PIEZOTOME CUBE

Adopt PIEZOTOME® extraction to favor bone preservation with immediate implant placement

PIEZOTOME® CUBE

with Essential kit

F50100

Delivered with a multifunction footswitch, a PIEZOTOME® CUBE LED handpiece, 1 handpiece holder, an Essential II kit (6 tips: BS1S, BS4, SL1, SL2, SL3 et LC2), a PIEZOTOME® autoclave dynamometric wrench, 1 bracket, 2 sterilizable irrigation lines, 5 clips and 15 perforators.

1. 1.2. 1.3. 1.4. 1.5. 1.6. 1.7. 1.9.

PIEZOTOME® CUBE

with Universal kit

F50113

Delivered with a multifunction footswitch, a PIEZOTOME® CUBE LED handpiece, 1 handpiece holder, an Universal kit (6 tips: BS6, LC1, LC2, CE1, CE3 et PZ1), a PIEZOTOME® autoclave dynamometric wrench, 1 bracket, 2 sterilizable irrigation lines, 5 clips and 15 perforators.

For more information, please consult our website

Website

www.acteongroup.com/en/products/equipment

Class IIa medical devices (GMED) - CE 0459 - Manufacturer: SATELEC® - France

PIEZOTOME® CUBE ACCESSORIES

PIEZOTOME® CUBE LED HANDPIECE
Compatible with 2nd generation piezo tips ➜
Class IIa medical device (GMED) - CE 0459 - Manufacturer: SATELEC® - France
F12816

MULTIFUNCTION FOOTSWITCH
PIEZOTOME® CUBE
F50109

HANDPIECE HOLDER
F50133

PIEZOTOME® AUTOCLAVABLE DYNAMOMETRIC WRENCH
F50150

IRRIGATION LINE CLIPS x10
F50116

BRACKET FOR PIEZOTOME® CUBE LED
F50129

LIGHT RING
PIEZOTOME® CUBE LED handpiece
F12828

FOR FURTHER INFORMATION

Piezotome® Cube & Tips Catalog
Réf. D50111

Around Piezotome® Cube video

FAST, SAFE AND MINIMALLY INVASIVE

1.8.

IntraLift

OSTEOTOMY - PILOT DRILLING

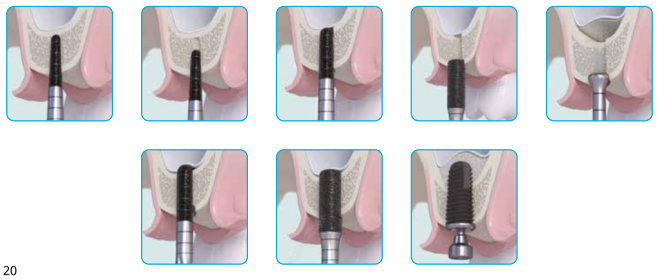
- **TKW1**
  Conical and diamond-coated tip for pilot drilling in very dense cortical bone (Ø 1.35mm).

OSTEOTOMY - SECONDARY DRILLING

- **TKW2**
  Cylindrical and diamond-coated tip dedicated for drilling and fracturing the sinus floor (Ø 2.1mm).
- **TKW3**
  Cylindrical tip dedicated to drill and widen the access canal to sinus membrane (Ø 2.35mm).
- **TKW4**
  Cylindrical and diamond-coated tip intended for the receptacle preparation and widening the access canal to the sinus membrane (Ø 2.8mm).

MEMBRANE DETACHMENT (ELEVATION)

- **TKW5**
  Tip Ø 3mm to be placed in the receptacle preparation for sinus membrane elevation by crestal approach.



FOR AN UNMATCHED VISIBILITY

SinusLift

VESTIBULAR BONE WINDOW CUT

OSTEOTOMY

- **SL1**
  Diamond-coated tip for vestibular bone window cut and for attenuation of sharp angles.

OSTEOPLASTY

- **SL2**
  Diamond-coated ball tip for smoothing the vestibular bone window and precise osteoplasty.

MEMBRANE DETACHMENT

- **SL3**
  Plateau tip served for sinus membrane elevation on the window's edges.
- **SL4**
  Spatula served for sinus membrane elevation inside the sinus.
- **SL5**
  Spatula used for sinus membrane elevation inside the sinus and for disengagement of anatomical structures.

11 Technical specifications of the medical device

11.1 Identification

Manufacturer	SATELEC, a company of Acteon group
Name of the medical device	Piezotome Cube

11.2 Generator

Supply voltage	100 - 240 VAC	*7.*
Power supply frequency	50 / 60 Hz	*7.*
Power consumption	150 - 150 VA	
Voltage supplied to handpiece	150 VAC	
Power setting range	D1 - D4	*5.*
Output frequency	28 kHz - 36 kHz	*3.*
Type of leakage currents	BF	
Operating mode	Intermittent: 10 minutes ON / 5 minutes OFF	
Electrical rating	I	
Fuse (mains connector)	2 fuses T2AL, 250 VAC	
Width	251 mm	
Height	160 mm, 481 mm with bracket	
Depth	271 mm	
Weight	3,500 g without accessories	
Ingress protection rating	IPX0	

11.3 Length of cords

Handpiece cord	2 500 mm +/- 50 mm	*1.2.*
Control pedal cord	2 500 mm +/- 50 mm	*7.2.*

11.4 Irrigation

Bottles or irrigation bags should not weigh more than one kilogram. A heavier container will make the medical device tip over.

