## Technical specifications for CUSA Clarity ultrasonic tissue ablation system

- 1. Ultrasonic surgical aspirator should have fragmentation, irrigation, and aspiration facilities. Should be the latest model of an ultrasonic surgical aspirator.
- 2.Should be Piezoelectric technology-based System and supplied with one handpiece frequency and should be in range of 36 kHz for Neurosurgery procedures.
- 3. Should have intuitive touchscreen interface which provides clear guidance from set-up through operation and on-screen help to provide real-time assistance and troubleshooting.
- 4. Console should be light weight mounted on trolley from the same manufacturer.
- 5. Should have tissues select/patient safety dedicated control which allows to increase selectivity while removing tissue close to critical structure and preserving blood vessels, pia matter & nerves etc.
- 6.Amplitude and aspiration settings can be adjusted with increments of 5 percent.
- 7. Should have adaptive power which adjust automatically to maintain tip vibration and amplitude.
- 8. Should have choice of various tips which can be selected /changed in the sterile field to accommodate tissue consistency and localization.
- 9. The hand piece should be ergonomically balanced light weight with thermal shield.
- 10. Should have easy connect cartridge and tubing set for quick set up.
- 11. Should have tracking of handpiece usage and check performed prior to every usage.
- 12. Should have the choice to select constant aspiration and on demand aspiration.
- 13. Should be supplied with adjustable dual foot pedal used to control the amplitude in on/off or progressive/ linear action.
- 14. Should have USB port for service help and upgrade software.
- 15. Should have in built high vacuum up to 640mmHg with constant tissue contact.
- .6. Should have maximum tip amplitude up to 420 microns or more.
- 17. Should have audible alert sounds and text message on the screen enhances troubleshooting with detailed explanation and resolution.
- 18. Integrated Irrigation pump, adjustable at 2-20ml/min and fast flush 0-25 ml/min.
- 19. Tip should have Pre-aspiration holes to minimize heat built-up, blockage, decreases misting of irrigation fluid, providing better visibility.

Dr. Vijendra Kumar Dr. Amit Upadhyay Dr. Arun Srivastava Dr. Kamlesh Bhaisora JDMM FO/Nominee Director Nominee

Chairman Deva Member Specifite nat Expert External Expert Member Member Member

M.S., M.C.H.

Additional Professor,
Dept. of Neurosurgery,
SGPGIMS, Lucknow, (U.P.)

- 20. The Handpiece, torque base and Extended use tips should be autoclavable.
- 21. System should be supplied with the following attachments and accessories:
- a) 36 KHz Universal Straight Handpiece -1 Nos.
- b) 36 kHz Curved Extended Standard Tip with flue- 6 Nos. for rapid tumor debulking.
- c) 36 Khz Curved Extended Shear Tip-6 Nos. for fibrous and tough tumors.
- d) 36 Khz Curved Extended Micro Tip plus-6 Nos. for TNTS & delicate procedures.
- e) Quick Connect Tubing Set -6 Nos.
- f) 36 kHz Torquing wrench Set- 4 Nos
- g) 36 kHz Reusable Torquing Base -1 Nos.
- h) 36 Khz Sterilization Case -1 Nos.

Contamination Guard- 4 Nos

- 22. US-FDA and European CE should be approved and enclosed the desired documents mentioning the name of item.
- 23. Cost of consumable item should be freeze for next 5 years

Dr.Amit Upadhyaya Dr.Aron Srivastava Dr.Vijeodra Kumar Dr.Kamlesh Bhaisora **JDMM** FO/Nominee **Director Nominee** Memberate Professor epartment of Neuro Chairman Member Member Member External Expert S. Luc Dr. Kamlesh Singh Bhaisora Kalyan Sina Su Cancer Institu

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Email: procurement.ksssci@gmail.com

# Proprietary Article Certificate (PAC) for Items/Goods

(Cavitaon Ultrasonic Surgeal Aspirator)

(1)	The	indented	goods	are	manufactured	by ···
	M/:	indented In 1997a Lifes	eimles	(Ireland)	limited	************
(2)	No	other make or model is ac	ceptable for t	the following rea	sons:	
	a)	Tissu Culchinity	of Ulbre	some transc	lucur (pgtent	ed tichnology
	b)		V			'1
	c)		••••••		••••	

Additional Professor & Hear Department of Neurosurgery ...... Kalyan Singh Super Specialty

(Signature of Indentor) Luckney

·Dr...Vijendra Kumar Additional Professor & Hees Department of Neurosurge (
Kalyan Singh Super Specially (Signature of HOD). Lucknew



To, The Director, Kalyan Singh super speciality cancer institute & Hospital Sultanpur Rd, Golf City, CG CITY, Lucknow, Uttar Pradesh 226002.

### **PROPRIETARY ARTICLE CERTIFICATE**

This is to certify that **CUSA Clarity** model which has a unique patented **Ultrasonic Aspirator Tissue Selectivity** feature is a proprietary product of Integra Lifesciences (Ireland). Below are the address details of the manufacturer:

Legal and Actual Manufacturer Details: Integra Lifesciences (Ireland) Limited IDA Business and Technology Park Sragh, Tullamore, County Offlay, Ireland.

For Integra Lifesciences Authorised Signatory

Name: Krishnan Nagasubramani Designation: Vice President, APAC

Jon Mers



To, The Director, Kalyan Singh super speciality cancer institute & Hospital Sultanpur Rd, Golf City, CG CITY, Lucknow, Uttar Pradesh 226002

Sub: - Tissue Select and Its Clinical Advantages

Sir,

**Tissue Select** is a unique and proprietary feature in **CUSA Clarity Model** which offers enhanced selectivity, enabling greater control when resecting near critical structures.

The Selectivity is achieved by using two simultaneous actions enabled by a **Force Sense Ceramic Transducer** inside the CUSA Clarity handpiece, which separates control of amplitude from power. The Adaptive power is reduced when the selectivity is increased, limiting power to the surgical site, and enabling the tip to stop vibrating when increase pressure is put on the resistant tissue.

**Tissue Select** is trusted **since 1998**, which uses pulsed vibration, rapidly alternating between high and low amplitude, to maintain the efficacy and speed of cavitation, while allowing surgeon more time to react, allowing greater precision and control around critical structures like collagen rich tissues: nerves, pia, arteries, veins, bile ducts, vessels etc.

#### **Clinical Benefits of Tissue Select**

- 1. Improves ability to differentiate in terms of fragmentation efficiency, between targeted tissue and critical Structures.
- 2. Allows increased safe contact time with critical structures, providing surgeon more time to react.
- 3. Provides tactile feedback when tip encounter critical structures.
- 4. Maintains tissue fragmentation, enabling safe and effective resection near critical anatomy.

5. Shorter operating time, less blood loss during surgery and decrease in complications.

**Yours Sincerely** 

For Integra Medical Devices India Pvt Ltd

Tejinder Singh Jassal General manager- India & South Asia March 28, 2025

Place: Gurgaon

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