



EDCO FORUM[®]

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TENS FOUND TO PROVIDE CLINICALLY MEANINGFUL REDUCTION IN PAIN.

Health Economics Study Provides the TENS Evidence CMS Seeks

Clinical guidelines published by the American Society of Anesthesiologists Task Force on Chronic Pain Management recommend the use of transcutaneous electrical nerve stimulation (TENS) for chronic low back pain (CLBP) and other chronic non-cancer neuropathic, somatic, or visceral pain syndromes.

In June 2012, however, the U.S. Center for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) which restricts reimbursement to patients in approved clinical trials. The CMS NCD calls for explicit achievement of clinical metrics in order to further evaluate the value of TENS for helping to reduce pain and improve quality of life for patients with CLBP.

“What Medicare is asking for is randomized controlled trials in patient populations with some kind of comparative treatment and evidence that you followed these patients over time,” said Michael Minshall, MPH, Senior Director, Healthcare Economics & Reimbursement at DJO Global.

Minshall and his team performed a retrospective analysis of a commercial and Medicare administrative claims database. After parsing patient records (2008-2010), the researchers identified those that had at least two ICD-9-CM coded claims for low back pain during a consecutive three-month period.

“We looked at real world utilization. We did not exclude patients with comorbidities. We *did* include patients who are high risk for CLBP and other comorbidities. The study’s inclusion and exclusion criteria are pretty minimal if not nonexistent.” Minshall said. “Most published clinical trials in CLBP are three to six months in length and probably not long enough to clearly assess the value of TENS and may exclude CLBP patients with significant comorbidities and other medical problems.”

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NAVIO™ ASSISTED PARTIAL KNEE REPLACEMENT

Search the medical literature and you will not yet find studies published about Blue Belt Technologies’ Navio™ Orthopedic Surgical System. However, talk with orthopedic surgeon Raul Marquez, MD, an instructor on the use of computer aided technology and navigation techniques, and you’ll quickly learn that this innovative system offers clinical advantages. “The Navio™ is excellent,” said Dr. Marquez, who is on staff at Cornerstone Regional Hospital in Edinburg, TX.

What Makes the Navio™ System Unique?

Computed Tomography (CT) Free

- No pre-operative imaging required.
- Saves patient from radiation exposure.

Handheld with Precision and Reproducibility

- Reliability and consistency outcomes.
- Puts robotics into the surgeon’s hand.
- Reduces the presence of outliers.

Open Platform

- Open implant architecture offers greater choice to robotic-assisted procedures.

Portability

- No complex calibration required.
- Easy operating room integration.
- Quick room turnover.
- Small footprint.

Surgeon Controlled

- Reduces the reliance on the manufacturing representative to drive a case forward.
- Puts the control in the surgeon’s hands.

Cost Efficiency

- Economically sound.
- Low cost-of-entry.
- Rapid and achievable results.

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Researchers Respond to CMS Call for Rigorous Research

To address Medicare's call for hard evidence, researchers compared primary outcomes (inpatient hospital and outpatient treatment including physical therapy utilization; incidence of back surgery; and other direct medical costs) across treatment groups. The study used propensity scoring statistical methodology to match nearly 23,000 CLBP patients in a 1:1 fashion with nearly 23,000 demographically and clinically similar CLBP patients who did not use TENS. This methodology allows researchers to compare outcomes between groups of patients who differ only on which treatment they receive while holding all other demographic and clinical variables consistent between the two groups.

"It's hard to refute the study. There's 23,000 patients. We followed 23,000 patients for a year before and a year after the device and compared them with 23,000 patients who did not get TENS but had clinically diagnosed back pain." Minshall said.

TENS Found to Provide Clinically Meaningful Reduction in Pain

Peer-reviewed studies provide evidence that TENS ameliorates back pain. For example, "TENS may be a useful adjuvant in the management of chronic low back pain which may be more difficult to manage than new-onset acute low back pain." said Robert Pivec MD, with the Rubin Institute for Advanced Orthopedics at the Sinai Hospital of Baltimore. "TENS is [also] an effective non-opioid alternative that not only decreases back pain, but also appears to reduce opioid use."

