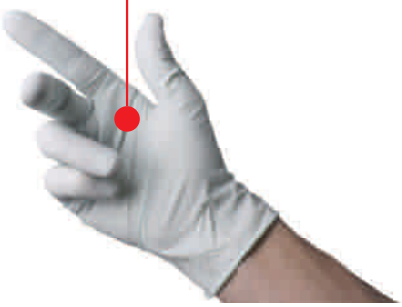
Safe and **atraumatic** ultrasonic piezo bone surgery

OPERATING ROOM
CERTIFIED

M+



COMEG
medical technologies

ULTRASONIC PIEZO CLINICAL BENEFITS

Ultrasonic piezo bone surgery was initially used by CMF surgeons and then extended to many other specialties, due to its great clinical benefits in oral and extra-oral surgeries:

Intraoperative

Safety

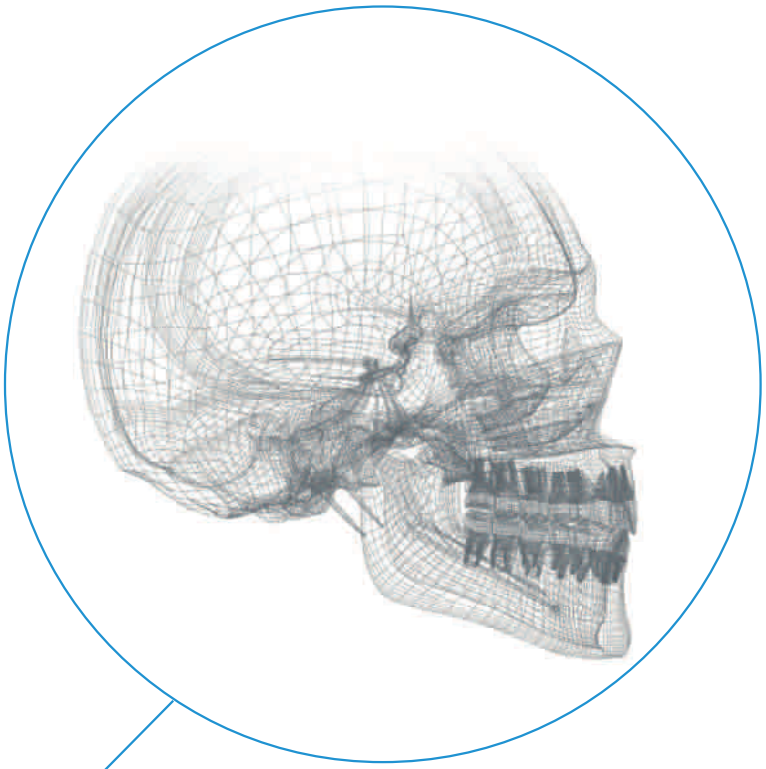
- Selective cut: soft tissues are preserved (nerve, arteries, dura mater)
- Avoid bone overheating

