SHAW SCALPEL SYSTEM DISPOSABLE HANDLE

Part Number 7013-9050 - Qty 1
Part Number 7023-9050 - Qty 6

For use with the Shaw Scalpel System Model SG6 Controller



OPERATING MANUAL

℞ ONLY

French, Italian, German, Spanish, and Portuguese versions are available on www.everismedical.com. If you require a paper version, please email info@everismedical.com, and a paper version IFU will be provided to you at no cost within 7 calendar days.

INTRODUCTION

Shaw Scalpel BLADES are similar in size, shape, and sharpness to traditional steel scalpel blades; however, Shaw Scalpel blades can be heated to a user selected temperature appropriate for sealing small vessels as they are cut.

To cut and simultaneously seal blood vessels effectively with minimum tissue damage, the sharp steel cutting edge of a heated scalpel blade must be uniformly maintained at the desired temperature within narrow limits. The Shaw Scalpel System utilizes micro-circuitry incorporated within the blade itself to maintain the cutting edge temperature within the necessary tolerance, selectively delivering additional thermal energy only to those regions of the blade using heat due to tissue contact. By so doing, the Shaw Scalpel System automatically compensates for the varying degrees of heat loss that occur during surgical procedures (depending on the type of tissue being incised and the rate at which cutting is carried out), maintaining the cutting edge in the desired temperature range.

In contrast with electrosurgical devices, the Shaw Scalpel System passes no electrical current through the patient, and there is no sparking or electrical arcing to the tissue. Electrosurgical devices "cut" and/or cauterize using electrical currents which pass through the patient vaporizing tissue at the point of contact and generating heat and tissue damage down the path of the electrical current. The Shaw Scalpel System cuts tissue with a sharpened steel edge, like a conventional cold-steel scalpel blade, and simultaneously seals blood vessels using heat thermally conducted to the tissue from an elevated-temperature blade which is electrically insulated from the patient. By thermally transferring heat from uniformly-controlled, essentially constant temperature blade, the amount of tissue damage associated with hemostatic cutting is minimized.

INTENDED PURPOSE

The Shaw Scalpel System is intended to be used in patients of all ages during surgical procedures to cut tissue and seal small vessels as they are cut to achieve hemostasis with minimum tissue damage. The Device uses heat through the blade tip to perform precise dissection and coagulation of soft tissue. It is intended to facilitate targeted tissue incision and reliable bleeding control in the operating room.

INDICATIONS FOR USE

The Shaw Scalpel System is indicated for use in surgical procedures that require simultaneous tissue incision, dissection, and controlled hemostasis. It is intended to facilitate simultaneously sealing blood vessels as they are cut, with minimum damage to surrounding tissue, including, but not limited to:

- Precise tissue resection and excision of metastatic disease, particularly those around critical anatomy
- Neural protection and preservation of vital anatomical structures
- Management of bleeding during dissection

CONTRAINDICATIONS

The Shaw Scalpel System is contraindicated in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or OXYGEN or NITROUS OXIDE, and for use on the central nervous system or central circulatory system.

POTENTIAL ADVERSE EFFECTS

Known potential adverse effects include, but are not limited to: thermal injury to tissue, including nerves or other delicate tissues, inability to effectively provide hemostasis of larger vessels, and an increased risk of facial paresis when compared to traditional surgical scalpels.

NOTICE TO USERS AND/OR PATIENTS

Any serious adverse effects that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SYSTEM WARNINGS

1. EXPLOSION HAZARD – The Shaw Scalpel System is contra indicated in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or OXYGEN or NITROUS OXIDE.
2. NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.
3. Electrical shock hazard. Do not remove cover. Refer to manufacturer for service.
4. Do not attach unapproved components to the HTSS unit to avoid electrical shock.
5. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
6. Do not place the HTSS controller unit in direct contact with or within 1 m of any type of electro-surgical equipment. This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment radiates electromagnetic fields and, if not installed and used in accordance with the instructions, may cause harmful interference. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, or is affected by interference from other devices, the user is encouraged to try to correct the interference by one or more of the following measures:
   - Reorient or relocate the receiving device.
   - Increase the separation between the equipment.
   - Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
   - Consult the manufacturer.
7. The HTSS's maintenance port is to be used by Everis personnel only. The port is not to be accessed, for any purpose, by the customer. Any attempt to connect via the maintenance port will result in a termination of any warranties that may exist and may damage the unit.
8. To power equipment specifically designed by Everis. Any attempt to plug, non Shaw Scalpel equipment into the output connector may result in damage to the Shaw Scalpel unit thereby terminating any warranties and may result in an unsafe electrical condition, increased electrical emissions, or decreased immunity of the Shaw Scalpel system. Anyone who connects additional equipment via the auxiliary output terminal is therefore responsible for configuring a medical system and is responsible that the newly configured system complies with the requirements of the system standards IEC 60601-1 and IEC60601-1-2. If the user has questions regarding any connections to the AUX output port, they should contact Everis.
9. Ensure the sound volume is adequately adjusted so that alarms and alerts are clearly heard.