The study's extensive review supported Dr. Pivec's clinical experience and revealed some telling health outcomes. Hospital and clinic visits were less for patients treated with TENS. In addition, TENS patients required less use of diagnostic imaging (31 compared to 46 events per 100 patients) and fewer physical therapy visits (94 vs. 107 per 100 patients). Back surgeries were also performed less in the TENS group (7.5 vs. 9.2 surgeries per 100 patients).

Though there is no specific measure of quality of life recorded in administrative claims data, "the fact that the patients went to the doctor less and utilized fewer medical resources is highly indicative that they tended to be feeling better, especially given they started at a lower baseline of health." noted Anthony Strike, Market Manager, Electrotherapy at DJO Global.

TENS Offers Tangible Healthcare Savings for CLBP Patients

"What our study demonstrates and demonstrates pretty clearly is that TENS may provide demonstrable value and improved efficiency for the healthcare system." commented Minshall.

Further analysis emphasizes just how much of a savings. "The economics speak for themselves." said Minshall. Researchers developed the chart on this page to translate their findings into potential offsets of Medicare costs. Of the nearly 50 million Medicare beneficiaries who received care in 2012, we estimated that 1.5 million were treated for CLBP. If medical resource savings observed in our study were applied to the Medicare population, 27,000 back surgeries could be avoided at an estimated cost of nearly \$900 million to Medicare. Prescribing TENS instead of surgery could have saved Medicare not only this tremendous expense, but overall projected cost offsets approaching \$1.3 billion while putting TENS on every Medicare-treated CLBP patient would cost \$881 million and provide nearly \$418 million in estimated savings.

TENS Positive for Patient Satisfaction

"Pain is a key driver in a patient's decision to seek treatment from clinicians. Many clinicians are concerned about giving prescriptions for narcotics to reduce pain. The EMPI TENS device has been shown to be effective in meeting those patient and clinician needs." Wolfington said.

"In addition, physicians that offer conservative care options prior to surgery have seen an increase in patient satisfaction. TENS is available both in the physical therapy clinic as well as in a home version with the EMPI Active. Therefore patients can get engaged in their care and continue their pain control treatment from the MD office to the clinic to their home." explained Wolfington.

To encourage patient engagement in overall health and selection of conservative treatments (which reduce the risk of long periods of inactivity and the related health issues), DJO Global launched the *Motion is Medicine* (MIM) initiative. MIM aims to help patients restore motion and improve their lives by addressing four common areas; pain, alignment, strength and

TENS vs. No-TENS in Chronic Low Back Pain (CLBP)

Illustration for Estimated Costs and Projected Savings to Medicare Patients in the USA

| Total Number of Medicare Beneficiaries (2012) ¹ | Point Prevalence of CLBP ^{2,3} | Estimated % of CLBP Patients Treated ^{4,5} | Estimated Number of Patients w/CLBP Treated in Medicare | |
|--|---|---|---|---|
| 49,435,610 | 10.2% | 30% | 1,512,730 | |
| Event | Incremental Event Rate Difference over 1 Year of Follow-Up in All Patients ⁶ | Events Avoided from CLBP Patient Population | Average Cost per Event ⁷ | Potential Cost offsets over CLBP Patients |
| Back Surgery | 0.018 | 27,229 | \$32,555 | \$886,444,457 |
| Imaging | 0.146 | 220,859 | \$832 | \$183,754,298 |
| Physical Therapy | 1.267 | 1,916,628 | \$92 | \$176,329,821 |
| ER Visits | 0.033 | 49,920 | \$760 | \$37,939,260 |
| Opioid Therapy | 0.203 | 307,084 | \$46 | \$14,125,870 |
| TOTAL POTENTIAL COST OFFSETS | | | | \$1,298,593,705 |
| TENS Cost | \$295.00 | | | |
| Supply Cost (1 Month) | \$47.90 | | | |
| 6 Month Supply Cost | \$287.40 | | | \$881,013,757 |
| Total Cost Per Pt | \$582.40 | | | |
| Potential Cost Reductions for payer | | | | \$417,579,948 |

