

Ultrasonic handpiece with cutting tips for a broad range of applications

Piezoelectric System

Instructions for Use



Table of Contents

Introduction	Piezoelectric System	2
	• Intended use	2
	• Features and benefits	2
	<hr/>	
	Technical Description	4
	<hr/>	
	Warnings	8
	<hr/>	
	Installation	10
	<hr/>	
	Functions and Settings	12
	• Startup	12
	• Settings	12
	• Irrigation function	12
• Light function	12	
• Piezoelectric System function	13	
• Toolbox	14	
• Piezoelectric mode	15	
• Safety	15	
• Shutting down the device	15	
• Cutting tips	16	
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Maintenance	Maintenance	17
	• Sterilization	17
	• Irrigation line maintenance	17
	• Device maintenance	17
	• Handpiece maintenance	18
	• Preventive and corrective maintenance	19
	• Fuse replacement	19
	• Operating faults	20

Electromagnetic Compatibility	Electromagnetic Compatibility	21
	• Table 1: Emission	21
	• Table 2: Immunity (all devices)	22
	• Table 3: Immunity (not life-supporting devices)	23
	• Table 4: Recommended separation distances	24
	• Cable lengths	24
Additional Information	Additional Information	25
	• Disposal and recycling	25
	• Manufacturer's liability	25
	• Regulations	25
	Symbols	26
	Cleaning and Sterilization	28
Product Information	Cutting tips	37
	Instruments	43
	Ordering Information	44

Piezoelectric System.

Ultrasonic handpiece with cutting tips for a broad range of applications.

Intended use

The Piezoelectric System distributed by Synthes is an ultrasonic surgical system consisting of handpieces and associated tips for cutting bone and bone substitutes. It can be used for osteotomy, osteoplasty, decorticating, drilling, shaping, and smoothing of bones and teeth in a variety of surgical procedures, including general orthopaedic, otolaryngological, maxillofacial, oral, hand, foot, neurosurgical, spine, and plastic / reconstructive surgery.

To maximize the benefits of this device and ensure it has a long working life, read this manual carefully before using the system.

Features and benefits

Cruise Control® System

- No loss of power regardless of the environment and / or treatment performed
- Active only on mineralized tissue, with reduced risk to soft tissue
- Minimum pressure required, resulting in higher precision and reduced hand fatigue for the clinician
- Four power setting modes: 3 for bone cutting based on bone density and 1 for soft tissue detachment

LED handpiece

- Up to 60 watts of power for efficient osteotomies
- No heat generation and vibration free, reduces surgeon discomfort
- Six powerful LEDs for enhanced vision at the operative site
- Attached cable



Progressive, multifunction foot pedal

- Real-time adjustment of the ultrasonic power according to the anatomical constraints encountered
- The power of the ultrasonics can be precisely adapted for areas where nerves, arteries or membranes are present
- Total control of the console through the foot pedal, which allows hands-free operation in the sterile field, without touching the console screen

Cutting tips

- No heat generation, reduces the risk of necrosis
- Narrow kerf for highly precise bone surgery procedures
- Broad range of applications

Console

- User-friendly touch-sensitive LCD screen for ease of operation
- Cable connectors for up to two handpieces, eliminating the need to change cutting tips during procedures
- Two peristaltic pump housings
- Two brackets for irrigation solution






Technical Description

a) LCD touch screen

The LCD touch screen is used to define the settings of the Piezoelectric System.

The Piezoelectric System settings are adjusted by applying reasonable pressure to the screen keys.


Identification functions

Reduce  or increase  the irrigation flow rate  in ml/min

Flush or prime irrigation 

ON/OFF irrigation  or 

Select a program: D1, D2, D3, D4

D1  is the most powerful setting for dense bone

D4  is for detachment of soft tissue

Reduce  or increase  power within a program 

Handpiece light ON/OFF 

Progressive  or full ON/OFF power 

Save settings 








Startup screen

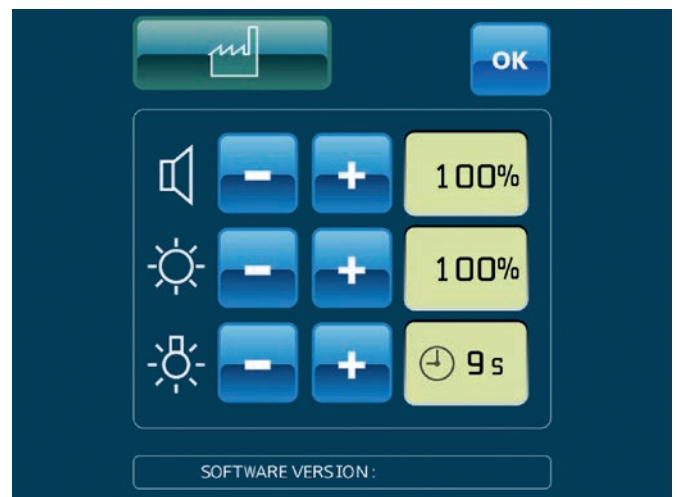
Identification of key areas:

Toolbox mode 

Toolbox

Identification of information display

- Audio volume  symbol and value
- Screen brightness symbol  and value
- Light off/time-out symbol  and value
- Software version
- Reset factory configuration 
- Validate configuration 



b) Control unit back panel

The power receptacle with its grounding pin is used to connect the console to the power supply using a plug-in power cord **1**.

The foot pedal connector is used to connect the console to the multifunction control foot pedal **2**.

The fan **3**, protected by a metal grille, keeps the Piezoelectric System at its optimum performance level.

The irrigation pole holders **4** hold the irrigation poles.

The power switch is used to switch the console ON or OFF **5**.

A potential equalization connector for an equipotential earth plug is integrated in the console **6**.



c) Irrigation pumps

The irrigation pumps **7** are located on either side of the console, and accommodate Synthes supplied irrigation tubing with cassettes. The irrigation cassettes are installed by lifting the pump covers and inserting the cassettes horizontally into the cassette housings.

d) Front panel

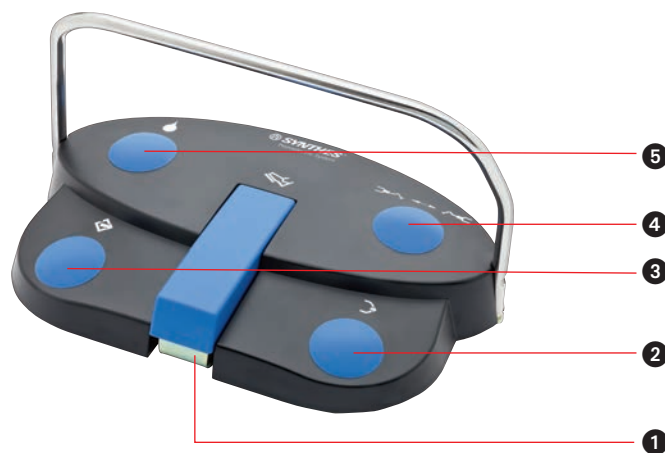
The two cable connectors **8** accept the connector of the Piezoelectric System handpiece cable.

e) Control foot pedal

The functions on the control foot pedal allow the user to work in a sterile environment. Once the settings have been adjusted on the console, the user does not need to touch the LCD screen.

Foot pedal button definition

- 1** Handpiece control (ON/OFF or progressive)
- 2** Flush/prime irrigation
- 3** Change program (D1– D4)
- 4** Select left or right handpiece
- 5** Irrigation ON/OFF



f) Technical characteristics

Manufacturer: SATELEC

Distributor: Synthes GmbH

Device name: Piezoelectric System

Electrical power supply

Voltage: 100 VAC to 230 VAC

Frequency: 50 Hz / 60 Hz

Rated power: 150–150 VA

Piezoelectric System function

Operation

- Intermittent service: 10 min. ON / 5 min. OFF

Output characteristics

- No-load voltage: 250 volts
(nominal value without handpiece)
- Min. ultrasonic frequency: 28 kHz
- Irrigation flow rate: 10 to 120 ml/min. (nominal value)
- Adjustment in 10 ml/min. steps (nominal value)
- Flush flow rate: 120 ml/min. (nominal value)

Protection

- Electrical equipment class: Class I
- Type BF applied part

Safety devices

- Safety shut off if internal malfunction
- 2 fuses (power receptacle):
 - 5 mm × 20 mm / T2AL 250 VAC
 - 1 internal fuse not accessible to the user
- Reference F1: 5 mm × 20 mm – T10AL 250 VAC

Overall dimensions

Control unit

- Width: 472.9 mm
- Height: 149.5 mm
- Height with bracket: 471.1 mm
- Depth: 339.9 mm
- Weight: 5 kg without accessories

Handpiece cable

- 2.9 meters

Temperatures

- Operation: +10 °C to +30 °C
- Storage: 0 °C to +50 °C

Humidity

- Operation: 30% to 75%
- Storage: 10% to 100% including condensation

Atmospheric pressure

- Operation: 800 hPa to 1060 hPa
- Storage: 500 hPa to 1060 hPa

Warnings

Device users

Attention

- The Piezoelectric System must not be used if the patient and/or the operator has a cardiac stimulator (pacemaker) or any other active implant (e.g. a cochlear implant).
- Use of the Piezoelectric System is restricted solely to qualified, trained and competent health care practitioners in the normal context of their work with the Piezoelectric Surgery System.
- If you have received this device in error, please contact your local Synthes representative.

