

# Safe and atraumatic ultrasonic piezo bone surgery



PIEZOTOME® Solo M+



PIEZOTOME® M+



IMPLANTCENTER™ M+



OPERATING ROOM  
CERTIFIED



# 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

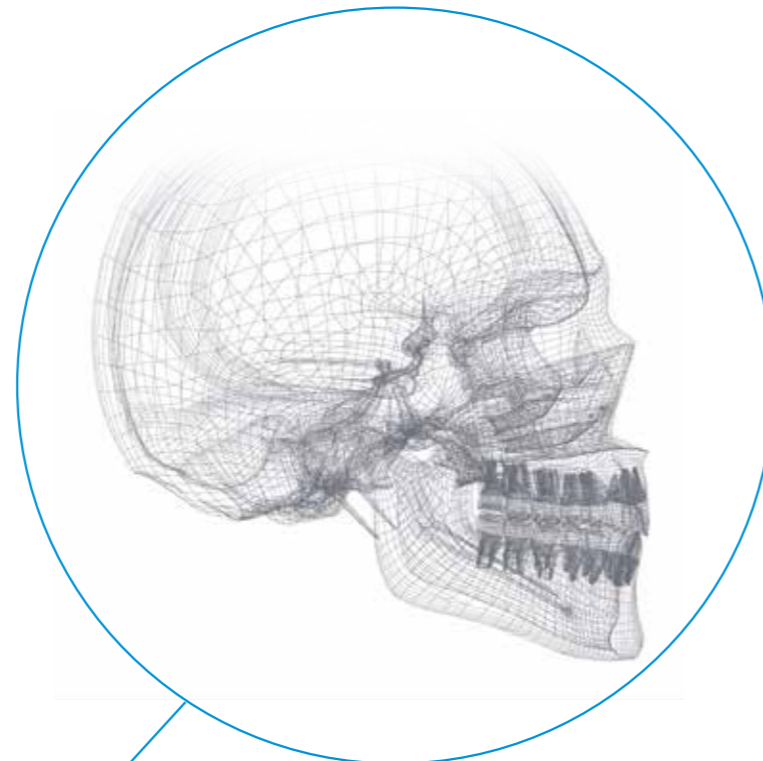
- Selective cut: soft tissues are preserved [nerve, arteries, dura mater]
- Avoid bone overheating