"Some payors, including CMS, now require that physicians use conservative modalities prior to giving authorization or payment for surgical intervention," said Sharon Wolfington, President of Global Recovery Sciences, DJO Global. "Clinical research has shown that certain risk factors are predictive of readmissions and complications following surgical intervention. As a result, many clinicians are using this data to create patient triage pathways for both conservative care and surgical care based on those risk factors."

stability. MIM encourages CLBP patients to select treatment options which optimize activity level, thereby decreasing their risk for diabetes, heart disease and other conditions associated with low levels of physical activity. ♦

For more information about this TENS Study and Motion is Medicine, please visit djoglobal.com/empi and djoglobal.com; or speak to a representative at the AAOS conference, Booth #1349.

THE CHECKPOINT® STIMULATOR/LOCATOR

A Significant Advance in Neuroprotective Surgery

Recent advances in nerve stimulation technology allow surgeons to practice “neuroprotective surgery” – employing surgical techniques designed to protect and preserve nerves during surgery. The **CHECKPOINT® Stimulator/Locator**, from **Checkpoint Surgical**, is a state-of-the-art hand-held, intra-operative nerve and muscle stimulator that helps surgeons *locate, identify and evaluate* motor nerve tissue and muscle function in surgical procedures that require careful and precise soft tissue dissection or nerve exploration and repair.

With more than 45 million surgeries performed in the United States each year, the Checkpoint addresses an important issue: protecting nerves from intra-operative nerve injury. The risk of nerve injury during surgical procedures is significant and such an injury can be life-altering for the patient. The Checkpoint can assist in locating a nerve through surrounding tissue allowing the surgeon to activate the nerve without dissecting it out or avoid the area where the nerve is detected.

Scott H. Kozin, MD, Professor of Orthopaedic Surgery at Temple University, and Chief of Hand Surgery at Shriners Hospitals for Children (Philadelphia, PA), said that prior to having the Checkpoint he used a relatively inexpensive, disposable device that did not reliably or reproducibly provide information to help in his surgical decision making. “The old device often did not work properly and provided only a single electrical stimulation that was not phasic. Because that stimulator was not able to replicate what happens when a normal nerve fires, it could give a false negative or a false positive.” Dr. Kozin continues, “The Checkpoint, on the other hand, works 100% of the time, provides a bi-phasic current that is adjustable in terms of the dose and pulse width, and it provides consistently reliable information that gives me confidence when making decisions during surgery.”

About 50-60% of Dr. Kozin’s practice involves pediatric nerve cases, many of which include procedures for brachial plexus injury in infants. Dr. Kozin notes that the Checkpoint makes the surgery more efficient for him, while helping to identify the nerves that are primarily affected by the injury. “When I expose the brachial plexus, I use the Checkpoint to define both normal and abnormal anatomy. I can stimulate the phrenic nerve to make sure it is appropriately mobilized out of the way and working, and then I stimulate the various roots of the

brachial plexus to confirm that my surgical findings are consistent with my physical examination prior to surgery. Once I know the uninjured nerves are working and safely mobilized out of the way, I can turn my attention to the damaged nerve segments.”

Dr. Kozin cites another example where he used the Checkpoint in a pediatric procedure. “We had a fracture of the forearm, where the ulnar nerve was trapped in the bone. We chiseled away the bone and then had to decide whether to resect the nerve and graft it, or determine whether the nerve still had ample fascicles in it for function. The Checkpoint demonstrated there was some conduction into the hand, so we opted not to resect it. In the past, I didn’t have a device that I could rely upon to make this kind of decision, and now I do.”