Maximum volume of irrigation solution bags	1,000 ml	
Maximum weight of irrigation solution bags	1,000 g	
Nominal water output flow at the end of the handpiece Cube LED	0 ml/min to 120 ml/min	*4.*
Maximum water output flow at purge	120 ml/min	

11.5 Footswitch

Width	173 mm
Height	140 mm including arch
Depth	176 mm
Weight	1,060 g
Ingress protection rating	IPX1

ACTEON® MAKES THE DIFFERENCE

CUBE LED HANDPIECE

Upgraded conception based on ACTEON®
6 ceramic rings
- More power than ever

Lighter with perfectly balanced design
- Natural gesture, rotation free for less hand fatigue

Full white color LED ring (100,000 Lux) **2.1.**
- Great tissue distinction and posterior areas visibility

TIPS **6.**

Many exclusive designs
- Clinical versatility

Strengthened by surface treatment
- Excellent durability

FAST ASSEMBLY
6.2. TORQUE WRENCH

- Saves precious time
- Robust stainless steel dynamometric wrench

TOTAL ADAPTABILITY

Autoclavable handpiece holder with 2 positions protecting from accidental fall:
- "Clip" table
- "On" table

ABSOLUTE CONTROL

Weighted multifunctional footswitch

MAKE IT EASY

PERISTALTIC PUMP
- Fast and intuitive insertion of the irrigation line in the pump
- Small size and robust
- Precise adjustment (ml/min) and regular flow rate reaching the tip's end

EXTERNAL IRRIGATION LINE
- Extend the handpiece lifetime
- Immediate visual control throughout the procedure
- Provide complete sterile work and ease maintenance
- Autoclavable or single use delivered sterile

DURABILITY

Piezotome® Cube accessories are designed, with robust and durable materials like stainless steel, limiting the use of plastic.
A willingness of ACTEON® to offer you a clinical accompaniment over the years.

STERILISATION **2.2.**
CONSCIENTIOUSNESS

- Easy maintenance
- Direct access to all parts
- Meeting hygiene constraints

7.7 Screen of the medical device

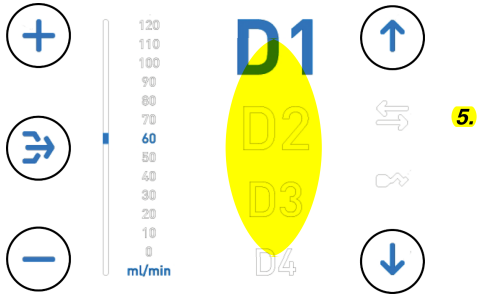
The screen of the medical device serves as the interface display.

It is tactile such that practitioners can make adjustments by pressing the active areas.

> Always make adjustments with your finger. Never use stylets or instruments, as these may damage the screen.

> The touch zones are capacitive and extremely sensitive. The screen must therefore be constantly clean and dry to avoid disturbing user-defined settings.

The tactile areas, those with which you can interact with the medical device, are as shown below.



Set the irrigation flow by pressing the tactile zones + and −

Select the requisite mode by pressing the tactile zones ↑ and ↓

Activate the purge by pressing the tactile zone

7.8 Setting the power

The ultrasound power must be adjusted in accordance with the tip used and the required treatment.

Select the requisite mode by pressing the tactile zones ↑ and ↓

Each tip must be used in accordance with the settings defined in the power settings table for intraoral surgery ultrasonic generators [J58010].

7.9 Setting the irrigation flow

The medical device must be set to minimum power to adjust the irrigation flow rate. Press the footswitch until a spray appears.

Because work habits, feedback and professional training differ from one professional to another, the user must ensure that the irrigation flow is compatible with the procedure to be carried out to prevent burns to the clinical site.

Adjust the irrigation flow using the irrigation flow configuration arrows. This setting depends on the tip used and on the procedure to be carried out.

Set the irrigation flow by pressing the tactile zones + and −

7.9.1 Activating the purge function/starting irrigation

Press and hold the purge icon for as long as necessary.

Activate the purge by pressing the tactile zone

7.10 Air inlets

Air inlets ensure correct ventilation of the control unit. Leave them uncovered to allow air to circulate.

7.11 Control pedal

The pedal can be set either in ON/OFF mode or in progressive operation. 7.

Pressing the foot-switch automatically activates the handpiece ultrasounds and the irrigation function. 7.

The control footswitch fitted with its cord must be disconnected for daily cleaning using an alcohol disinfectant wipe.

The light function remains active for approx. 9 seconds after the pedal is released.

For further information, refer to the chapter entitled *Pedal Overview page 1*.

