General Instructions

Range of standard dental tips and files

This document is an English translation of the original French version.
Reference J02100 version V5 and drawing number RG30FR010E

Contents

1 Documentation

This document contains the following information:

- Patient, practitioner and environment safety
- Installing your medical device in optimum conditions
- Identifying the manufacturer or the latter's representatives if necessary

1.1 Associated documentation

Document title	References
Consulting electronic user instructions	J00007
Cleaning, disinfection and sterilisation instructions for tips	J02001
Endo One Kit clinical tips	J08001
Newtron P5 User Manual	J61101
Newtron P5 XS B.LED User Manual	J62151
Newtron Booster User Manual	J60111
PerfectMargin Rounded Kit clinical tips	J08131
PerfectMargin Shoulder Kit clinical tips	J08201
PerfectMargin Veneers Kit clinical tips	J08181
Endosuccess Retreatment Kit clinical tips	J08121
Excavus Kit clinical tips	J08141
Canal Access Preparation Kit clinical tips	J08171
Endosuccess Apical Surgery Kit clinical tips	J08161
PerioPrecision Kit clinical tips	J08151
Apical Surgery clinical tips	J08061
Periosoft clinical tips	J08191
BDR clinical tips	J08031
Periofine clinical tips	J02171
Periodontics clinical tips	J08021
IrriSafe clinical tips	J08081
Files - ET40 clinical tips	J08041
ImplantProtect Kit clinical tips	J02131
Condensation-Loosening-clinical tips	J08071
Scaling clinical tips	J08011
Ultrasonic generator power settings table	J58000
Cleaning, disinfection and sterilisation protocols for handpieces	J12911

1.2 Electronic documentation

The user instructions for your device are available in electronic format on the specified website and not in printed format. If the website is unavailable, try again later. You can also request a free printed copy of the user instructions within seven days via our website, by telephone or in writing.
The electronic user instructions are available in PDF format (Portable Document Format). You will need to have a PDF file reader installed to read the electronic user instructions. 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.

> Never use your device without first reading the user instructions.

The device user instructions can be consulted at the following addresses:www.ultradent.com and www.satelec.com.
When you receive your device, you are asked to print and/or to download all documents or sections of documents that you may need to refer to in the event of an emergency, if you are unable to connect to the internet or if your electronic display tool is not working (computer, tablet, etc.). We recommend that you visit the website regularly to consult and to download the latest version of your device's user instructions. Users are asked to keep documentation close at hand for reference when necessary.
All paper or electronic documentation relating to your medical device must be kept for the device’s entire service life. Keep the original documentation for your medical device and its accessories for future reference. When loaning out or selling the medical device, the documentation must be provided with it.

2 Warnings

2.1 Federal Law

> The indication below applies to the United States of America only.

The United States Federal Law restricts the use of this medical device in its territory to qualified, fit and certified dental health professionals (either directly or under their supervision).

2.2 Warning applicable to all countries in which the device is sold

> The information below is based on the requirements of standards to which the manufacturers of medical devices must adhere (as stated in standard IEC62366).

2.3 User population

This medical device must only be used by qualified dental health practitioners, fit and certified to perform their professional duties.

Users must know and comply with the rules of dental practice in compliance with knowledge acquired in the field and the key medical hygiene principles including cleaning, disinfection and sterilisation of medical devices.

The medical device can be used by any adult dental practitioner of any weight, age, height, gender or nationality.

The user must wear gloves.

The user is not the patient.

The user must not be prone to any of the following:

- visual impairments: any vision problems must be corrected by glasses or lenses.
- arm disability that may prevent the user from holding a handpiece;
- hearing difficulties that could prevent the user hearing audible alarms depending on medical devices;
- difficulty memorizing or concentrating that could affect the setting of sequences or the performance of treatment protocols.

2.4 Specific user training

No specific training other than initial professional training is required to use this medical device.

The practitioner is responsible for performing clinical treatments and for dangers that may arise due to a lack of skill and/or training.