### 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

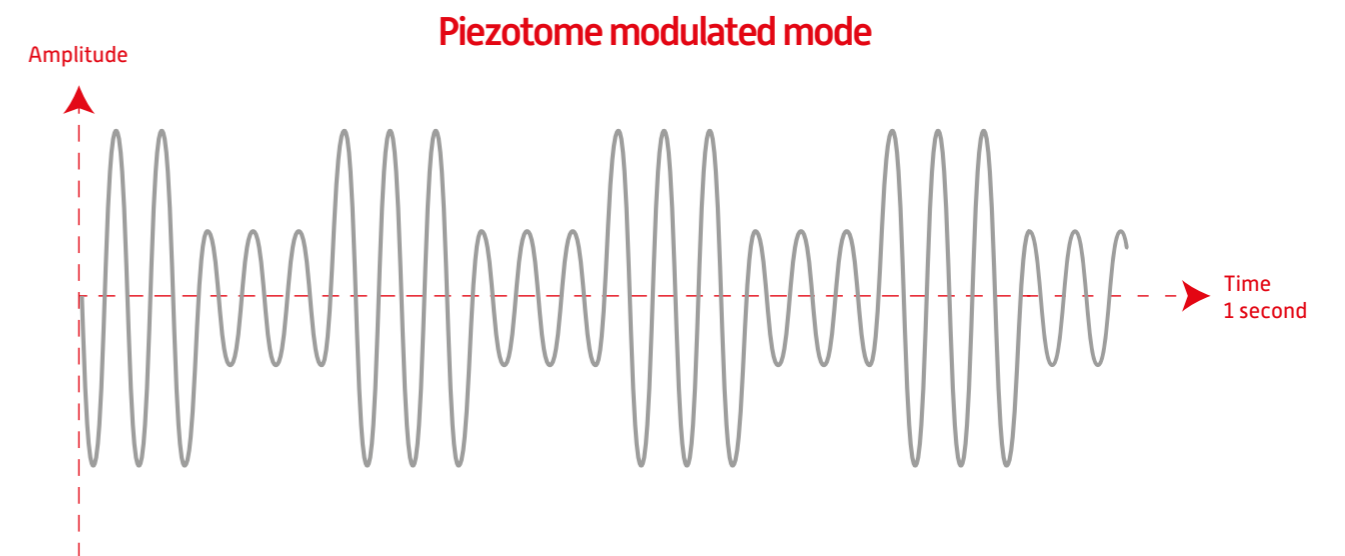
### Healing

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

# MINIMALLY INVASIVE SURGERY

## 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 oral or extra-oral surgery where **precision and safety** is a must.



### References

- 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 [upon request]. **Safe and atraumatic ultrasonic piezo bone surgery**

# 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.

### PRESERVATION

#### Soft tissue preservation

- Safety: preserve soft tissue [Piezo modulated mode]

#### Bone preservation

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

### EFFICACY

#### 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

### COMFORT

#### 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 boosted 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**. Approved by independent notified body, each device fulfills the most demanding medical regulatory standards. The advanced electronics prevent any interfering emissions.

Find out more from your biomedical engineer.



CONCENTRATED  
ULTRASONICS



THE ULTRASONIC  
EXPERT



THE ALLIANCE  
OF TECHNOLOGIES

**OPERATING ROOM  
CERTIFIED**

- Class IIb
- Equipotential plug
- IEC 60601-1 – 3<sup>rd</sup> Edition
- Footswitch certified IPX6 & IPX8
- BVS Safety Marking (USA only)

Technology

## CONCENTRATED ULTRASONICS

PIEZOTOME® Solo M+, compact and efficient, brings together all of the powerful, reliable and safe components of the M+ range for maximum performance and safety.

### Clinical indications

**Active on hard tissue while preserving soft tissue.**

Small bones osteotomies, osteoplasties, drilling, smoothing where safety and precision are essential.



Power mode from d1 (most powerful) to d4

d1

d2

d3

d4



OPERATING ROOM  
CERTIFIED

#### DELIVERED WITH

- 1x bracket
- 5x 3m single use irrigation lines with perforators
- 1x handpiece holders
- 1x IPX6 M+ footswitch
- 1x M+ wrench
- 1x 3m mains cord

## CONNECTED ACCESSORIES

### PIEZOTOME® M+ LED handpiece

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



### Peristaltic pump for controlled irrigation

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



### Footswitch (operating room certified IPX6 guarantee against water-jet)

Makes it possible to control the principal actions to respond to the sterile environment:

- Power mode
- Ultrasound ON/OFF

PIEZOTOME® Solo M+



## ULTRASONICS EXPERT

PIEZOTOME® M+ is a versatile device. Its dual connection allows you to connect two handpieces thus enabling faster clinical procedures. Easy adjustment settings with its touch screen and multifunction footswitch for perfect control throughout the surgical procedure.



The ultrasonic expert for fast and secure bone surgery



OPERATING ROOM  
CERTIFIED

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

## CONNECTED ACCESSORIES



### PIEZOTOME® M+ LED handpiece

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



### Touch interface

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



### 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

PIEZOTOME® M+

## THE ALLIANCE OF TECHNOLOGIES

IMPLANTCENTER™ M+ is a unique concept combining the power of a rotary motor and the safety of piezoelectric instrumentations. It therefore ensures total independence for the surgeon and leads to a multitude of surgeries.

The alliance of technologies for safe and atraumatic bone surgery



OPERATING ROOM  
CERTIFIED

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

## DIVERSITY OF CONNECTED ACCESSORIES

The perfect alliance of rotating and ultrasonic technologies.

