BoneScalpel™ System

Instructions For Use

AESCULAP®

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1. General Safety Statements

WARNING 1.1 The BoneScalpel system is an electro-mechanical device, which under certain circumstances could present an electrical shock hazard to the operator and/or patient. Please read manual thoroughly and follow directions stated herein to assure maximum safety during operation. This manual shall be kept in close proximity to the system for easy referral when needed.

WARNING 1.2 The BoneScalpel system is intended to be used in various types of invasive, surgical procedures. There may be indirect danger to the patient should the device fail during the procedure. It is recommended that the facility follows its back-up equipment protocols.

CAUTION 1.1 Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

1.1. EMC Statement

The BoneScalpel system is designed and tested to comply with FCC regulations for conducted and radiated emissions under Part 18 Subchapter J. and to comply with IEC EN60601-1-2: 2007 guidelines for EMC.

CAUTION 1.2 This device is considered medical electrical equipment. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this operator's manual.

CAUTION 1.3 Portable and mobile RF communication equipment can affect medical electrical equipment. If RF equipment is in use monitor the Bonescalpel for proper function during procedure.

CAUTION 1.4 The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the device. Use only Aesculap branded equipment and accessories.

CAUTION 1.5 The console should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, the console should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Compatibility Guidance (in accordance with EN/IEC 60601-1-2:2007)

Guidance And Manufacturer's Declaration – Electromagnetic Emissions (Table 201)		
The BONESCALPEL SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of BONESCALPEL SYSTEM should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The BONESCALPEL SYSTEM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BONESCALPEL SYSTEM is suitable for use in all establishments other than domestic 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 1.1 Guidance & manufacturer's declaration on electromagnetic emissions (EN table 201)

Guidance And Manufacturer's Declaration – Electromagnetic Immunity (Table 202)			
The BONESCALPEL SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the BONESCALPEL SYSTEM should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	o ±6 kV contact o ±8 kV air	o ±6 kV contact o 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	o ±2 kV for power supply lines O ±1 kV for input/output lines	o ±2 kV for power supply lines o ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	o ±1 kV differential mode O ±2 kV common mode	o ±1 kV differential mode o 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines 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 5 sec	<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 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BONESCALPEL SYSTEM requires continued operation during power mains interruptions, it is recommended that the powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Table 1.2 Guidance & manufacturer's declaration on electromagnetic immunity (EN table 202)

List of Cables		
Item	Cable Length	Type
Handpiece cable	15 ft | 4.6 m	shielded 2-conductor
Power cord	10 ft | 3.0 m	unshielded 3-conducter
Footswitch cable	14 ft | 4.3 m	shielded 2-conductor

Table 1.3 List of cables

Guidance And Manufacturer's Declaration – Electromagnetic Immunity (Table 204)			
The BONESCALPEL SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the BONESCALPEL SYSTEM should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the BONESCALPEL SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BONESCALPEL SYSTEM is used exceeds the applicable RF compliance level above, the BONESCALPEL SYSTEM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BONESCALPEL SYSTEM. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 1.4 Guidance & manufacturer's declaration on electromagnetic immunity (EN table 204)

Recommended Separation Distances Between Portable And Mobile RF Communications Equipment And The BONESCALPEL SYSTEM (Table 206)			
The BONESCALPEL SYSTEM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BONESCALPEL SYSTEM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BONESCALPEL SYSTEM below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	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	0.12	0.23
0.1	0.37	0.37	0.37
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 1.5 Recommended separation distances (EN table 206)

1.2. Electrical Safety Statement

The BoneScalpel System is designed and tested to comply with UL 60601-1 and EN 60601-1.

WARNING 1.3 The BoneScalpel system generates high voltages within the console itself and the connected handpiece. To avoid injury, the console should never be operated before ensuring that its cover is properly closed and not tampered with. Do not attempt to remove or disassemble the cover. There are no user-serviceable parts inside the console. All service should only be performed by an authorized Aesculap USA representative.

WARNING 1.4 Proper system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the console. Never pull on the power cord to remove it from the receptacle.

WARNING 1.5 Connecting the console to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or to create a shock or fire hazard. Confirm that the voltage selector switch on the console rear panel is set to the local voltage setting and ensure that the correct fuses are being used. Refer to section 12.1 on fuse replacement.