“The Checkpoint is a much more sophisticated device than the one we had before,” notes Milan Stevanovic, MD, PhD, Professor of Orthopedics and Surgery, University of Southern California; Departments of Orthopaedic Surgery and Pediatrics at the Childrens Hospital Los Angeles (Los Angeles, CA). “With the Checkpoint, you can more efficiently and precisely locate and evaluate the nerves. With the variable stimulation intensity control, I am able to change the amount of stimulation to the nerve to be sure there is some transmission. Additionally, with this device we can also locate and stimulate nerves deeper into the tissue than with the previous stimulator, which would only allow you to stimulate a nerve if you dissected it.” Dr. Stevanovic says he uses the Checkpoint in cases involving pediatric patients with brachial plexus palsy, obstetric brachial plexus palsy, as well as adults with traumatic injury of the brachial plexus. “I can also use the Checkpoint if I need to identify the axillary nerve or other nerves in the shoulder if a total joint surgeon needs us to dissect a nerve to prevent any injury around the joints.”

Checkpoint® is being used by surgeons in a variety of orthopedic procedures that require careful and precise soft tissue dissection including brachial plexus procedures, shoulder and elbow revision, reverse shoulder arthroplasty, and non-union fracture repair. The Checkpoint is not only a reliable tool for locating and identifying nerves, but also helps surgeons assess nerve and muscle function from initial exposure, throughout the case, and prior to closing. If suboptimal function is observed, the surgeon can assess options to



Checkpoint® Stimulator/Locator

improve function. This kind of feedback allows surgeons to make on-the-spot clinical decisions with greater confidence.

Developed by a world-class team of surgeons and biomedical engineers, the FDA-cleared Checkpoint® is a single-use device that is easy to use. The Checkpoint’s unique combination of features allows surgeons full control over a wide range of stimulus settings (.5mA, 2mA, 20mA), for nerve and muscle stimulation. A slide control allows precise variation of the pulse width from 0 to 200 microseconds, so surgeons can adjust the stimulation as the situation warrants. The reliable electronic circuitry provides a biphasic waveform with continuous adjustable stimulation, always within safe parameters, and an LED indicator light provides continual visual feedback to confirm that stimulation is being delivered. The Checkpoint comes sterile and ready to use and there is no need for advance set-up. The comfortable, ergonomic device is designed for one-handed use that allows greater maneuverability with an unobstructed view of the surgical site.

Checkpoint Surgical, headquartered in Cleveland, Ohio, is devoted to providing physicians with state-of-the-art medical devices that support “neuroprotective surgery,” leading to better patient outcomes. A surgeon needs to experience Checkpoint personally to really appreciate the true value that the technology delivers. ♦

To trial Checkpoint at your hospital or surgery center, you need only to email info@checkpointsurgical.com. For more information about the Checkpoint® Stimulator Locator; call 877-478-9106; visit the website at www.checkpointsurgical.com or speak to a representative at the AAOS conference, Booth #6055.

CONTRAINDICATION:

Do NOT use this Stimulator when paralyzing anesthetic agents are in effect, as an absent or inconsistent response to stimulation may result in inaccurate assessment of nerve and muscle function.

Other orthopedic surgeons echo Dr. Marquez's sentiment. Pennsylvania-based orthopedic surgeon Brian R. Hamlin, MD, who performs about 150 primary knees and 30 to 40 partial knee surgeries per year, said, "I have been working with Blue Belt since 2011 regarding development of workflows and improving usability. Surgeons that have an interest in partial knee replacement and desire to give their patients the greatest likelihood of long term success should seriously consider a robotic-assisted system like the Navio™ System."

The Navio™ System Gives Surgeons Precise Robotic Control

FDA granted 510(k) clearance to sell and market the Navio™ System in December 2012 and the first unit was sold in the U.S. in January 2013. Six months prior to this, however, Navio™ received CE marking (formerly the EC mark) for distribution in Europe. Therefore, the first Navio™ assisted partial knee replacement was performed in Belgium in July 2012.