7.12 Mains Connector

The mains connector with its earthing pin is used to connect the device to the electrical network via a disconnectable mains cord.

7.13 Switch

The mains switch is used to switch on (position I) or to stop (position O) the medical device.

7.14 Fuse recess

The recess holds two fuses designed to protect the medical device in the event of overvoltage or an internal fault.

Please read the instructions listed in the chapter *Replacing the fuses page 25*

7.15 Irrigation lines

The autoclavable irrigation lines can be reused after cleaning, disinfection and sterilisation.

After use, sterile irrigation lines should be discarded in a biomedical waste container.

Bottles or irrigation bags should not weigh more than one kilogram. A heavier container will make the medical device tip over.

The medical device is not designed to deliver medicinal substances.

The medical device may only be used with bags or bottles of saline solution or sterile water.

SECURE & BROADEN YOUR SCOPE IN SURGERY

6.

Extraction

Syndesmotomy
For maximum bone preservation
LC1, LC2 (x2), LC2L, LC2R, Ninja® tips
Ref. F87546

Widening the ligamentary space. LC tips separate the tooth from its attachment system for a rapid extraction, with less luxation, keeping intact the alveolar bone edge.

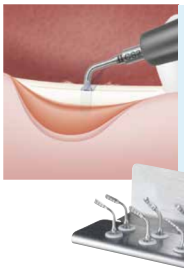
F87540: EXTRACTION Pack (*An Extraction II kit, a sterilization box, a Piezotome® LED handpiece and its autoclavable cord, a dynamometric wrench*)

BoneSurgery

Osteotomy/ Osteoplasty
Clean and thin cut for maximal bone volume
BS1S, BS2L, BS2R, BS4, BS5, BS6 tips
Ref. F87509

Performing bone graft, allows cutting, excising and remodeling bone structures reducing the risk of soft tissue lesions.

F87500: BONE SURGERY Pack (*A Bone Surgery II kit, a sterilization box, a Piezotome® LED handpiece and its autoclavable cord, a dynamometric wrench*)



CrestSplitting

Rapid and minimally invasive technique for controlled expansion
CS1, CS2, CS3, CS4, CS5, CS6 tips
Ref. F87567

The increasing tips thickness allows a smooth crest expansion limiting the risk of bone fracture.

F87560: CREST SPLITTING Pack (A CS kit, a sterilization box, a Piezotome® LED handpiece and its autoclavable cord, a dynamometric wrench)

SinusLift

Lateral Sinus Lift
Unbeatable comfort: selective and hemostatic cut
SL1, SL2, SL3, SL4, SL5 tips
Ref. F87519

A thin cut performed without effort, limiting any risk of sinus membrane perforation or antral artery damage.

F87510: SINUS LIFT Pack (A SL II kit, a sterilization box, a Piezotome® LED handpiece and its autoclavable cord, a dynamometric wrench)

IntraLift

Crestal Sinus Lift
Minimally invasive surgery for smooth sinus floor fracture
TKW1, TKW2, TKW3, TKW4, TKW5 tips
Ref. F87536

Sinus lift by the crestal approach: the IntraLift Kit makes it possible to perform non invasive surgery in full safety.

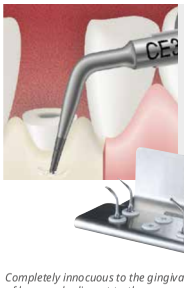
F87530: Intralift™ Pack (A Intralift™ II kit, a sterilization box, a Piezotome® LED handpiece and its autoclavable cord, a dynamometric wrench

PiezoCision

Accelerated Orthodontic Surgery
Minimal incisions, minimally invasive
PZ1, PZ2L, PZ2R, PZ3 tips
Ref. F87576

Treatment of malocclusions by ultrasonic corticotomies for a quicker and minimally invasive surgery, flapless or sutureless. Bone stimulated by micro-incisions accelerates tooth movement, the treatment is 3 to 4 times faster.*

F87570: Piezocision™ Pack (A Piezocision™ kit, a sterilization box, a Piezotome® LED handpiece and its autoclavable cord, a dynamometric wrench)



CrownExtension

Crown Lengthening
Incomparable precision and accessibility
BS6, CE1, CE2, CE3 tips
Ref. F87554

Completely innocuous to the gingiva guaranteeing the integrity of bone and adjacent teeth.