Precision

- Thin & precise osteotomies
- Maximize bone volume

Comfort

- No handpiece vibration
- Low pressure



Post-operative

Smoothness

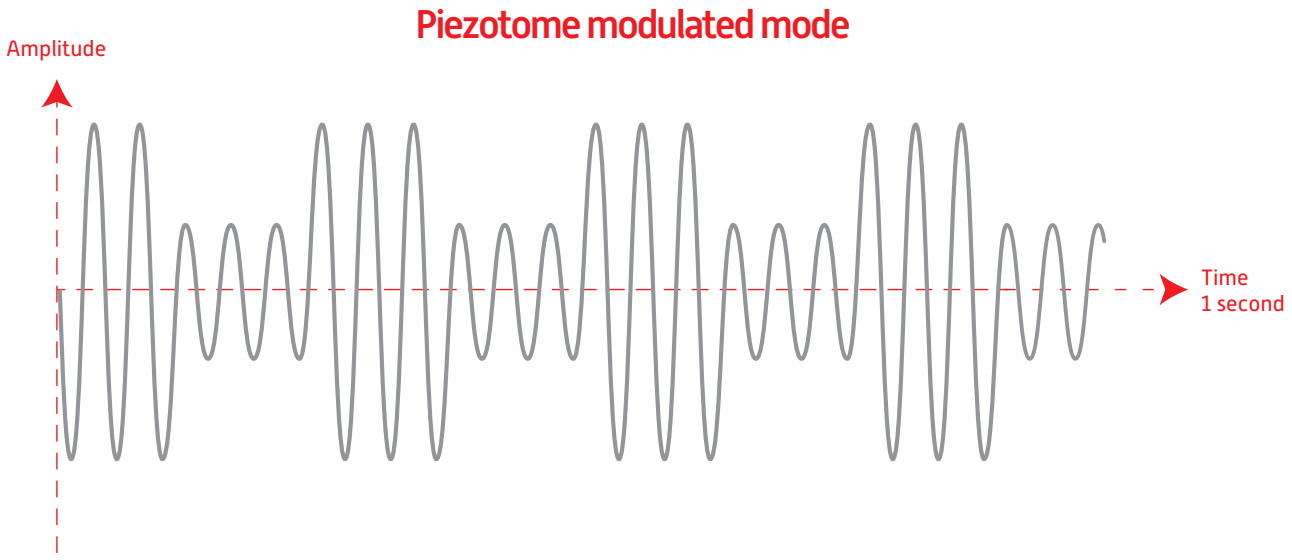
- Reduced pain
- Less swelling and bruising
- More natural results

Healing

- Favors bone regeneration
- Fast recovery
- Stable and long term results

Safety

The generator produces a modulated frequency ranging from 28 to 36 kHz. This signal alternates between high and low amplitude, known as the PIEZOTOME® modulated mode. The bone is cut at a frequency close to its relaxation frequency, limiting the risk of injury to fragile anatomical structures [nerves, arteries]. Bone cutting is precise, cell regeneration is optimized and the healing is of high quality. The ultrasonic piezoelectric technology is suitable for any type of surgery where **precision and safety** is a must.



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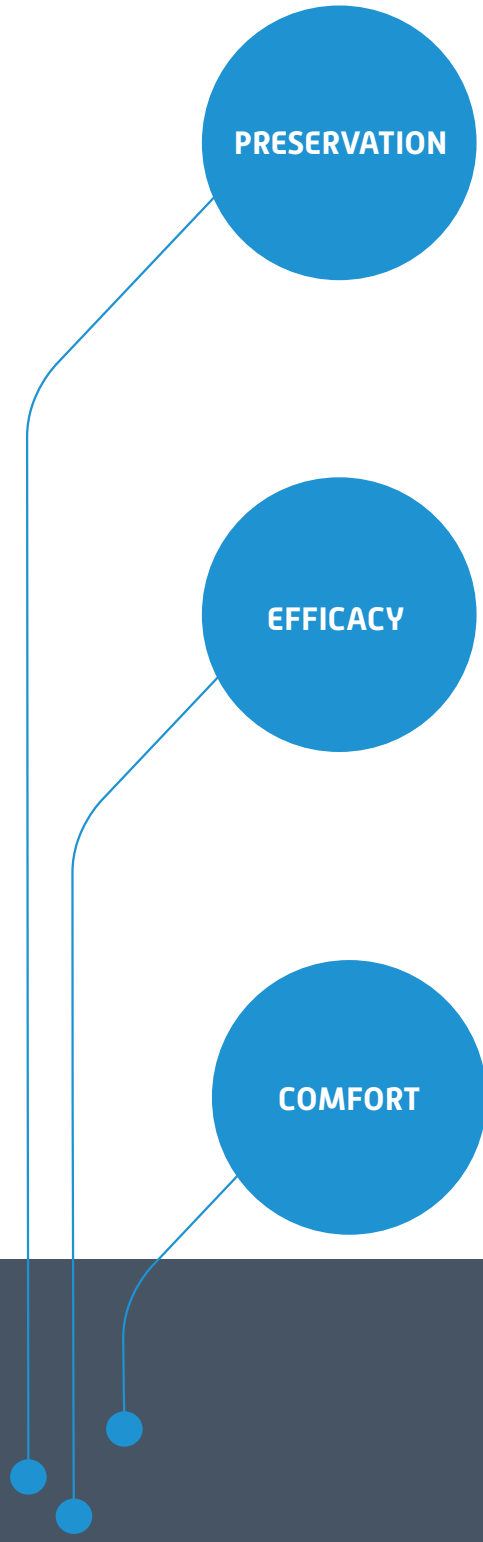
- Gerbault O, Daniel RK, Kosins AM. **The role of Piezoelectric Instrumentation in Rhinoplasty Surgery.** Aesthetic Surgery Journal 2015;36(1):21-34.
- A. Troedhan, MD, DMD, PhD. **Piezotome Rhinoplasty Reduces Postsurgical Morbidity and Enhances Patient Satisfaction: A Multidisciplinary Clinical Study**. Journal of Oral and Maxillofacial Surgery, Volume 74, Issue 8, 1659.e1 - 1659.e11
- Reside J, Everett E, Padilla R, Arce R, Miguez P, Brodala N, De Kok I, Nares S. **In vivo assessment of bone healing following PIEZOTOME® ultrasonic instrumentation.** Clinical Implant Dentistry Related Research 2015;17(2):384-94. Doi: 10.1111/cid.12094. Epub 2013 jun 13.
- Compendium M+ REF D57819

