

# User Manual



M+ handpiece





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# Foreword

The SATELEC<sup>®</sup> medical device that you are about use is designed for professional use only. It is therefore a key tool with which you will provide treatment within the context of your work.

These medical devices are designed to be used exclusively within a hospital or private clinic operating theatre. Patients will be under general anaesthesia unless the procedure only requires local anaesthesia.

To ensure optimum safety for yourself and your patients, comfort in your daily practice and to benefit fully from your medical device's technology, please read the documentation provided carefully.

If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.

Please refer to the instructions for the entire range of SATELEC<sup>®</sup> M+ ultrasonic medical generators for information about the following:

- documentation format;
- documentation archiving period;
- warnings concerning user and patient populations;
- treatment area;
- medical device usage interactions, contraindications and prohibitions;
- electromagnetic compatibility;
- disposal and recycling of the medical device;
- manufacturer responsibility.

Please refer to the various cleaning, disinfection and sterilisation protocols for information about the following:

- preparation of parts for sterilisation;
- detailed manual and automatic protocols;
- information concerning conditioning for sterilisation;
- recommendations for the inspection of parts.



# 1 Documentation

This document contains the following information:

- indications for use
- medical device description
- installation of the medical device
- medical device use
- preparation prior to cleaning and disinfecting the medical device
- monitoring and general maintenance of the medical device
- maintenance to be performed by the user.

## 1.1 Associated documentation

This document must be used in association with the following documents:

Document title	References
Method for consulting electronic user instructions	J00000
Cleaning, disinfection and sterilisation protocols for SATELEC <sup>®</sup> tips	J02001
Cleaning, disinfection and sterilisation protocols for the Piezotome <sup>®</sup> M+ handpiece	J12801
Piezotome <sup>®</sup> M+ handpiece user manual	J57521
Pack M+ Quick Start	J57870
Pack M+ Quick Clean	J57871
User manual for sterile M+ bone surgery tips	J87601
User manual for non sterile M+ bone surgery tips	J87611
M+ bone surgery tips Quick Reference	J87621
User manual for the sterile CMF kit	J57831
User manual for the non-sterile CMF kit	J57881

## 1.2 Electronic documentation

The user instructions for your device are provided in electronic format and not in printed format. However, you can request a free printed copy of the user instructions within 7 days via our website, by telephone or in writing.

The electronic user instructions are available in PDF format (Portable Document Format) and you will need to have a PDF file read software installed to read the instructions.

The device user instructions can be consulted at the following address:

[www.satelec.com/documents](http://www.satelec.com/documents)



Electronic user  
informations



It is important for you to have read and understood the content of the user instructions relating to the use of your device and its accessories prior to use.

We recommend that you visit the website regularly to consult and/or to download the latest version of your device's user instructions.





# 2 Required information

## 2.1 Indication for use

The Piezotome<sup>®</sup> M+ surgical piezoelectric handpiece can be used for osteotomy, osteoplasty, decortication, drilling, shaping and smoothing of teeth and bone in various surgical procedures, including but not limited to general, orthopaedic, otolaryngological, maxillofacial, oral, hand and foot, neurosurgery, spinal and plastic/reconstructive surgery.

The Piezotome<sup>®</sup> M+ handpiece-cord assembly is a medical device accessory specifically designed for use in combination with SATELEC<sup>®</sup> bone surgery devices in order to enable the device to be used. This use must comply with the indications specified in the manufacturer instructions.

The device can be used on patients of all ages, including paediatric patients.

## 2.2 Operating principle

The Piezotome<sup>®</sup> M+ handpiece is fitted with an ultrasound piezoelectric transducer. The handpiece has a light function that can illuminate the treatment area. The light function is provided by an LED ring, resulting in a service life that is much greater than standard technologies such as light bulbs or optical fibre.

## 2.3 Date of first inclusion of EC marking

2013

## 2.4 Latest document update

09/2013

## 2.5 Repairing or modifying the medical device

Contact the supplier of your device. Using the services of an unapproved repairer could render your device dangerous for you and your patients.

Do not repair or modify the device without seeking the prior permission of SATELEC<sup>®</sup>.