Across the last year, surgeons around the globe trialed the Navio™ System in various practice settings, including teaching hospitals, community hospitals, and outpatient ambulatory surgical centers. They used five different manufacturer's implant systems to perform precision partial knee replacement surgery using the Navio™ robotic-assisted system. The results revealed the accuracy and consistency of the Navio™.

The Navio™ system incorporates patented technology to provide precise robotic control to surgeons via an intelligent, handheld, computer-assisted bone cutting tool. Thereby, it provides the pluses of robotics, while also allowing surgeons to be in better control of the surgical procedure.

Surgeries Go "As Planned"

"My experience [with the Navio™] to date has been very good. In all cases the final result matched perfectly to our plan." Dr. Hamlin said. Through a CT-free approach, Navio enables kinematic and anatomic registration, sophisticated implant planning with soft-tissue balancing techniques and robotic-assisted bone preparation for precise and repeatable results.

"Ultimately we all desire as orthopedic surgeons to provide for our patients the best outcomes. We know from data using traditional techniques that long term outcomes are directly related to the accuracy of implant placement/position. Therefore, it only makes sense that a system that allows one to place the implants in a position that optimizes alignment, gap balance, and tracking should be embraced." Dr. Hamlin explained.

"The Navio™ offers exceptional accuracy—what you plan is what you get" said Dr. Marquez, who has performed close to 7,000 surgeries in his career—of those, 500 were performed using robotics. The Navio™ software permits surgeons to strategically place the implant while simultaneously balancing the soft tissue of the knee. By controlling the exposure of the bur from the guard, the Navio™ prevents clinicians from cutting outside the defined boundaries while placing the implant.

Ease of Use, Accuracy, and Affordability Set the Navio™ Apart

Robotic-assisted systems allow surgeons to better tailor treatment plans to each patient and more accurately prepare the bone to ensure positive outcomes. Orthopedic surgeons who have used the Navio™ System highlighted three tangible benefits of this new robotic-assisted system.

Ease of Use

"The Navio is less cumbersome than other robotic-assisted systems. Compared to other systems it is much smaller, which makes it easier to transfer from one place to another for surgery and for cleaning, said Dr. Marquez.

"I prefer Navio™ over the competing robotic technology due to ease of use. It is an imageless system. The patients' important anatomic landmarks are registered at the beginning of the procedure building a virtual representation of their femoral and tibial anatomy from which the surgical procedure is planned." Dr. Hamlin said.

Accuracy

"Accuracy is superb," said Dr. Hamlin. "The Navio™ System cuts the bone exactly where you plan. The ability to have a balanced gap throughout the range of



Navio™ Orthopedic Surgical System

motion is far superior to what one can do with a freehand technique."

"Compared to conventional techniques, robotic assistance with the Navio™ System has substantially improved the precision of bone preparation, prosthesis alignment, and soft tissue balance in partial knee replacement, all of which may improve outcomes and durability." Jess Lonner, MD, orthopedic surgeon at the Rothman Institute in Philadelphia said.

Affordability

"Compared to other systems, the Navio™ is both safer and more affordable." Patients usually recover faster." said Dr. Marquez. "There is less soft tissue dissection. Patients often have an excellent range of motion and many do not require physical therapy. In general, patients experience about half the usual recuperation time."

"The cost for the Navio™ System is significantly less than the competing robotic-assisted systems on the market. On a case-by-case basis it is less expensive for the patient and the healthcare system—as no pre-op imaging is required. This is going to become even more significant as we move towards bundled payments." Dr. Hamlin noted.

About Blue Belt Technologies

Blue Belt Technologies, Inc. is developing the next generation of "smart" surgical instruments for initial use in orthopedic procedures. ♦

For more information about the Navio™ Orthopedic Surgical System, please call Blue Belt Technologies at 763-452-4950; visit www.BlueBeltTech.com or speak to a representative at the AAOS conference, Booth #735.