Interactions

- The device complies with applicable electromagnetic compatibility standards. However, the user should ensure that any potential electromagnetic interference does not cause an additional risk (presence of radiofrequency emitters, electronic devices, etc.).
- The device is not designed to withstand shocks delivered by an electric defibrillator.
- Do not attempt to connect to the Piezoelectric System connectors any accessories other than those supplied by Synthes.
- The tips are specifically designed for the Piezoelectric System. The system is not compatible with other manufacturers' system tips.
- Cutting saw and scalpel tips are ultra sharp instruments and must be used with caution. It is recommended to use diamond and decorticating tips in sensitive clinical areas.

To reduce the risk of accidents, the precautions stipulated below must be taken.

Electrical connection

To avoid risk of electric shock, this device must be connected to an electrical power supply with a protective ground.

- The electric supply to which the device is connected must comply with the standards in force in your country.
- If loss of electrical power during use is likely to generate an unacceptable risk, the device must be connected to a suitable power source (e.g. UPS).

Using the device

- Do not use the device if it appears to be damaged or faulty.
- Turn the device OFF before unplugging the power cord.
- To unplug the power cord, grip the cord plug and hold the wall socket.
- Never use any irrigation solution containers other than those intended for suspension from the supplied brackets.
- The device must only be used with bottles or bags of physiological saline or sterile water.
- The capacity of the irrigation solution containers used must not exceed one liter per bracket.
- When the device is not to be used for a long period of time, unplug the console from the electric supply.
- Do not exert excessive force on the screen.
- Do not move the console during use.

Overheating, burns

To avoid any risk of burns or overheating, irrigation must always be switched ON and active when the handpiece is in use.

The user shall regularly control the level of irrigation to ensure its coolant action to the tip. A lack of irrigation presents a hazard to the patient.

Environment

- Do not cover the console or obstruct the ventilation vents.
- Do not immerse the device in liquid, and do not use it outdoors.
- Do not tilt the console at an angle greater than 5°.
- Do not place the console near a heat source.
- Ensure that the cables and power cord are not in a traffic path.
- The device must not be stored or operated in an explosive atmosphere.
- Do not expose the console to water vapor, or splashes.
- Condensation inside an electrical device may be dangerous.
- If the console must be moved from a cool place to a hot place, allow it to warm up to the new room temperature before use.
- The device is not designed to work near ionizing radiation.
- Do not insert metal objects into the device (risk of electric shock, short-circuit or emission of hazardous substances).

Maintenance

- Before and after each procedure, ensure that all accessories are cleaned and sterilized.

Accessories

- The device and accessories have been designed and developed together to ensure maximum safety and performance.
- Use of accessories from other manufacturers is a potential hazard to the user, the patient and the device.

Repairs

Do not attempt to repair or to modify the device without authorization by Synthes. When the device is modified or repaired, specific checks and verifications must be performed to ensure that the device can be used safely.

The device should be sent to the Synthes office for repair if it is faulty or malfunctions. Use of unauthorized repairers could damage the system and void the warranty. If in doubt, contact your local Synthes representative.

Faulty devices may not be used. If it is no longer possible or feasible to repair the tool it should be disposed of. (Cf. the section "Disposal and recycling" in the chapter "Additional Information", p. 25).

Other than the above mentioned care and maintenance no further maintenance work can be carried out independently or by third parties.

Caution: The manufacturer shall assume no responsibility for damage resulting from unauthorized maintenance.

Installation

Unpacking the device

Upon receipt of the device, check for any damage caused in transit.

Contact your local Synthes representative if necessary.

Recommendations

The electrical connection of the Piezoelectric System must comply with the applicable standards in your country.

⚠ Warning: To avoid any risk of electric shock, this device must be connected to an electrical power supply with a protective ground.

Installation

⚠ Important: Do not place the Piezoelectric System close to or on top of another device. Do not place the power cord and the foot pedal cable in a wire cover or in a cable guard. Do not operate the handpiece unless the irrigation is switched to the ON position. Do not disconnect the handpiece cables when the device is switched ON and the foot pedal is pressed. Do not insert or remove cutting tips when the handpiece is ON. The handpiece, wrench and Vario Case must be cleaned and sterilized before each use. Do not use the system with parts other than those supplied by Synthes. Check the integrity of the device and its accessories before and after each use in order to detect any problems.

- Position the console on a fixed horizontal surface, or one with a slope of no more than 5°.
- Check that the power switch is in the OFF position.
- Connect the power cord to the receptacle on the back of the console.
- Connect the power cord to a grounded power outlet.
- If necessary, connect the equipotential earth plug to the potential equalization connector on the console.
- Connect the foot pedal cable to the foot pedal connector on the back of the console.
- Position the foot pedal so that it is easily accessible for use.
- Insert the irrigation poles into the bracket holders.
- Connect the handpiece cable to the connector on the front of the console. The default setting is for the right connector.
- Ensure that the console is close enough to the work area to be used without pulling on the cables or power cord.
- Place the handpiece on the sterile field.

The pump housings are designed to accommodate Synthes supplied irrigation tubing with cassettes.

- Lift the pump cover and insert the irrigation tubing cassette horizontally into the cassette housings.
- Insert the sterile spike into the connection on the irrigation bag. Avoid touching the spike.
- Connect the irrigation tubing to the irrigation port on the handpiece. Use the sterile clips provided to attach the tubing to the handpiece cable.
- Suspend the irrigation bottles or bags from the irrigation poles.
- Adjust the position of the console to suit your angle of view.



Handpiece function

- Thread the selected cutting tip onto the handpiece by turning the tip. Use the flat wrench or the torque wrench to tighten the tip. Turn the flat wrench gently clockwise to tighten and ensure not to overtighten the tip. When using the torque wrench, turn it clockwise. Optimum torque is reached after one click. Do not overtighten the tip once the click is heard. Overtightening of the tip can damage the threads on the tip or the handpiece. To remove the tip, turn the wrench counterclockwise.
- Prime the irrigation circuit by pressing the flush/prime button on the console screen or the multifunction foot pedal.
- When the irrigation solution reaches the end of the tip, release the foot pedal or the button.
- Use the Piezoelectric System in accordance with good medical practices.



Functions and Settings

Startup

⚠ Important: After turning the console off, wait four seconds before restarting it.

By default, when the device is switched on, the right-hand handpiece is selected if two handpieces are connected.

If only one handpiece is connected, the device selects the correct side. If no handpiece is connected, the device selects the right side in Piezoelectric System mode.

Settings

The settings are saved when each program is configured and are retrieved whenever that program is selected.


Irrigation function

The Piezoelectric System is not designed to administer drugs. It must be used only with bottles or bags of physiological saline or sterile water with an individual capacity not exceeding one liter.

The Piezoelectric System must only be used with Synthes supplied irrigation tubing that is designed for the system.

a) Flush/prime



The flush/prime function is located on the LCD screen and on the foot pedal.



Press button  or the foot pedal button to switch on the flush/prime function.

The flush/prime function stays on as long as the button is pressed.

The flush can be switched on while the device is being used.

b) Flow rate adjustment

The irrigation flow rate is adjusted using buttons  or .


Each time the corresponding button is pressed, the flow rate is adjusted. Press and hold buttons  or  to scroll the flow rate values.


The adjusted value is displayed on the LCD screen **1** and stored in the current program.


The flow rate can be adjusted while the device is being used.

c) Irrigation ON/OFF

⚠ Important: To avoid any risk of burns or overheating, irrigation must always be switched ON and active when the handpiece is in use.


The irrigation is switched ON or OFF by pressing button  or the foot pedal button.

When irrigation is selected, the symbol  is shown.

When irrigation is not selected, the symbol  is shown. Irrigation must always be switched ON and active when the handpiece is in use. Damage to the tip or necrosis may result if irrigation is not used.