If the device is modified or repaired, specific checks and tests must be carried out to ensure that the medical device is still safe to use.

In the event of doubt, contact an approved dealer or the SATELEC<sup>®</sup> customer service team:

[www.acteongroup.com](http://www.acteongroup.com)

[satelec@acteongroup.com](mailto:satelec@acteongroup.com)

SATELEC<sup>®</sup> at the request of technical personnel working for the network of dealers approved by SATELEC<sup>®</sup>, provide all information required to repair the faulty parts on which they may perform repairs.

## 2.6 Accessory usage conditions

Accessories, handpieces must be cleaned, disinfected and sterilised prior to use.



# 3 Removal from packaging, installation, connections

## 3.1 Removing the medical device from its packaging

When you receive your medical device, check for any damage that may have occurred during transportation. If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.

## 3.2 Installing the medical device

Place the control unit in the position that is suitable for your activity. Check that the cords do not hinder the movement or free circulation of anyone. The medical device must be placed on a secure and flat surface or a surface with a maximum slope of 5 degrees.

Fix your medical device using the attachments provided to ensure that the device cannot be removed without the use of a tool.

Adjust the position of your medical device to correspond to your angle of vision and the characteristics of your workstation, e.g. lighting or distance between the user and the medical device.

Ensure that your medical device is readily accessible.

| Do not install your medical device near or on another device.

## 3.3 Installing cords

Check that the cords do not hinder the movement or free circulation of anyone. Make sure that it is not possible to wheel over or walk on the different cords. Cords attached to their I-Surge LED micromotor must be readily accessible. Make sure that the cord is slack during use.

Never rotate the handpiece connector on its cord as this can damage your medical device.



# 4 Medical device description

## 4.1 I-Surge LED micromotor

Only SATELEC<sup>®</sup> handpieces can be connected to the medical device. For further information, refer to the documentation listed in chapter *Associated documentation* page 5.


## 4.2 Installing a tip

| The Piezotome<sup>®</sup> M+ handpiece is a high-technology instrument that must be used with care.

- Rotate the M+ tip to screw it onto the handpiece along the horizontal axis of the handpiece part.
- When screwed in, tighten the tip with the wrench.
- Tighten with a gentle clockwise rotation of the wrench, but never tightening excessively.

| A tip vibrates correctly when it is perfectly tightened without being forced beyond its stop point. The tip must be removed after each use to prevent self-locking and allow the tip and handpiece to be cleaned and sterilised.

## 4.3 Connecting the Piezotome<sup>®</sup> M+ handpiece

The Piezotome<sup>®</sup> M+ handpiece and cord are connected on the front face of the ultrasound generator, on the ultrasound connector or connectors carrying the ultrasound logo 

Align the mark on the cord connector with the mark on the plug. Insert the connector until you hear a click.

## 4.4 Connecting and disconnecting M+ accessories during use

| Do not connect/disconnect the cords when the medical device is switched ON and the footswitch is pressed.

| Do not tighten or loosen the tips when the handpiece is activated.

## 4.5 Handpiece support

The handpiece can be placed on the support before and after use. The handpiece nozzle is placed in the lowest notch so as to allow any remaining fluid to drain away.

## 4.6 Cords

The Piezotome<sup>®</sup> M+ cord is only compatible with the Piezotome<sup>®</sup> M+ handpiece. It ensures circulation and is used to connect the medical device to the Piezotome<sup>®</sup> M+ handpiece.



# 5 Cleaning, disinfecting and sterilising

The instructions relating to cleaning, disinfection and sterilisation protocols for accessories provided by SATELEC® have been approved for each medical device and accessory. The applicable protocols are listed in the chapter *Associated documentation page 5*.

They can be downloaded at the following address:

[www.satelec.com/documents](http://www.satelec.com/documents)

In all cases, the local regulations in force relating to the cleaning, disinfection and sterilisation protocols for accessories take precedence over the information provided by SATELEC®.

| Do not use antiseptic products containing flammable substances.

## 5.1 Cleaning and sterilising the handpiece

To detach the tip, turn the wrench in the anticlockwise direction.