SYSTEM PRECAUTIONS

1. In the unlikely event that the handle is unable to be turned off normally due to a mechanical failure or due to debris in the handle, the controller should be turned off and the disposable replaced.
2. It is important that the Shaw Scalpel System (HTSS) operator be familiar with the System's Operator's Manual, its precautions, procedures, and safety issues. Read the complete operators manual before using this equipment.
3. Do not position the HTSS unit to make it difficult to remove and insert the unit's separable power cord plug.
4. Hazardous electrical and thermal outputs. This equipment to be used only by qualified
5. medical personnel.
6. Disconnect power to the HTSS before cleaning the unit to avoid electrical shock. To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the HTSS unit to hospital grade receptacles only.
7. The HTSS should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HTSS should be observed to verify normal operation in the configuration in which it will be used.
8. Do not operate the HTSS in the presence of Magnetic Resonance Imaging Equipment.
9. The recommended temperature setting for skin incisions is 70° C. For minimal scarring, make the initial skin incision with the scalpel handle in the OFF position. Cutting with the blade unheated will eliminate the possibility of superficial skin scars due to contact with a heated blade.
10. User should select the lowest set point temperature that will afford adequate hemostasis for the maximum anticipated rate of tissue cutting, thereby minimizing unnecessary (thermal) necrosis of tissue.
11. Care should be taken when using the HTSS to dissect around nerves and other delicate structures to avoid thermal injury to these structures.
12. The Model SG6 Shaw Scalpel System needs special precautions regarding EMC and needs to be installed and operated according to the information in the tables presented at the back of this manual and portable and RF communications equipment can affect the operation of the product.
13. All service must be performed by Everis Inc. personnel only.
14. Repair and/or modification of the HTSS by anyone other than qualified service personnel may significantly compromise the unit's ability to perform effectively and/or void the equipment warranty.
15. Opening the HTSS unit and/or breaking the tamper-proof seal will void the equipment warranty.
16. Shaw Scalpel handles are single-use devices.
17. If required by local code, connect the HTSS unit to the hospital equalization connector with an equipotential cable.
18. After use, this device may be contaminated. Handle and dispose of it as biohazardous waste in accordance with facility protocol and local regulations.
19. The Handle and Footswitch connector ports on the front of the Shaw Scalpel controller are not to be utilized for any other purpose than to connect to specified compatible components designed by Everis Inc.
20. DO NOT allow saline, or any other fluid, to enter the handle during use. Saline is highly conductive and will interfere with the circuitry inside the handle causing the handle not to work properly.
21. Rx Only – CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
22. USE WITH PLASTIC ADHESIVE DRAPES – When the skin incisions are to be made through a plastic adhesive skin drape, use the scalpel handle and blade in the OFF position (handle switched OFF).