1.3. Environmental Statement

This equipment consists of materials that may be recycled if disassembled by a specialized company. Please observe local and federal regulations regarding the disposal of packing materials and old equipment.

1.4. Summary Of Safety Notices

Please read this section of the manual carefully. It contains a summary of all precaution, warning and caution statements contained in the manual. However, the user is advised to read the entire manual and operate the device only in accordance with all of the instructions contained herein.

Servicing of this device should only be performed by qualified technicians authorized by Aesculap USA. There are no service controls accessible to the user.

Conventions on Warnings, Cautions and Notes	
WARNING	Denotes potentially dangerous situation that could result in death or serious injury to patient, operator or staff.
CAUTION	Denotes potentially dangerous situation that could result in moderate injury to patient, operator or staff.
NOTE	Indicates potential hazard that may result in product damage.

Table 1.6 Conventions on warnings, cautions and notes

List Of Warnings

WARNING 1.1 The BoneScalpel system is an electro-mechanical device, which under certain circumstances could present an electrical shock hazard to the operator and/or patient. Please read manual thoroughly and follow directions stated herein to assure maximum safety during operation. This manual shall be kept in close proximity to the system for easy referral when needed.

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WARNING 1.5 Connecting the console to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or to create a shock or fire hazard. Confirm that the voltage selector switch on the console rear panel is set to the local voltage setting and ensure that the correct fuses are being used. Refer to section 12.1 on fuse replacement.

WARNING 3.1 Tip and irrigant temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal , set the irrigation flowrate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 7, a minimum flow setting of 70% should be used. Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures.

WARNING 3.2 Tissue necrosis may result if tip is not moved relative to tissue. A continuous tip motion is recommended in order to minimize contact duration with the ultrasonic tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert tip frequently.

WARNING 4.1 Contact to vibrating elements like extension and ultrasonic tip may cause burns and should be avoided by all means. The handpiece should only be held at the black housing area. A protective silicone sleeve, included with certain tips, reduces the risk of thermal damage but does not eliminate it. Contact with the silicone sleeve should be avoided or kept brief with minimal amount of contact pressure. Pressure and extended exposure can still result in excessive frictional

heat and cause burns.

WARNING 4.2 Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures of the skull, when using the BoneScalpel accessories.

WARNING 4.3 Ultrasonic tips can break under excessive use in extreme conditions, e.g. when cutting for extended duration in tight cavities with limited lateral motion. The tip could break into two or more fragments with the main fragment remaining attached to the handpiece. All fragments must be retrieved immediately from the surgical site. The fragments should be checked to ensure that no further pieces are missing. It is possible that a fragment is propelled outside of the surgical cavity. Diagnostic imaging, such as X-ray, must be used if a fragment cannot be found to confirm that the broken piece is outside of the surgical cavity.

WARNING 4.4 Breakage of ultrasonic tips will result in sharp edges that can be harmful to soft tissue even without activation of ultrasound. Tips can bend or deform before they actually brake. Tips showing signs of deformation or cracking should be replaced immediately since tip breakage is otherwise imminent. Do not bend or twist the ultrasonic tips since it reduces the structural integrity and can result in tip breakage during use. Dispose of deformed or broken tips immediately in a sharps container.

WARNING 6.1 Immediately suspend operation if Electrical Fault appears on display and/or an Electrical Fault audible alarm sounds. Remove ultrasonic tip from surgical site. Turn Mains Power OFF. Do not touch any metallic parts of handpiece, extension, ultrasonic tip or generator while fault is indicated.

WARNING 7.1 Improper connection of the handpiece cable may present a shock hazard. Confirm that handpiece connector is dry prior to plugging it in.

WARNING 7.2 Do not operate pump with pump cover in raised position. Rollers might pinch loose clothing or fingers. Personal injuries may result. Cooling of the ultrasonic tip and irrigation at the treatment site will be inhibited.

WARNING 7.3 Tip and irrigation temperatures may exceed the tissue necrosis point with BoneScalpel accessories for hard tissue removal if insufficient irrigation flow rates are used. Always set the irrigation flowrate for hard tissue removal to a setting no less than the comparable vibration setting. For example, if the vibration setting is 7, a minimum flow setting of 70% should be used.