### The rotating motor

#### Features

- Cranio-Maxillo-Facial certified
- Durable (brushless motor): robust, maintenance-free
- No vibration
- Sterilizable for perfect asepsis

#### Performances

- Perfect balance between torque and speed for unmatched stability
- High torque: 6Ncm
- Large speed rotation motor: 100 - 40.000Rpm



### PIEZOTOME® M+ LED handpiece

- Boosted handpiece: 6 ceramic rings
- Cold LED light improved 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:

- Global unit control
- PIEZOTOUCH™ mode: progressive power regulation

IMPLANTCENTER™ M+

# ACCESSORIES

Performance comes together with specifically designed long lasting durable components.



## Handpiece – POWERFUL

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



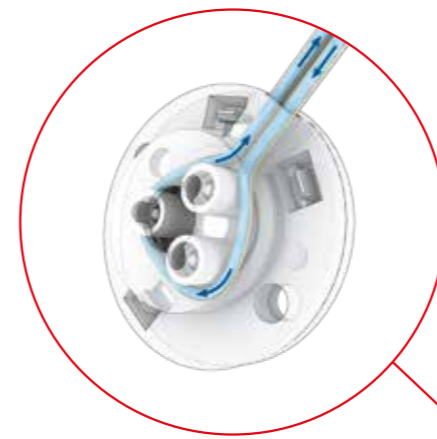
### Perfect asepsis

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



### All in one

- Delivered in its autoclavable metal case
  - Ready for sterilization
- Ref. F57802**



### Peristaltic pump for controlled irrigation

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

### Disposable irrigation line

Ref. F57378 x1  
Ref. F57379 set of 5



## 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)



## 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

### Kits & tips

Disposable, delivered sterile or  
5x re-usable, delivered non-sterile

Connected



# 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

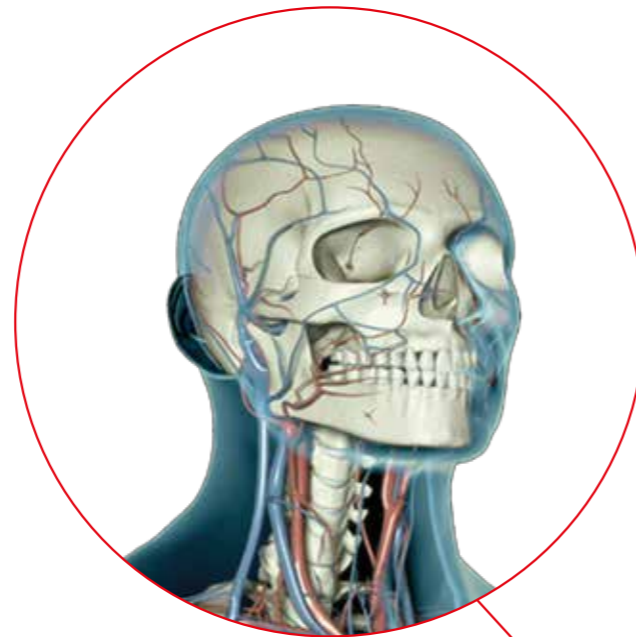
- Frontal sinus osteotomy
- Craniosynostosis
- Parietal graft

## 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
F57803	F87612	F87605	F87606	F87608	F87618	F87615
F57804	F87982	F87983	F87984	F87985	F87974	F87978

- 5x re-usable
- Single use

## BS1L - Saw

Saw [0.6mm] with laser marking at 3, 6, 9, 12 and 15mm

- Deep osteotomy

## BS2L XL & BS2R XL - Left & Right angled saws

Long lateral saws [39.5mm length] for easier access adapted to patients anatomy

- Osteotomy

## BS1RD - Rounded saw

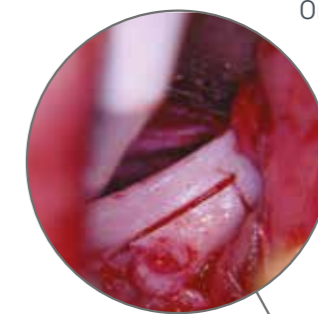
With its rounded shape the tip is active on a 280° surface and its length [40mm] makes it possible to reach posterior areas easily