When Safety & Efficacy Matter

NEWTRON® TECHNOLOGY

The Perfect Match

Ultrasonic power generators are piloted by patented NEWTRON® technology electronics.
The electronic module, the handpiece and the tips are perfectly tuned providing great efficacy and clinical benefits.



Soft tissue preservation

- Safety: preserve soft tissue (Piezo modulated mode)

Bone preservation

- Highly precise cut
- Linear tip vibrations
- Controlled and regular tip amplitude

Frequency adjustment

- Maximum performance for each tip
- Optimal and continuous efficiency irrespective of the load applied

Power regulation

- Constant performance even in dense bone
- Effortless cutting without pressure

For both surgeon and patient

- Safe with effortless cutting
- Increased tactile sensation
- Reduced post-operative pain

MINIMALLY INVASIVE SURGERY

Efficacy

Electric current generates a deformation of the piezoceramic rings. The movement of these rings leads to vibrations, thus the tip vibrates in a very regular longitudinal movement.

- Patented electronic technology
- 6 ceramic rings for a powerful handpiece

Our powerful piezoelectric generators broaden the scope of surgical applications

When Safety & Efficacy Matter

THE CHOICE OF HIGH TECHNOLOGY

COMEG devices are **operating room certified** and each device fulfills the most demanding medical regulatory standards.

The ultrasonic expert for fast and secure bone surgery

PIEZOTOME M+
Piezo.Ultrasonic.Surgery.Unit

THE ULTRASONIC EXPERT

2 year warranty on unit and handpiece

OPERATING ROOM CERTIFIED

- Class IIb
- Equipontential plug
- IEC 60601-1 – 3rd Edition
- Footswitch certified IPX6 & IPX8
- BVS Safety Marking
- 473W x 150H x 340D mm
- 5kg

DELIVERED WITH
- 2x brackets
- 5x 3m single use irrigation lines
- 5x single use perforators
- 2x handpiece holders
- 1x IPX8 M+ multifunction footswitch
- 1x M+ wrench
- 1x 3m mains cord

PIEZOTOME® M+ FEATURES

The Piezotome® M+ is a highly reliable unit, specially designed together with its accessories to meet everyones's priority.

PIEZOTOME® M+ LED handpiece

- 2 handpiece connections
- Powerful handpiece: 6 ceramic rings
- Cold LED light for high visibility and low heat generation
- 3 m long cord adapted to the operating room environment

Footswitch (operating room certified IPX8 guarantee watertightness)

Easy to move due to its arch, offers optimal control of the main functions:

- Power settings
- Choice of the active handpiece
- PIEZOTOUCH™ mode: progressive power regulation

Touch interface

- Large 5.7'' operator-oriented screen
- Easy and intuitive settings
- Memory function

Features

ACCESSORIES

Performance comes together with specifically designed long lasting durable components.