23. USE WITH ELECTROSURGICAL UNITS – DO NOT touch the Shaw Scalpel blade to any electrosurgical (e.g., Bovie) tip as significant damage to the Shaw Scalpel controller unit will result. Keep at least 1 cm between the blade and the electrosurgical tip. The Shaw Scalpel CANNOT BE USED to conduct electro-surgical current through clamps.
24. AVOIDING INADVERTENT PATIENT BURNS – DO NOT rest the Shaw Scalpel handle and/ or blade on surgical drapes or on the patient during use. When energized, the blade is sufficiently hot such that patient burns can result from inadvertent patient contact. When the Shaw Scalpel handle is not being used, it is HIGHLY RECOMMENDED that the handle ON/OFF switch be positioned OFF. Care should be taken to avoid unintended activation of COAG mode by inadvertently depressing the COAG switch or foot pedal.
25. GROUNDING – Reliability can only be achieved when the equipment is connected to a properly equivalent receptacle marked “Hospital Grade”.
26. STERILIZATION – The Model SG6 Shaw Scalpel Handle is provided STERILE provided the primary sterile packaging is unopened and undamaged. In the event that the sterile barrier has been compromised, discard the handle and obtain a new one. The device may not perform as intended by the manufacturer if it is reused. The manufacturer cannot guarantee the performance, safety and reliability of a reprocessed device. Reuse is prohibited. Dispose of after one use following your facility's disposal protocols.
27. Remove and discard of used disposables following local regulations for proper disposal of contaminated material.
28. Electrical shock hazard. Do not remove cover. Refer to manufacturer for service.
29. If the user has any questions regarding compatibility of accessories or cables they should contact Everis.

COMPONENT PRECAUTIONS

1. Model SG6 Shaw Scalpel System Blades are provided sterile and ARE NOT intended for reuse. The device may not perform as intended by the manufacturer if it is reused. The manufacturer cannot guarantee the performance, safety and reliability of a reprocessed device. Reuse is prohibited. Dispose of after one use following your facility's disposal protocols.
2. Blades are surgically sharp and used blades may be extremely hot to the touch. Always use a sponge, clamp or hemostat to grasp the used blade. Always follow proper sharps precautions when handling a blade and biohazard disposal techniques when discarding a used blade.
3. DO NOT BEND THE BLADE – Care should be taken not to bend the blade while cleaning, insertion, or reinsertion as the heater leads may become broken and the blade stop working.
4. The HTSS blade’s non-stick coating cleans most effectively when hot. Best results are obtained using dry 4x4 gauze when the blade is hot.
5. Accurate calibration can only be achieved if the blade is at room temperature when it is inserted into the handle. If the blade becomes accidentally dislodged from the handle, turn the handle OFF, dip the blade in sterile water to cool it to room temperature, and then reinsert it.
6. Never use any type of abrasive pad to clean the blades. The abrasives will damage the circuit and render the blade unusable.
7. To remove a blade from the handle, pull the blade straight out of the handle. Bending, twisting or flexing the blade could damage the blade contacts and retainers within the handle causing it to no longer function.
8. If you are getting multiple error messages during blade insertion, try inserting the blade into the handle BEFORE plugging the handle into the controller unit.
9. DO NOT allow saline, or any other fluid, to enter the handle during use. Saline is highly conductive and will interfere with the circuitry inside the handle causing the handle not to work properly.
10. DO NOT use any type of instrument (e.g. hemostats) to insert the blade into the handle as this would damage the blade’s imprinted circuitry and render it inoperable.
11. The handle must be energized for the COAG switch to work.
12. DO NOT immerse the handle in liquid of ANY KIND. The handle contains electronic contacts and moisture sensitive electrical components which can be damaged and fail to function if immersed in liquids of any kind. DO NOT allow any solution to penetrate to the interior of the handle.
13. External Cleaning is the only controller maintenance that can be performed by the user.
14. Servicing the controller unit by other than and qualified service personnel approved by Everis renders the Warranty void.
15. Before cleaning the controller, detach the controller unit from the AC power source.
16. DO NOT immerse the controller.
17. DO NOT use an abrasive cloth or cleaners, especially on the display screen.
18. After use, this device may be contaminated. Handle and dispose of it as biohazardous waste in accordance with facility protocol and local regulations.

SYSTEM DESCRIPTION

MODEL SG6 SHAW SCALPEL SYSTEM



The Model SG6 Shaw Scalpel System consists of four components:

1. **CONTROLLER** – An electronic power supply/controller that energizes the blade and provides various automatic calibrations, sensing, and control functions. It has user controls with visual and audible indications of instrument status.

2. **SINGLE-USE, DISPOSABLE HANDLE –** A single-use, disposable handle connected to the controller unit with a light-weight, flexible electrical cable. Disposable scalpel blades are inserted into the disposable handle. The user is able to control blade temperature, on/off and COAG modes directly from the handle.

