problems in the system.
18. Well-equipped Service Center, should be ISO certified

B. Foot switch & cable

C. Accessories

1. Generator cart
2. Adapters for ultrasonic and radiofrequency instruments.
3. Hand piece/ Hand pieces (Transducer) compatible with various hand instruments used in open and laparoscopic surgeries. - 2
4. RF energy 5mm Lap. Hand Activated probe capable of sealing blood vessels upto 7mm in diameter, 35 cm with 3mm curved tip and 5 mm straight tip with active articulation of 55 degree each side using articulation wheel and 360 degree knob rotation. - 5
5. Ultrasonic 5mm Lap. Hand Activated Curved Coagulating Shear with next generation adaptive tissue technology which gives regulated power delivery for improved thermal management and audible feedback tone for greater surgical efficiency, capable of sealing blood vessels upto 7mm in diameter using three hand-activation buttons – Max, Min & Advanced Hemostasis, proprietary non-stick coated active blade to reduce tissue sticking, 36 cm shaft length with ergonomic handle. - 10

[Handwritten signatures and initials]

[Signature: Dimple]

[Signature: Rishi]

[Signature: Jyoti]

[Signature: Megha]

[Signature: Sidharth]

[Signature: Anuj Kumar]

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI – 110 029**

PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE

- | | | |
|----|---|---|
| 1. | Item/Type/Model No. required along with specification | Combined Single Generator for Ultrasonic Cutting & Coagulation Device with Advanced Radio Frequency Energy on Buy back basis |
| 2. | Is the item a spare part attachment or accessory for an existing equipment | No |
| 3. | Name of the manufacturers/Supplier of the item proposed by the indenter. | M/s Johnson & Johnson Pvt. Ltd., Mumbai/
M/s Oriental Surgical Works, Delhi |
| 4. | Are they sole manufacturers/sold distributors of the item | 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 advantage/cost effectiveness of the recommended item from these offered by other. | No |
| 6. | What were the efforts made to locate alternative source of supply of use other substitutes. | Internet/ No other alternative source for supply of other substitutes |
| 7. | Why open/limited tender can't be resorted to, for locating alternative source. | These are proprietary items of M/s Johnson & Johnson Pvt. Ltd., Mumbai |
| 8. | Are the proprietary items certifying that the rates are reasonable or not. | Rates certificate from the firm is enclosed |
| 9. | Any other justification for procuring item from single source. | Only single Manufacturer |

The above mentioned information is provided by the firm.

Signature of Indenter
(Demanding Officer)



DR. P.N. DOGRA
Senior Lecturer/Assistant Professor
Department of Pathology
All India Institute of Medical Sciences
Ansari Nagar, New Delhi-110 029

DR. P.N. DOGRA
आचार्य एवं (Counter Signed)
(Head of the Department)
अखिल भारतीय आयुर्विज्ञान संस्थान
All India Institute of Medical Sciences
अंसारी नगर, नई दिल्ली/Ansari Nagar, New Delhi-29, INDIA

I certify that the item at Sr. No.1 above is required to be procured on single tender basis as the source of supply is definitely known/the specified brand proposed was advantages in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

(Strike out whichever is not applicable)