Handpiece – **POWERFUL**

- Ceramic rings for faster surgeries
- Cold LED light (100,000 Lux) for enhanced visibility even in posterior areas
- No overheating
- Lighweight handpiece for an easy handling and less hand fatigue

All in one

- Delivered in its autoclavable metal case
- Ready for sterilization

Ref. F57802

Perfect asepsis

- Fully sterilizable (autoclavable & washer-disinfectable)
- Nose easily dismantled for perfect asepsis

Pump & Irrigation – **SAFE**

A perfect control of irrigation is necessary for:

- Removing bone debris
- Reducing the risk of bone necrosis
- Generating a hemostatic effect due to the cavitation (implosion of microbubbles releasing oxygen)

Peristaltic pump for controlled irrigation

- Quick set-up
- Robust
- Precise and constant flow rate (avoids bone overheating)
- Silent running

Tips – **ROBUST**

- Designed to respect the patients anatomy
- Fast assembly screwing system: saves time during surgery
- Medical grade stainless steel
- Strengthened by thermic and surface treatments
- Synthetic diamond-coated tip
- Sterile tips treatment: gamma-ray

Connected

ULTRASONIC RHINOPLASTY

A smooth and less traumatic procedure offering precise bone reshaping and controllable long term results.

Precise bone treatment

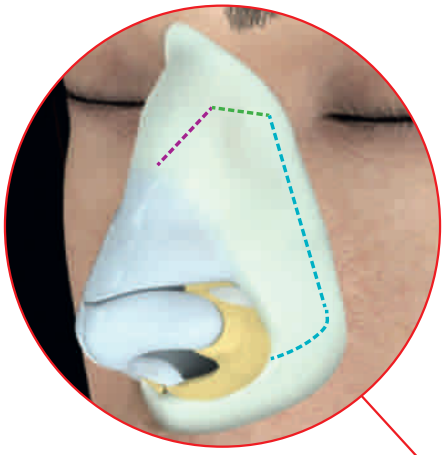
- The new ultrasonic rhinoplasty protocol allows default corrections (nose too hard, wide or bumpy) with no unwanted fracture even on brittle, thin or unstable bones.

Direct vision

- Surgery performed under direct vision for better precision.

Fast recovery

- Faster social-life re-integration: less ecchymosis and edema with more natural results.



Ultrasonic rhinosculpture

RHS2H and RHS2F tips allow to sculpt bones without any fracture

Rhinoplasty with precise osteotomies

--- Lateral osteotomy – RHS3L or RHS3R
--- Transverse osteotomy – RHS3L or RHS3R
--- Median oblique osteotomy – RHS5

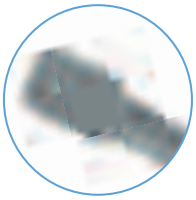
Dr Gerbault MD, Vincennes, France

" Piezoelectric surgery is a real disruptive technology in rhinoplasty, it allows a paradigm shift in the way of reshaping bones in rhinoplasty. It simplifies dramatically the way to perform hump reduction and osteotomies in rhinoplasty and adds a new dimension by allowing the possibility to sculpt and to polish nasal bones. Stable bones can be positioned with an unparalleled accuracy under direct vision and reshaped to achieve a perfect symmetry and smoothness of the bony vault. Moreover, this technique is easy, with a quick learning curve, simple to teach and the recovery is very fast as post-op ecchymosis is significantly reduced. For the first time in the history of rhinoplasty, a custom reshaping of the nasal bones is easily achievable. "

DESIGNED FOR RHINOPLASTY

Developed in collaboration with Dr Gerbault, these tips are designed for a total respect of the anatomy (smoothness), they do not alter the skin nor the vessels for shorter post-surgical recovery.