2.5 Patient population

This medical device is designed to be used with the following patient populations:

- children ;
- Teenagers,
- Adults,
- Old Age Pensioners.

This medical device can be used on any patient of any weight (except children), age, height, gender or nationality.

2.6 Patient population restriction

This medical device must not be used on the following patient populations:

- infants ;
- pregnant or breastfeeding women due to restrictions associated with the possible use of medical solutions such as anaesthetics;
- patients with medical issues,
- Patients allergic to some of the medical device components,
- patients with a clinical site not suitable for treatment,

The table below lists all the allergenic factors known to date based on the material of tips and files:

Tip type	Allergenic factor
Smooth	Tip made of surgical stainless steel as per ASTM F899 - 12b Surgical stainless steel contains: • nickel • chromium
Smooth	Medical device chemical content: • Titanium
Smooth	The alloy of the medical device contains: • Titanium • Aluminium • Niobium
Smooth (plastic)	Unknown at the time the document was drafted
Ribbed	Tip made of surgical stainless steel as per ASTM F899 - 12b Surgical stainless steel contains: • nickel • chromium
Diamond-coated	Tip made of surgical stainless steel as per ASTM F899 - 12b Surgical stainless steel contains: • nickel • chromium Diamond polishing crimping binder alloy contains: • nickel
Files	Tip made of surgical stainless steel as per ASTM F899 - 12b Chemical composition of the file holder: • nickel • chromium

The patient must be calm, relaxed, still, ideally lying flat on a dental chair.
The user is the only person who can decide whether or not to treat his/her patients.

2.7 Parts of the body or types of tissues treated

Treatment must only be performed on the patient's oral environment.

2.8 Applied parts

Elements in direct contact with the patient	Tip File

2.9 Essential performance

The manufacturer has determined that the medical device did not manage essential performances.
On the date on which this document was written, no adverse effect other than the allergenic factors indicated in the chapter *page 3* is known.

2.10 Basic safety in normal use

As a highly skilled medical expert, the practitioner can immediately detect any problems at the treatment area and react accordingly.
It is advisable to have a spare medical device or an alternative means with which to perform the medical treatment in the event of device failure.

2.11 Normal usage conditions

The normal usage conditions are as follows:

- storage;
- installation;
- use;
- maintenance;
- disposal.

2.12 Irrigation spray

The irrigation spray is required to cool down or rinse the treatment area.

In some specific applications, irrigation-free tips can be used.

In special treatment applications, e.g. endodontics, it is possible not to use irrigation, only if the following conditions are adhered to:

- use a visual aid, e.g. microscope or magnifying glass
- work with an assistant
- continually monitor the clinical site to immediately identify any heating risk
- continual work on the clinical site must remain under one minute
- apply an irrigant locally;
- dry with medical air.

> The practitioner has to continually monitor the clinical site to immediately identify any heating risk

Medical devices must be used with the irrigation recommended by the manufacturer.

2.13 Service life

The shape and weight of the medical devices are determined to obtain maximum performance of the ultrasonic generator. The medical device will perform best if the user pays attention to these two characteristics. Therefore, we strongly advise against the modification of the structure of the medical devices by filing, twisting or by performing other types of modification.

In addition, tip ageing leading to normal wear can modify the medical devices characteristics. Systematically replace a medical device that is damaged due to wear or accidental impact such as a fall or distortion, etc.

As it is not possible to establish a maximum number of uses (that may be determined by many parameters such as duration of use, hardness of tissue, the force applied, wear), we recommend that medical devices being routinely used are replaced at least once a year. Replace the medical device if the tip does not vibrate at the expected frequency, the treatment is not progressing as normal and is taking longer or is at a standstill.

2.14 Broken tips and files

The ultrasonic force generated by the handpiece is adequate to carry out treatments. The practitioner does not need to apply force to the clinical site as extra and excessive mechanical force may cause the medical device to break.

The medical devices have been developed to ensure safe use in association with SATELEC (a company of the Acteon group) handpieces, in accordance with the set power levels.