Light function

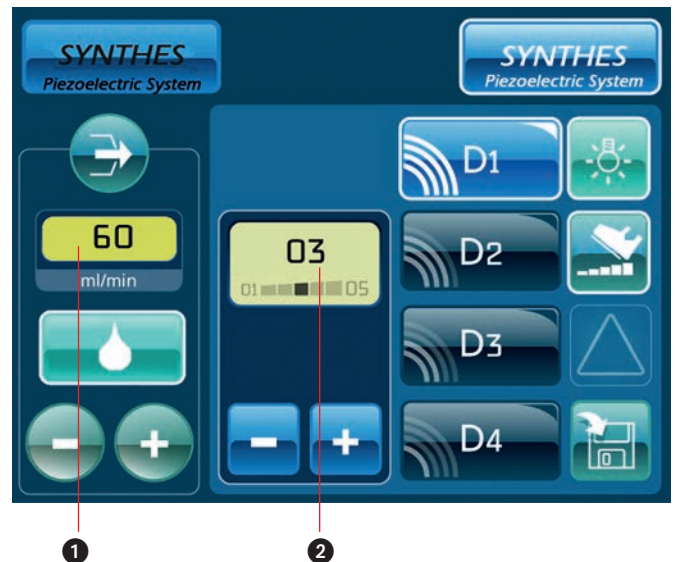
The light function is displayed on the LCD screen.

Pressing button  switches the light function available for the Piezoelectric system functions ON or OFF.

The light function has a default light-off time-out of nine seconds.

The light function switches OFF when the time-out has elapsed.

If necessary, you can change the light time-out by changing the settings in the Toolbox section of the console screen option.



Piezoelectric System function

⚠ Important: The Piezoelectric System function settings can be customized by the user. The Piezoelectric System function settings can be adjusted whether or not a handpiece is connected to the console.

The program giving the highest power is D1.

Power Level	Program	Main functions
Very powerful	D1	
Powerful	D2	Osteotomy, osteoplasty
Medium	D3	
Low	D4	Soft tissue detachment

Programs correspond to the following level of powers:

Program Mode	D1				
Level of Fine Tuning	1	2	3	4	5
Power value	82%	86%	90%	95%	100%
Frequency Modulation	60 Hz				

Program Mode	D2				
Level of Fine Tuning	1	2	3	4	5
Power value	64%	68%	72%	74%	78%
Frequency Modulation	60 Hz				

Program Mode	D3				
Level of Fine Tuning	1	2	3	4	5
Power value	44%	48%	52%	56%	60%
Frequency Modulation	60 Hz				

Program Mode	D4				
Level of Fine Tuning	1	2	3	4	5
Power value	41%	46%	51%	56%	60%
Frequency Modulation	30 Hz				

The Fine Tuning **2** gives the possibility to adjust the level of power energy within each mode from 1 to 5. The power value is a percentage of the maximum power value (D1– D4).

Select the left or right Piezoelectric System function by pressing the Synthes button or the foot pedal button.

⚠ Important: In progressive mode, for programs D1 to D3, the delivered power ranges between power level 1 of program D3 and the configuration defined by the user (program and power level). In progressive mode, the power delivered by program D4 ranges only between levels 1 and 5, according to the value defined by the user.

Select handpiece light ON/OFF, by pressing button .


Confirm the new settings by pressing button .

The saving of the various settings is confirmed by an audible signal and a visual signal (button flashing).




Repeat this sequence if necessary in order to adjust all the programs.

Toolbox




⚠ Important: The Piezoelectric System has a Toolbox function used to make various adjustments, including brightness, light off/time-out, audio volume and factory configuration reset.

To access the Toolbox function, switch the device OFF, wait four seconds, switch device ON, then press button  on the welcome screen within 2 seconds.




a) Audio volume adjustment

Adjust audio volume value  using buttons  or . Audio volume is adjustable from 0% to 100%. The relative value of the audio volume is displayed.


b) Screen brightness adjustment

Adjust the brightness  value using buttons  or . Brightness is adjustable from 30% to 100%. The brightness level setting is displayed.



c) Light off/time-out adjustment

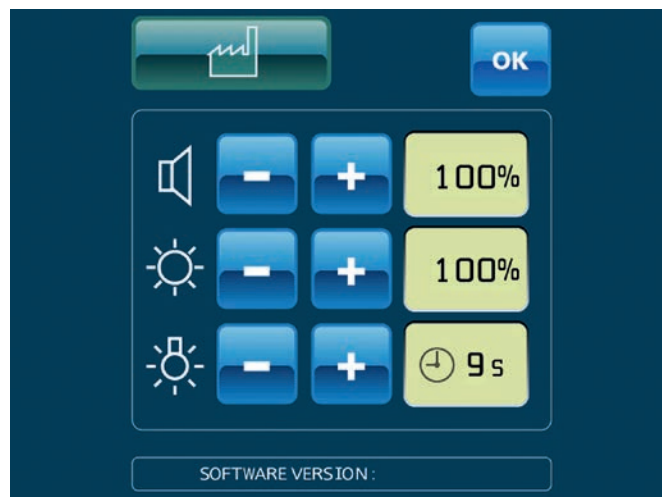
Adjust the time-out length value  by using buttons  or . The length of the time-out function can be adjusted from nine (9) to eighteen (18) seconds.

d) Storing settings

To store the modified settings, press button . The welcome screen will reappear.

e) Factory configuration reset

Press button  to restore the factory configuration settings. The factory configuration for the Piezoelectric System functions becomes effective when button  is pressed. The welcome screen will reappear.



f) Software version


The version of the software is displayed at the bottom of the Toolbox Screen.


The Piezoelectric System is configured in the factory with the following settings:

Piezoelectric mode

Power level	Program	Fine Tuning	Irrigation in ml/min	Main functions
Very powerful	D1	3	60	Osteotomy, osteoplasty
Powerful	D2	3	60	
Medium	D3	3	60	
Low	D4	3	60	Soft tissue detachment

Safety

The console is equipped to detect malfunctions of the device. If an internal operation error occurs, the transmission fault symbol  is displayed in the error zone and the device beeps four times. To cancel this default, simply switch OFF the device from the ON/OFF button. Wait a few seconds and switch ON again to restart the device.

When the handpiece is disconnected, the handpiece missing icon  is displayed in the error zone and the device beeps four times.

Shutting down the device

Upon completion of the medical procedure:

- Remove the bottles or bags of irrigation from the brackets.
- Remove the irrigation line spike from the bottle or bag.
- Immerse the irrigation line spike in a vessel containing distilled or sterile water.

Important

- **Rinse to remove saline solution from the handpiece by running the prime/flush function until the vessel and the irrigation line are completely empty.**
- **Switch the device OFF (position O).**
- **Remove the irrigation tubing clips.**
- **Disconnect the irrigation tubing from the handpiece and dispose in a safety container for soiled medical items.**
- **Disconnect the handpiece from the console.**
- **Disconnect the ultrasonic cutting tips. Dispose in a safety container for soiled, sharp, medical instruments.**

Cutting tips

The cutting tips are divided in four categories:

- Cutting saw tips
- Cutting diamond tips
- Cutting scalpel tips
- Decorticating tips

These cutting tips can be used for osteotomy, osteoplasty, decorticating, drilling, shaping, and smoothing of bones and teeth in a variety of surgical procedures, including general orthopaedic, otolaryngological, maxillo-facial, oral, hand, foot, neurosurgical, spine, and plastic/reconstructive surgery.

⚠ Caution: The tips are specifically designed for the Piezoelectric System. The system is not compatible with other manufacturers' system tips.

Principles of utilization

⚠ Important: An efficient use of these ultrasonic tips requires very slight pressure to be effective.

The power of the Piezoelectric System applied to each cutting tip should be set on the console screen according to the recommended mode, fine tuning and irrigation level. Refer to page 37 for recommended power settings.

To avoid any risk of burns or overheating, irrigation must always be switched ON and active when the handpiece is in use. The user shall regularly control the level of irrigation to ensure its coolant action to the tip. A lack of irrigation represents a hazard to the patient. The irrigation level is given as a minimum and must be increased when necessary.

Duration of use

Synthes recommends using a new cutting tip for every surgery. The maximum power and minimum irrigation settings must be strictly followed.

Caution: The sterile cutting tips are provided for single use only. Do not re-sterilize or re-use the single-use tips.

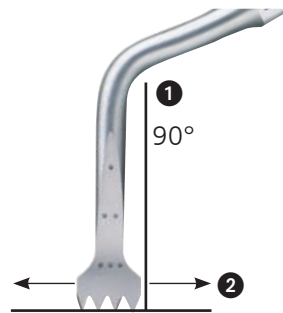
Cutting saw and diamond tips

The intended uses of the tips are osteotomy and osteoplasty.

Use a "brush-stroke" movement:

- Place the tip perpendicular to the surface to be treated ①.
- Move the tip with a slow back and forth movement, in line with the cut ②.
- Apply only very slight pressure – never use force.

NEVER USE THE TIP AS A LEVER: use only the appropriate elevator to lift the bone graft.



Cutting scalpel tips

The intended uses of this tip category are osteotomy, osteoplasty and bone harvesting.

Use a repeated, short pulling movement.

