

BONESCALPEL™

With SonicOne® Technology



ULTRASONIC OSTEOSURGERY

PRECISION OSTEOTOMY

SOFT TISSUE SPARING

BONE PRESERVING

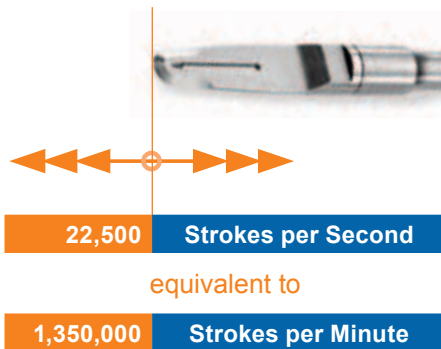
REDUCED BLEEDING

IMPROVED EFFICIENCIES

MISONIX®
ULTRASONIC SURGICAL DEVICES

The Ultrasound Advantage.

The Misonix BoneScalpel™ is a novel, ultrasonic surgical device that enables rapid, safe and precise osteotomies. It is designed to provide clean cuts through osseous structures with minimal loss of viable bone while sparing adjacent soft tissues.



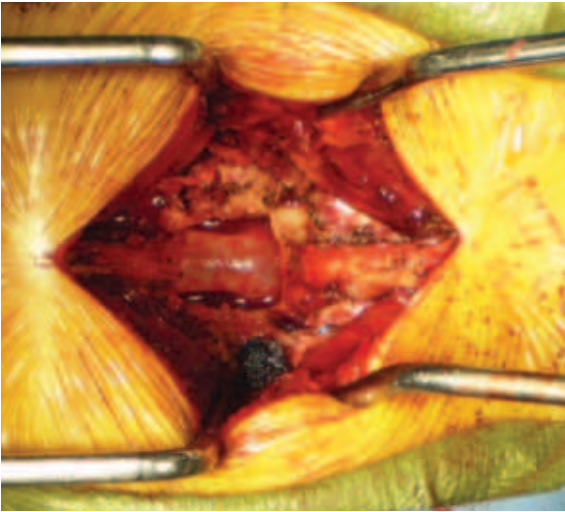
The BoneScalpel handpiece receives an electrical signal with the nominal frequency of 22.5 kHz from the ultrasonic console. A piezoelectric transducer converts the input signal into mechanical oscillations that are further amplified in order to achieve efficient cutting characteristics.

The blunt BoneScalpel blade oscillates in a linear, piston-like motion enabling an effortless dissection of hard, cortical bone.

“ I have used the BoneScalpel in more than 200 cases in the cervical, thoracic and lumbar spine. This instrument is a superb device for cutting bone sharply and precisely with almost no detritus. Since ultrasound energy dissipates in soft tissue (dura, nerves, vascular structures etc.) this device is the ideal tool for bone removal in critical areas. The BoneScalpel is one of the most important advancements in spine surgery during the last years and it is here to stay. ”

Daniel Rosenthal, MD
Neurosurgeon
Bad Homburg, Germany

TISSUE-SPECIFIC OSTEOSURGERY



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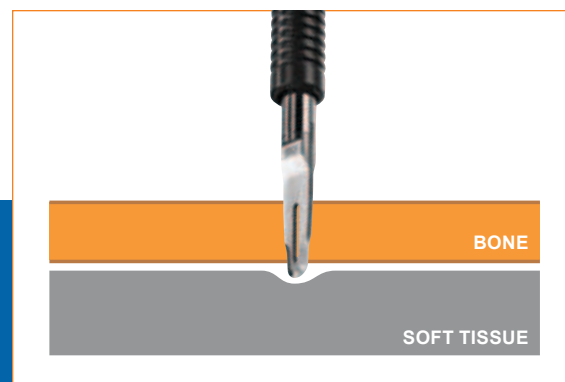
Ultrasonic OsteoSurgery is tissue-specific as it allows for precise removal of rigid bone while being atraumatic to elastic soft tissues. Loss of viable bone can be minimized and intra-operative bleeding reduced, keeping the surgical site clear of blood. Reductions in O.R. time can be significant.