F87550: CROWN EXTENSION Pack (A CE II kit, a sterilization box, a Piezotome® LED handpiece and its autoclavable cord, a dynamometric wrench)

Essential

The 6 fundamental ACTEON® tips
BS1S, BS4, SL1, SL2, SL3, LC2 tips
Ref. F87528

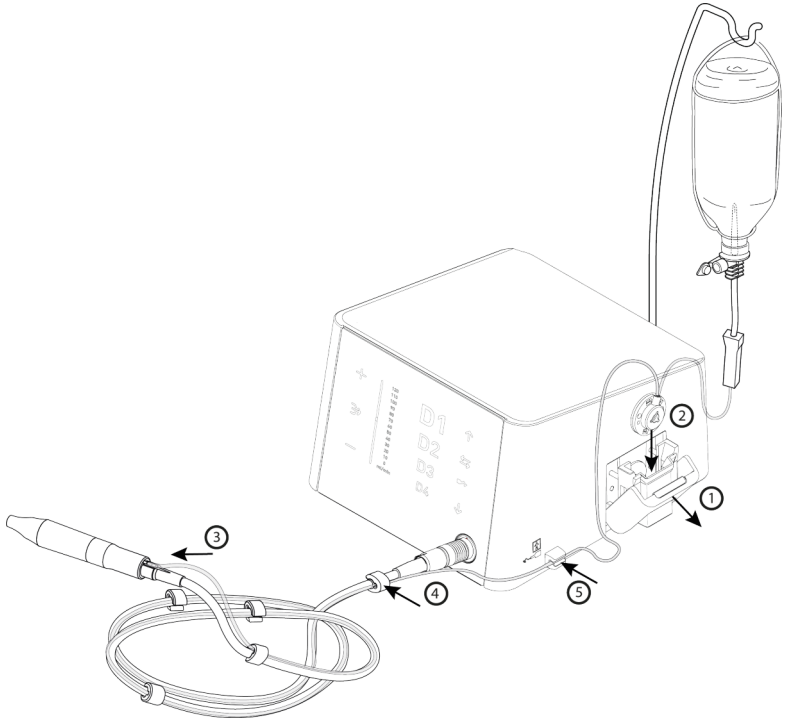
Kit delivered with the following references: F50510, F50100

For osteotomy, osteoplasty, extraction and lateral sinus lift.

F87529: ESSENTIAL Pack (*An Essential kit, a sterilization box, a Piezotome® LED handpiece and its autoclavable cord, a dynamometric wrench*)

All kits are delivered with an autodavable metal support and an universal wrench.

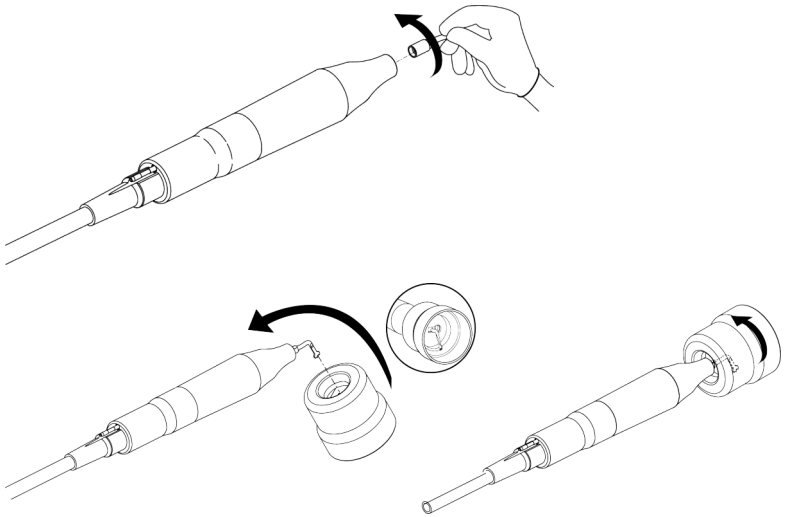
*Sebaoun JD, Surmenian J, Ferguson DJ, Dibart S. Acceleration of orthodontic tooth movement following selective alveolar decortication: biological rationale and outcome of an innovative tissue engineering technique. *International Orthodontics*. 2008;6:235-249.



5.5 Attaching a tip *6.2.*

The tips that can be used on this medical device are referred to as "second generation". They are recognizable by the engraving II on the base. They are incompatible with first-generation Implant Center and Piezotome tips.
Conversely, older-generation tips are incompatible with Piezotome Cube, Implant Center Cube, Implant Center 2 LED, Piezotome 2 and Piezotome Solo LED.
A tip vibrates correctly when it is perfectly tightened without being forced beyond its stop point. Tighten it moderately using the wrench supplied to ensure optimum ultrasonic function. Over-tightening of the tip can result in breakage of the tip or handpiece.

| To prevent self-locking of the tip, the latter must be removed and sterilised after each use. *6.3.*



The wrench is a sliding torque wrench. After a few turns, the wrench will seem to slide or turn without resistance. This means the tightening torque is reached. ***6.2.***

4 Manual instructions

4.1 Pre-disinfection and cleaning – Manual method

Equipment: soft brush, soft lint-free swab, lint-free cloth, syringe, pipette or water spray, alkaline cleaner, ultrasonic cleaner.