MEDITAB INTELLIGENT MEDICAL SOFTWARE FOR NEUROLOGICAL AND SPINE SURGEONS

With a Laptop or Tablet PC You Can Have Full Access To Patient Charts From Any Location in Real Time

Neurological and spine surgeons are a specialty that requires particular tools and modules for specific patient services from their Electronic Health Record (EHR). Because Meditab's Intelligent Medical Software (IMS) is tailored to work the way you do, it is easy to capture, manage and use health information to make informed decisions at the point of care, which lowers costs and improves patient outcomes.

Founded in 1998 by practicing pharmacists and physicians, Meditab Software Inc. provides an innovative suite of intelligent, integrated and intuitive software solutions supporting healthcare delivery at private practices, hospitals, diagnostic centers and health clinics. Meditab's solutions meet the needs of your practice, regardless of size or specialty.

Darien Behravan D.O., AQPM, founder of the Bay Area Pain and Spine Institute in San Francisco and a Stanford University fellowship-trained pain management specialist, has used Meditab software since 2004 and champions it enthusiastically. "My two favorite aspects of the software are its user-friendliness and the fact that when I need changes made to the software that reflect my practice, Meditab is highly responsive and makes those updates right away. With other software companies, you may wait eight months to a year for an update—but not Meditab."

Spine Surgeon Electronic Medical Office (EMO)

Meditab's unique team approach builds your custom solution and helps you seamlessly transition to an Electronic Medical Office (EMO). Installation, training and ongoing support are all performed by a local team of Meditab professionals.

"I have had people on staff who are computer savvy and I have also had staff with an aversion to computers and software," reports Dr. Behravan. "Both quickly learn the Meditab software. The company provides modules that include scheduling, billing, prescriptions, imaging, letters and forms, among others. I can call Meditab ahead of time, and they have my modules saved, so I can train staff whenever I want. I will have the new hire go through the module and view it multiple times to learn the system."

Affordable, Modular And Scalable

Whether on a Web-based or client-server platform, Meditab's IMS is affordable, modular and scalable in nature. Meditab

collaborates with clients to meet their needs, and practices can start small and grow as their needs change. The scalable design supports both the single-doctor clinic and the large multi-clinic enterprise. This approach ensures the affordability of the software.

You can manage patient intake, scheduling, authorizations, referrals, claims, reports, and all other administrative tasks within your practice, implementing only those modules pertinent to the way your office or clinic delivers healthcare.

IMS Clinical™

As a HIPAA compliant software application for medical practices, IMS meets and exceeds ambulatory practice needs. The software is built with innovative functionality such as clinical decision support, flow charts, health maintenance, chronic care management, e-prescribing, electronic labs and much more.

IMS Clinical™ helps providers to determine the proper diagnosis, and recommends appropriate treatment plans common to the providers' practice habits. You can manage patient exams, screenings, immunizations, and tests due for the patient. You can automate schedules and orders to improve both compliance to care measures and patient health.

Specifically designed to meet "meaningful use" criteria, Meditab Chronic Care Management (CCM) allows for the proactive management of chronic conditions through flow-sheets, clinical alerts, and innovative reports. User defined flow sheets allow providers to easily graph, trend, and view patient progress over a specified period of time by capturing, analyzing, and trending critical care measures.

Imaging

When it comes to imaging, you can readily access, tag, annotate, and/or import images to the encounter note for visual representation. Imaging allows for connectivity with 3rd party imaging system (PACS, X-ray, etc.) that can be accessed from the patient chart.

"I can easily save a pdf file into the patient's chart," states Dr. Behravan. "With two clicks, the entire record is updated. The software substantially cuts down on the amount of time required for charting. Besides that, I have virtual private network (VPN) access, so I can sit on the beach in Hawaii and still be able to access patient charts."

"My two favorite aspects of the software are its user-friendliness and the fact that when I need changes made to the software that reflect my practice, Meditab is highly responsive."