- Apply slight pressure.
- Never use force.
- Never use the tip as a lever.

Decorticating tips

The intended use of this tip category is soft tissue decortication.

During its use, it is essential to keep contact with the soft tissue and the bone.

- Apply slight pressure.
- Never use force.
- Never use the tip as a lever.

Maintenance

Sterilization

⚠ Important: The device must be switched OFF during reprocessing procedures. Do not use disinfection agents containing flammable substances.

⚠ Caution: The sterile cutting tips are provided for single use only. Do not re-sterilize or re-use the single-use tips.

The maintenance and/or sterilization instructions provided in this guide must be applied before each use of the device.

Sterilized items must be allowed to dry and cool to room temperature before use. Universal precautions for handling contaminated/biohazardous material should be observed.

⚠ Caution: The tips are specifically designed for the Piezoelectric System. The system is not compatible with other manufacturers' system tips.

Irrigation line maintenance

Sterile irrigation tubing

⚠ Caution: The irrigation tubing supplied by Synthes is for single use only, and must always be discarded after use. Do not re-sterilize the single-use irrigation tubing. Do not attempt to modify the irrigation tubing. The re-use of irrigation tubing is a potential hazard to the surgeon, patient and the device.

Device maintenance

⚠ Important: Never use an abrasive cleaning agent on the console or the foot pedal.

Do not use sprays or liquids to clean and disinfect the console.

Do not immerse the console or foot pedal.

Do not sterilize the console, brackets or the foot pedal.

The console, foot pedal and brackets must always be cleaned and disinfected after each procedure, using alcohol disinfectant wipes for medical use.

Regular monitoring of the Piezoelectric System is necessary in order to detect any problem.

Keep the console ventilation vents clean, to avoid abnormal heating.

The handpiece and cable can be sterilized in an autoclave.

For minimum sterilization requirements refer to page 28.

⚠ Caution: After multiple uses, and during successive sterilizations, make sure before use that the handpiece-cable assembly is not damaged.

Handpiece maintenance

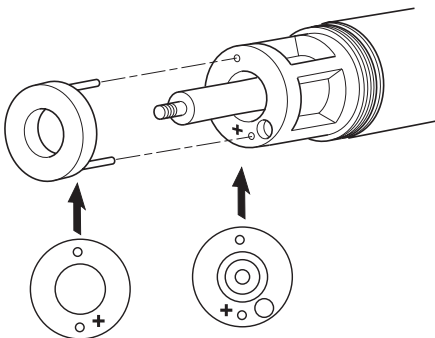
⚠ Important: Handpiece must be disassembled prior to cleaning and sterilization.

After each use, the handpiece irrigation circuit must be rinsed with distilled or sterile water for a minimum of 20 seconds.

⚠ Important: Before medical procedures, test the LED to verify the correct positioning of the LED ring on the handpiece.

Assembly

- Connect the LED ring to the handpiece, making sure it is positioned correctly (align the “+” marks on the LED ring and on the handpiece body near the LED ring electrical contacts).
- Insert the light diffuser over the LED ring as shown.
- Screw the nose cone onto the handpiece.



Cleaning and disinfection

The handpiece must be cleaned and disinfected after each procedure by manual cleaning or automatic washer.

For handpiece sterilization, refer to the minimum sterilization requirements for the system (page 28).

Cutting tip must always be discarded after use. Do not attempt to modify the cutting tip. The re-use of the tip may lead to the decrease of its performance and proper characteristics.

The re-use of tips is a potential hazard to the surgeon, patient and the device.

⚠ Important: Do not attempt to repair or modify the device without authorization from Synthes. When the device is modified or repaired, specific checks and verifications must be performed to ensure that the device can be used safely.

Do not use an unauthorized repair center, which might make your device dangerous for you and/or your patient.

⚠ Warning: The device should be sent to the Synthes office for repair if it is faulty or malfunctions. Use of an unauthorized repair center could damage the system and will void the warranty. If in doubt, contact your local Synthes representative.

Monitoring

Regular monitoring of the device and its accessories is necessary in order to detect any insulation fault or damage. It is important to keep the control unit ventilation vents clean, to avoid overheating.

Preventive and corrective maintenance

The Piezoelectric System does not need any preventive maintenance other than monitoring of the accessories and routine cleaning/disinfection.

Fuse replacement

The Piezoelectric System is protected by two fuses located in the power receptacle.

To replace the fuses:

- Switch the device OFF (position O).
- Unplug the power cord from the electrical power supply.
- Unplug the power cord from the receptacle. Insert the tip of a flat screwdriver into the notch above the fuse drawer to release it.
- Replace the old fuses with new fuses of the same type and rating.
- Push the fuse drawer back into its housing until it clicks to indicate the correct position.
- Plug the power cord into the receptacle. Plug the power cord into the electrical power supply.

Note: The device also has an internal fuse not accessible to the user.

Contact your local Synthes representative for service.

Operating faults		
Fault detected	Possible causes	Solutions
Device does not operate (LCD screen off)	Power cord not plugged in properly.	Check the electric socket. Contact your local Synthes representative.
	Power switch in position O (OFF).	Place the power switch in position I (ON).
	No power voltage.	Contact your local Synthes representative.
	Power receptacle fuse(s) blown.	Replace the power receptacle fuses.
	Internal fuse blown.	Contact your local Synthes representative.
Device does not operate (LCD screen on)	Transmission fault.	Switch the device OFF then ON again. Contact your local Synthes representative.
No spray	Irrigation solution bag or bottle empty.	Replace the bag or bottle of irrigation solution.
	Irrigation off.	Press the irrigation ON/OFF button.
	Irrigation line clogged.	Change irrigation tubing.
Inadequate spray	Incorrect irrigation flow rate adjustment.	Adjust the irrigation flow rate.
Power fault weak tip vibration	Tip worn or distorted.	Replace the tip.
	Incorrect power adjustment.	Refer to page 37 for the necessary information.
	Incorrect use: incorrect angle of attack or inadequate pressure on the cutting surface of bone.	Contact your local Synthes representative.
No ultrasonic function	Incorrect tip tightening.	Retighten the tip with the wrench.
	Faulty connector contact.	Clean the connector contacts.
	Handpiece cable wire cut.	Contact your local Synthes representative.
No light	Handpiece light ring absent.	Install the light ring.
	Faulty light ring.	Replace the light ring.
	Faulty light ring connector contacts.	Clean the light ring connector contacts.
	Light ring oriented incorrectly.	Position the light ring according to the positioning index.
	Faulty handpiece and/or cable connector contacts.	Clean the handpiece and/or cable connector contacts.
	Other.	Contact your local Synthes representative.
Leak in the irrigation pump	Broken tube in the irrigation tubing cassette.	Replace the irrigation tubing.

If the suggested solutions are unsuccessful, please contact your local Synthes representative.

Electromagnetic Compatibility

⚠ Important: The power cord, the ultrasonic hand-piece cables and the multifunction foot pedal cable must be kept away from each other.

The Piezoelectric System requires special precautions regarding electromagnetic compatibility. It must be installed and prepared for use as described on pages 10 –11.

Certain types of mobile telecommunication devices such as mobile telephones can interfere with the Piezoelectric System. The recommended separation distances, as specified in the tables below, must be complied with.

The Piezoelectric System must not be used near or on top of another device. If this cannot be avoided, its operation under the conditions of use must be checked beforehand.

The use of accessories other than those specified or sold by Synthes may damage the system and void the warranty.

Table 1: Emission

Guidelines and manufacturer’s declaration – electromagnetic emissions

The Piezoelectric System is intended for use in the electromagnetic environment specified in the table below. The user and/or installer must ensure that the system is used accordingly.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions – CISPR 11	Group 1	The Piezoelectric System uses RF energy for internal operation. Therefore, its radiofrequency emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions – CISPR 11	Class A	The Piezoelectric System is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2: Immunity (all devices)**Guidelines and manufacturer's declaration – electromagnetic immunity**

The Piezoelectric System is intended for use in the electromagnetic environment specified below. The user and/or installer must ensure that the device is used accordingly.

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with a synthetic material (carpet, etc.), the relative humidity must be at least 30%.
Electrical fast transient / IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment (hospital, clinic).
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 250 cycle	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 250 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the use of the system requires continued operation during power mains interruptions, it is recommended that the product be powered from a separate power supply (UPS, etc.)
Magnetic field at 50 Hz IEC61000-4-8	3 A/m	3 A/m	The intensity of the magnetic field should be equivalent to that of a typical commercial or hospital environment (hospital, clinic).

Table 3: Immunity (not life-supporting devices)

Guidance and manufacturer's declaration – electromagnetic immunity

The Piezoelectric System is intended for use in the electromagnetic environment specified in the table below. The user and/or installer must ensure that the device is used accordingly.