## SL1 - Diamond-coated

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

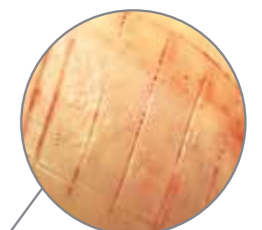
## BS4 - Circular scalpel

- Osteoplasty
- Bone harvesting



Courtesy of Dr Troedhan, Vienna, Austria

Orthognathic surgery



Courtesy of Dr Solyom, Toulouse, France

CMF

# OPEN 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, too wide or bumpy) with no unwanted fracture even on brittle, thin or unstable bones.

## Direct vision

- Surgery performed under direct vision for enhanced precision.

## Fast recovery

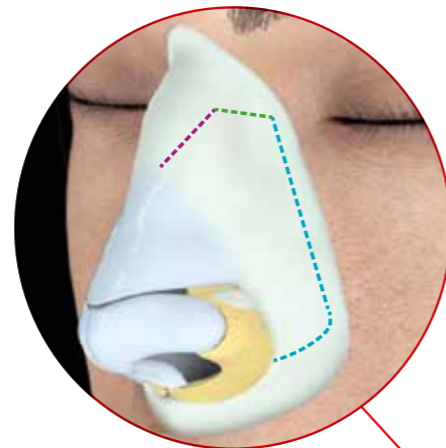
- Faster social-life re-integration: less ecchymosis and edema with more natural results.

## Ultrasonic rhinosculpture

RHS2Hb and RHS2Fb tips are designed to sculpt bones without fracturing them

## 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."

# THE ESSENTIALS: GERBAULT RHINOPLASTY TIPS

Developed in collaboration with Dr. Gerbault, these tips are designed specifically for the nose anatomy; they do not alter the skin nor the blood vessels allowing for a quicker post-surgical recovery.



Rhinoplasty Gerbault Kit	RHS2Hb	RHS2Fb	RHS3L	RHS3R	RHS5	RHS6
F87681 F87999	F87686 F87969	F87687 F87968	F87677 F87991	F87678 F87992	F87679 F87993	F87680 F87994

- 5x re-usable
- Single use



**RHS2Hb - Hard rasp**  
Use on thick skin or dense bone

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

**RHS2Fb - Fine rasp**  
Use on thin skin or thin bone

## RHS3L & RHS3R - Rounded saws

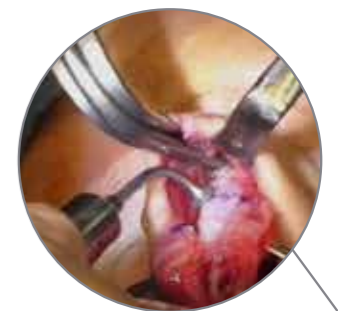
- Left & Right angled saws
- Lateral and transversal osteotomies

## RHS5 - Thin saw

- Straight thin saw
- Median oblique osteotomy
  - Rib graft

## RHS6 - Diamond-coated drill

- Diamond-coated tip dedicated to nasal bone drilling or nasal spine drilling
- Bone suture
  - Septal suture to bone



Courtesy of Dr Gerbault, Vincennes, France

## THE EXPERTS: GERBAULT RHINOPLASTY TIPS

The Expert kit provides unprecedented bone access. Each tip has been designed specifically to respect the anatomy and answer to the different steps of bone treatment in rhinoplasty, from bone rasping to osteotomies 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
F87689 F88000	F87688 F87996	F87686 F87969	F87687 F87968	F87677 F87991	F87678 F87992
	RHS4L	RHS4R	RHS5	RHS6	
	F87683 F87998	F87682 F87997	F87679 F87993	F87680 F87994	