**- Darien Behravan, D.O., AQPM,
Bay Area Pain and Spine Institute**

As a "Hybrid" system, IMS offers users the option to choose from multiple styles of data input such as:

- Point & Click
- Handwriting Recognition
- Voice-to-text
- Dictation

HITECH Incentive Payments

President Obama signed into law the American Recovery and Reinvestment Act of 2009 (ARRA) February 17, 2009 to not only stimulate the economy but also to transform the healthcare system in an effort to improve quality, safety and efficiency of care. To help facilitate this vision, the Health Information Technology for Economic and Clinical Health Act (HITECH) established programs under Medicare and Medicaid to provide incentive payments for the "meaningful use" of certified EHR technology.

The Medicare (up to \$44,000 per provider) and Medicaid (up to \$63,750 per provider) EHR incentive programs will provide incentive payments to eligible professionals and eligible hospitals as they adopt and implement certified EHR technology. October 1, 2012 will be the last day for eligible professionals to begin their 90-day reporting period to demonstrate "meaningful use" for stimulus incentives to receive payments in 2013.

Meditab has a team of nationally certified Authorized Partners in your community, committed to giving you personal service, support, implementation, training, consulting and to assist you in determining what your practice will need to demonstrate "meaningful use" and take advantage of the ARRA incentives.

For more information about Meditab for your medical practice, please call (510) 632-8021 or (866) 99-GO-EMR; visit our website at www.meditab.com or speak to a representative at the AAOS conference, Booth# 6055.

MISONIX BONEscalpel™ BONE CUTTING SYSTEM

New Ultrasonic Surgical Device Facilitates Rapid, Safe, Precise, and Hemostatic Osteotomies

The Misonix BoneScalpel™ provides precise cuts through osseous structures with minimal loss of viable bone and minimal trauma to adjacent soft tissues. This new ultrasonic surgical device combines important safety and control aspects associated with hand instruments, such as Kerrison punches and Leksell Rongeurs, with the convenience and ease of powered instruments, such as drills, burrs and saws.



BoneScalpel - Ultrasonic handpiece configurations

“The BoneScalpel is a powerful addition to our armamentarium of bone removal devices,” asserts Dr. Nicholas Theodore of Barrow Neurosurgical Associates, Ltd., headquartered in Phoenix. A neurosurgeon whose subspecialties include neurological trauma surgery, complex spinal surgery and peripheral nerve surgery, Dr. Theodore recently received a highly prestigious NIH RO-1 grant, less than 10 percent of which are funded nationally, to study spinal injuries and novel approaches to spinal surgery. He has been using the BoneScalpel for more than a year and says that the instrument “allows us to make very precise cuts adjacent to critical structures, such as the spinal cord.”

Isador H Lieberman, M.D., MBA, FRCSC, and orthopedic surgeon at the Scoliosis & Spine Tumor Center, Texas Back Institute and Texas Health Presbyterian Hospital in Plano, reports, “The BoneScalpel is a safe and effective bone cutting device that can be used to facilitate osteotomies in a variety of spine surgeries. This device may obviate the need for and risk of high speed

burrs and oscillating saws during spine surgery. It’s a very versatile and safe device, with multiple applications to carve and craft bone.”

After using the BoneScalpel for almost two years now in more than 200 cases in the cervical, thoracic and lumbar spine, Daniel Rosenthal, M.D., a neurosurgeon specializing in minimal access approaches to the spine in Bad Homburg, Germany, adds, “This instrument is a superb device for cutting bone sharply and precise with almost no detritus. Since ultrasound energy dissipates in soft tissue such as dura, nerves and vascular structures, this device is the ideal tool for bone removal in critical areas.”

How It Works

The Misonix BoneScalpel™ handpiece uses an electrical signal of 22.5 kHz from its ultrasonic console. A piezoelectric transducer converts the input signal into mechanical vibrations at the same ultrasonic frequency that are further amplified in order to achieve efficient cutting characteristics. The blunt blade oscillates in a linear, piston-like

motion, enabling an effortless dissection of hard, cortical bone. This 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 tissues. A patented liquid pathway directs the irrigation fluid to the blade-tissue interface, compensating for thermal effects, and facilitating safe, clean and non-necrotic bone dissection.