Electromagnetic environment – guidance

Portable and mobile radiofrequency communications devices must not be used near the system (including its cables) at a distance less than that recommended and calculated according to the frequency and power of the emitter.

Immunity test standard	IEC 60601 test level	Compliance level	Recommended separation distance
Conducted disturbance, radiofrequency fields. IEC 61000-4-6	3 V/m 150 kHz to 80 MHz	3 V/m	$d = 1.2 \sqrt{P}$
Radiated radiofrequency electromagnetic field. IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

Where P is the maximum power rating of the emitter in watts (W) according to the manufacturer's specifications and d is the recommended minimum separation distance in metres (m).

The electromagnetic field strengths of fixed radiofrequency emitters, as determined by an electromagnetic environment measurement^a, must be less than the compliance level in each frequency range^b.

Interference may occur near equipment marked with the symbol .

Notes

- **At 80 MHz and 800 MHz, the higher frequency range applies.**
 - **These specifications may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and persons.**
-

a The electromagnetic field strengths of fixed radiofrequency emitters, such as base stations for mobile telephones (cellular/cordless), mobile radios, amateur radio, AM/FM radio broadcasts and TV broadcasts cannot be determined exactly by theory. To assess the electromagnetic environment due to fixed radiofrequency emitters, an electromagnetic environment measurement must be made. If the measured radiofrequency field strength in the immediate environment where the product is used exceeds the compliance level specified above, the performance of the product must be tested to verify whether it conforms to the specification. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.

b In the 150 kHz to 80 MHz frequency range, the electromagnetic field strengths must be less than 3 V/m.

Table 4: Recommended separation distances**Recommended separation distances between portable and mobile RF communications equipment and the Piezoelectric System**

The Piezoelectric System is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled. The Piezoelectric System user and/or installer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radiofrequency communications equipment emitters and the Piezoelectric System, according to the maximum output power of the equipment, as recommended in the table below.

Rated maximum power of the emitter (W)	Separation distance in meters (m) according to emitter frequency		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

For emitters rated at max. power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the emitter, where P is the max. power rating of the emitter in watts (W) according the manufacturer.

Notes: At 80 MHz and 800 MHz, the higher frequency range applies. These specifications may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and persons.

Cable lengths

Cables and accessories	Maximum length	Complies with
Handpiece cables Foot pedal cable Power supply cord	Less than 3 m	RF emission, CISPR 1, Class B/Group 1 Harmonic current emission: IEC61000-3-2 Voltage fluctuation: IEC61000-3-3 Immunity to electrostatic discharge: IEC61000-4-2 Immunity to electrical fast transients/bursts: IEC61000-4-4 Immunity to surges: IEC61000-4-5 Immunity to voltage dips, short interruptions and voltage variations: IEC61000-4-11 Immunity to conducted disturbances induced by radiofrequency fields: IEC61000-4-6 Immunity to radiated radiofrequency electromagnetic fields: IEC61000-4-3

Additional Information

Disposal and recycling

As electrical and electronic equipment, the device must be disposed of according to a specialized procedure for collection, pick-up and recycling or destruction (in particular on the European market, with reference to Directive n° 2012/19/EU of July 2012).

Please send tools that are no longer used to the local Synthes representative. This ensures that they are disposed of in accordance with the national application of the respective directive. The tools may not be disposed of with household waste.

Contaminated components should be decontaminated before return or disposal in order to prevent possible infection of third parties.

Manufacturer's liability

The manufacturer is not liable if:

- The manufacturer's installation recommendations have not been followed (supply voltage, electromagnetic environment, etc.).
- Repairs or other work have been done on the device by persons not authorized by the manufacturer.
- The device has been used connected to an electrical system that does not comply with current regulations.
- The device has been used in ways other than those specified in this manual.
- Accessories (tips, handpiece, irrigation lines, etc.) other than those supplied by Synthes have been used.
- The instructions in this document have not been followed.
- Sterile single-use accessories have been re-used.

Note: The manufacturer reserves the right to modify the device and/or the user's manual without notice.

Regulations





















This medical device is classified as Class IIb according to European Directive relevant to Medical Devices currently in force.

















The equipment is manufactured in compliance with the current IEC60601-1, IEC60601-1-2 and IEC60601-1-4 standards.

The equipment is manufactured in compliance with the UL60601-1 and CAN / CSA C22.2 No. 601.1 standards.

This equipment has been designed and manufactured according to an ISO 13485 certified quality assurance system.

Symbols

	Handpiece not connected		Piezoelectric function
	Transmission fault		Foot pedal ON/OFF mode
	Toolbox		Foot pedal progressive mode
	Reduce a value		Storing of settings
	Increase a value		Piezoelectric program
	Reduce flow rate		Confirmation
	Increase flow rate		Audio volume
	Flush/prime		Brightness
	Irrigation		Time-out length
	Light		Factory configuration

	Refer to the accompanying documentation		Potential equalization connector
	Type BF applied part	 <small>MEDICAL EQUIPMENT UL60601-1 CAN / CSA C22.2 No. 601.1</small>  <small>3ZG5</small>	WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1 AND CAN / CSA C22.2 No. 601.1
I	Class I		
	EC marking		
	Do not dispose of in household waste		Degree of protection against liquid of the Control foot pedal
	Date of manufacture		Single use, do not re-use
	Alternating current	Rx only	US federal laws restrict this device to sale by or on the order of a physician
	Control foot pedal		Refer to instruction manual
0	Device power OFF		Do not use if package is damaged
I	Device power ON		Manufacturer identification
	Handpiece ON		

Cleaning and Sterilization

These recommendations are for reprocessing, specifically cleaning, Synthes Piezoelectric System re-usable medical devices, including the Piezoelectric System handpiece-cable assembly and the flat wrench, as well as for the nonsterile tips and torque wrench.



Cautions

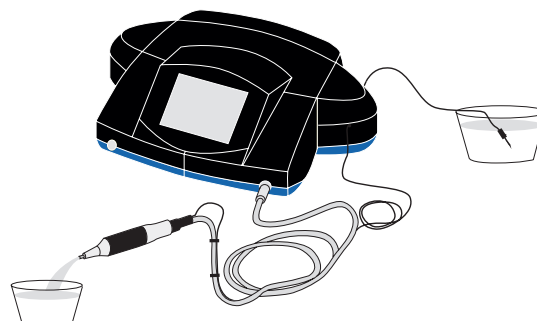
- Do not use steel wool or abrasive cleaners.
- Avoid solutions containing iodine or high chlorine content.
- Contaminated or used Synthes accessories should not be loaded in a Vario Case and cleaned in a mechanical washer.
- Metallic handpiece nosepiece, LED ring, light diffuser and handpiece-cable assembly cannulation require particular attention during cleaning.
- All devices must be thoroughly cleaned.
- Synthes doesn't recommend or support the flash sterilization of Synthes instruments.
- Synthes instruments are critical devices and must be terminally sterilized prior to use.
- The sterilization parameters are only valid for devices that are adequately cleaned.
- The following parameters are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment.
- The recommended cleaning method for the Piezoelectric handpiece and its accessories is manual and mechanical. Do not place the Piezoelectric handpiece-cable assembly in an ultrasonic cleaner.
- Use a soft, lint-free cloth moistened with a neutral pH cleaner to wipe the console and foot pedal. Do not immerse.

Processing instructions for handpiece-cable assembly and flat and torque wrench

Point of use care

- Wipe blood and/or debris from the devices throughout surgical procedure to prevent it from drying onto the surface.
- After the operation, remove the single-use tip at the front of the Piezoelectric handpiece assembly. Dispose in a safety container for soiled, sharp, medical instruments.

Important: In the operating room, rinse the irrigation line of the Piezoelectric System handpiece-cable assembly using distilled or sterile water. Operate the irrigation pump for 20 seconds after each use to prevent the drying of debris inside the handpiece. Disconnect and dispose of irrigation tubing and clips in proper container.



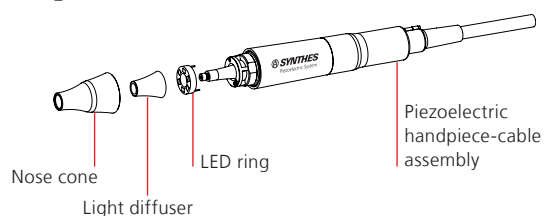
Soiled devices should be separated from noncontaminated devices to avoid contamination of personnel or surroundings.

Devices should be covered with a towel dampened with purified water to prevent blood and/or debris from drying.

Containment and Transportation

Soiled devices should be transported separately from noncontaminated devices to avoid contamination.

Preparation for decontamination



It is recommended that devices should be reprocessed as soon as possible following use. Piezoelectric System devices should be reprocessed no more than two hours after use.