Hard Tissue Response

- BoneScalpel™ cuts bone in preference to soft tissues because of the greater rigidity of the bone – and the unique design of our ultrasonic instruments.
- When rigid bone comes in contact with the BoneScalpel blade it does not bend, deform or move away.
- As result bone absorbs a large portion of the blade's energy and is destroyed at the point of contact with the blade.

Soft Tissue Response

- In contrast, soft tissue responds elastically in contact with the blade, that is it moves, deforms and vibrates.
- This results in substantial dampening of the energy transferred from the blade to the tissue.
- The energy absorbed by the soft tissue at the point of contact with the blade is generally not sufficient to cut the tissue unless soft tissue is held against the blade at high tension for a long period of time.



INDICATIONS AND CLINICAL EXPERIENCE

The BoneScalpel system is indicated for use in the fragmentation and aspiration of both soft and hard (e.g.: bone) tissue as used in the following surgical specialties:

- Orthopedic Surgery
- Plastic and Reconstructive Surgery
- Neurosurgery
- Thoracic Surgery
- Wound Care
- General Surgery

It is also indicated for use in debridement of wounds, such as, but not limited to burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications, in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.

The BoneScalpel has been used for bone fragmentation in the following orthopedic, reconstructive and neurosurgical procedures:

Lumbar

- Laminotomy
- Foraminotomy
- Sacral laminoplasty
- Decompression of spinal canal (ipsi-lateral, contra-lateral by undercutting)
- Decompression in revision cases
- Sequestrectomy
- Facetectomy
- Transforaminal lumbar interbody fusion

Cervical

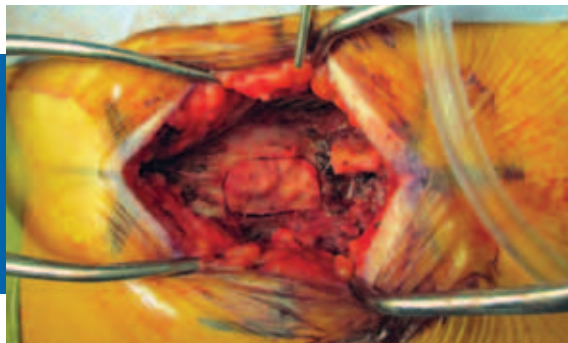
- Laminectomy
- Laminoplasty
- Foraminotomy
- Osteophyte resection
- Resection of osteochondrosis
- Robinson-Smith procedure
- Anterior corpectomy
- Anterior foraminotomy
- Intra-oral dens resection

Spinal Deformity

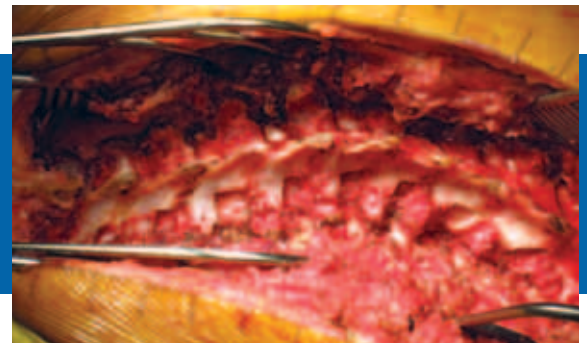
- Correction of deformity in lumbar, thoracic and cervical spine

Minimally Invasive Spine

- Microscopic approach
- Approach through MIS retractor (e.g. METRx)
- Thoracoscopic approach (not cleared in the U.S.)