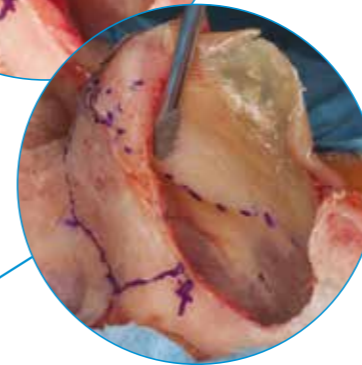
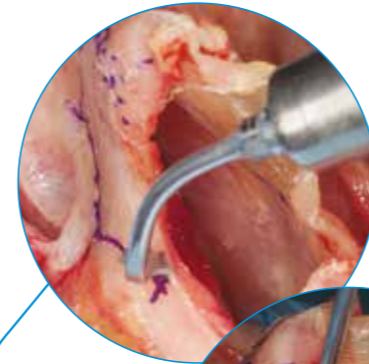
Dr Gerbault MD, Vincennes, France

"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."

- 5x re-usable
- Single use

## 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: osteotomy on dense bone and in case of thick skin

- Nasal pyramid remodeling
- Osteotomy 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

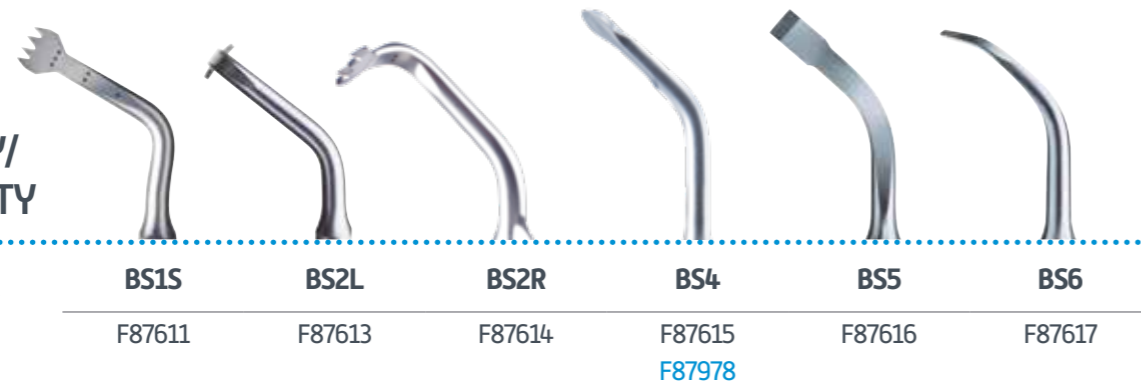
Courtesy of Dr Gerbault, Vincennes, France

