भारत सरकार/Government of India
स्वास्थ्यऔर परिवारकल्याणमंत्रालय/ Ministry of Health and Family Welfare
प्रधानमंत्री स्वास्थ्य सुरक्षा योजना/PMSSY
अखिलभारतीयआयुर्विज्ञानसंस्थान/All India Institute of Medical Sciences
www.aiimsmangalagiri.edu.in मंगलगिरि, आंध्रप्रदेश/Mangalagiri, Andhra Pradesh

Ref: AIIMSM/PROC/63/2025-High End Ultrasonic Cutting & Coagulation with the Advance Bipolar Sealing System

Date: 05-12-2025

Call for Objection

Subject: Inviting comments/objections, if any, before declaring proprietary article for procurement of "**High End Ultrasonic Cutting & Coagulation with Advance Bipolar Sealing System**" for the department of OBG, AIIMS Mangalagiri.

The OBG Department, AIIMS Mangalagiri, has to procure "**High End Ultrasonic Cutting & Coagulation with Advance Bipolar Sealing System**" through Proprietary Article basis.

The proposal submitted by **M/s. Johnson & Johnson Private Limited** is the authorized Channel Partner of **M/s. Ethicon Endo-Surgery, LLC** branded products within the territory of India of this item along with Proprietary Article Certificate are attached & uploaded on Institute website.

The above documents are being uploaded for open information to submit objections, comments if any from any manufacturer/supplier before declaring proprietary article of the said equipment/items to be procured, within 10 days (i.e. 15-12-2025) from the date of issuance/uploading of the notification.

The objection should be raised in the technical compliance sheet as enclosed in **Annexure-I,** if any Firm claiming the suitability of their product with respect to specification mentioned.

The comments should be sent to the office of Procurement Cell, Room no: 2151, Logistic block at AIIMS Mangalagiri in a sealed envelope with above reference on or before 15-12-2025 up to 05:00 PM from the date of uploading on institutional website, failing which it will be presumed that any other manufacture/vendor is having no comment to offer and case will be decided on merits.

-sd-
AAO (Procurement Cum Stores)
AIIMS Mangalagiri

P-3 FORM

(To be attached with P-2 form for proprietary items)

AIIMS Mangalagiri

PROPRIETARY ARTICLE CERTIFICATE

It is certified that the item, Ultrasonic cutting and coagulation unit with advanced bipolar sealing system Make: "Ethicon Endo-surgery", required in the P2 form, is a proprietary and unique product manufactured by Ethicon Endo-surgery, LLC part of the Johnson and Johnson family of companies. To the best of my knowledge M/S Johnson & Johnson Private limited is the exclusive distributor of the product Ultrasonic cutting and coagulation unit with advanced bipolar sealing system for territory of India.

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

This product has the following unique features:

1. System should have a single generator and universal connector to connect Ultrasonic energy and Advanced RF energy instruments & System should have automatic instrument recognition.
2. System should come equipped with system diagnostics and troubleshooting guide to pinpoint any problems in the systems, it should depict the consumables life with details of phase margin and impedance.
3. System should work on high frequency of 55 khz which enables it to seal 7 mm vessel independently with pure ultrasonic mode with temperature around 100 degree Celsius.
4. 55 khz or higher frequency for Ultrasonic energy should enable instruments for back scoring, Otomi creation & cavitation effect on tissue.
5. System should have option to change power level of ultrasonic energy to customize energy delivery as per procedure.
6. System should have pure ultrasonic energy mode & hand instruments that provide tissue / vessel seal strength up to & including 7mm with pure ultrasonic energy.
7. System should be compatible with integrated transducer ultrasonic probe technology for prompt set up and plug and play system, this will eliminate the need of tightening of hand instruments.
8. System should be enabled with tissue adaptive functions which modulate and regulate the power delivery simultaneously giving feedback to user surgeon.
9. System should be compatible with 100 to 110-degree articulation equipment. System should be compatible with fully integrated ultrasonic energy Device robotic ultrasonic

arm & Robotic energy activation cable, which enable fully autonomous action in Robotic procedures.