Sacral Laminectomy



Facetectomy

CLINICAL EXPERIENCE

The BoneScalpel has been used for bone fragmentation in the following orthopedic, reconstructive and neurosurgical procedures:

Maxilla

- Maxillary osteotomy
- Maxillary corticotomy
- Maxillectomy, hemi-max.
- LeFort I osteotomy
- Exostosis excision
- Sinus lift

Mandible

- Mandibular osteotomy
- Mandibular corticotomy
- Mandibulectomy
- Sagittal split osteotomy
- Sagittal osteotomy
- Mandibular Decortication
- Genioplasty

Skull Base and Cranial

- Suboccipital craniotomy
- Orbital-zygomatic craniotomy
- Craniotomy for orbital tumors
- Orbital reconstruction
- Correction of craniosynostosis

Pediatrics

- Pediatric craniotomy
- Pediatric craniosynostosis
- Pediatric sternotomy in revision

Oncology

- Bone tumor resection

Reconstructive Surgery

- Bone harvest from fibula, iliac crest, chin, and parietal
- Maxillary and mandibular reconstruction
- Orbital reconstruction
- Vastus intermedius perforator periosteal flap (VIPP) for complex facial reconstruction
- Osteo-periosteal flap for revascularisation of femoral head (hip necrosis)



LeFort I



Chin graft



Displasia



Orbitotomy

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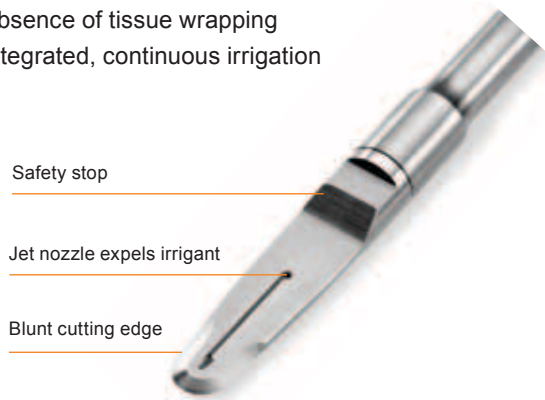
- Linear blade travel
- Straight ultrasonic blade
- Blade thickness as small as 0.5 mm
- Insertion depth as deep as 20 mm
- Dynamic cooling & lubrication

The BoneScalpel cuts osseous structures through the linear, ultrasonic stroke of a blunt blade. The microscopic movement is comprised of highly repetitive impacts to the bone at a rate of 22,500 strokes per second. The recurring impacts diminish the integrity of the rigid bone resulting in a controlled dissecting split.

The resulting osteotomy kerf can be as thin as 0.5 mm and up to 20 mm deep. A patented liquid pathway directs the irrigation fluid to the blade-tissue interface, facilitating safe, clean, and non-necrotic bone dissection.

SOFT TISSUE SPARING

- Elastic tissue response
- Absence of tissue wrapping
- Integrated, continuous irrigation



The BoneScalpel osteotomy is atraumatic to soft tissues. The blade is blunt and travels in a linear motion, which eliminates wrapping and tearing. In addition, soft tissue has elastic properties that allow it to deform and rebound without failure to its integrity. Osteotomies can be performed in close proximity to delicate structures.

Tissue response to the ultrasound action differs by tissue density, collagen content, blade pressure and exposure time. Integrated, continuous irrigation is used to compensate for thermal effects. A continuous, lateral sweeping motion is recommended in order to minimize contact duration with the ultrasonic blade.

REDUCED BLEEDING

- Coagulum due to protein denaturation
- Patented fluid pathway for efficient irrigation
- Minimal & controllable tissue necrosis

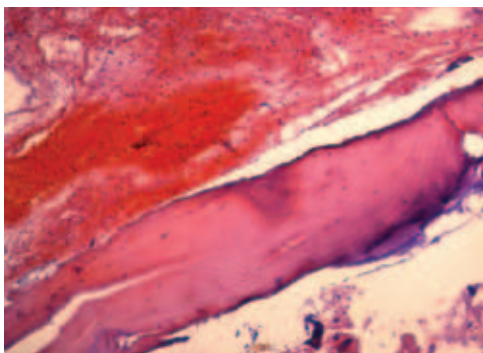
Coagulation starts below the necrosis threshold minimizing intra-operative bleeding and keeping the surgical site clean and relatively blood free. Tissue

necrosis remains minimal and can be mitigated through adjustment of system parameters and surgical technique. A proprietary fluid pathway is instrumental in directing irrigation for purposes of cooling and lubrication over the blade and directly into the kerf.



