PIEZOSURGERY INC.
a mectron company

PIEZOSURGERY® *flex*

THE NEW STANDARD OF CARE.

PIEZOSURGERY® - consistently improving surgical outcomes.

PIEZOSURGERY® has caused a paradigm shift in osseous surgery and is becoming the new standard of care.

We invite you to learn about our technology, which gives you maximum intra-operatory precision and control – and minimal stress for you and your patients. Once you learn more, we know PIEZOSURGERY® will become an intrical element in your daily practice, as it has for thousands of leading clinicians worldwide.

→ MAXIMIZE SURGICAL PRECISION

Maximum surgical precision and intra-operative tactile sensation for minimally invasive surgeries thanks to micrometric cuts.

→ CUT BONE, NOT SOFT TISSUE

Our Patented Dual Wave Technology is designed to cut bone and not soft tissues. This provides maximum safety for surgeons and patients.

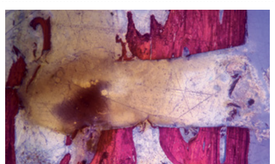
→ MAXIMIZE INTRA-OPERATORY VISIBILITY

Maximum intra-operative visibility due to temporary hemostasis induced by the cavitation effect.

→ *WHY PIEZOSURGERY®?*

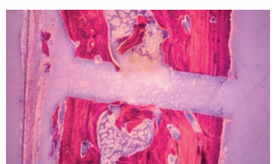
Saws and burs limit your intra-operative control and may cause damage to bone and soft tissues. Additionally, the friction caused by their movement can lead to tissue overheating and necrosis.

PIEZOSURGERY® allows surgeons to have maximum control through its microvibrations, thus achieving extreme precision and safety.

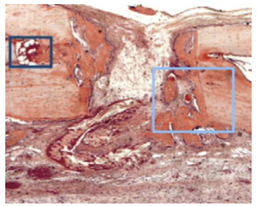


→ *Bone bur*

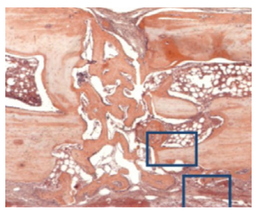
→ *Bone saw*



→ *PIEZOSURGERY®*



Bone bur



PIEZOSURGERY®

PIEZOSURGERY® uniquely promotes tissue healing while cutting.

Several clinical and histological studies have shown that PIEZOSURGERY® is superior to saws and burs not only in terms of intra-operative precision and safety, but also in regard to tissue healing.

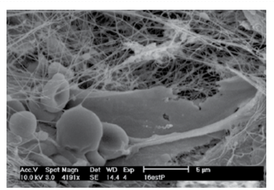
When a surgeon uses PIEZOSURGERY® instead of conventional instruments, there is a significant acceleration in the healing response: inflammation is more controlled, there is a significant early increase in bone morphogenetic protein (BMP) levels, and faster new bone formation.[1,2]

Additionally, PIEZOSURGERY®'s unique cutting action characteristics allow preserving the integrity of soft tissues such as membranes and the periosteum, for an enhanced healing response when compared to manual instruments.[3]

Because PIEZOSURGERY® respects soft tissues and reduces intra-operative bleeding, the overall iatrogenic trauma is reduced, with immediate, tangible patient benefits. Patients don't lose as much blood, don't experience as much post-operative swelling, and overall report reduced discomfort associated with the surgical procedure.[4]

→ *IMPROVE BONE HEALING WITH THE USE OF PIEZOSURGERY®[1]*

- reduction in the number of inflammatory cells and cytokines at the surgical site.
- promotion of BMP release and neo-osteogenesis.
- faster healing and bone remodeling.



→ HISTOLOGICAL RESULTS

Comparative studies have demonstrated both the clinical and histological advantages of the PIEZOSURGERY® device.

Gleizal A, Li S, Pialat JB, Béziat JL. **Transcriptional expression of calvarial bone after treatment with low-intensity ultrasound: An in vitro study.** Ultrasound Med Biol. 2006; 32(10):1569-1574

→ *IMPROVED PATIENT OUTCOMES*

- fewer surgical complications compared to traditional surgical instruments.
- less swelling after surgery with PIEZOSURGERY®.
- faster and better osseointegration after implant site preparation.
- faster and less traumatic post-operative recovery.

[1] Vercellotti et al. Int J Periodontics Restorative Dent 2005;25:543–549.
[2] Preti et al. J Periodontol 2007;78:716-722.
[3] Stoetzer et al. GMS Interdiscip Plast Reconstr Surg DGPW. 2014; 3:Doc18.
[4] Crippa et al. Eur Arch Otorhinolaryngol. 2011 Feb 16.