Rhinoplasty Gerbault Kit	RHS2Hb	RHS2Fb	RHS3L	RHS3R	RHS5	RHS6
F87999	F87969	F87968	F87991	F87992	F87993	F87994



RHS2Hb - Hard rasp

Use on thick skin or dense bone

RHS2Fb - Fine rasp

Use on thin skin or thin bone

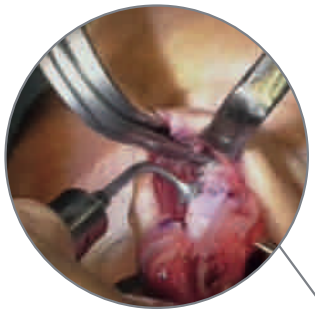
- Fine reshaping of the nose pyramid
- Removal of the bony hump
- Smoothing of bone irregularities

RHS3L & RHS3R - Rounded saws

Left & Right angled saws

- Low lateral, lateral and transversal osteotomies

Bone removal



Courtesy of Dr Gerbault, Vincennes, France (RHS2H tip)

RHS5 - Thin saw

Straight thin saw

- Median oblique osteotomy
- Rib graft

RHS6 - Diamond-coated

Diamond-coated tip dedicated to nasal bone drilling or nasal spine drilling

- Bone suture
- Septal suture to bone

THE EXPERTS : GERBAULT RHINOPLASTY TIPS

The Expert kit provides unprecedented bone access and allows for safe treatment of the septum. Each tip has been designed specifically to answer the aesthetic and functional steps of bone treatment in rhinoplasty from bone rasping and cutting to treating the septum with a completely unobstructed and clear view. Thus, any bone convexity or asymmetry can be assessed and treated.

Rhinoplasty Gerbault Expert Kit	RHS1	RHS2Hb	RHS2Fb	RHS3L	RHS3R
F88000	F87996	F87969	F87968	F87991	F87992

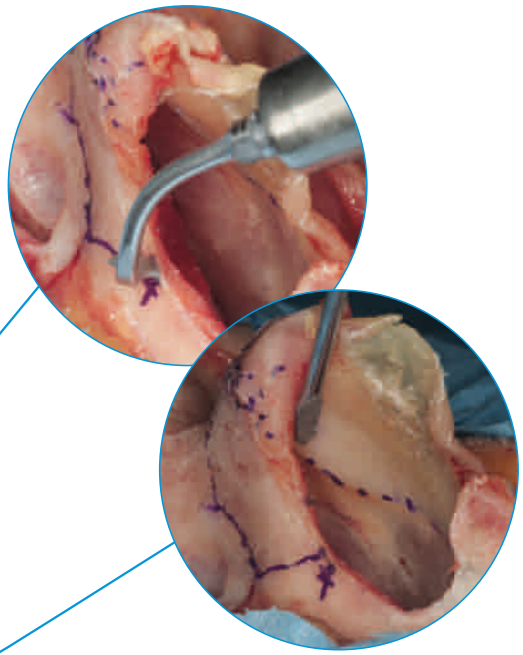
RHS4L	RHS4R	RHS5	RHS6	RHL5
F87998	F87997	F87993	F87994	F87967

Dr Gerbault MD, Vincennes, France

" Rhinoplasty has dramatically changed with ultrasonic rhinoplasty: from a partially blind approach where bones were rasped and broken with the risk of unwanted fracture, it has become a completely visually controlled operation where bones are reshaped and mobilized without altering their stability. This accurate control on shape, position and smoothness of bones is achievable thanks to the use of piezoelectric instruments through a wide sub periosteal exposure of the whole bony vault, and is safe as they don't damage soft tissues and preserve bone supports. Ultrasonic rhinoplasty is an easy procedure. The dorsum and keystone smoothness is achieved by using very thin saws and rasps. Bones can be drilled to suture cartilages to bones, change their orientation or to improve their stability. Finally, long piezoelectric tips enable to straighten the septum or to harvest long pieces of septum without risking to destabilize it. Piezoelectric surgery is part of the current evolutions of 21st century surgery: aesthetic and functional rhinoplasty are profoundly impacted by this disruptive technology. "

SHAPED FOR ALL TYPES OF NOSE

COMEG miniaturized rhinoplasty instruments paired with M+ piezoelectric ultrasonic devices allow the reshaping and mobilization of bones without sacrificing bone stability as soft tissue is preserved.