3. **DISPOSABLE BLADES –** Various sizes and shapes of sterile disposable scalpel blades are available which are similar in size and shape to conventional cold steel scalpel blades. Blades are single-use only and should never be reused. The Shaw Scalpel blades incorporate heating and temperature-sensing micro-circuitry which provides heat for hemostasis and sensing feedback to the controller. DO NOT bend the blade – Care should be taken not to bend the blade while cleaning, insertion, or reinsertion as the heater leads may become broken and the blade stop working.

4. **FOOTSWITCH** – An optional footswitch (REF 7013-8410) is available which allows the surgeon to set the desired temperatures of the blades as well as activate CUT or COAG modes. The footswitch has two modes: (1) CUT/COAG and (2) TEMP UP/ DOWN. Switching from mode (1) to mode (2) and vice-versa is controlled by depressing the black MODE button on the top of the footswitch. When in the TEMP UP/ DOWN mode, depressing and releasing the left (yellow) pedal will decrease the set point temperature by 10° C; whereas, depressing and releasing the right (blue) pedal will increase the set point temperature by 10° C. When in the CUT/COAG mode, depressing and holding the left (yellow) pedal will energize the scalpel blade to come to the selected temperature. Similarly, depressing and holding the right (blue) pedal will energize the scalpel blade to come to the COAG temperature of 300° C

IMPORTANT FEATURES

SURGICAL FEATURES

1. **Retains the Precision of Surgical Steel** – Thermal Scalpel blades are similar in size and shape to conventional scalpel blades and have the same sharp surgical steel cutting edges to retain the precision and “feel” of the conventional scalpel when cutting.

2. **Reduces Blood Loss** – The Thermal Scalpel conducts heat from its sharp, heated blade to a thin layer of tissue adjacent to the cutting edge. The heat seals most blood vessels (less than 2mm in diameter) as they are cut, producing near-bloodless incisions with the precision of sharp surgical steel.

3. **Maintains a Clean, Dry Surgical Field** – The Thermal Scalpel seals as it cuts tissue, largely eliminating the flow of blood into the incised area. This clean, clear operative field contributes to improved precision and visibility at the incision site.

4. **Minimizes Tissue Damage** – Hemostatic incisions made with the Thermal Scalpel result in visibly less tissue damage than when electrosurgical units are used. Independent experiments have shown that the breaking strength and infection resistance of healing wounds made with the Shaw Scalpel were essentially equal to those obtained with conventional cold-steel scalpels and better than those made with electrosurgical units.

5. **Shortens Surgery** – Experience indicates that a net reduction in overall operating time generally results when an appropriate technique is developed and with sufficient experience in the use of the Thermal Scalpel.

6. **Eliminates Patient Currents and Muscle Stimulation** – Since no electrical current passes through the patient when using the Shaw Scalpel System, a grounding pad is not needed and the risk of accidental electrical current burns at grounding sites is eliminated. Muscle stimulation associated with passing electrical currents through the body is also eliminated, improving surgical precision.

SYSTEM FEATURES

1. **Sterile, Disposable Scalpel blades** – Shaw Scalpel blades are individually packaged sterile and ready for use. They are discarded when they become dull, just like conventional cold-steel scalpel blades. Blades are single-use only and should never be reused.

2. **Automatic Calibration** – The Shaw Scalpel System automatically calibrates each blade, typically within 6 seconds of its insertion into the handle. The blade is ready to be energized as soon as the calibration is complete.

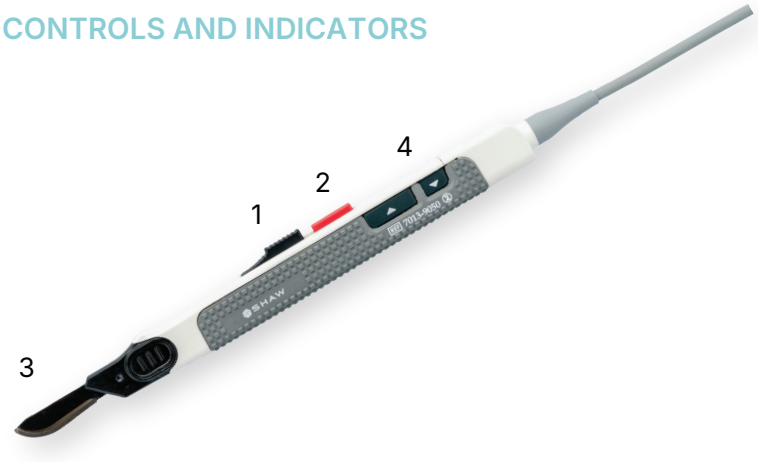
3. **User-Selectable Cutting Temperature** – The user is able to select the desired cutting temperature over a range of 70° C to 300° C in increments of 10° degrees C using the front panel "Temperature Up" ▲ or "Temperature Down" ▼ buttons OR by using the UP/DOWN arrows on the handle. Thermal COAG Mode – The Shaw Scalpel System provides a high temperature Thermal COAG Mode, suitable for sealing vessels not sealed as they are cut. The blue button on the handle provides convenient switching between the selected cutting and Thermal COAG temperatures. The Thermal COAG Mode is preset to 300° C.