“The BoneScalpel doesn’t spin and doesn’t perceptibly oscillate, but creates very fine, clean cuts in the bone without all the pounding and without the risk of a burr spinning and catching soft tissue. It gives you the precision and efficiency with much less risk,” concludes Dr. Lieberman.

When rigid bone comes in contact with the BoneScalpel blade it does not bend, deform or move away. As a result, the bone absorbs a large portion of the energy and the recurring impacts at 22,500 times per second diminish the bone’s integrity, allowing for a controlled, dissecting split.

In contrast, soft tissue responds elastically to contact with the impacting blade; it moves, deforms and vibrates. The absorbed energy is generally not sufficient to cut soft tissue unless it is held against the blade at high tension or for a long period of time. Tissue response to the ultrasound action differs by tissue density, collagen content, blade pressure and length of exposure.

Result: A New Level of Efficiency

The resulting osteotomy is very precise and its kerf can be as thin as 0.5 mm and up to 20 mm deep into the bone without any visible bone dust that is typical for rotary sharps. Loss of viable bone is thus minimal and coagulative effects contribute to minimal bleeding and a cleaner surgical site.

According to Dr. Theodore, “One nice aspect of the BoneScalpel is that as it cuts, it has a hemostatic effect. I am impressed by the fact that when we are doing a cervical, lumbar or thoracic surgery and are taking bone away, the blood loss is much less than it would be without the instrument.”

The BoneScalpel allows more 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 and bilateral facetectomies. “The BoneScalpel certainly has made bone resection easier and quicker,” Dr. Theodore states.



BoneScalpel - Ultrasonic Console

Dr. Lieberman notes that, “Using the BoneScalpel, I am now able to complete bilateral facetectomies from T2/3 to T11/12 in less than 15 minutes.”

Dr. Theodore concludes, “It improves efficiency and safety by diminishing the need to use non-powered hand tools.”

Facilitating Tumor Resections

“I use the BoneScalpel in arthrorectomy or vertebrectomy, and to decompress the foramina,” says Dr. Rosenthal. “In my opinion, it replaces the saw or drill in spine surgery.” He also finds the BoneScalpel highly useful when it comes to resecting bone tumors. “Vertebrectomy for tumor disease can be performed more accurately and cleanly. Debris is negligible, so the chances of spreading tumorous tissue with the instrument are markedly reduced.”

Dr. Theodore, who handles everything in the spine from congenital developmental problems in children, to disorders of the aging population, to trauma and infection, states that he has used the BoneScalpel in several bone tumor surgeries. “Once we define the anatomy, the BoneScalpel helps us to minimize blood loss when cutting through bone. Tumors

tend to be very vascular, and the instrument helps us to remove that tissue in a less bloody fashion.” He comments that he also appreciates the safety profile of the tip.

Minimally Invasive Spine Surgery

Most of the BoneScalpel’s blade designs are universal and for multifunctional surgical use, with a choice of cutting directions. Cutting and shaving tips are available with extended reach for approaches to deep body cavities or applications in microscopic and minimally invasive spine surgery.

“Being less invasive is a philosophy of minimizing the collateral tissue damage while still targeting the pathology,” asserts Dr. Lieberman. The BoneScalpel is unique in that it offers tissue selective bone cutting for minimizing viable bone loss and sparing nerves and blood vessels.

Dr. Rosenthal, himself a pioneer in endoscopic spinal surgery, assures that “Complex tasks in deep seated areas can be accomplished with the long blade configurations.” He even calls the BoneScalpel “one of the most important advancements in spine surgery during the last few years” and predicts “it will become a preferred surgical tool for the next decade and beyond.” ♦

For more information about the Misonix BoneScalpel™ please call 1-800-694-9612, email sales@misonix.com; visit our website at www.misonix.com.



MEDCO FORUM®

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