However, the tips may break depending on frequency of use, force exerted or by being dropped.

> To mitigate the risks, however minimal, use a suction device such as a saliva ejector. You should also encourage your patient to breathe through the nose.

3 Interactions, contraindications, prohibitions

This includes information relating to the interactions, contraindications and prohibited operations known by the manufacturer on the date on which this document was written.

3.1 Using accessories not supplied by the manufacturer

The medical device was designed and developed with its accessories to guarantee maximum safety and performance. The use of accessories from another source could put you and your patients at risk and could damage your medical device.

Do not try to connect accessories not provided by SATELEC, a company of Acteon group to your medical device connector(s) or to the handpiece.

Even if the manufacturer or dealer of your accessory claims full compatibility with SATELEC, a company of Acteon group equipment, it is advisable to exercise caution with regards to the origin and safety of the product offered. Look out in particular for lack of information, information in a foreign language, very attractive prices, suspect appearance, mediocre quality or premature wear. If necessary, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team.

3.2 Prohibited uses

The medical device may not be stored or used outside the temperature, atmospheric pressure and humidity ranges recommended in the User Manual supplied with your medical device.

Only use the medical device for the purpose for which it has been designed.

4 Medical device description

4.1 Definition of the medical device

In this document, standard dental tips and files are referred to as medical devices.

4.2 Indication for use

This medical device is used with an ultrasonic dental handpiece and a dental piezoelectric ultrasonic generator.
It is designed for the treatment of prophylaxis,periodontics, endodontics and preservation and restoration dentistry.

4.3 Prophylaxis

Tips used for prophylaxis treatment are as follows:
#1, #2, 1S, #3, 10P, 10X, 10Z

4.4 Periodontics

Tips used for periodontics treatment are as follows:
H1, H2L, H2R, H3, H4L, H4R, P2L, P2R, PFR, PFU, PFL, PH1, PH2L, PH2R, TK1-1L, TK1-1S, TK2-1L, TK2-1R, IP1, IP2L, IP2R, IP3L, IP3R

4.5 Endodontics

Tips used for endodontics treatment are as follows:
AS3D, AS6D, AS9D, ASLD, ASRD, CAP1, CAP2, CAP3, ET18D, ET20, ET20D, ET25, ET25L, ET25S, ET40, ET40D, ETBD, ETPR, K10-21, K10-25, K15-21, K15-25, K25-21, K25-25, K30-21, K30-25, P14D, P15LD, P15RD, S04, S12-70D, IRR20-21, IRR25-21, IRR20-25, IRR25-25

4.6 Conservative and Restorative Dentistry

Tips used for conservative and restorative dentistry treatment are as follows:
5AE, C20, EX1, EX2, EX3, EXL, EXR, PM1, PM2, PM3, PM4, PMS1, PMS2, PMS3, PMV1, PMV2, PMV3, PMV4, PMV5, PMV6,

4.7 Medical device types

There are four types of standard dental medical devices:

- smooth tips
- ribbed tips
- diamond-coated tips
- files.

5 Good practice

5.1 Removing the device from its packaging

When you receive your device, check for any damage that may have occurred during transportation.
If the packaging is damaged, contact your supplier to proceed with a return.
If the medical device is damaged or you are in doubt about its condition, contact your supplier.
If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.
If you have any questions or requirements, contact your supplier.