Minimum duration of step	Cleaning instructions
1 minute	Rinse the soiled device under cold running water. Use a soft-bristled brush, a swab or a lint-free cloth to remove most of the contamination. Use a syringe, a pipette or a water spray with an alkaline or enzymatic cleaning solution to rinse the tip cannulation.
10 minutes	Immerse the medical device in a freshly prepared alkaline cleaning solution in an ultrasonic cleaner for at least ten minutes. Adhere to the manufacturer's exposure time, concentration, water quality and temperature recommendations.
1 minute	Rinse the device under cold running water. Use a syringe, a pipette or a water spray to rinse the tip cannulation.
4 minutes	Wash and disinfect the medical device using an alkaline cleaning solution. Remove surface contamination using a soft brush or a swab. Wash the medical device in water to prevent contaminants from spreading into the air
1 minute 30 seconds	Rinse the medical device in deionised or purified water. Use a syringe, a pipette or a water spray to rinse the tip cannulation.
	Visually inspect the medical device. Repeat this procedure until the medical device is visibly clean. Perform a final rinse of the device using distilled or purified water. Dry the medical device using a soft lint-free cloth or medical grade clean compressed air

4.2 Sterilisation *6.3.*

Unless otherwise specified, non-sterile products can be resterilised using validated steam sterilisation methods (ISO 17665 or national standards). SATELEC, a company of Acteon group recommends the following:

Sterilisation exposure time	Sterilisation exposure temperature	Drying time
4 minutes	132 °C	15 minutes minimum and 20 minutes
18 minutes	134 °C	15 minutes minimum and 20 minutes
4 minutes	134 °C	15 minutes minimum and 20 minutes
3 minutes	134 °C	15 minutes minimum and 20 minutes

Saturated steam sterilisation with pre-vacuum

The drying times vary from 15 to 60 minutes according to the following criteria:

- the type of packaging material, such as a sterile barrier system or rigid reusable containers;
- steam quality;
- device materials;
- total mass;
- steriliser performance;
- usual practices for the geographical area;
- varying cool-down times.

The manufacturer accepts no responsibility for sterilisation procedures performed by the end user or the customer that are not performed according to the manufacturer’s recommendations.

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 21427 rev. 11**
Délivrée à Paris le 03 avril 2020
Issued in Paris on April 3rd, 2020

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'assurance Qualité/ *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

SATELEC, a Company of ACTEON Group

17 av. Gustave Eiffel, ZI du Phare
33700 MERIGNAC FRANCE

Catégorie du(des) dispositif(s) / *Device(s) category*

Dispositifs médicaux et dispositifs électro médicaux pour l'art dentaire, l'électro chirurgie et les équipements de chirurgie des os et substituts osseux, avec leurs accessoires stériles et non stériles

Medical devices and electromedical devices for dental art, electrosurgery and bone and bone substitute surgery equipments , with associated sterile and non-sterile accessories

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P159650 / P601259, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P159650 / P601259, the quality system - for design, manufacturing, and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **April 3rd, 2020 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED 2AS GMED GROUPE LNE Digitally signed by Béatrice LYS

On behalf of the President
Béatrice LYS
Technical Director

GMED_b2p3RS-F-V0-07-2018

GMED - 21427 rev. 11
Modifie le certificat 21427-10

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Code NBOG** *NBOG code*	**Classe du DM** *MD class*
Consoles de commande (ultrasonique, d'aéropolissage et / ou moteur) avec leurs accessoires stériles et non stériles destinées à l'art dentaire (soins conventionnels et/ou de chirurgie intra-orale) -- *Control consoles (ultrasonic, air polishing and / or motor) with associated sterile and non-sterile accessories for dentistry (conventional and or intraoral surgery)*			
SUPRASSON P5 BOOSTER	TA10	MD 1106	IIa
P5 NEWTRON -- P5 NEWTRON LED -- P5 NEWTRON XS -- P5 NEWTRON XS LED -- ULTRAWAVE -- ULTRAWAVE XS LED	TF48	MD 1106	IIa
NEWTRON BOOSTER	TBAB	MD 1106	IIa
NEWTRON P5 B.LED -- NEWTRON P5 XS B.LED	TBAC	MD 1106	IIa
VDW.ULTRA Standalone Ultrasonic -- P5 PRO Ultra Piezo Ultrasonic	TF50	MD 1106	IIa
PROPHYMAX	TC21	MD 1106	IIa
AIR MAX	TC20	MD 1106	IIa
GENIUS -- ENDO DUAL	TO69	MD 1106	IIa
PIEZOTOME SOLO LED	TO23	MD 1106	IIa
PIEZOTOME 2 -- IMPLANTCENTER 2	TO24	MD 1106	IIa
PIEZOTOME CUBE	TO37	MD 1106	IIa
Modules de commande (ultrasonique, moteur) destinés à être intégrés dans un système électronique de soins dentaires avec leurs accessoires stériles et non stériles -- *Control modules (ultrasonic, motor) intended to be integrated in dental care electronic system with associated sterile and non-sterile accessories*			
SP NEWTRON -- SP 4055 NEWTRON -- SP NEWTRON LED	TM07	MD 1106	IIa
XINETIC	TBAA	MD 1106	IIa
Consoles de commande d'électrochirurgie avec leurs pièces à main et leurs électrodes d'électrochirurgie stériles et non stériles et leurs accessoires stériles et non stériles -- *Electro surgery control consoles with handpiece holder, electrosurgery electrodes with associated sterile and non-sterile accessories*			
SERVOTOME -- Electrode Holder -- Neutral electrode (Bracelet) Active Electrodes: I22S -- I22CA -- TR22L -- TR22R -- TR22T -- FC25B -- FC32B -- FC10N -- I40S -- I40CA	TB15	MD 1106	IIb
Consoles de commande (ultrasonique, moteur) avec leurs accessoires stériles et non stériles destinées à la chirurgie des os et substituts osseux -- *Control consoles (ultrasonic, motor) with associated sterile and non-sterile accessories for bone and bone substitute surgery*			
PIEZOTOME SOLO M+	TO27	MD 1104	IIb
PIEZOTOME M+ -- IMPLANTCENTER M+	TO26	MD 1104	IIb
PIEZOELECTRIC SYSTEM	TO22	MD 1104	IIb
Pièces à main ultrasoniques dentaires stériles et non stériles -- *Sterile and non-sterile dental ultrasonic handpieces*			
NEWTRON (Handpiece) -- SUPRASSON (Handpiece)	TG42	MD 1106	IIa
NEWTRON LED (Handpiece)	TG46	MD 1106	IIa
NEWTRON SLIM (Handpiece) -- NEWTRON SLIM B.LED (Handpiece)	TBAE	MD 1106	IIa