4. **Audible Signals** – The controller provides audible tones to indicate certain system functions and status. The signal volume can be turned up or down by the rotating knob on the back of the unit. The audible functions include: pressing any button on the controller or handle, blade heating, blade cooling, Thermal COAG, and blade removal. Also, a tone is heard when there are certain problems with the blade(s).

5. **Visual Displays** – The Model SG6 controller has one display on the front of the unit.

6. **Equipotential** – Uniform potential. Means for eliminating noise or interference with sensitive equipment by application of a potential equalization conductor. If required by local code, connect the HTSS unit to the hospital equalization connector with an equipotential cable.

HANDLE CONTROLS AND INDICATORS



1. ACTIVATE BUTTON - Sliding the black activate button rearward (toward the cable) mechanically latches the switch and activates the blade. Tangerine dot is visible when switch is in the "ON" position. Sliding the switch forward (toward the blade) deactivates the blade.

2. MAX TEMPERATURE BUTTON - Depressing the red button on the handle activates the Max Temperature mode as long as the switch is depressed. Releasing the switch causes the temperature to revert to the original temperature setting. NOTE: Max Temperature mode can only be activated if the activate button is in the "ON" position.

3. **BLADE** - The blade/hub assembly includes a magnetic interface. The blade/hub should automatically seat fully into the Disposable Handle with zero force required when the blade/hub assembly is placed into the mating portion of the Disposable Handle. NOTE: The handle should be in the "OFF" position before inserting the blade.

4. **TEMPERATURE CONTROL SWITCHES** - With the ON/OFF switch in the "OFF" (forward) position, depressing the UP '▲' arrow temperature control switch increases the temperature. Depressing the down '▼' arrow temperature control switch decreases the temperature. The temperature changes as long as the switch is depressed. The temperature remains at the last setting when the switch is released.

HANDLE, BLADE, AND FOOTSWITCH COMPATIBILITY

1. **HANDLE Compatibility** – The Model SG6 Shaw Scalpel Controller (REF 7013-8400) is compatible with the following Shaw Scalpel handle/cable configurations: REF 7013-9050 – Model SG6 Handle w/ Integral Cable Assembly – Qty 1 REF 7023-9050 -- Model SG6 Handle w/Integral Cable Assembly - Qty 6

2. **BLADE Compatibility –** The Model SG6 Shaw Scalpel Controller is compatible with the following thermal scalpel blades:

   REF **7013-5810 –** #10 Blade - Sterile Disposable - Quantity 24
   REF **7023-5810 –** #10 Blade - Sterile Disposable - Quantity 10
   REF **7023-5812 –** #12 Blade - Sterile Disposable - Quantity 10
   REF **7013-5815 –** #15 Blade - Sterile Disposable - Quantity 24
   REF **7023-5815 –** #15 Blade - Sterile Disposable - Quantity 10

3. **FOOTSWITCH Compatibility**

   The Model SG6 Shaw Scalpel Controller is compatible with the optional Footswitch (REF **7013-8410**).

OPERATING INSTRUCTIONS

1. **POWER ON**

   Turn on POWER to the system by placing the POWER SWITCH located at the front lower left side of the controller in the UP or 'I' position. The unit will briefly (less than 10 seconds) undergo a self-test. Once the self-test is completed, the display will illuminate with the default set-point temperature setting (70˚ C) and prompt the user to connect the handle.