RHS1 - Scraper

Curved tip to remove important bone excess: ostectomy on dense bone and in case of thick skin

- Nasal pyramid remodeling
- Ostectomy of the dorsal hump and lateral convexity

RHS2Hb - Hard rasp

Use on thick skin or dense bone

RHS2Fb - Fine rasp

Use on thin skin or thin bone

- Fine reshaping of the nose pyramid
- Removal of the bony hump
- Smoothing of bone irregularities
- Smoothing of bone and hard cartilaginous graft

RHS3L & RHS3R - Rounded saws

Left & Right angled saws

- Lateral osteotomies

RHS4L & RHS4R - Angulated saws

Left & Right angled saws

- Transverse osteotomies
- Partial costal bone grafting

RHS5 - Straight saw

Straight thin saw

- Median oblique osteotomy
- Costal bone grafting

RHS6 - Diamond-coated drill

Diamond-coated tip dedicated to nasal bone drilling or nasal spine drilling

- Bone suture
- Septal suture to bone

RHL5 - Long saw

Long straight saw for the treatment of the septum

- Cephalic osteotomy
- Caudal osteotomy

Courtesy of Dr Gerbault, Vincennes, France

ULTRASONIC CRANIO-MAXILLO-FACIAL SURGERY

Piezoelectric surgery is a new bone cutting technique increasing safety, especially in anatomically difficult to reach areas.
Micrometric vibrations ensure very **thin and precise osteotomies** with stable and long term results for a broad range of clinical applications:

Cranio

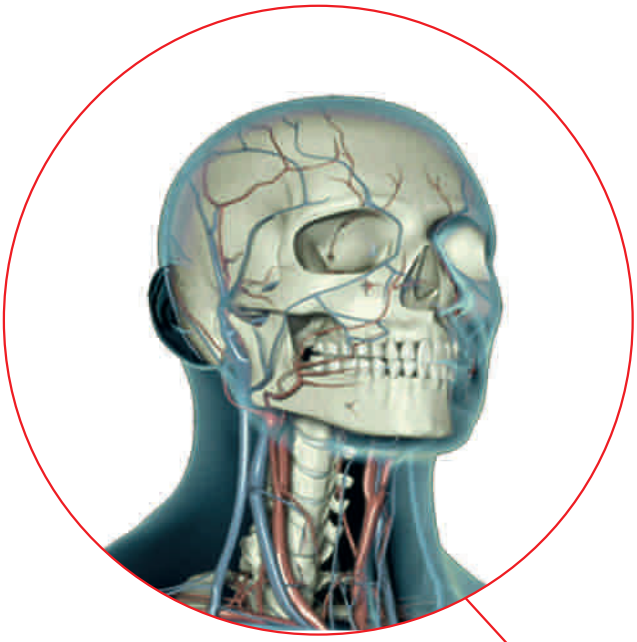
- Frontal sinus osteotomy
- Craniosynostosis
- Parietal graft

Maxillo

- LeFort I osteotomy
- Bilateral Sagittal Split Osteotomy (B.S.S.O)
- Genioplasty

Facial

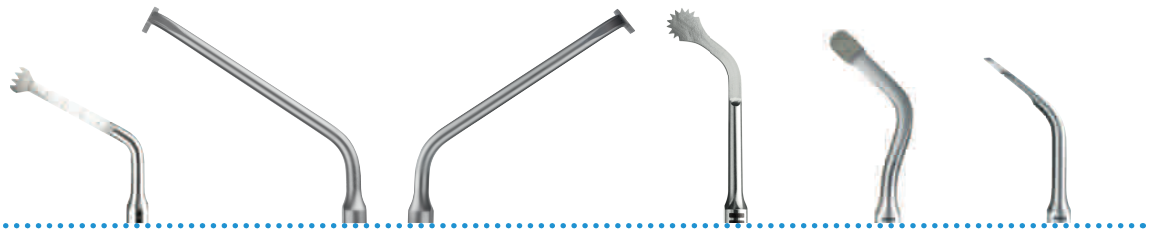
- LeFort II & III osteotomy
- Zygomatic bone osteotomy
- Reconstruction