GMED 0459

On behalf of the President
Béatrice LYS
Technical Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Code NBOG** *NBOG code*	**Classe du DM** *MD class*
Pièces à main ultrasoniques de chirurgie intra-orale stériles et non stériles -- *Sterile and non-sterile ultrasonic handpieces for intraoral surgery*			
PIEZOTOME LED (Handpiece) -- PIEZOTOME SOLO (Handpiece) -- CUBE LED (Handpiece)	TE10	MD1106	IIa
Pièces à main ultrasoniques destinées à la chirurgie des os et substituts osseux stériles et non stériles -- *Sterile and non-sterile ultrasonic handpieces for bone and bone substitute surgery*			
PIEZOTOME M+ LED (Handpiece) -- PIEZOELECTRIC SYSTEM (Handpiece)	TO42	MD 1104	IIb
Pièces à main d'aéropolissage dentaire stériles et non stériles et leurs accessoires stériles et non stériles -- *Sterile and non-sterile Dental air polishing handpiece with associated sterile and non-sterile accessories*			
AIR-N-GO EASY	TC07	MD 1106	IIa
PROPHYPEN	TC22	MD 1106	IIa
Inserts dentaires stériles et non stériles -- *Sterile and non-sterile dental tips*			
1 -- 1S -- 2 -- 3 -- 10P -- 10X -- 10Z -- P14D -- P15LD -- P15RD -- S12-70D -- AS3D -- AS6D -- AS9D -- ASLD -- ASRD -- 5AE -- PM1 -- PM2 -- PM3 -- PM4 -- C20 -- EX1 -- EX2 -- EX3 -- EXL -- EXR -- PMS1 -- PMS2 -- PMS3 -- PMV1 -- PMV2 -- PMV3 -- PMV4 -- PMV5 -- PMV6 -- H1 -- H2L -- H2R -- H3 -- H4L -- H4R -- PH1 -- PH2L -- PH2R -- P2L -- P2R -- PFU -- PFL -- PFR -- TK1-1S -- TK1-1L -- TK2-1L -- TK2-1R -- IP1 -- IP2L -- IP2R -- IP3L -- IP3R -- ET18D -- ET20 -- ET20D -- ET25 -- ET25S -- ET25L -- ET40 -- ET40D -- ETBD -- ETPR -- SO4 -- CAP1 -- CAP2 -- CAP3 -- K10/21 -- K15/21 -- K25/21 -- K30/21 -- K10/25 -- K15/25 -- K25/25 -- K30/25 -- IRR 25/21 -- IRR 25/25 -- IRR 20/21 -- IRR 20/25 -- CAVI 1-BD -- CAVI 2-DC -- CAVI 3-DF -- REDO 1 -- REDO 2 -- REDO 5 -- MAXI MPR	TG30	MD 0401	IIa
Inserts de chirurgie dentaire (intra-orale) stériles et non stériles -- *Sterile and non-sterile tips for intraoral surgery*			
BS2L II -- BS2R II -- BS4 II -- BS5 II -- BS6 II -- LC1 II -- SL1 II -- SL2 II -- SL3 II -- SL4 II -- SL5 II -- BS1S II -- BS1L II -- TKW1 II -- TKW2 II -- TKW3 II -- TKW4 II -- TKW5 II -- LC2 II -- LC2L II -- LC2R II -- NINJA II -- CE1 II -- CE2 II -- CE3 II -- BS1RD II -- CS1 II -- CS2 II -- CS3 II -- CS4 II -- CS5 II -- CS6 II -- PZ1 II -- PZ2R II -- PZ2L II -- PZ3 II	TE25	MD 0401	IIa
Inserts de chirurgie des os et substituts osseux non stériles -- *Non-sterile tips for bone and bone substitute surgery*			
Saw 20.9 x 14.1 x 4.0 x 0.6mm for Piezoelectric System (03.000.401) -- Saw 20.1 x 21.4 x 4.0 x 0.6mm for Piezoelectric System (03.000.402) -- Saw Left 17.8 x 15.2 x 4.0 x 0.6mm for Piezoelectric System (03.000.403) -- Saw Right 17.8 x 15.2 x 4.0 x 0.6mm for Piezoelectric System (03.000.404) -- Scalpel round 22.45 x 12.6 x 3.9 dia x 0.7mm for Piezoelectric System (03.000.405) -- Scalpel Flat 21.6 x 11.1 x 3.0 x 0.5mm for Piezoelectric System (03.000.406) -- Scalpel 17.7 x 15.5 x 1.2 x 0.5mm for	TO49	MD 1104	IIb