# Rhinoplasty

# A COMPLETE AND DIVERSIFIED RANGE

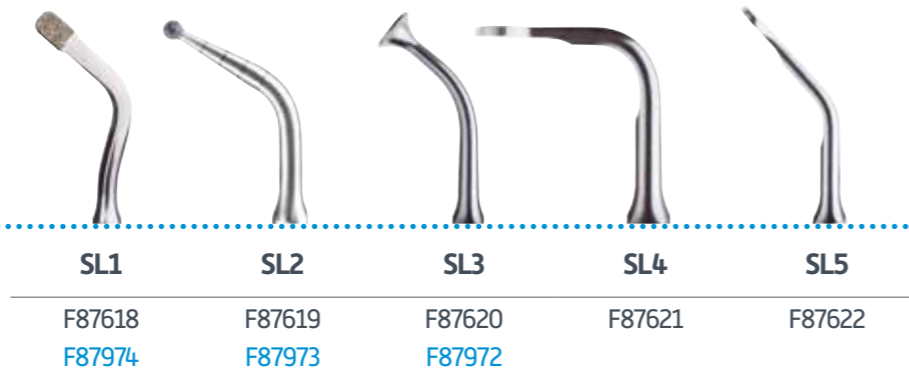
## OSTEOTOMY/ OSTEOPLASTY

Clean and thin cut  
for maximal  
bone volume  
Ref. F57805



## LATERAL SINUS LIFT

Maximal comfort:  
selective and hemostatic cut  
Ref. F57806



## SYNDESMOTOMY

For maximum  
bone preservation  
Ref. F57809



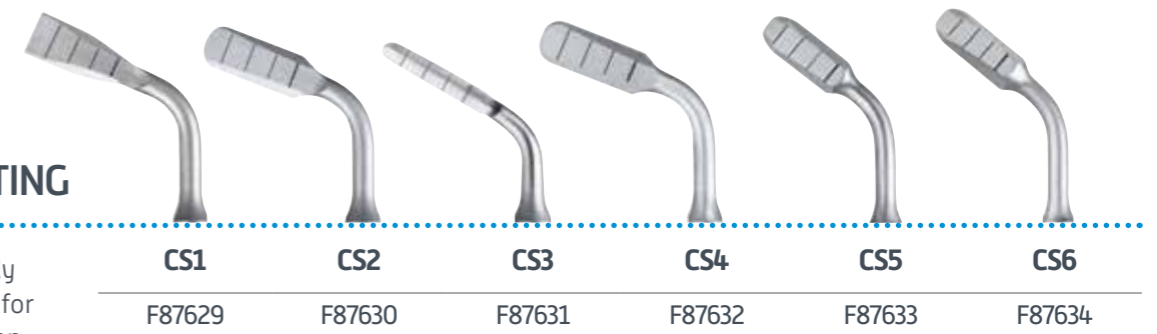
## CROWN EXTENSION

Excellent precision and accessibility  
Ref. F57810



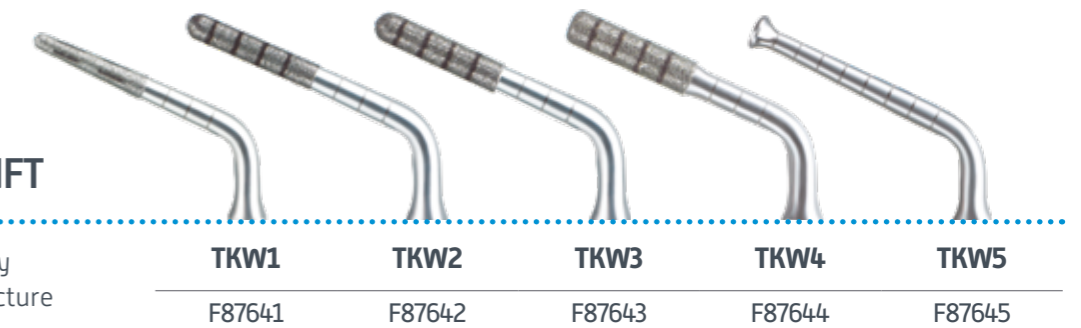
## CREST SPLITTING

Rapid and minimally  
invasive technique for  
controlled expansion  
Ref. F57808