BONE PRESERVING

- Non-abrasive, controlled split
- Minimal bone loss
- Efficient cooling of osteotomy site
- Reduced bone necrosis



The BoneScalpel's controlled, non-abrasive split, in combination with the thin blade geometry, minimizes loss of bone from the osteotomy itself. In addition, the ultrasonic cut can be controlled to avoid necrosis of the bone surfaces. Preservation of cortical and cancellous bone is favorable compared to other power instruments. Macroscopic observation confirms absence of visible necrosis; vitality of osteoblasts was confirmed following random sampling of collected bone debris.

IMPROVED EFFICIENCIES

The Misonix BoneScalpel™ combines important safety and control aspects associated with hand instruments, like Kerrison punches and Leksell Rongeurs, with the convenience and ease of powered instruments, such as drills, burrs and saws.

The longitudinal blade motion enables precision osteotomies free of gyroscopic effects and facilitates cutting techniques for en-bloc bone dissection and in close proximity to delicate soft tissue structures.

Coagulative effects contribute to a reduced bleeding and a clean surgical site. This allows for a new level of efficiency in performing osseous resections, with the opportunity to alter surgical technique and shorten O.R. time.

Substantial time savings have been reported for advanced osseous resections in the spinal anatomy such as multilevel laminectomies, bilateral facetectomies, and intra-oral resection of the dens.



RECIPROCATING SURGICAL BLADES AND TIPS

- Atraumatic tip designs and reciprocating ultrasound action for controlled bone removal and preservation of soft tissues
- Universal tip designs for multifunctional surgical use
- Choice of cutting directions for front insertion, side- and undercutting
- Multiple tips with extended reach for applications in microscopic or MIS surgery and approaches to deep body cavities



RECIPROCATING SHAVING TIP

- Powerful, burr-like bone removal
- Abrasive surface enables side- and undercutting in hard to reach areas and in close proximity to delicate soft tissue structures
- No walking/skiving upon tip activation
- No wrapping or tearing of soft tissues

The BoneScalpel shaving tip allows for delicate yet powerful bone fragmentation in tight cavities. Due to the absence of wrapping or tearing of soft tissues the tip can be operated in close proximity to delicate soft tissue structures. Placed in position, the tip does not walk or skive upon activation unlike rotary power instruments that suffer from a gyroscopic effect. This allows for very controlled and precise bone removal.



UNIVERSAL RECIPROCATING BLADE

Product development experts from Misonix joined forces with maxillofacial surgeons Roland Gilles (MD, DDS) and Sophie Dammous (MD, DDS) to enhance the BoneScalpel and expand its application in orthopedics, reconstructive and neurological surgery:

Design Objectives

1. The blade's blunt distal tip with its rounded shape and beveled edges was maintained to enable cutting from the top and direct insertion deeper into the bone.
2. Unilateral serrations were added to allow bone cutting with the lateral blade side similar to a reciprocating saw.
3. All cutting surfaces are designed to be atraumatic for protection of underlying nerves and blood vessels. The unilateral serrations are coarse and relatively smooth. The contralateral side is left blunt for safe maneuvering within the oral cavity.
4. Multiple line markers were added on the blade surface to gauge insertion depth into the bone.
5. A soft protective element out of silicone was added to prevent burns to lips or mucosa. In addition, it provides an improved grip area.



We adapted the ultrasonic blade of the BoneScalpel to serve as a universal instrument for orthognathic and maxillofacial surgery. We have since performed well over 100 procedures including orthognathic, reconstructive and oncologic surgeries. Using the BoneScalpel we have much better control over the osteotomy and have observed significantly fewer bad splits and reductions in nerve impairment, swelling, hematoma, operative time and hospital stay.