10. System should have Advanced RF Energy with temperature-controlled mechanism hand instruments that provide tissue / vessel seal strength up to & including 7mm to withstand bursting pressure of more than 6-7 times the systolic pressure, compatible with Hand probe with 5mm shaft diameter with 110-degree articulation.
11. Hand Piece (transducer) should compatible with leading robotic system arm.
12. System should be compatible with ultrasonic hook for laparoscopic procedures.
13. System should be compatible with ultrasonic hook & blade for open procedures.

The above features are beneficial for teaching and learning purposes. To the best of my knowledge these features are not available in any other product

Sign of indenter

Designation Associate Professor

Department OBG

Dr. SAIREM MANGOLNGANBI CHANU
MS (OG), Dip. RM & ART, Dip. Urogynaecology
Regd. No. RMC 27717
Associate Professor
Department of Obstetrics & Gynecology
All India Institute of Medical Sciences
MANGALAGIRI, ANDHRA PRADESH

Recommendation

7/12/2025

Signature of Head of department /section

Professor & Head
Dept.of Obstetrics and Gynecology
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh

Ethicon
Endo-Surgery
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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

Proprietary Certificate & Agreement for Representation

We hereby certify that the "Bezel part for Harmonic® Generator" is a proprietary product of Ethicon Endo-Surgery, LLC part of the Johnson & Johnson family of companies.

We further certify that M/s Johnson & Johnson Private Limited, India is our affiliate and is authorized to market the products in India through its regional branch offices at Chennai, Delhi, Mumbai, and Kolkata. Johnson & Johnson Private Limited India and its regional branch offices are authorized to submit offers and commit, sign, finalize, execute orders and also to appoint distributors, dealers and liaison agents for selling the complete range of products on our behalf.

We also certify for adequacy of technical expertise of the products offered by M/s Johnson & Johnson Private Limited India and will give them back-up support towards supply, spares & technical updates.

On behalf of Ethicon Endo-Surgery, LLC

Mary Galeano, RAC
Regulatory Affairs Specialist II

11 Apr 2017
Date

14/5/2024.
Professor & Head
Dept.of Obstetrics and Gynecology
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh.

Dr. VANDANA. K, MS (OBG)
Regd. No. APMC 75189
Assistant Professor
Department of Obstetrics & Gynaecolog
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh.

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

ETHICON
Johnson & Johnson SURGICAL TECHNOLOGIES

LETTER OF AUTHORIZATION

This is to certify that **Johnson & Johnson Private Limited,** with registered office at **LBS Marg, Mulund (West), Mumbai – 400080** and a corporate office at **501, Arena Space, Off JVLR, Behind Majas Depot, Jogeshwari (East), Mumbai – 400060,** is our affiliate company in India. They are solely authorized to Import, Sell, and Service **Ethicon Endo-Surgery, LLC** products in India. They are also solely authorized to participate in all tenders floated in India for **Ethicon Endo-Surgery, LLC** product purchases and will provide necessary support on an ongoing basis.

Signed for and on behalf of:
Ethicon Endo-Surgery, LLC

William Godwin

Digitally signed by William Godwin
DN: c=US, o=JNJ, ou=Subscribers, cn=William Godwin, 0.9.2342.19200300.100.1.1=1017888
Reason: I am approving this document.
Date: 2023.10.12 10:31:42 -04'00'
Adobe Acrobat version: 2020.013.20064

Brian Godwin
Associate Director - Regulatory Affairs

Date

Professor & Head
Dept.of Obstetrics and Gynecology
All India Institute of Medical Sciences
Mangalagiri, Andhra Pradesh.