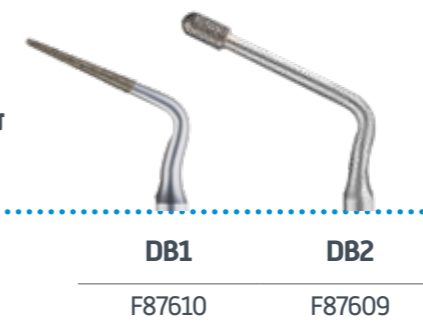


## CRESTAL SINUS LIFT

Minimally invasive surgery  
for smooth sinus floor fracture  
Ref. F57807



## BONE DRILLING & REMODELING

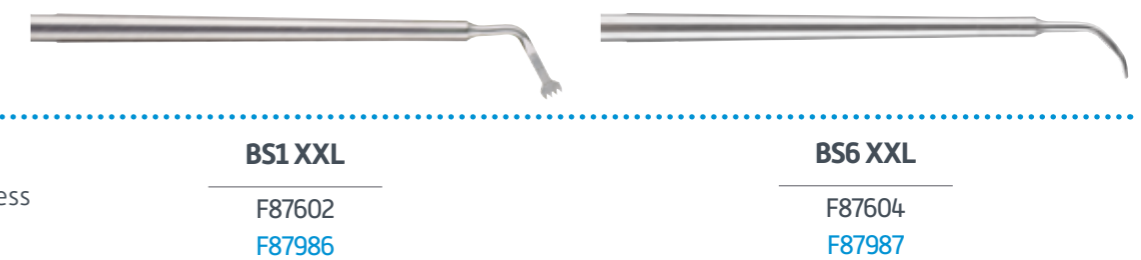


## DEEP BONE ACCESS



## LONG LENGTH TIPS

For minimally invasive  
techniques and easier access





## RhinoPlasty GERBAULT

## RhinoPlasty Expert - GERBAULT

## OtherTips

## SinusLift

## CrestSplitting

TIPS	Recommended mode	Fine setting*	Irrigation ml/mn
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### Rhinoplasty Basic & Expert

RHS1	D1	3	60
RHS2Fb	D1	3	60
RHS2Hb	D1	3	60
RHS3L/RHS3R	D1	3	60
RHS4L/RHS4R	D1	3	60
RHS5	D1	3	60
RHS6	D1	3	80

### Bone Drilling & Remodeling

DB1	D1	3	80
DB2	D1	3	80-100

### Deep Bone Access

LC1XL	D1	3	80-100
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### Long Length Tips

BS1XXL	D1	3	80
BS6XXL	D1	3	80

### Lateral sinus lift

SL1	D1	3	60
SL2	D1	3	60
SL3	D4	3	50
SL4	D4	3	30
SL5	D4	3	30

### Crest Splitting

	Mandible	Maxilla		
CS1	D2	D3	3	80-100
CS2	D2	D3	3	80-100
CS3	D2	D3	3	80-100
CS4	D2	D3	3	80-100
CS5	D2	D3	3	80-100
CS6	D2	D3	3	80-100

## CranioMaxilloFacial

## BoneSurgery

## IntraLift

## Extraction

## CrownExtension

TIPS	Recommended mode	Fine setting*	Irrigation ml/mn
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### Cranio-Maxillo-Facial (CMF)

BS1L	D1	3	60
BS1RD	D1	3	80
BS2LXL/BS2RXL	D1	3	60
BS4	D1	3	60
SL1	D1	3	60

### Osteotomy & Osteoplasty

BS1S	D1	3	60
BS2L/BS2R	D1	3	60
BS4	D1	3	60
BS5	D3	3	60
BS6	D1	3	60

### Crestal sinus lift

TKW1	D2	3	100
TKW2	D2	3	100
TKW3	D2	3	100
TKW4	D2	3	100
TKW5	D2	3	100

### Syndesmotomy

LC1	D1	3	80-100
LC2	D1	3	80-100
LC2L/LC2R	D1	3	80-100
NINJA™	D1	3	80-100

### Crown extension

BS6	D1	3	60
CE1	D1	3	60-80
CE2	D2	3	60-80
CE3	D1	3	60-80

\*Not applicable to Piezotome® Solo M+

# Tips Settings



## • THE BEST FOR YOU...

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"<sup>1</sup> → "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"<sup>2</sup>
- "ACTEON® produced the least increase of intraosseous temperature" versus competitors units<sup>3</sup>

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"<sup>2</sup>

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"<sup>4</sup>
- "A very quick performance was observed using Piezotome®"<sup>2</sup>
  - PIEZOTOME® = 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 3<sup>rd</sup> 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

## • ... AND FOR YOUR PATIENTS

1

### BETTER HEALING PROCESS AND BONE REGENERATION

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

2

### SMOOTHNESS: Less traumatic

- Decreased postsurgical morbidity "...significant reduction or almost absence of postsurgical ecchymosis/edema and significant reduction of pain"<sup>5</sup>
- "Increased patient satisfaction significantly"<sup>5</sup>
- 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"<sup>6</sup>

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  
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