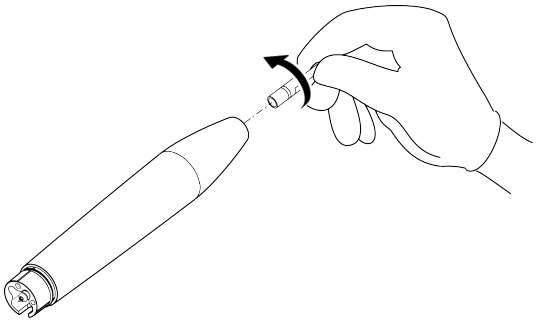
5.2 Rings and colour code

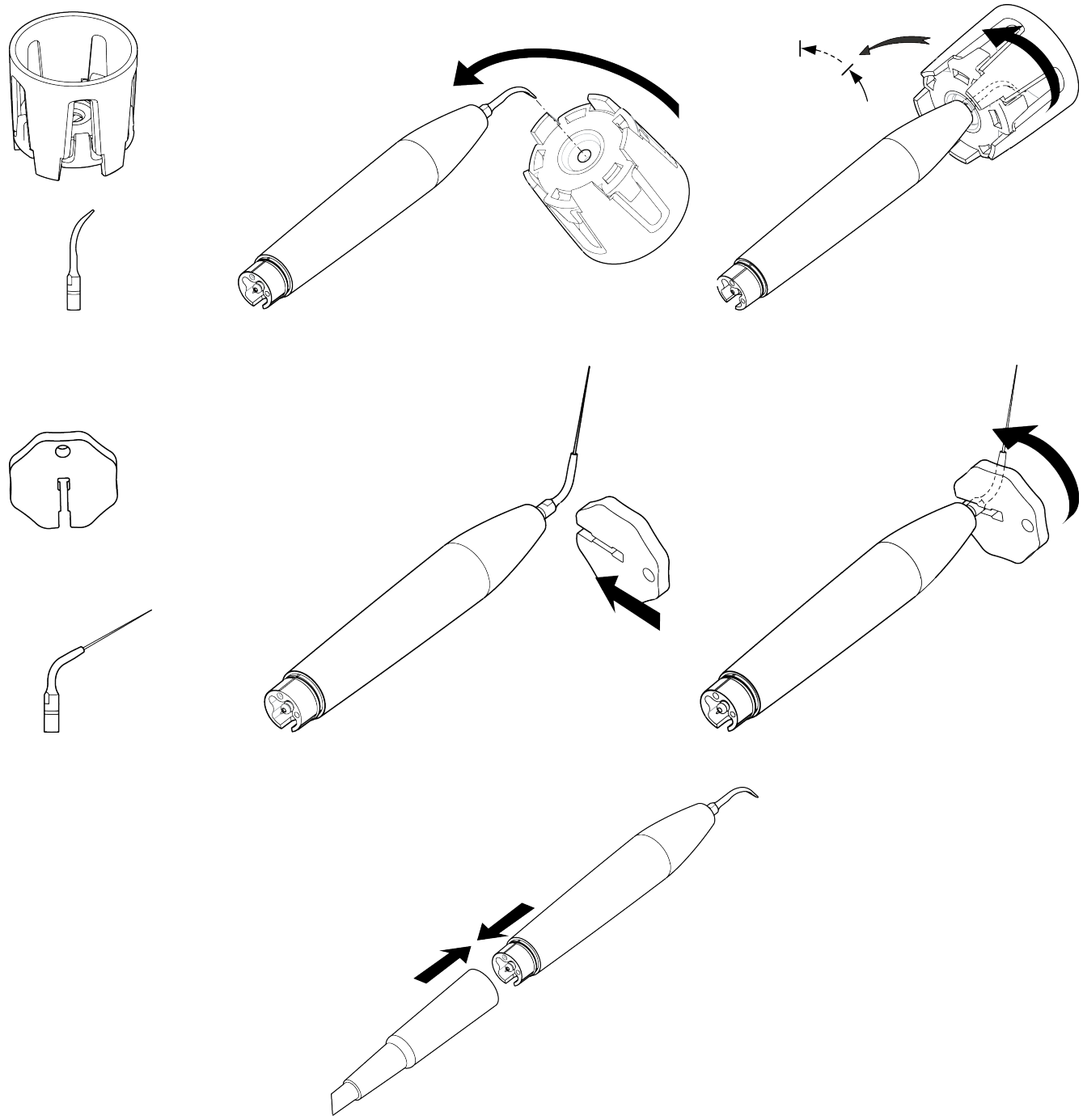
Tips and files have a coloured ring to identify the power settings which suit their application.

> Periosoft® tips do not have coloured rings, but they are intended for periodontics treatment.