2. **POWER OFF**

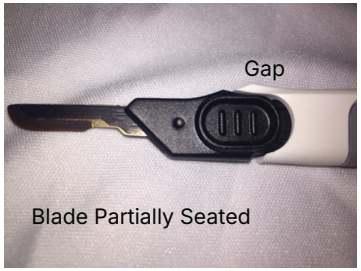
Turn off POWER to the system by placing the POWER SWITCH located at the front lower left side of the controller in the DOWN or '0' position.

3. **HANDLE INSERTION**

With the controller powered ON and the handle ON/OFF switch in the OFF position, attach the handle cable to the controller by aligning the arrow on the handle cable connector with the arrow on the mating front panel connector and inserting it into the front panel receptacle.

4. **BLADE INSERTION AND CALIBRATION**

Turn on POWER to the system by placing the POWER SWITCH located at the front lower left side of the controller in the UP or 'I' position. The unit will briefly (less than 10 seconds) undergo a self-test. Once the self-test is completed, the display will illuminate with the default set-point temperature setting (70° C) and prompt the user to connect the handle.





If there is a pause during blade insertion, an error message may appear. Simply remove the blade assembly and reinsert. Once the blade is successfully inserted into the handle, the controller unit will begin calibrating the blade. Calibration should be completed within 10 seconds. If calibration is successful, the controller unit will display a message indicating that the blade has been calibrated.

NOTE: DO NOT use any type of instrument (e.g. hemostats) to insert the blade into the handle as this would damage the blade's imprinted circuitry and render it inoperable.

NOTE: Accurate calibration can only be achieved if the blade is at room temperature when it is inserted into the handle. If the blade becomes accidentally dislodged from the handle, turn the handle OFF, dip the blade in sterile water to cool it to room temperature, and then reinsert it.

If calibration is not successful, an error message will appear on the controller unit's display. In that case, remove the blade and re-insert it into the handle in one continuous motion. If the controller unit continues to display an error message that the blade is not calibrated, insert another new blade repeating steps.

If calibration with a second blade is not successful, then the controller unit is unable to read the blade via the handle. Replace the handle and reinsert a blade.

5. **USING THE SHAW SCALPEL**

With the controller powered ON, the handle attached and a blade inserted into the handle, VERIFY that the controller display reads 70° C.

With the handle switched OFF, the blade temperature can be elevated or lowered in increments of 10° C by using the UP '▲' or DOWN '▼' arrows on the side of the handle, or the front of the controller unit, or by using the optional footswitch pedals (See Optional Footswitch Controls). The temperature controls work only when the handle is switched OFF.

Slide the handle yellow ON/OFF switch to the ON position to expose the tangerine-colored dot. The handle is now activated and the blade will be heated to the displayed temperature setting.

To activate the thermal COAG mode, depress the blue Thermal COAG switch on the top of the handle. The blade temperature will approximate 300° C in the thermal COAG mode.

NOTE: The handle must be energized for the COAG switch to work.

6. **USING THE OPTIONAL FOOTSWITCH**

The footswitch has two modes: (1) CUT/COAG and (2) TEMP UP/DOWN. Switching from mode (1) to mode (2) and vice-versa is controlled by depressing the black MODE button on the top of the footswitch. When in the TEMP UP/DOWN mode, depressing and releasing the left (yellow) pedal will decrease the set point temperature by 10° C; whereas, depressing and releasing the right (blue) pedal will increase the set point temperature by 10° C. When in the CUT/COAG mode, depressing and holding the left (yellow) pedal will energize the scalpel blade to come to the selected temperature. Similarly, depressing and holding the right (blue) pedal will energize the scalpel blade to come to the COAG temperature of 300° C.

SURGICAL USE & TECHNIQUES

1. CUTTING TEMPERATURES

- **SKIN** – The recommended temperature setting for skin incisions is 70° C. For minimal scarring, make the initial skin incision with the scalpel handle in the OFF position. Cutting with the blade unheated will eliminate the possibility of superficial skin scars due to contact with a heated blade (See WARNINGS and PRECAUTIONS).

- **OTHER TISSUES –** For other tissues, the appropriate temperature setting is typically between 180° C and 300° C.

2. INFLUENCE OF CUTTING SPEED ON HEMOSTASIS

In practice, the surgeon generally selects the lowest set point temperature that will afford adequate hemostasis for the maximum anticipated rate of tissue cutting, thereby minimizing unnecessary (thermal) necrosis of tissue. The determination of the appropriate set point temperature is determined by the surgeon by raising the set point temperature until adequate hemostasis is achieved. Alternatively, the surgeon can, at any selected point temperature, modulate the speed of tissue cutting according to the vascularity of the tissue being incised.