PIEZOSURGERY® *flex*

Designed to be flexible

PIEZOSURGERY® flex is an efficient, versatile, and user-friendly device offering safety and precision in a wide variety anatomical situations.

THE RIGHT MIX OF POWER AND PRECISION

- Quick and effective cutting action
- Soft tissue protection
- Improved intra-operative control and surgical sensitivity
- Maximum flexibility in designing osteotomies

HIGH-QUALITY SURGICAL INSERTS

- Thinner, more precise osteotomies
- Minimal bone loss along the whole depth of cut

TECHNOLOGY AND PERFORMANCE

Thanks to its mix of power and precision utilizing high-quality surgical inserts, PIEZOSURGERY® flex provides the best surgical outcomes making interventions possible which are extremely **challenging with traditional tools.**

SETTINGS TABLE

The recommended parameters (mode, power, and irrigation) always provide the best efficiency for each insert.

EASY TO HANDLE IN THE O.R.

- Touch surface display
- External irrigation system
- 3m handpiece cord
- 5m power cord

PATENTS

Piezosurgery®, **has been awarded over 35 U.S. and international patents**, and has had the privilege of working with thousands of leading clinicians worldwide.

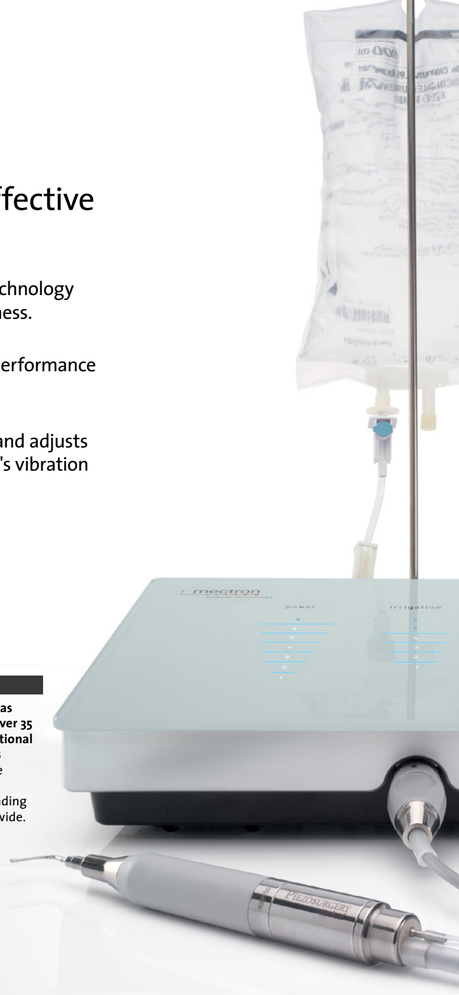
Picture taken from surgeries performed by Dr. S. Stea and Dr. P. Biondi, Maria Cecilia Hospital, Lugo-Cotignola, Italy

US PATENTS 8,109,931, 808,295, 8,002,783, 6,695,847, D539,909, D539,908, D509,899, D509,588.

Designed to be effective

Mectron's PIEZOSURGERY® technology guarantees cutting effectiveness.

- MODE SETTING
  offers the best surgical performance for each insert.
- FEEDBACK SYSTEM
  automatically monitors and adjusts the tuning of each insert's vibration frequency.



SURGICAL CHOICES.

PIEZOSURGERY® has dedicated inserts for a wide variety of clinical applications.

Our technology is designed to empower surgeons to perform more and better surgeries. PIEZOSURGERY® has over 25 inserts specifically designed for use in many applications in clinical surgery and procedures.

OSTEOTOMY

MT1-10
Osteotomy microsaw
Operative length: 10 mm
Saw width: 4 mm
Saw thickness: 0.55 mm
Item# 3600001

MT1S-10
Osteotomy microsaw
Operative length: 10 mm
Saw width: 3 mm
Saw thickness: 0.35 mm
Item# 3600007

MT1-20
Osteotomy microsaw
Operative length: 20 mm
Saw width: 4 mm
Saw thickness: 0.6 mm
Item# 3600002

MT2L-4
Left angled microsaw
Operative length: 4 mm
Saw width: 4 mm
Saw thickness: 0.6 mm
Item# 3600004

MT2R-4
Right angled microsaw
Operative length: 4 mm
Saw width: 4 mm
Saw thickness: 0.6 mm
Item# 3600003

MT3-8
Osteotomy flat scalpel
Operative length: 8 mm
Scalpel width: 1.4 > 2 mm
Scalpel thickness: 0.5 mm
Item# 3600005

MT3-20
Osteotomy flat scalpel
Operative length: 20 mm
Scalpel length: 10 mm
Scalpel width: 1.8 > 2.4 mm
Scalpel thickness: 0.6 mm
Item# 3600006