Disassemble the handpiece prior to cleaning

- The front part of the Piezoelectric handpiece assembly, the nose cone, must be unscrewed.
- Remove the light diffuser.
- Disconnect the LED ring from the Piezoelectric handpiece, pulling it gently.

The handpiece, cable and handpiece components (nose cone, LED ring and light diffuser) should be manually pre-cleaned prior to processing in an automated washer.

Soak and/or rinse heavily soiled devices prior to cleaning, to loosen any dried soil or debris. Use a neutral pH enzymatic cleaner solution to soak devices. Follow the enzymatic cleaner manufacturer's instructions for use, for correct exposure time, temperature, water quality (i.e. pH, hardness) and concentration. Use cool tap water to rinse devices.

Piezoelectric System devices must be first cleaned separately from their Vario Cases. Lids should be removed from Vario Cases for the cleaning process, if applicable.

It is the responsibility of the end user to ensure that all equipment used to reprocess Synthes supplied devices is properly installed, validated, maintained and calibrated.

Cleaning – manual method for handpiece-cable assembly and flat and torque wrench

Equipment: soft-bristled brush, lint-free swab, enzymatic cleaner with a pH of 7– 9.5.

1. Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush and/or lint-free swab to assist in the removal of gross soil and debris.
2. Use a syringe to flush the cannulation with a neutral enzymatic cleaner solution.
3. Soak device in a neutral enzymatic cleaner solution for a minimum of ten minutes. Follow the enzymatic cleaner manufacturer's instructions for use for correct exposure time, temperature, water quality (i.e. pH, hardness) and concentration.
4. Rinse device with cool water for a minimum of two minutes.
5. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner solution. Use a soft-bristled brush to remove soil and debris on the nose cone, light diffuser, LED ring, handpiece-cable assembly and the threaded fitting. Gently use a lint-free swab to remove soil and debris on the inside of the nose cone, and LED ring. Clean device under water to prevent aerosolization of contaminants.
6. Rinse device thoroughly with deionized or purified water for two minutes.
7. Manually clean device for a minimum of two minutes in a neutral pH detergent solution. Use a soft-bristled brush for the nose cone, light diffuser, LED ring, handpiece-cable assembly and the threaded fitting. Gently use a lint-free swab for the inside of the nose cone, light diffuser and LED ring. Clean device under water to prevent aerosolization of contaminants.
8. Use a syringe, pipette, or water jet to flush the cannulation with deionized or purified water and rinse device thoroughly with deionized or purified water for two minutes.
9. Visually inspect device. Repeat the manual cleaning procedure until no visible soil remains on device.
10. Perform a final rinse on device using deionized or purified water.
11. Dry device using a soft, lint-free cloth or clean compressed air.

Pre-cleaning – mechanical method for handpiece-cable assembly and flat and torque wrench

Note: Ultrasonic cleaning may cause further damage to devices that have prior surface damage.

Equipment: Soft-bristled brushes, lint-free swab and/or soft, lint-free cloth, syringe, pipettes, and/or water jet, ultrasonic cleaner, washer/disinfector, neutral enzymatic cleaner and/or neutral detergent with a pH 7–9.5 are recommended, cleaners with a pH-value up to 11 and higher than 11 respectively should only be used considering the data regarding material compatibility according to its data sheet. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct dilution concentration temperature exposure time and water quality.

Note: Ultrasonic process – flat/torque wrench and nose cone only.

1. Disassemble device if applicable. (Refer to page 29 for disassembly information).
2. Rinse soiled device under running cold tap water for a minimum of one minute. Remove gross soil using a soft-bristled brush, a lint-free swab or soft, lint-free cloth.
3. Manually clean device for a minimum of two minutes in a freshly prepared neutral pH enzymatic cleaner solution. Follow the enzymatic cleaner manufacturer's instructions for the correct dilution, temperature, water quality (i.e. pH, hardness) and exposure time. Use a soft-bristled brush and/or lint-free swab to remove soil and debris. Clean device under water to prevent aerosolization of contaminants.

Note: Fresh solution is a newly-made, clean solution.

4. Rinse device using cool to lukewarm running tap water for a minimum of one minute. Use a syringe, pipette or water jet to flush the cannulation.

5. Prepare a fresh detergent solution using a neutral pH enzymatic cleaner. Follow the enzymatic cleaner manufacturer's instructions for the correct dilution, temperature, water quality (i.e. pH, hardness) and exposure time. **Ultrasonic process – flat wrench and nose cone only.**

Note: Fresh solution is a newly-made, clean solution.

6. Clean only flat wrench and nose cone ultrasonically for 15 minutes.
7. Rinse device in cool to lukewarm running tap water for a minimum of two minutes. Use a syringe, pipette or water jet to flush the cannulation.
8. Visually inspect device. Repeat Steps 2–7 until no visible soil remains on device.

Mechanical method – (after preclean)

Note: The washer/disinfector should fulfill requirements specified in ISO 15883. Whenever possible, use MIS injector unit to process lumens and cannulations.

Step	Duration (minimum)	Cleaning instructions
Pre-wash	2 minutes	Cold tap water
Wash I	2 minutes	Cool to warm tap water; use neutral enzymatic detergent, pH 7– 9.5
Wash II	5 minutes	Warm tap water; use detergent, pH 7– 9.5
Rinse	2 minutes	Rinse with warm DI or PURW (> 40 °C)
Dry	40 minutes	≥ 90 °C

Thermal Disinfection

For automated cleaning, thermal disinfect at 93°C for a minimum of 5 minutes.

Drying

If a dry cycle is not included in a mechanical washer or if the device is not processed in a mechanical washer:

- Dry each device thoroughly inside and out to prevent rusting and malfunction.
- Use a soft, lint free cloth to avoid damage to the surface.
- Pay special attention to threads or areas where fluid can accumulate.
- Open and close devices so that all areas are reached.
- Dry hollow parts using the medical air jet with clean compressed air.

Sterilization for handpiece-cable assembly and flat and torque wrench

Nonsterile Piezoelectric System devices must be terminally sterilized prior to use.

If not otherwise specified, nonsterile Piezoelectric System devices may be resterilized using validated steam sterilization methods (ISO 17665 or national standards). Manufacturer recommendations for handpiece-cable assembly and flat wrench are as follows.

Cycle type	Pressure	Sterilization exposure time	Sterilization exposure temperature	Min dry time
Saturated steamforced air removal (Pre-vacuum) (minimum 3 pulses)	2.9 bar absolute @ 132 °C	Minimum 10 minutes	Minimum 132 °C Maximum 138 °C	Minimum 20 minutes

- Dry times generally range from 20 to 60 minutes due to differences in packaging materials (Sterile Barrier System, e.g., wraps or re-usable rigid container systems), steam quality, device materials, total mass, sterilizer performance, and varying cool-down time.
- The distributor and manufacturer accept no responsibility for sterilization procedures performed by the customer that are not performed according to these Synthes recommendations.

Inspection

- Synthes supplied instruments should be inspected after processing (any method listed above).

Additional Information

This information is provided in accordance with ANSI / AAMI ST81: 2004, ISO 17664: 2004, AAMI TIR 12: 2004 and AAMI ST 77: 2006.

The recommendations provided above have been validated by the medical device manufacturer as being capable of sterilizing a nonsterile medical device. It remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

All users should be qualified personnel with documented expertise, competency and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.

Users should wear appropriate personal protective equipment (PPE) when processing devices.

Manufacturer contact

Please contact your local Synthes representative.

Processing instructions for nonsterile tips and torque wrench

Point of use care

- Rinse the irrigation Piezoelectric System hand-piece-cord assembly and tip under running tap water for 20 to 30 seconds after each use to prevent the drying of soil and/or debris inside the unit and tip. Same procedure for torque wrench.
- Wipe blood and/or debris from the tips and torque wrench to prevent it from drying onto the surface.
- Tips and torque wrench should be covered with a towel dampened with purified water to prevent blood and/or debris from drying.

Preparation for decontamination

It is recommended that devices should be reprocessed as soon as possible following use. Piezoelectric System devices should be reprocessed no more than two hours after use.

Clean long, narrow cannulations meticulously. Alkaline cleaners with a pH >10 are recommended. Follow the alkaline cleaner manufacturer's instructions for use for correct exposure time, temperature, water quality (i.e. pH, hardness) and concentration.

Devices should be cleaned in a fresh, newly-made solution. Whenever possible, a washer/disinfector should be used for tips and torque wrench. Prevent overloading of wash baskets for ultrasonic cleaning and washer/disinfector.

Piezoelectric System devices must be first cleaned separately from their Vario Cases or wash baskets for the cleaning process, if applicable.

It is responsibility of the end user to ensure that all equipment used to reprocess Synthes supplied devices is properly installed, validated, maintained and calibrated.