3. SEALING BLEEDERS

- The heat from the Shaw Scalpel blade will seal most (less than 2mm in diameter) blood vessels as they are cut.

- For a vessel not sealed as it is cut, promptly use the blade's heat to seal it by exerting light pressure on the bleeder with the flat side of the blade.

- For larger bleeders, activate the Thermal COAG mode by depressing and holding down the blue Thermal COAG switch (or optional footswitch pedal) and holding the flat side of the blade on the bleeder until hemostasis is achieved.

4. MAINTAIN A DRY OPERATIVE FIELD

- The most effective use of the Shaw Scalpel thermal energy such that bleeding does not begin. This is done by making incisions using long, relatively slow, authoritative strokes (rather than short, "choppy" strokes) to maintain constant and meticulous hemostasis at every step, and prevent the onset of bleeding.

- Bleeding vessels are sealed by the direct contact of the hot blade to tissue, thus providing heat transfer to the tissue at the bleeding site. Accordingly, if pools of blood occur from vessels not sealed as they are cut, suction or sponge the area before applying the Shaw Scalpel blade to seal the bleeders. Heat from the blade dissipates in pools of blood and cannot get through these pools to reach the tissue to seal the bleeder. Pools of blood simply coagulate on the blade, thermally insulating it.

5. CHANGING THE BLADE

If the blade becomes dull or the change blade message appears on the controller display, switch the handle ON/OFF switch to off and wait for the temperature display to turn Green indicating the blade is safe to handle. Replace the dull or damaged blade with a new blade.

CAUTION: To remove a blade from the handle, grab the plastic hub and pull the blade straight out of the handle. Bending, twisting or flexing the blade could damage the blade contacts and retainers within the handle causing it to no longer function.

CAUTION: Used blades are surgically sharp and may be extremely hot to the touch. Always use caution when removing the blade/hub assembly. Always follow proper sharps precautions when handling a blade and biohazard disposal techniques when discarding a used blade.

6. CLEANING THE BLADE DURING USE

Clean any coagulated blood or tissue debris from a HOT blade by LIGHTLY wiping the blade using DRY 4x4 gauze. Using WET gauze will cool the blade causing the blood and coagulum to adhere to the surface of the blade. Only light pressure is needed. Excess pressure will result in the bending of the blade and the subsequent damage to the blade electrical circuit.

NOTE: The Teflon non-stick coating cleans most effectively when hot. Best results are obtained using dry 4x4 gauze when the blade is hot.

NOTE: If the blade becomes accidentally dislodged from the handle, turn the handle OFF, dip the blade in sterile water or saline solution to cool it to room temperature, and then reinsert it. Accurate calibration can only be achieved if the blade is at room temperature when it is inserted into the handle.

CAUTION: Care should be taken not to bend the blade while cleaning, insertion, or reinsertion as the heater leads may become broken and the blade stop working.

CAUTION: Never use any type of abrasive pad to clean the blades. The abrasives will damage the circuit and render the blade unusable.

WARRANTY

Everis warrants to the original purchaser that reasonable care has been used in the manufacture of the MODEL SG6 Shaw Scalpel SYSTEM (HTSS) CONTROLLER and that, when properly used, it will be free from defects in material or workmanship for a period of one (1) year after the date of shipment from Everis or any of its authorized distributors.

NOTE: Shaw Scalpel scalpel handles and blades are single-use disposable instruments warranted to be free from defects in materials and workmanship for first use for a period of Sixty (60) days from the date of shipment.