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Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Code NBOG** *NBOG code*	**Classe du DM** *MD class*
Piezoelectric System (03.000.407) -- Spade round 24 x 11.05 x 4.0 x 0.65mm for Piezoelectric System (03.000.408) -- Lift 22.9 x 10.1 x 5.0 mm dia x 0.4mm for Piezoelectric System (03.000.411)			
BS1 XXL M+ -- BS1L M+ -- BS1RD M+ -- BS2L XL M+ -- BS2R XL M+ -- BS4 M+ -- BS6 XXL M+ -- RHL5 M+ -- RHS1 M+ -- RHS2Fb M+ -- RHS2Hb M+ -- RHS3L M+ -- RHS3R M+ -- RHS4L M+ -- RHS4R M+ -- RHS5 M+ -- RHS6 M+ -- RHS2F M+ -- RHS2H M+ -- SL1 M+ -- SL2 M+ -- SL3 M+ -- SL4 M+ -- SL5 M+ -- BS1S M+ -- BS2R M+ -- BS2L M+ -- BS5 M+ -- BS6 M+ -- LC1 M+ -- LC1 XL M+ -- LC2 M+ -- LC2 L M+ -- LC2 R M+ -- NINJA M+ -- CE1 M+ -- CE2 M+ -- CE3 M+ -- TKW1 M+ -- TKW2 M+ -- TKW3 M+ -- TKW4 M+ -- TKW5 M+ -- CS1 M+ -- CS2 M+ -- CS3 M+ -- CS4 M+ -- CS5 M+ -- CS6 M+ -- DB1 M+ -- DB2 M+	TO51	MD 1104	IIb
Inserts de chirurgie des os et substituts osseux stériles -- *Sterile tips for bone and bone substitute surgery*			
Saw 20.9 x 14.1 x 4.0 x 0.6 mm for Piezoelectric System, sterile (03.000.401S) -- Saw 20.1 x 21.4 x 4.0 x 0.6 mm for Piezoelectric System, sterile (03.000.402S) -- Saw left, 17.8 x 15.2 x 4.0 x 0.6 mm for Piezoelectric System, sterile (03.000.403S) -- Saw, right, 17.8 x 15.2 x 4.0 x 0.6 mm for Piezoelectric System, sterile (03.000.404S) -- Scapel round, 22.45 x 12.6 x 3.9 mm dia x 0.7 mm for Piezoelectric System, sterile (03.000.405S) -- Scapel flat, 21.6 x 11.1 x 3.0 x 0.5 mm for Piezoelectric System, sterile (03.000.406S) -- Scapel 17.7 x 15.5 x 1.2 x 0.5 mm for Piezoelectric System, sterile (03.000.407S) -- Spade round, 24 x 11.05 x 4.0 x 0.65 mm for Piezoelectric System, sterile (03.000.408S) -- Diamond, 24.6 x 12.85 x 2.6 x 0.6 mm for Piezoelectric System, sterile (03.000.409S) -- Diamond round, 21.9 x 12.4 x 1.8 mm for Piezoelectric System, sterile (03.000.410S) -- Sinus Lift, 22.9 x 10.1 x 5.0 mm dia x 0.4 mm for Piezoelectric System, sterile (03.000.411S) -- Saw 105.7 x 4.0 x 0.6mm for Piezoelectric System, sterile (03.000.412S) -- Saw left 39.5 x 4.0 x 0.8mm for Piezoelectric System, sterile (03.000.418S) -- Saw right 39.5 x 4.0 x 0.8mm for Piezoelectric System, sterile (03.000.419S) -- Scalpel flat 105.1 x 3.0mm for Piezoelectric System, sterile (03.000.421S) -- Scalpel 32.1 x 1.2mm for Piezoelectric System, sterile (03.000.423S) -- Saw round 38.9 x 5.0mm dia x 0.6mm for Piezoelectric System, sterile (03.000.424S) -- Diamond cylindrical, 30.7 x 4.7 x 2.3mm for Piezoelectric System, sterile (03.000.425S) -- Diamond conical 26.8 x 11.0 x 0.5mm for Piezoelectric System, sterile (03.000.426S)	TO50	MD 1104	IIb