Tips and torque wrench may be processed using

- a manual ultrasonic cleaning and/or
- b Mechanical method with manual pre-cleaning and ultrasonic cleaning.

a) Cleaning – manual method for nonsterile tips and torque wrench

Equipment: soft-bristled brush, lint-free swab, alkaline cleaner with a pH >10.

1. Rinse soiled device under running cold tap water for a minimum of two minutes. Remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth. Use a syringe or pipette or water jet to flush tip and torque wrench cannulation and hard-to-reach areas with an alkaline cleaner solution.
2. Soak device ultrasonically in a fresh, newly-made alkaline cleaner solution for a minimum of ten minutes at 35 °C.
3. Rinse device with cool water for a minimum of two minutes. Use a syringe, pipette or water pistol to flush tip and torque wrench cannulation and hard-to-reach areas.
4. Manually clean device in a freshly prepared alkaline cleaner solution for a minimum of five minutes at 35 °C. Use a softbristled brush to remove soil and debris. Clean device under water to prevent aerosolization of contaminants.
5. Rinse device thoroughly with DI or PURW. Use a syringe, pipette or water pistol to flush tip cannulation. Repeat rinse for a minimum of two minutes.
6. Visually inspect the device. Repeat the manual cleaning procedure until no visible soil remains on devices.
7. Perform final rinse using DI or PURW.
8. Dry device using a clean, soft, lint-free cloth or clean compressed air.

b) Pre-cleaning-mechanical method for nonsterile tips and torque wrench

Note: The manual pre-cleaning method has to be performed for tips prior to automated cleaning

Note: Ultrasonic cleaning may cause further damage to devices that have prior surface damage.

Equipment: soft-bristled brush, lint-free swab, alkaline cleaner with a pH >10.

Pre-cleaning method for tips and torque wrench

1. Rinse soiled device under running cold tap water for a minimum of one minute. Remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth. Use a syringe or pipette or water pistol to flush tip and torque wrench cannulation and hard-to-reach areas with an alkaline cleaner solution.
2. Manually clean device in a newly-made alkaline cleaner solution with a pH >10 for a minimum of 2 minutes at 35 °C. Use a soft-bristled brush to remove soil and debris. Clean device under water to prevent aerosolization of contaminants.
3. Rinse device with cool water for a minimum of one minute. Use a syringe, pipette or water pistol to flush tip and torque wrench cannulation and hard-to-reach areas.
4. Clean device ultrasonically at 35 °C for a minimum of fifteen minutes. Prepare a newly made alkaline cleaner solution with a pH >10.
5. Rinse device thoroughly with DI or PURW. Use a syringe, pipette or water pistol to flush tip and torque wrench cannulation. Repeat rinse for a minimum of two minutes.
6. Visually inspect the device. Repeat the manual cleaning procedure until no visible soil remains on device.

Mechanical method – (after preclean) for nonsterile tips and torque wrench

Note: The washer/disinfector should fulfill requirements specified in ISO 15883. Whenever possible, use MIS injector unit to process lumens and cannulations.

Step	Duration (minimum)	Cleaning instructions
Pre-wash	2 minutes	Cold tap water
Wash	10 minutes	Cool to warm tap water ($\leq 40\text{ }^{\circ}\text{C}$); use alkaline detergent
Neutralize	2 minutes	Warm tap water with neutralizer; if necessary
Rinse	2 minutes	Rinse with warm DI or PURW ($> 40\text{ }^{\circ}\text{C}$)
Thermal disinfection	7 minutes	$\geq 94\text{ }^{\circ}\text{C}$
Dry	40 minutes	$\geq 90\text{ }^{\circ}\text{C}$

Inspection

- Processed tips and torque wrench must be inspected for corrosion, damage such as scratches and notches, discoloration, or residue. Damaged instruments should be discarded. Tips and torque wrench should not be lubricated.
- Before the cleaned products are packaged and sterilized, carefully examine them to see if they are clean, undamaged and function properly. Repeat cleaning steps until no visible soil remains on device.
- Do not use severely damaged instruments, instruments with unrecognizable markings, corrosion, or blunt cutting surfaces.

Packaging

Use an appropriate sterilization wrap or re-usable rigid container system for sterilization, such as a Sterile Barrier System according to ISO 11607. Care should be taken to protect tips and torque wrench from contact with other objects that may damage the surface or the Sterile Barrier System.

Sterilization

If not otherwise specified, nonsterile Piezoelectric System devices may be resterilized using validated steam sterilization methods (ISO 17665 or national standards). Manufacturer recommendations for nonsterile tips and torque wrench are as follows:

Cycle type	Pressure	Sterilization exposure time	Sterilization exposure temperature	Min. dry time
Saturated steamforced air removal (Pre-vacuum) (minimum 3 pulses)	2.9 bar absolute @ 132 °C	Minimum 4 minutes	Minimum 132 °C Maximum 138 °C	Minimum 20 minutes

- Dry times generally range from 20 to 60 minutes due to differences in packaging materials (Sterile Barrier System, e.q., wraps or re-usable rigid container systems), steam quality, device materials, total mass, sterilizer performance, and varying cool-down time.
- The distributor and manufacturer accept no responsibility for sterilization procedures performed by the customer that are not performed according to these Synthes recommendations.

Storage

Storage conditions for products labeled “STERILE” are printed on the packaging label. Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Use products in the order in which they are received (“first-in, first-out principle”), taking note of any expiration date on the label.

Cutting tips

Cuttings tips power setting according to applications.







Surgical procedures: general orthopaedic, otolaryngological, maxillofacial, oral, hand, foot, neurosurgical, spine, and plastic/reconstructive surgery.

Article Number	Description	Maximum Recommended Mode	Maximum Fine Tuning	Minimum Irrigation in ml/min
03.000.401S*	Saw 20.9 × 14.1 × 4.0 × 0.6 mm for Piezoelectric System, sterile			60
03.000.402S*	Saw 20.1 × 21.4 × 4.0 × 0.6 mm for Piezoelectric System, sterile			60
03.000.403S*	Saw left 17.8 × 15.2 × 4.0 × 0.6 mm for Piezoelectric System, sterile			60
03.000.404S*	Saw right 17.8 × 15.2 × 4.0 × 0.6 mm for Piezoelectric System, sterile			60
03.000.405S*	Scalpel round 22.45 × 12.6 × 3.9 mm dia × 0.7 mm for Piezoelectric System, sterile			60
03.000.406S*	Scalpel flat 21.6 × 11.1 × 3.0 × 0.5 mm for Piezoelectric System, sterile			60
03.000.407S*	Scalpel 17.7 × 15.5 × 1.2 × 0.5 mm for Piezoelectric System, sterile			60
03.000.408S**	Spade round 24.0 × 11.05 × 4.0 × 0.65 mm for Piezoelectric System, sterile			30
03.000.409S*	Diamond 24.6 × 12.85 × 2.6 × 0.6 mm for Piezoelectric System, sterile			60
03.000.410S*	Diamond round 21.9 × 12.4 × 1.8 mm for Piezoelectric System, sterile			60
03.000.411S**	Sinus Lift 22.9 × 10.1 × 5.0 mm dia × 0.4 mm for Piezoelectric System, sterile			50

*Osteotomy, osteoplasty, shaping, and smoothing of bones and teeth

**Decorticating

Cuttings tips power setting according to applications.**Surgical procedures: general orthopaedic, otolaryngological, maxillofacial, oral, hand, foot, neurosurgical, spine, and plastic/reconstructive surgery.**

Article Number	Description	Maximum Recommended Mode	Maximum Fine Tuning	Minimum Irrigation in ml/min
03.000.412S*	Saw 105.7 × 4.0 × 0.6 mm for Piezoelectric System, sterile			80
03.000.418S*	Saw left 39.5 × 4.0 × 0.8 mm for Piezoelectric System, sterile			60
03.000.419S*	Saw right 39.5 × 4.0 × 0.8 mm for Piezoelectric System, sterile			60
03.000.421S*	Scalpel flat 105.1 × 3.0 mm for Piezoelectric System, sterile			80
03.000.423S*	Scalpel 32.1 × 1.2 mm for Piezoelectric System, sterile			80–100
03.000.424S*	Saw round 38.9 × Ø 5.0 × 0.6 mm for Piezoelectric System, sterile			80
03.000.425S*	Diamond cylinder 30.7 × 4.7 × 2.3 mm for Piezoelectric System, sterile			80–100
03.000.426S*	Diamond conical 26.8 × 11.0 × 0.5 mm for Piezoelectric System, sterile			80–100

*Osteotomy, osteoplasty, shaping, and smoothing of bones and teeth

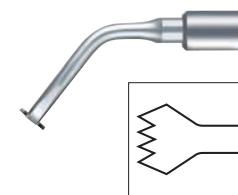
03.000.401S Saw 20.9 × 14.1 × 4.0 × 0.6 mm for Piezoelectric System, sterile