v.Prof.Dr.Dr. Troedhan, Vienna, Austria

" The M+ Piezosurgical device, for the first time in the history of Piezoelectric-Surgery provides sufficient power for a fast surgical procedure in all cases of large osteotomies in orthognathic surgery, reconstructive surgery needing large autologous bone-transplants from the skull and in cosmetic surgery on facial hard-tissues. With its unrivaled precision and atraumaticity in bone-cutting CMF surgical procedures can usually be completed in less time than with traditional rotary or oscillating instruments with substantially less blood loss. In facial cosmetic surgery the application of newly developed ultrasonic surgical protocols provide a significant reduction of postsurgical morbidity and enhanced patient satisfaction with the outcome. "

FOR SAFER AND MORE ACCURATE SURGERY



CMF Kit	BS1L	BS2L XL	BS2R XL	BS1RD	SL1	BS4
F57804*	F87982	F87983	F87984	F87985	F87974	F87978

BS1L - Saw

Saw (0.6 mm) with laser marking at 3, 6, 9, 12 and 15 mm

- Deep osteotomy

BS2L XL & BS2R XL - Left & Right angled saws

Long lateral saws (39.5 mm length) for easier access adapted to patients anatomy

- Osteotomy

BS1RD - Rounded saw

With its rounded shape the tip is active on a 280° surface and its length (40 mm) makes it possible to reach posterior areas easily

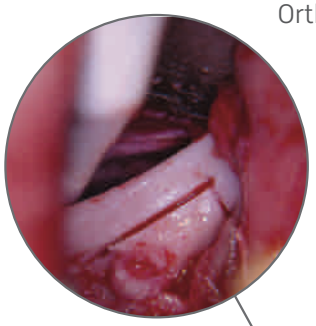
SL1 - Diamond-coated

- Vestibular bone window cut
- Smoothing of sharp angles
- Bone incisions close to delicate structures

BS4 - Circular scalpel

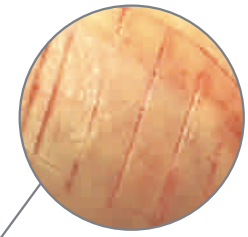
- Osteoplasty
- Bone harvesting

Orthognathic surgery



Courtesy of
Dr Troedhan, Vienna, Austria

Cranial surgery



Courtesy of
Dr Solyom, Toulouse, France

* Single use tips

OTHER TIPS TO COMPLETE THE RANGE

CIRCULAR SCALPEL

Angled at 130°, for osteoplasty and harvesting of bone particles or chips.

BS4

F87978

PLATEAU

Non-cutting tip, for membrane detachment.

SL3

F87972

DIAMOND COATED TIP

For bone cutting close to soft tissue and for attenuation of sharp angles.

SL1

F87974

DIAMOND COATED BALL

To perform very fine bone incisions and precise osteoplasty.

SL2

F87973

Long length tips for minimally invasive techniques and easier access

BS1 XXL

F87986

SAW

Extra long saw to perform osteotomies in posterior areas.

BS6 XXL

F87987

SCALPEL

Extra long scalpel particularly recommended for osteoplasty.

Single use tips

Clinical Expertise

RECOMMENDED SETTINGS

	TIPS	Maximum recommended mode	Fine setting*	IRRIGATION ml/mn
CranioMaxilloFacial	BS1RD	D1	3	80
	BS1L	D1	3	60
	BS2LXL / BS2RXL	D1	3	60
	BS4	D1	3	60
	SL1	D1	3	60
RhinoPlasty GERBAULT	RHS1	D1	3	60
	RHS2Hb	D1	3	60
RhinoPlasty Expert - GERBAULT	RHS2Fb	D1	3	60
	RHS3L / RHS3R	D1	3	60
	RHS4L / RHS4R	D1	3	60
	RHS5	D1	3	60
	RHS6	D1	3	80
	RHL5	D1	3	60
OtherTips	BS4	D1	3	60
	SL1	D1	3	60
	SL2	D1	3	60
	SL3	D4	3	50
	BS1XXL	D1	1	80
	BS6XXL	D1	3	80

THE BEST FOR YOU (AND YOUR PATIENTS)