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On behalf of the President
Beatrice LYS
Technical Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Code NBOG** *NBOG code*	**Classe du DM** *MD class*
BS1 XXL M+ -- BS1L M+ -- BS1RD M+ -- BS2L XL M+ -- BS2R XL M+ -- BS4 M+ -- BS6 XXL M+ -- RHL5 M+ -- RHS1 M+ -- RHS2Fb M+ -- RHS2Hb M+ -- RHS3 LM+ -- RHS3 R M+ -- RHS4L M+ -- RHS4R M+ -- RHS5 M+ -- RHS6 M+ -- SL1 M+ -- SL2 M+ -- SL3 M+	TO52	MD 1104	IIb
Poudres pour dispositif d'aéropolissage dentaire -- *Powders for dental air polishing device*			
AIR-N-GO "CLASSIC"	TC10	MD 0401	IIa
AIR-N-GO "PERIO"	TC12	MD 0401	IIa
Moteurs avec leurs accessoires stériles et non stériles destinées à l'art dentaire -- *Motors with associated sterile and non-sterile accessories for dentistry*			
U.N.I MT	TF31	MD 1106	IIa
U.N.I MT.BL	TF34	MD 1106	IIa
Genius motor -- ENDO DUAL motor	TO68	MD 1106	IIa
Moteurs avec leurs accessoires stériles et non stériles destinés à la chirurgie intra-orale et/ou des os et substituts osseux -- *Motors with associated sterile and non-sterile accessories for intraoral surgery and / or bone and bone substitute surgery*			
I-SURGE -- I-SURGE LED	TF18	MD 1106	IIa
Nécessaire d'Inserts dentaires stériles et non stériles -- *Sterile and non-sterile dental tips Procedure Packs*			
Kit Détartrage (F00934) -- Kit Hygiène (F00935) -- Kit Paro (F00936) -- Kit Maintenance (F00937) -- Kit Perio Précision (F00939) -- Kit Excavus (F00739) -- Kit Endo One (F00732) -- Kit Implant Protect (F02120) -- Kit Endo success retreatment (F00737) -- Kit Endo success canal access prep (F88180) -- Kit Endo success apical surgery (F00069) -- Kit Perfect margin rounded (F00738) -- Kit Perfect margin shoulder (F00736) -- Kit Perfect Margin Veneers (F02020) -- Kit Newtron paro (F87321) -- Kit Newtron micro-retro (F87325) -- Kit Newtron retro (F87326)	TG30	MD 0401	IIa
Pack Newtron Paro (F87320) -- Pack Newtron Paro 2 (F87520) – Pack Newtron Retro (F87322) – Pack Newtron (F87324) -- Pack Newtron 2 (F87524)	TA16	MD 0401	IIa
Nécessaires d'Inserts de chirurgie dentaire (intra-orale) stériles et non stériles – *Sterile and non-sterile tips for intraoral surgery Procedure Packs*			
Kit Bone Surgery 2 (F87509) -- Kit Sinus Lift 2 (F87519) -- Kit Intralift 2 (F87536) -- Kit LC Extraction 2 (F87546) -- Kit Crown Extension 2 (F87554) -- Kit Crest Splitting 2 (F87567) -- Kit Piezocision II (F87576) -- Kit Essential II (F87528) -- BS1L II + Key (F87527)	TE25	MD 0401	IIa
Pack Piezotome 2 (F87523) – Pack Bone Surgery 2 (F87500) – Pack SL Sinus Lift 2 (F87510) – Pack Intralift 2 (F87530) – Pack Extraction 2 (F87540) – Pack Crown Extension 2 (F87550) – Pack Crest Splitting 2 (F87560) – Pack Piezocision II (F87570) – Pack Essential II (F87529)	TE26	MD 0401	IIa

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Nécessaires d'Inserts de chirurgie des os et substituts osseux non stériles – *Non-sterile tips for bone and bone substitute surgery Procedure Packs*			
KIT CMF NON STERILE (F57803) -- KIT RHS BASIC M+ N STER (F87681) -- KIT RHS EXPERT M+ N STER (F87689) -- KIT PRE-IMPLANTAIRE M+ (F57805) – KIT SINUS LIFT M+ (F57806) – KIT INTRALIFT M+ (F57807) – KIT CREST SPLITTING M+ (F57808) – KIT EXTRACTION M+ (F57809) – KIT M+ CROWN EXTENSION N STER (F57810)	TO51	MD 1104	IIb
PIEZOTOME M+ PACK (F57802)	TO53	MD 1104	IIb
Nécessaire d'Inserts de chirurgie des os et substituts osseux stériles – *Sterile tips for bone and bone substitute surgery Procedure Packs*			
KIT CMF STERILE (F57804) -- RHINOPLASTY ESSENTIAL KIT STERILE (F87999) -- RHINOPLASTY EXPERT KIT STERILE (F88000)	TO52	MD 1104	IIb

Identification du site couvert et des activités
Identification of location and activities

SATELEC - A Company of ACTEON Group - 17 av. Gustave Eiffel – ZI du Phare - 33700 MERIGNAC - FRANCE
Conception, fabrication et contrôle final
Design, manufacture and final control

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Béatrice LYS
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