Ultrasonic Cutting and coagulation unit with advanced bipolar sealing system

1. System should have a single generator and universal connector to connect Ultrasonic energy and Advanced RF energy instruments & System should have automatic instrument recognition.
2. System should be USFDA approved to ensure the global patient safety standard.
3. System should have a touch screen display for fast setup, operation, on-screen diagnostics and other information.
4. Generator should have USB port for any upcoming technology upgradation.
5. System should be a single generator with foot activation that provides Ultrasonic energy and Advanced RF energy technology for soft tissue dissection and vessel sealing.
6. System should conform to the following international standards for example EN (IEC) 60601-1, EN (IEC) 60601-1-2, EN (IEC) 60601-2-2, EN (IEC) 60601-1-8
7. System should not have lateral thermal spread more than 1 mm.
8. System should come equipped with system diagnostics and troubleshooting guide to pinpoint any problems in the systems, it should depict the consumables life with details of phase margin and impedance.
9. System should work on high frequency of 55 khz which enables it to seal 7 mm vessel independently with pure ultrasonic mode with temperature around 100 degree Celsius.
10. 55 khz or higher frequency for Ultrasonic energy should enable instruments for back scoring, Otomi creation & cavitation effect on tissue.
11. System should have option to change power level of ultrasonic energy to customize energy delivery as per procedure.
12. System should be equipped with advanced RF energy technology that provides temperature-controlled energy delivery which should maintain tissue temperature approximately at 100-degree Celsius, lateral spread less than Imm for better surgical outcome.
13. System should have pure ultrasonic energy mode & hand instruments that provide tissue / vessel seal strength up to & including 7mm with pure ultrasonic energy.
14. System should be compatible with integrated transducer ultrasonic probe technology for prompt set up and plug and play system, this will eliminate the need of tightening of hand instruments.
15. System should be enabled with tissue adaptive functions which modulate and regulate the power delivery simultaneously giving feedback to user surgeon.
16. System should be compatible with 100 to 110-degree articulation equipment. System should be compatible with fully integrated ultrasonic energy Device robotic ultrasonic arm & Robotic energy activation cable, which enable fully autonomous action in Robotic procedures.
17. System should have Advanced RF Energy with temperature-controlled mechanism hand instruments that provide tissue / vessel seal strength up to & including 7mm to withstand bursting pressure of more than 6-7 times the systolic pressure, compatible with Hand probe with 5mm shaft diameter with 110-degree articulation.

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18. Hand Piece (transducer) should compatible with leading robotic system arm.
19. System should be compatible with ultrasonic hook for laparoscopic procedures.
20. System should be compatible with ultrasonic hook & blade for open procedures.
21. System should consist of followings component-
    - Generator with 5 years of warranty.
    - Foot Switch & Cable with 5 years of warranty
    - Hand Piece (transducer)- 2 units (one for open, one for Lap instruments)
    - OEM cart- 1

Probes for Minimally Invasive Surgery:

1. 5mm Lap Hand & footswitch Activated Curved Coagulating Shears with integrated handpiece capable of sealing blood vessels up to 7 mm in diameter with pure ultrasonic energy with shaft length 36 cm shaft length approx. capable of back coring, Spot coagulation and otomy creation, should be having a 18 mm or longer Maryland like curved active blade - 3 pc
2. Pure RF energy hand probe with 5mm shaft diameter of shaft rotation with straight tip in the shaft length 35-37cm or more and seals and transect vessels up to 7mm, sealing strength 7 times systolic pressure with 100 degree or more articulation with 360 degree of shaft rotation lap devices should be having temperature-controlled mechanism within the jaw controlling temperature below 100 degree- 3 pc

Probes for Open Surgery:

1. Vessel sealer device Curved large Jaw - Shaft length 20 cms Advanced bipolar tissue sealer with 10mm shaft diameter, 1.2mm lateral spread, sealing strength 7 times systolic pressure. use in open surgical procedures with curved and tapered tip and uses an advanced algorithm for intelligent and efficient energy delivery. Device to have intuitive design with separate Seal and Cut button and 360-degree continuous shaft rotation. - 2 Units
2. Vessel sealer device Curved Jaw - Shaft length 37 cms Advanced bipolar tissue sealer with 5mm shaft diameter, 24 mm Jaw length, 21.8 mm cut length and 13.4 mm Jaw aperture designed for use in open or laparoscopic surgical procedures with curved and tapered tip and uses an advanced algorithm for intelligent and efficient energy delivery. Device to have intuitive design with separate Seal and Cut button and 360-degree continuous shaft rotation. - 2 Units
3. Hand activated curved taper tip coagulating shears compatible with ultrasonic cutting and coagulation device,17cm length,16mm curved active blade capable of sealing blood vessels up to and including 5mm in diameter, with ergonomic symmetrical finger ring grip — 2 Units

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ANNEXURE – I

SPECIFICATIONS

Objection should be submitted in following format:

S. no	Item specification as given	Specification offered by firm	Deviation if any	Remarks