UNIVR
Round shape osteotomy microsaw
Shaft length: 30 mm
Operative length: 5 mm
Saw width: 4.5 mm
Saw thickness: 0.5 mm
Item# 3600008

MT6S-10
Osteotomy microsaw
Operative
length: 10 mm
Saw width: 4 mm
Saw thickness: 0.35 mm
Item# 3600011

MT7-3
Osteotomy microsaw
Shaft length: 33 mm
Operative length: 3 mm
Saw width: 3.5 mm
Saw thickness: 0.8 mm
Item# 3600012

MT9-13
Osteotomy microsaw
Shaft length: 45 mm
Operative length: 3 mm
Saw width: 3.3 > 4.4 mm
Saw thickness: 0.35 mm
Item# 3600016

OSTEOPLASTY

MP-1
Osteoplasty trapezoidal
Width at the top: 3 mm
Width at the bottom: 4 mm
Thickness: 0.8 mm
Item# 3610001

MP-2
Osteoplasty circular
Shank length: 15 mm
ø 4 mm
Thickness: 0.8 mm
Item# 3610002

MP3-A30
Osteoplasty circular scalpel
Shank length: 22 mm
ø 2.4 mm
Scalpel angle: 30°
Item# 361003

DRILLING

MD2-08
Ø 0.8 mm
Micro-perforation sharp cylinder insert,
Operative length:
12 mm
Item# 3620010

MD2-10
Ø 1.0 mm
Micro-perforation sharp cylinder insert,
Operative length:
12 mm
Item# 3620004

MD3-12
Ø 1.2 mm
Micro-perforation sharp cylinder insert,
Operative length:
12 mm
Item# 3620005

MD3-14
Ø 1.4 mm
Micro-perforation sharp cylinder insert,
Operative length:
12 mm
Item# 3620006

MD3-16
Ø 1.6mm
Micro-perforation sharp cylinder insert,
Operative length:
12 mm
Item# 3620007

MD3-18
ø 1.8 mm
Micro-perforation sharp cylinder insert,
Operative length:
12 mm
Item# 3620008

FINISHING

MF1
Diamond flap scalpel
Length: 4 mm
Width: 2.9 mm
Thickness: 1 mm
Item# 3630001

MF2
Diamond cylinder insert
Operative
length: 12 mm
ø 2.4 mm
Item# 3630002

MF3
Diamond ball insert
Operative
length: 9 mm
ø 1.7 mm
Item# 3630003

MF4
Diamond conic insert
Operative
length: 10 mm
ø 1.4 > 0.6 mm
Item# 3630004

MF5
Diamond truncated cone insert
Operative
length: 20 mm
ø 2.8 > 2.2 mm
Item# 3630005

MF6
Blunt cone compressor
Operative
length: 15 mm
ø 5 mm
Item# 3630006

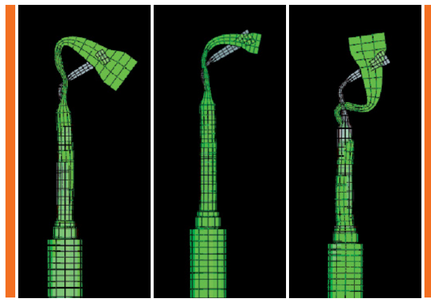
ONGOING CUTTING EDGE INNOVATION.

With new, clinician-designed inserts released every year, PIEZOSURGERY®'s vast array of insert options will never hold you back.

Our commitment to maximizing your return on investment drives us to expand the range of clinical applications for PIEZOSURGERY® devices through the ongoing development of innovative insert designs.

All PIEZOSURGERY® inserts are developed in response to specific clinical needs and result from collaborations with universities and clinical practitioners. Our rigorous insert development process includes finite elements analyses, computer simulations, serial prototyping, and extensive laboratory and clinical research.

Thanks to clinical experience and our cutting-edge technological know-how, over 25 PIEZOSURGERY® insert designs are now available to surgeons worldwide – and new inserts are released every year.



INSERT DEVELOPMENT

1. inserts are developed in close collaboration with prestigious universities.
2. finite element analyses and computer simulations are performed for all inserts, ensuring safety and durability.
3. extensive laboratory and clinical testing prior to release on the market.

CUT EFFICIENTLY

- effective and safe SHARP inserts
- fine and uniform cutting
- used for osteotomy, and osteoplasty

CUT SAFELY CLOSE TO NERVES

- diamond-coated SMOOTHING inserts for precise and controlled operation on bone structures
- safe osteotomy close to delicate anatomical structures

CLINICAL VERSATILITY

- BLUNT inserts for soft tissue preparation

SURGICAL OPTIONS

- Depending on their clinical application, inserts are coated with specially selected diamonds.
- Different diamond sizes ensure optimal surgical performance in each clinical application.