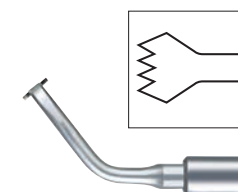
03.000.402S Saw 20.1 × 21.4 × 4.0 × 0.6 mm for Piezoelectric System, sterile



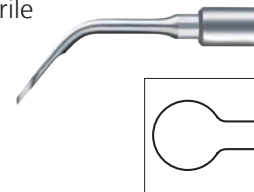
03.000.403S Saw left 17.8 × 15.2 × 4.0 × 0.6 mm for Piezoelectric System, sterile



03.000.404S Saw right 17.8 × 15.2 × 4.0 × 0.6 mm for Piezoelectric System, sterile

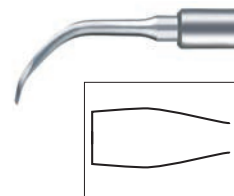


03.000.405S Scalpel round 22.45 × 12.6 × 3.9 mm dia × 0.7 mm for Piezoelectric System, sterile



Cutting tips

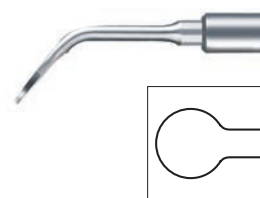
03.000.406S Scalpel flat 21.6 × 11.1 × 3.0 × 0.5 mm for Piezoelectric System, sterile



03.000.407S Scalpel 17.7 × 15.5 × 1.2 × 0.5 mm for Piezoelectric System, sterile



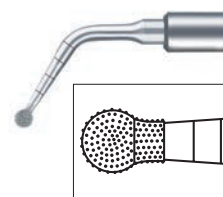
03.000.408S Spade round 24.0 × 11.05 × 4.0 × 0.65 mm for Piezoelectric System, sterile



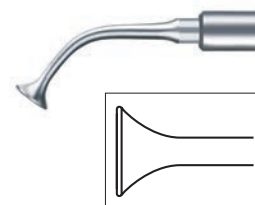
03.000.409S Diamond 24.6 × 12.85 × 2.6 × 0.6 mm for Piezoelectric System, sterile



03.000.410S Diamond round 21.9 × 12.4 × 1.8 mm for Piezoelectric System, sterile



03.000.411S Sinus Lift 22.9 × 10.1 × 5.0 mm dia × 0.4 mm for Piezoelectric System, sterile



03.000.412S Saw 105.7 × 4.0 × 0.6 mm
for Piezoelectric System, sterile



03.000.418S Saw left 39.5 × 4.0 × 0.8 mm for Piezoelectric System, sterile



03.000.419S Saw right 39.5 × 4.0 × 0.8 mm for Piezoelectric System, sterile



03.000.421S Scalpel flat 105.1 × 3.0 mm
for Piezoelectric System, sterile



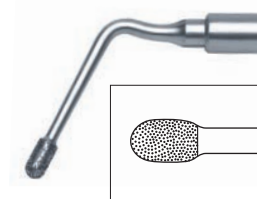
03.000.423S Scalpel 32.1 × 1.2 mm for Piezoelectric System for Piezoelectric System, sterile



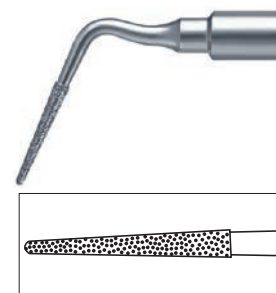
03.000.424S Saw round 38.9 × Ø 5.0 × 0.6 mm for Piezoelectric System, sterile



03.000.4×5S Diamond cylinder 30.7 × 4.7 × 2.3 mm for Piezoelectric System, sterile



03.000.426S Diamond conical 26.8 × 11.0 × 0.5 mm for Piezoelectric System, sterile



Instruments

05.001.400 Console for Piezoelectric System



05.001.401 Hand Piece for Piezoelectric System



05.001.402 Pedal for Piezoelectric System



05.001.403 Torque Wrench for Piezoelectric System



05.001.404 Flat Wrench for Piezoelectric System



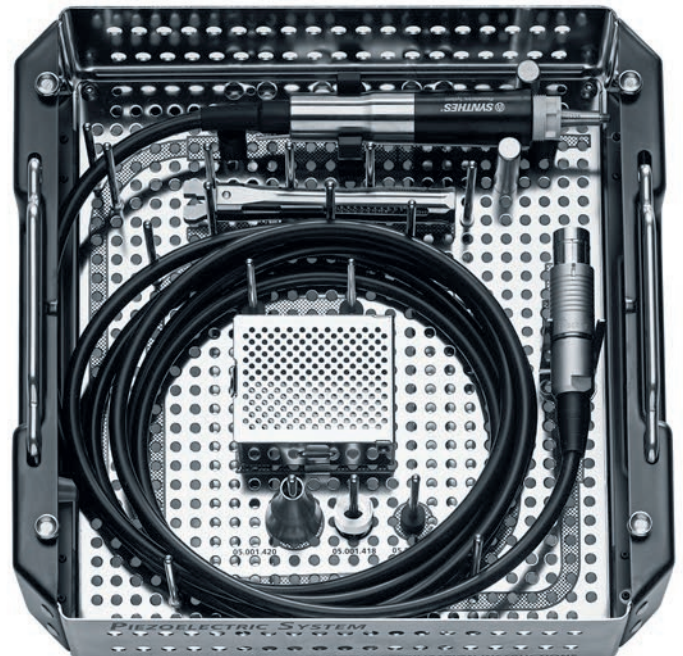
Ordering Information

01.001.597 Piezoelectric System Set

05.001.400	Console for Piezoelectric System
05.001.401	Hand Piece for Piezoelectric System
05.001.402	Pedal for Piezoelectric System
05.001.404	Flat Wrench for Piezoelectric System

Cutting tips

03.000.4015*	Saw 20.9 × 14.1 × 4.0 × 0.6 mm for Piezoelectric System, sterile
03.000.4025*	Saw 20.1 × 21.4 × 4.0 × 0.6 mm for Piezoelectric System, sterile
03.000.4035*	Saw left 17.8 × 15.2 × 4.0 × 0.6 mm for Piezoelectric System, sterile
03.000.4045*	Saw right 17.8 × 15.2 × 4.0 × 0.6 mm for Piezoelectric System, sterile
03.000.4055*	Scalpel round 22.45 × 12.6 × 3.9 mm dia × 0.7 mm for Piezoelectric System, sterile
03.000.4065*	Scalpel flat 21.6 × 11.1 × 3.0 × 0.5 mm for Piezoelectric System, sterile
03.000.4075*	Scalpel 17.7 × 15.5 × 1.2 × 0.5 mm for Piezoelectric System, sterile
03.000.4085*	Spade round 24.0 × 11.05 × 4.0 × 0.65 mm for Piezoelectric System, sterile
03.000.4095	Diamond 24.6 × 12.85 × 2.6 × 0.6 mm for Piezoelectric System, sterile
03.000.4105	Diamond round 21.9 × 12.4 × 1.8 mm for Piezoelectric System, sterile
03.000.4115*	Sinus Lift 22.9 × 10.1 × 5.0 mm dia × 0.4 mm for Piezoelectric System, sterile
03.000.4125	Saw 105.7 × 4.0 × 0.6 mm for Piezoelectric System, sterile
03.000.4185	Saw left 39.5 × 4.0 × 0.8 mm for Piezoelectric System, sterile
03.000.4195	Saw right 39.5 × 4.0 × 0.8 mm for Piezoelectric System, sterile
03.000.4215	Scalpel flat 105.1 × 3.0 mm for Piezoelectric System, sterile
03.000.4235	Scalpel 32.1 × 1.2 mm for Piezoelectric System, sterile
03.000.4245	Saw round 38.9 × Ø 5.0 × 0.6 mm for Piezoelectric System, sterile
03.000.4255	Diamond cylindrical 30.7 × 4.7 × 2.3 mm for Piezoelectric System, sterile
03.000.4265	Diamond conical 26.8 × 11.0 × 0.5 mm for Piezoelectric System, sterile



*Cutting tips are also available nonsterile packed.

Accessories

03.000.400.015	Irrigation Tubing for Piezoelectric System, sterile, pack of one article
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03.000.400.055	Irrigation Tubing for Piezoelectric System, sterile pack of five articles
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68.001.400	Vario Case for Piezoelectric System, without Lid, without Contents
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689.537	Lid (Stainless Steel), size 1/2, for Vario Case
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Additionally available

05.001.403	Torque Wrench for Piezoelectric System
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05.001.417	LED Ring, for Handpiece, for Piezoelectric System
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05.001.418	Light Diffuser Cone for Handpiece for Piezoelectric System
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05.001.419	Irrigation Pole for Piezoelectric System
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05.001.420	Nose Cone for Handpiece for Piezoelectric System
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