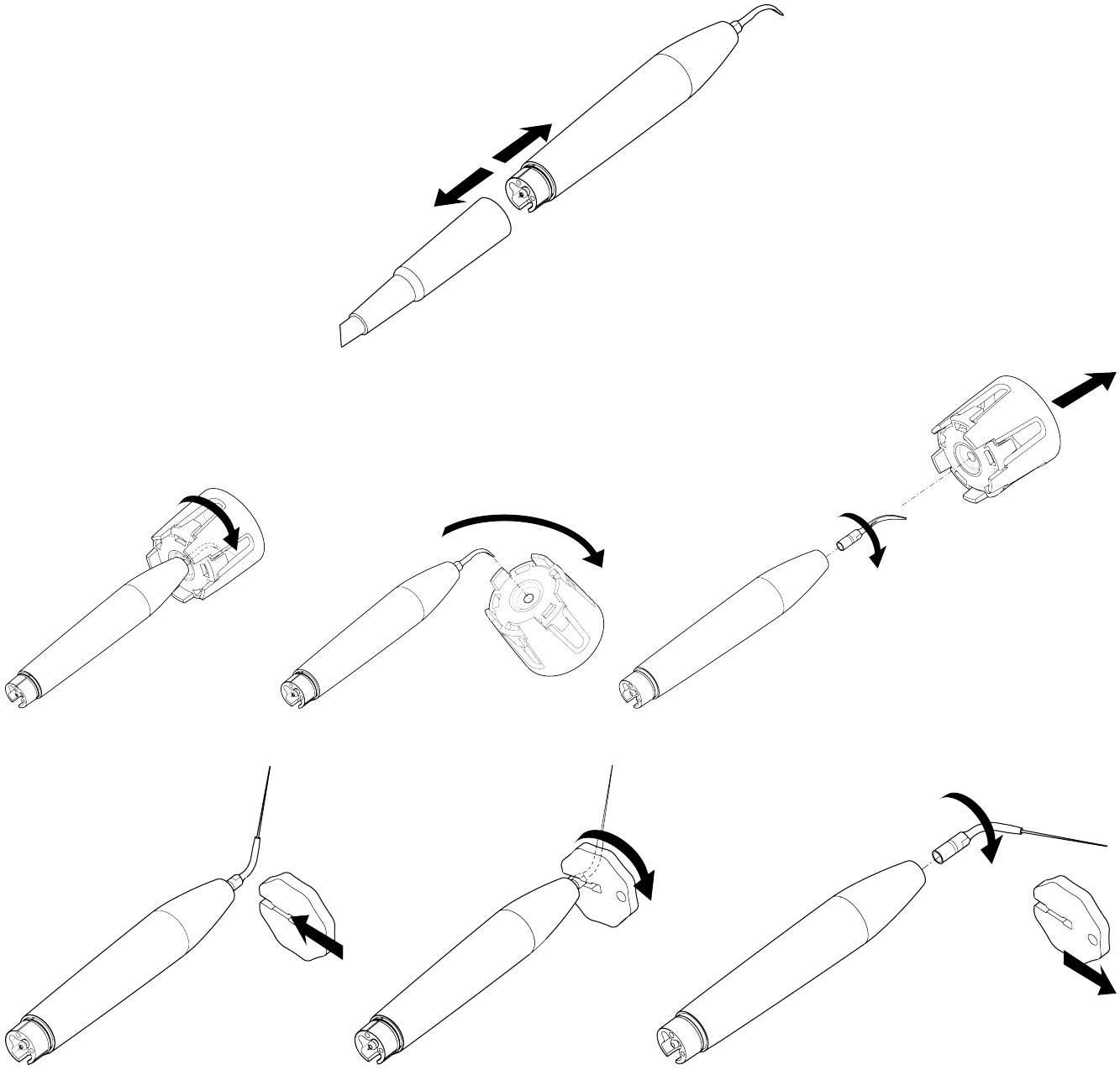
Ring	Power
	
	
	
	

5.3 Installation





5.4 Disassembly



5.5 Setting the power and irrigation rate

Please refer to the power settings table for ultrasonic generators, J58000

5.6 Repairing or modifying the medical device

Medical devices can be neither repaired nor modified.