Roland Gilles, MD, DDS
Sophie Dammous, MD, DDS
Oral & Maxillofacial Surgeons
Liege, Belgium

CONFIGURATIONS FOR MINIMALLY INVASIVE SURGERY

Precise bone removal, sparing of soft tissues and long, narrow access paths to remote body areas are important characteristics of minimally invasive bone surgery. The BoneScalpel offers blades with extended reach, e.g. for surgery in heavy patients, anterior, lateral or thoracic access.

Long straight and long curved configurations are available for microscopic applications or for access through micro retractors for minimally invasive or endoscope-assisted spine surgery.



The micro bone shaving tip expands possibilities for bone removal by enabling side- and undercutting for tissue-specific bone fragmentation in small cavities and hard to reach areas.



“ The BoneScalpel has allowed me to take my microscopic spinal surgery to a new level. I have precise control over all blades and shavers without any walking, skiving, wrapping or tearing. Additionally, it is so gentle to nerves and arteries that I did not have a single dural tear in 100 surgeries from lumbar to cervical despite taking on more complex anatomies and older patients in their 80s and 90s. ”

Uwe Hassepass, MD
Neurosurgeon
Pforzheim, Germany

ORDERING INFORMATION

BONE SCALPEL™ SYSTEM

BCM-SY	<p>Misonix BoneScalpel™ - Ultrasonic OsteoSurgery System</p> <p>Featuring:</p> <ul style="list-style-type: none"> • Ultrasonic OsteoSurgery • Ultrasonic Debridement and Cleansing <p>Includes:</p> <ul style="list-style-type: none"> • Ultrasonic Console • Two handpieces with wrenches • Footswitch and system accessories <p>Console can be configured for 110-130V, 60Hz and 200-240V, 50Hz</p>
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BONE SCALPEL REUSABLE ITEMS - AUTOCLAVABLE

BCM-HP	Ultrasonic handpiece, universal, for hard and soft tissue applications
BCM-SS	Probe cover, for hard tissue tips
BCM-H2	Probe cover, for soft tissue tips
BCM-CW	Counter wrench, for BoneScalpel handpiece
BCM-2W	T-wrench, for hard and soft tissue tips
BCM-CBS	Small cleaning brush set
BCM-CBL	Large cleaning brush set
E-SYSCART	System cart

BONE SCALPEL SINGLE USE ITEMS - STERILE

MXB-T	Irrigation Tube set
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TIPS FOR HARD TISSUE REMOVAL

MXB-10	Bone Scalpel – 10mm, Blunt • includes 10mm blade and short extension
MXB-10LC	Bone Scalpel – 10mm, Blunt, Long Curved • includes 10mm blade, long curved extension, and silicone sleeve
MXB-10LS	Bone Scalpel – 10mm, Blunt, Long Straight • includes 10mm blade, long straight extension and silicone sleeve
MXB-20	Bone Scalpel – 20mm, Blunt • includes 20mm blade and short extension
MXB-B1	Bone Scalpel – 20mm, Unilateral Serrations • includes blade, short extension and silicone sleeve
MXB-S1	Bone Shaver – Micro Hook • includes shaver tip, short extension and silicone sleeve

TIPS FOR SOFT TISSUE REMOVAL

MXC-C1	Curette Style Titanium Probe for Debridement
MXC-R1	Cylindrical Titanium Probe for Debridement
MXC-X1	Hatched Titanium Probe for Debridement

“ The ultrasonic BoneScalpel allows me to perform a more precise and less traumatic osteotomy for my spinal deformity surgeries. I have used it in over 20 cases so far and with each procedure, I am learning more about its utility in enhancing the precision of spine surgery. Using the blade I am now able to complete bilateral facetectomies from T2/3 to T11/12 in less than 15 minutes. ”

Isador H Lieberman MD MBA FRCSC
Orthopedic Surgeon
Texas Back Institute
Plano, TX

Schedule a BoneScalpel demonstration by contacting your local Misonix representative
or Misonix Customer Service at 1-800-694-9612 (U.S.) or +1-631-694-9555 (Int).
e-mail: sales@misonix.com

