

Admn/Prop/64/2018-AIIMS.JDH

Dated: 07<sup>th</sup> February 2019

Subject: Purchase of Ultrasonic Bone Scalpel for the department of Neurosurgery at AIIMS,

Jodhpur on proprietary basis - **Inviting comments thereon.** 

The Institute is in the purchase of Ultrasonic Bone Scalpel for the department of

Neurosurgery at AIIMS, Jodhpur from M/s Misonix Inc., 1937, New Highway, Farmingdale, NY

11735, New York on proprietary basis. The proposal submitted by M/s Cure Surgical, S-12, FF,

Green Park Extension, New Delhi- 110016 and PAC certification by user are attached.

The above document are being uploaded for open information to submit objection,

comments, if any from any manufacturer regarding proprietary nature of the equipment within

21days of issue giving reference Admn/Prop/64/2018-AIIMS.JDH. The comments should be

received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 28th

February 2019 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.** 





#### LETTER OF AUTHORIZATION

January 23, 2018

To Whom It May Concern,

We, Misonix, Inc. located at 1938 New Hwy Farmingdale, NY 11735, U.S.A. herewith contractually authorize:

**CURE SURGICALS** S-12, 1<sup>ST</sup> FLOOR, GREEN PARK EXTENSION NEW DELHI-110016, INDIA

as our exclusive distributor in India for the purpose of commercialization, importation, promotion, technical support and sales for the following list of medical products:

- SonaStar® Ultrasonic Surgical Aspiration System, Disposables and Accessories
- BoneScalpel® Ultrasonic Surgical Aspiration System, Disposables and Accessories

The above listed medical products are solely manufactured by Misonix, Inc. in the U.S.A.

This authorization is limited to the terms and conditions of the commercial distribution agreement between Misonix and Cure Surgicals, including agreements that may exist in the future, and cannot be considered as modification of any kind of said agreement(s).

This authorization is valid until April 1, 2019.

Best Regards,

Scott Ludecker

Senior Vice President - Global Sales & Marketing Misonix, Inc.

1938 New Hwy, Farmingdale, New York 11735 P. 631-694-9555 F: 631-694-9412

SB





#### PROPRIETARY CERTIFICATE

To whom it may concern,

Misonix® and BoneScalpel® are registered trademarks of Misonix Inc., 1938 New Highway, Farmingdale, NY 11735. The Misonix® BoneScalpel® System is a proprietary medical device indicated for use in the fragmentation and aspiration of both soft and hard (e.g.: bone) tissue in the following surgical specialties including, without limitation, Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery Gynecology, Thoracic Surgery, and Wound Care.

System is comprised of a generator, which feeds a 22.5 kHz electrical signal to a piezoelectric crystals mounted in a hand-held handpiece; the crystals then vibrate at the same frequency. The titanium tip attached to the handpiece amplifies the vibration. Tips have unique design features to facilitate surgeons in removal of soft and hard tissue in the surgical specialties listed above. Also, tips have lumens to supply irrigation to the surgical site, maintain thermal equilibrium of the tip, and flush fragmented material and waste liquids from the area. Wound care procedure kits are designed with front handpiece housings which connect to the hospital aspiration system to remove fragmented material and waste liquids from the surgical site. Aspiration in other surgical specialty kits is accomplished by using the hospital aspiration system without connection to the handpiece.

If you have questions contact:

John Salerno Vice President, QA/RA Misonix® Inc. 1938 New Hwy, Farmingdale, NY 11735

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### PROPRIETARY CERTIFICATE

Misonix and BoneScalpel are registered trademarks of Misonix Inc., 1938 New Highway, Farmingdale, NY 11735. The Misonix BoneScalpel System is a proprietary medical device indicated for use in the fragmentation and aspiration of both soft and hard (e.g.: bone) tissue in the following surgical specialties including, without limitation, Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecology, Thoracic Surgery, and Wound Care.