1

SECURITY: Cutting selectivity, no soft tissue lesions

- "Piezotome® surgery is superior in atraumaticity and soft-tissue safety (...) no lesions of the mandible nerve were detected with Piezotome® surgery"[1] -> "0 lesion with Piezotome® vs 16% of hypesthesia with rotary instruments"
- LeFort I osteotomy "...total absence of soft tissue injuries, both in the posterior pedicle and in the vascular elements and palatal tissues"[2]
- "ACTEON® produced the least increase of intraosseous temperature" vs Mectron & Esacrom units[3]

2

GREAT INTRAOPERATIVE CONTROL: Optimal visibility (cavitation), limits blood (hemostasis), remove bone debris and avoid temperature rises

- "Throughout the procedure a clear and stable view was achieved, with a low level of bleeding and adequate irrigation of the cutting area"[2]

3

FAST PROCEDURE:

- "... in 5 cases in which we used this technique, the duration of the osteotomy was 8 to 15 minutes, a trivial period in the entire surgery"[4]
- "A very quick performance was observed using Piezotome®"[2]
    - ACTEON® = 137s
    - vs Piezon Master Surgery: 142s / vs Piezosurgery 3: 144s / vs VarioSurg : 149s

1- *Ultrasonic Piezotome® Surgery: is it a benefit for our patients and does it extend surgery time? A retrospective comparative study on the removal of 100 impacted mandibular 3rd molar*. A.Troedhan, A.Kurrek, M.Wainwright. Open Journal of Stomatology, 20113

2- *LeFort I segmented osteotomy experience with Piezosurgery in orthognathic surgery*. S.Olate, L.Pozzer, A.Unibazo, C.Huentequeo-Molina, F.Martinez, M.de Moraes. Int J Clin Exp Med 2014;7(8):2092-2095

3- *Performance of ultrasonic devices for bone surgery and associated intraosseous temperature development*. S.Harder, S.Wolfart, C.Mehl, M.Kern. The International Journal of Maxillofacial Implants Volume24, Number 3, 2009

4- *Mandibular condylectomy revisited: technical notes concerning the use of an ultrasonic system*. S.Olate and al. J Oral Maxillofac Surg 2013

THE BEST FOR YOUR PATIENTS

1

BETTER HEALING PROCESS AND BONE REGENERATION

- "Piezoelectric instrumentation favors preservation of bone"[3]
- Better bone turnover and densification. "Bone instrumented by piezoelectric surgery appears less detrimental to bone healing than high-speed rotating device"[4]

2

SMOOTHNESS: Less traumatic

- Decreased postsurgical morbidity "...significant reduction or almost absence of postsurgical ecchymosis/edema and significant reduction of pain"[5]
- "Increased patient satisfaction significantly"[5]
- More natural results

3

SAFE AND STABLE RESULTS

- Stable and long term results "...osteotomies can be performed with stability, because the underlying periosteum and mucosa are not damaged..." & "...allow the surgeon to easily stabilize unstable bones by drilling holes"[6]

4- *In vivo assessment of bone healing following Piezotome® ultrasonic instrumentation.* J.Reside, E.Everett, R.Padilla, R.Arce, P.Miguez, N.Brodala, I.De Kok, S.Nares. Clinical Implant Dentistry and Related Research, June 2013

5- *Piezotome rhinoplasty reduces postsurgical morbidity and enhances patient satisfaction: A multidisciplinary clinical study.* A.Troedhan. YJOMS57235 J Oral Maxillofac Surg 2016

6- *The role of piezoelectric instrumentation in rhinoplasty surgery.* O.Gerbault, RK.Daniel, AM.Kosins. Aesthetic Surgery Journal 2015;36(1);21-34

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Proven clinical benefits

Local contact:

Find out more on our YouTube channel

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- Focused specifically in **Minimally Invasive Surgery (MIS)**
- **Global presence** on 6 continents
- **Meeting the specific needs** for GYN, URO, ENT, LAP, ARTHRO, CMF and PLASTIC surgery
- **Intuitively connecting physicians** with the appropriate solutions

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