Place the tip in infectious clinical waste containers.

The clips and irrigation line are single-use and must be discarded in the appropriate container after any use.

Refer to the cleaning, disinfection and sterilisation protocols for accessories listed in chapter *Associated documentation page 5*.





## 6 Monitoring and general maintenance of the medical device

Before and after use, check the medical device and its accessories entirely for any problems. This is necessary to detect any isolation fault or damage. If necessary, replace damaged parts.

Check that the air inlets on the control unit are clean to prevent any overheating.

| The clips holding the irrigation lines may cause wear of the handpiece cords. Check each handpiece cord individually before and after use.



# 7 Maintenance

Maintenance of the medical device essentially involves preventive maintenance operations, covering the following aspects:

- checking of accessories;
- everyday cleaning, disinfection and sterilisation procedures.

## 7.1 Preventive maintenance

Symptoms: the nozzle, shroud or cord of the handpiece has cracks

Possible causes	Solutions
Repeated sterilisation cycles	Replace the handpiece and cord

## 7.2 Identifying incorrect operation

In the event of incorrect operation, refer to the tables below to quickly identify and repair the non-complex parts of the medical device.

If the incorrect operation is not described in the tables below, please contact your supplier or the customer service team at SATELEC®.

Do not use the medical device if it appears to be damaged or faulty. Isolate the medical device and make sure that it cannot be used.

### 7.2.1 Not working

Symptoms: the screen is off, the medical device failed to start

Possible causes	Solutions
Faulty connection between the mains cord and the medical device	Connect the mains cord to the medical device
Faulty connection between the mains cord and the electrical wall socket	Connect the mains cord to the electrical wall socket
Switch in position 0	Set the switch to position I
Mains fuses in the mains connector not working	Replace the mains fuses with fuses of the same type and rating
Internal fuse not working	Return the device to the SATELEC® customer service team
No electrical current	Contact your electrician
Transmission fault	Switch off the medical device then switch it on again Return the medical device to the SATELEC® customer service team

The medical device also has an internal fuse that cannot be accessed by the user.

### 7.2.2 Handpiece thread fitting

Symptoms: the tip is difficult to fit or is not correctly held in position

Possible causes	Solutions
Tip inserted incorrectly	Remove the tip then fit it back while being careful not to damage the thread fitting
Damaged thread fitting	Replace the handpiece

### 7.2.3 No spray or very little amount of spray

Symptoms: when the device is in use, irrigation is not working and no spray comes out the tip

Possible causes	Solutions
Irrigation solution bag empty	Replace the irrigation bag with a new one

Possible causes	Solutions
Irrigation deactivated	Start irrigation using the footswitch or touch-sensitive screen
Irrigation line blocked	Replace the irrigation line
Irrigation line pinched	Check the length of the irrigation line
Incorrect irrigation adjustment	Adjust the irrigation flow rate
The tip is blocked	Replace the tip

### 7.2.4 Light not working or too dim

Symptoms: the handpiece is not lighting up the clinical site

Possible causes	Solutions
LED ring missing in the handpiece nozzle	Install the LED ring
Faulty LED ring	Replace the LED ring
Cracks or fine cracks on the LED ring	Replace the LED ring
LED ring contacts faulty	Replace the LED ring
LED ring poles reversed	Install the LED ring with the correct polarity
Optical guide damaged	Replace the optical guide
Handpiece cord connector faulty	Dry the cord and medical device connectors Replace the handpiece and cord
Other	Return the medical device to the SATELEC® customer service team

### 7.2.5 Ultrasounds not working

Symptoms: the tip does not vibrate, vibration cannot be heard.