#### List of U.S. Issued Patents:

Product	Country	Patent No.	Description of Invention	
BoneScalpel	US	6,379,371	Flat ultrasonic bone cutting blade with liquid cooling	
BoneScalpel	US	6,443,969	Flat ultrasonic bone cutting blade with liquid cooling	
BoneScalpel	US	8,444,629	Ultrasonic probe with motion-responsive power shut-off	
BoneScalpel	US	8,343,178	Ultrasonic blunt blade method	
BoneScalpel	us	8,814,870	Hook-shaped ultrasonic cutting blade	
BoneScalpel	us	9,119,658	Hook-shaped ultrasonic cutting blade	
BoneScalpel	US	8,353,912	Ultrasonic discectomy method and tool	
BoneScalpel	us	8,894,673	Ultrasonic osleolome especially for skull and spine	
BoneScalpel	US	9,421,028	Ultrasonic osteolome especially for skull and spine	
BoneScalpel	US	D700,327	Ultrasonic osteotome design 1	
BoneScalpel	US	D715,434	Ultrasonic osteolome dasign 2	
BoneScalpel	US	D715,936	Ultrasonic osteolome design 3	
BoneScalpel	us	D715,435	Ultrasonic osteolome design 4	
BoneScalpel	US	D715,436	Ultrasonic estectome design 5	
Bone Scalpet	US	D680,218	Bone-cutting blade with single serrated edge (design)	
BoneScalpel	us	D667,117	Bone-cutting blade with two serrated edges (design)	
BoneScalpel	US	D685,087	Laparoscopic cannula with distal end offset or window	
BoneScalpel	us	D741,481	Hook blade with serrations	
BoneScalpel	US	9.211,137	Ultrasonic probe with Irrigant outlets in probe shark	
BoneScalpel	US	9,387,005	Flat blade with large shallow recess(os) for coolent	
Bone5calpel	US	9,788,852	Large shallow recesses in flats of blade serving as reservoir	
BoneScalpel	US	9,320,528	Ultrasonic blade with micro-pores for coolant conduction	
BoneScalpel	US	9,622,766	Probe with head traversing window in deflectable sheath	
BoneScalpel	us	9,672,697	High Efficiency Wound Debridement Probe	
BoneScalpel	US	7,778,027	Ultrasonic probe with motion-responsive power shul-off	
BoneScalpel	US	9,775,666	Automatic interruption stopping of us waveform	
BoneScalpel	us	6,738,814	Ultrasonic probe with bipolar cautery	
BoneScalpel	us	6,648,839	Ultrasonic probe with bipolar or monopolar cautery	
BoneScalpel	US	7,442,168	Ergonomic handplece with vibration damping	
BoneScalpal	US	6,902,536	Ultrasonic probe with width- adjustable cautary applicator	
BoneScalpel	us	7,223,267	Ultrasonic probe with detachable cautery forceps	
BoneScalpel	us	7,717,913	Ultrasonic probe with width- adjustable cautery applicator	

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#### List of Trademarks:

DOCKET#	MARK	REGISTRATION NO.	
M24-095	MISONIX	2,812,718	
M24-127EP	MISONIX	4.479,035	
M24-128JPN	MISONIX	5,069,488	
M24-170	MISONIX	3,862,225	
M24-211	BONESCALPEL	4,715,865	
M24-235	MISONIX	5,931,329	

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Misonia's authorized distributor is Cure Surgicals, S-12, 1st Floor, Green Park Extension, New Delhi -1110016, India, www.curesurgical.com.

If you have questions contact:

John Salemo

Vice President, QA/RA

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Thanks and Warm Regards,

Arenab Sarkare

Regulatory Affairs Specialist T. 631-927-9147

1938 New Hwy, Farmingdale, New York 11735



01/10/2018



JOSEPH J GIGANTE OTARY PUBLIC, STATE OF NEW YORK Registration No. 01GI5136905 Qualified in Nassau County

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### Technical specifications of Ultrasonic Bone Scalpel for Department of Neurosurgery

Ultrasonic bone scalpel, to be used for spinal surgeries and craniovertebral junction surgeries.

S.No.	Technical Specification of Ultrasonic Bone Scalpel System			
1	Ultrasonic console with inbuilt irrigation pump for Ultrasonic Osteo- surgery to work on 22.5 kHz ± 500kHz frequency with maximum 300 μ-amp ground leakage current. Console should deliver maximum output power of 130 Watt. It should have Irrigation Flow rate control (Variable up to 90ml/minute).			
2	Foot switch Control for Ultrasonic output			
3	Straight Hand piece should have piezo-electric transducer to convert input signal into mechanical oscillations with linear like motion with 1,300,000 to 1,350,000 strokes per minute.			
4	Straight Tips for hard tissue removal to be connected with hand piece with blade thickness as small as 0.5-1mm should be in following sizes:			
	a.	Bone scalpel Blade with integrated irrigation inside Blade (Includes 10mm blade & short extension).	05 Nos	
	b.	Bone scalpel Blade with integrated irrigation inside Blade (Includes 20mm Unilateral Serration blade & short extension).	05 Nos	
	c.	Bone shaver-Micro hook with cannulated integrated irrigation with Silicon extension 2mm.	05 Nos	
	d.	Bone shaver-Macro hook with Silicon extension 4mm.	05 Nos	
	e.	Bone scalpel Blade with integrated irrigation inside Blade(Includes 20mm blade & short extension)—	05 Nos	
	f.	Bone scalpel Blade with integrated irrigation inside Blade (Includes 25mm blade & short extension).	05 Nos	
	g.	Diamond shaver (approx. 4.5mm) with a channel for irrigation and silicon sleeve for bone shaving of large area.	05 Nos	
	h.	Bone scalpel with integrated irrigation inside Blade(Includes 20mm blade, blunt, long curved, MIS rigid sheath).	05 Nos	
	i.	Bone scalpel Blade with integrated irrigation inside Blade(Includes 10mm blade, blunt, long curved, MIS rigid sheath).	05 Nos	
	j.	Bone scalpel Micro Hook with cannulated integrated irrigation (Includes 2mm Micro Hook, blunt, long curved, MIS rigid sheath)	05 Nos	
	k. Irrigation Tube Set.		10 Nos	