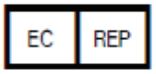
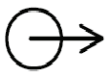
The sole and exclusive remedy with respect to any MODEL SG6 HTSS or any portion thereof found within its warranty period not to meet these standards is that after return to and examination by Everis, Everis will without charge at its option either repair or replace that portion of the MODEL SG6 HTSS found to be defective. This warranty shall not apply (a) if that portion of the MODEL SG6 HTSS has been repaired or altered by anyone other than qualified service personnel approved by Everis or altered in any way which, in Everis's judgment, affects its usability or reliability; or (b) if the sterile lot or serial number has been altered, effaced, or removed; (c) if the fault has been caused by abnormal conditions of operation or misuse including, but not limited to: dropping the controller unit; opening the controller unit; and/or permitting electrical contact with an active electro surgical (e.g., Bovie) electrode; operating the unit within 1 m of another electrosurgical controller unit; or, (d) if in the case of the scalpel blades or handles, the scalpel blades or handles have been reprocessed and reused. Except for the replacement of fuses, which can be accessed without opening the controller unit's enclosure, any warranty, implied or expressed, is considered void if the tamper-proof seal on the controller unit's enclosure is found to be broken. In all such cases, Everis's determination will prevail and any repairs or replacements, if requested, will be billed at Everis's prevailing normal rates. If so requested, estimates will be submitted before work is started.

Except for the replacement of fuses, which can be accessed without opening the controller unit's enclosure, any warranty, implied or expressed, is considered void if the tamper-proof seal on the controller unit's enclosure is found to be broken. In all such cases, Everis's determination will prevail and any repairs or replacements, if requested, will be billed at Everis's prevailing normal rates. If so requested, estimates will be submitted before work is started.

NOTE: An RMA# issued by Everis must be obtained before any part of the MODEL SG6 HTSS is returned.

NOTE: Handles and blades being returned must be cleaned, sterilized, and packaged in sterile packaging with labeling which verifies the sterility of the handle and/or blade prior to return to Everis. Any handle and/or blade not properly cleaned, sterilized and packaged as described in this warranty will be disposed of and no warranty will be in effect.

The foregoing express warranty, as conditioned and limited, is in lieu of and excludes all other warranties not expressly set forth herein whether expressed or implied by operation of law or otherwise including, but not limited to, any implied warranties or merchantability or fitness for particular purpose. Everis shall not be liable for any incidental or consequential loss, damage, expense or liability direct or indirect with respect to this product. Everis neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product.

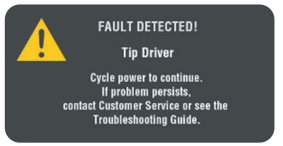
	Follow Instructions for Use
	Serial number
	Reference number
	Manufacturer
	Manufacturing date
	Caution
	Authorized Representative in the European Community
	Temperature decrease
	Temperature increase
	Consult instructions for use
	Do not dispose of this product in unsorted municipal waste stream. Dispose of this product according to - Local Regulations.
	CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
	Output handle connector

TROUBLESHOOTING
BLADE / HANDLE **ERROR MESSAGES**

Condition	Description	Visual Indication	IFU Instructions
Handle Usage Warning	The handle has been used previously and must be replaced to continue.		Discard the handle being used and replace it.
Defective Handle	When performing a handle diagnostic check, the console identified a problem with the handle.		Ensure that the handle is fully connected. If the problem persists, replace handle.
Replace Blade	Console can no longer read one of the two circuits on the blade or the blade resistance has become out of specification.		• Remove blade. Cool to room temp and reinsert into handle. If problem persists, replace blade. • If problem persists with the new blade, then the handle contacts may be damaged. Replace handle.
Hot Blade	The system is attempting to calibrate a hot blade.		Remove the blade and allow it to cool before continuing calibration or replace it.
Button Pressed	Console has detected that a button on the handle or footswitch is pressed during the detection mode.		Release all buttons on the handle before continuing.

Condition	Description	Visual Indication	IFU Instructions
Insert Blade	Console is unable to detect blade circuits.	Insert Blade	• Replace blade. • If problem persists with a new blade, then the handle contacts may be damaged. Replace handle.
Insufficient Power Fault	The console has not been able to achieve the set point temperature within a timeframe of 15 seconds.	 In addition to the fault symbol, the system displays information about the source of the fault.	Ensure that the handle is fully connected. If the problem persists, replace handle.

TROUBLESHOOTING
CONTROLLER FAULT MESSAGES

Condition	Description	Visual Indication	IFU Instructions
Heel or Tip Temperature Fault	The software detected that the heel or tip portion of the console is out of tolerance.	  In addition to the fault symbol, the system displays information about the source of the fault.	• Cycle power to the unit using the switch on the front panel. • If message does not clear, then unit must be returned for service.

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3439050ENG REV 3- 2026-06-24

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