Possible causes	Solutions
Tip loose	Fasten the tip using the wrench
Connector with the medical device faulty	Clean the cord contacts
Handpiece cord wire(s) cut	Return the handpiece and cord to the SATELEC® customer service team to have them replaced

### 7.2.6 Water leakage

Symptoms: there is a water leak at the level of the handpiece

Possible causes	Solutions
The handpiece irrigation inlet is damaged	Replace the handpiece and cord Return the handpiece to the SATELEC® customer service team

# 8 Technical specifications of the medical device

## 8.1 Identification

Manufacturer	SATELEC®
Name of the medical device	Handpiece PIEZOTOME® M+

## 8.2 Piezotome® M+ handpiece

Length (in mm)	130
Maximum diameter (in mm)	23
Weight (in g)	100 experienced when held, 265 with cord

## 8.3 Length of cords

Piezotome® M+ handpiece cord (in mm)	2900
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## 8.4 Irrigation

Nominal water output flow at the handpiece tip of the Piezotome Solo® M+ (in ml/min)	0 to 120 ml
Nominal water output flow at the handpiece tip of the Piezotome® M+ and the ImplantCenter™ M+ (in ml/min)	10 to 120 ml
Nominal water output flow at purge (in ml/min)	120 ml per min

## 8.5 Environmental characteristics

Operating temperature	10 to 30°C
Storage temperature	-20°C to 70°C
Operating humidity	30 to 75%
Maximum storage humidity	10% to 100% including condensation
Atmospheric pressure	500 hPa to 1060 hPa
Altitude	2000 metres maximum

## 8.6 Environmental restrictions

Usage premises	The medical device is designed to be used in an operating theatre or in premises suitable for the procedure involved.
Use in gas-filled atmosphere	The medical device is not designed to be used in an AP or APG gas-filled atmosphere.
Immersion	The medical device must not be immersed.

## 8.7 Main performance characteristics

- Ultrasonic vibrations of the surgical tip fitted to the end of the surgical handpiece.
- Vibration frequency 28 kHz or greater.
- Modulation frequency



# 9 Regulations and standards


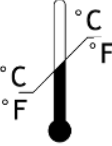
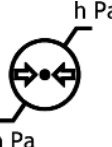






## 9.1 Official texts





This medical device complies with the essential requirements of European Directive 93/42/EEC. This equipment is designed and developed in compliance with the Electrical Safety standard IEC60601-1 in force. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system. This documentation complies with European regulation No.207/2012.

## 9.2 Medical class of the device

Class of medical device: IIb according to 92/42/EEC directive

## 9.3 Standardised symbols

Symbols	Meaning
	Authorised humidity range
	Authorised temperature range
	Authorised pressure range
	Quantity (1)
	Keep away from humidity
	Fragile
	Not to be used on patients with implantable medical devices
	Consult the User Manual
 Electronic user informations	Accompanying documentation in electronic format

Symbols	Meaning
	Sterilisation at 132 °C in an autoclave
	Washer disinfectant for thermal disinfection
	EC marking
	Year of manufacture

## 9.4 Manufacturer identification

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# 10 Disposal and recycling

As an item of Electrical and Electronic Equipment, the medical device must be disposed of via a specialist collection, removal, recycling or destruction channel. This applies in particular to the European market, in reference to Directive 2002/96/EC dated 27/01/2003.

When your medical device has reached the end of its service life, contact your nearest equipment dealer, or ACTEON GROUP head office or one of the company branches to find out how to proceed. The relevant contact details are given in chapter page 23.





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# 12 Glossary

with the device, or instructions for use available through a website [European regulation No.207/2012]

## A

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### **accessory**

includes micromotors, cords, hand-pieces, nozzles, LED rings, optical guides, tips, sterilisation boxes, and silicone supports used in conjunction with the control units

## B

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### **bag**

container filled with physiological saline solution or sterile water. Can designate either a flexible container or rigid container like a bottle.

## F

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### **fixed installed medical devices**

devices and their accessories which are intended to be installed, fastened or otherwise secured at a special location in a healthcare facility so that they cannot be moved from this location or detached without using tools or apparatus, and which are not specifically intended to be used within a mobile healthcare facility [European regulation No.207/2012]

## I

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### **Instructions for use**

information provided by the manufacturer to inform the user of the device of its safe and proper use, of its intended performances and of any precautions to be taken [European regulation No.207/2012]

### **instructions for use in electronic form**

instructions for use displayed in electronic form by the device, contained in portable electronic storage media supplied by the manufacturer together

## P

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### **professional users**

persons using the medical device in the course of their work and in the framework of a professional healthcare activity [European regulation No.207/2012]



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