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EVIDENCE-BASED.

The original, patented PIEZOSURGERY® technology is supported by thousands of peer-reviewed publications.

BONE HEALING

The minimal postoperative pain appears remarkable; in the same direction, the first impression about the rapidity of recovery appears noteworthy: it results in a reduced necessity of postoperative medications, due to a lesser production of granulation tissue and, consequently, to the possibility to better foresee the stabilized result with important anatomical and functional implications

Pirodda A., Raimondi M.C., Ferri G.G. **Piezosurgery in otology: a promising device but not always the treatment of choice.** Eur Arch Otorhinolaryngol. 2012 Mar;269(3):1059. doi: 10.1007/s00405-011-1841-2. Epub 2011 Nov 22.

SAFETY

Piezosurgery proved to be a useful and safe technique for selective bone cutting and removal of osteophytes with preservation of neuronal and soft tissue in ACDF. In particular, the angled inserts were effective in cutting bone spurs behind the adjacent vertebra which cannot be reached with conventional rotating burs.

Grauvogel J., Scheiwe C., Kaminsky J. **Use of Piezosurgery for removal of retrovertebral body osteophytes in anterior cervical discectomy.** Spine J. 2014 Apr;14(4):628-36. doi: 10.1016/j.spinee.2013.06.085. Epub 2013 Dec 4.

BENEFITS

PS allows easy, safe and precise bone cutting with no injury to neurovascular tissue, such as dura, transverse or sigmoid sinus, brain, and cranial nerves. No complications were noted during the procedure. Due to the absence of rotating power near neurovascular structures the drilling process was easy and comfortable for the surgeon.

Grauvogel J., Grauvogel T.D., Kaminsky J. **Piezosurgical lateral suboccipital craniectomy and opening of the internal auditory canal in the rat.** J Neurosurg Sci. 2014 Mar;58(1):17-22.

PRECISION

Piezosurgery seems suitable to perform precise thin osteotomies while limiting damage to the bone itself and to the underlying delicate structures even in the case of unintentional contact. These advantages make the piezoelectric bonescalpel a particularly attractive instrument in neurosurgery.

Iacoangeli M., Rienzo A.D., Nocchi N., Balercia P., Lupi E., Regnicolo L., Somma L.G., Alvaro L., Scerrati M. **Piezosurgery as a Further Technical Adjunct in Minimally Invasive Supraorbital Keyhole Approach and Lateral Orbitotomy.** J Neurol Surg A Cent Eur Neurosurg. 2015 Mar;76(2):112-8.

EASE

Piezoelectric osteotomy reduced surgical time, blood loss, and inferior alveolar nerve injury in bimaxillary osteotomy. Absence of macro-vibrations makes the instrument more manageable and easy to use and allows greater intraoperative control with higher safety in cutting in difficult anatomical regions.

Bertossi D., Lucchese A., Albanese M., Turra M., Faccioni F., Nocini P., Rodriguez Y Baena R. **Piezosurgery versus conventional osteotomy in orthognathic surgery: a paradigm shift in treatment.** J Craniofac Surg. 2013 Sep;24(5):1763-6. doi: 10.1097/SCS.0b013e31828f1aa8.

PRODUCTS

TROLLEY-CASE

POWER SUPPLY CABLE

CART

FLEX CONSOLE

IRRIGATION KIT

HANGER BAR

FLEX FOOT PEDAL

MEDICAL HANDPIECE

TORQUE WRENCH

DEVICE

FLEX CONSOLE (Includes: Flex Foot Pedal, Hanger Bar, Power Cord, Peristaltic Pump, Carrying Case)	5170002

MEDICAL ACCESSORIES

MEDICAL HANDPIECE	3120127
FLEX FOOT PEDAL	4620003
TORQUE WRENCH	2900080
HANGER BAR	1380002
HANDPIECE CONNECTOR CAP (Pack of 5)	3150086Bx
HANDPIECE CONNECTOR CAP (Single)	3150086
HANDPIECE NOSE CONE	3620099
POWER-SUPPLY CABLE	50026
PERISTALTIC PUMP	3210006
IRRIGATION KIT SINGLE USE (Box of 10)	3230008Bx
IRRIGATION KIT SINGLE USE (Pack of 5)	3230008Pк
IRRIGATION KIT SINGLE USE (Single)	3230008
CART	3540009
TROLLEY-CASE	4440018

PIEZOSURGERY INCORPORATED
a mectron company

is manufactured by:

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Via Loreto 15/A
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Italy

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the United States and Canada
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