In the event of doubt, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team:

www.acteongroup.com

satelec@acteongroup.com

6 Disinfection and sterilising

The instructions relating to cleaning, disinfection and sterilisation protocols for the medical device and accessories provided by SATELEC, a company of Acteon group have been approved for each medical device and accessory. The applicable guides are listed in the chapter *Associated documentation page 1*.
They can be downloaded at the following address: `www.satelec.com/documents`.

Download

Instructions For Use

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, a company of Acteon group.

7 Technical specifications of the medical device

7.1 Environmental characteristics

Ambient operating temperature	+10°C to +30°C
Storage temperature	-20°C to +70°C
Operating RH	30% to 75 %
Storage RH	10% to 100 %, including condensation
Atmospheric storage pressure	Between 500 hPa and 1060 hPa
Atmospheric operating pressure	Between 800 hPa and 1060 hPa
Maximum operating altitude	Equal to or less than 2000 metres

8 Regulations and standards

8.1 Latest document update

05/2018

8.2 Manufacturer identification

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8.3 Manufacturer responsibility

The manufacturer shall under no circumstances be liable in the following cases:

- Non-compliance with manufacturer recommendations
- Maintenance or repair procedures performed by people who are unauthorised by the manufacturer.
- Use of the device for purposes other than those specified in this manual.
- Use of accessories or handpiece not supplied by SATELEC, a company of Acteon group .
- Non-compliance with the instructions contained in this document.

> Note: the manufacturer reserves the right to modify the medical device and any documentation without notice.

8.4 Branch addresses

AUSTRALIA/NEW ZEALAND
ACTEON AUSTRALIA/NEW ZEALAND
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8.5 Disposal and recycling

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or the Acteon head office or one of the company branches to find out how to proceed. The relevant contact details are given in the chapter *Branch addresses page 19*.

The indication below applies to France only.

In compliance with the provisions of the French Environment Code relating to the disposal of electronic and electrical equipment waste or WEEE (Decree no. 2012-617 dated 2 May 2012), our Company fulfils its obligations to reclaim and dispose of its electrical and electronic equipment through the means established by the approved organisation Récylum, NOR approval: DEVP1427651A.

As a manufacturer, our Company is listed in the National Register of Producers kept by the ADEME (French Environment and Energy Management Agency). Professionals buying our products directly from the distribution chain are responsible for passing on this information about our established recycling methods to the end user.

In addition, the buyer agrees to take back our brand's devices at the end of their service life and to transfer them to one of the collection centres set up by Récylum for recycling (see list of collection centres on the site `http://www.recylum.com/`.

If necessary, Récylum can come and collect these devices from you free of charge once the quantity of devices has reached a certain level in the pallets-containers with which you are provided to store this waste.

A medical device that has reached the end of its service life must be disposed of in infectious clinical waste containers.

8.6 Applicable standards and regulations

This medical device complies with the essential requirements of European Directive 93/42/EEC. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.

8.7 Symbols

Symbol	Meaning
	Always wear safety goggles
	Always wear protective gloves
	Refer to the supporting documentation
	Consult the User Manual

Symbol	Meaning
	The accompanying documentation is available in electronic format
	Biohazard
	Sterilisation at 134°C in an autoclave
	Sterilisation at 132°C in an autoclave
	Washer-disinfector for thermal disinfection
	Ultrasonic bath
	CE marking
	CE marking
YYYY 	Year of manufacture
	Manufacturer
	Do not dispose of as household waste
	Recycle your lamps and professional electrical equipment with Récylum
Rx Only	Under the United States Federal Law, this medical device must only be sold by or under the orders of a qualified doctor.

9 Index

CE Marking 0459 General Instructions | J02101 | V5 | (98) | 05/2018 | RG30EN010E

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