WARNING 7.4 Heat is being generated at the tip/tissue interface. A continuous, lateral sweeping motion is recommended for general bone/tissue removal in order to minimize contact duration with the ultrasonic tip and minimize the temperature increase.

WARNING 8.1 Remove probe cover, ultrasonic tip and extension from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.

WARNING 9.1 Single-use items should be discarded following each surgical procedure according to hospital protocol for disposal of biocontaminated wastes. Do not attempt to reuse or re-sterilize any single-use items. Dispose ultrasonic tips in a sharps container.

WARNING 9.2 All reusable handpiece parts and accessories must be properly decontaminated, cleaned and sterilized before each use as per instructions contained in this manual. Failure to do so may lead to infections, which can ultimately cause patient death.

WARNING 9.3 The manufacturer has validated all cleaning and sterilization cycles given in this manual. It is highly recommended that the procedures given in this manual for cleaning and sterilizing the BoneScalpel System and related accessories be followed. It is the responsibility of the user of this device or any accessories used with it to validate procedures for cleaning and/or sterilization if they differ from the procedures as outlined in this manual.

WARNING 10.1 If a Mains Power fuse fails after replacement when the unit is reactivated, discontinue use of the device and contact an authorized Aesculap USA representative.

WARNING 12.1 Connecting the console to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or to create a shock or fire hazard. Confirm that the voltage selector switch in the console rear is set to the local voltage setting and ensure that the correct fuses are being used. Refer to section 12 on fuse replacement

List Of Cautions

CAUTION 1.1 Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

CAUTION 1.2 This device is considered medical electrical equipment. Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this operator's manual.

CAUTION 1.3 Portable and mobile RF communication equipment can affect medical electrical equipment. If RF equipment is in use monitor the Bonescalpel for proper function during procedure.

CAUTION 1.4 The use of accessories, transducers and cables other than those specified may result in increased emissions or

decreased immunity of the device. Use only Aesculap branded equipment and accessories.

CAUTION 1.5 The console should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, the console should be observed to verify normal operation in the configuration in which it will be used.

CAUTION 3.1 The BoneScalpel system and its accessories may emit harmful acoustic pressure if exposure exceeds recommended limits.

CAUTION 4.1 Ultrasonic energy is inhibited if excessive physical force is applied to the ultrasonic tip; use only enough force to guide the tip to the surgical site and to advance it through the tissue. Do not force the tip; allow the ultrasonic action to do the work.

CAUTION 4.2 Insufficient irrigation and high tip pressure (loading) under extended exposure, e.g. in tight cavities, are to be avoided in BoneScalpel hard tissue removal. It is recommended to withdraw and re-insert the ultrasonic tip repeatedly to re-establish adequate cooling and lubrication.

CAUTION 7.1 All reusable system components like handpiece, probe covers, counter wrench, and T-wrench are supplied industrially cleaned, but NON-STERILE. All items intended for use in the sterile field must be cleaned and sterilized as per the indicated instructions before first clinical use and before every subsequent clinical use.

CAUTION 7.2 All items intended for use in the sterile field must be cleaned and sterilized as per indicated instructions before each clinical use.

CAUTION 7.3 The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.

CAUTION 7.4 Do not place the soft silicone tube behind or in front of the rollers (latch removed in illustrations)

CAUTION 7.5 Do not pinch the soft silicone tube when the latch is locked.

CAUTION 7.6 Do not pinch barb fittings when closing the latch.

CAUTION 7.7 Prime the irrigation tubing prior to use. At all times ensure that the irrigant flows towards the handpiece when footswitch is depressed. If no irrigant is flowing, cease use until flow is restored.

CAUTION 7.8 The system check should always be done in advance of preparing patient for surgery to minimize risk to patient in case of system malfunction.

CAUTION 8.1 Ensure all connections and mating surfaces of handpiece, extension and ultrasonic tip are clean and dry before assembly.

CAUTION 9.1 Use manual cleaning techniques only. Do not use ultrasonic cleaners or automated washers to clean the handpiece as both methods could damage handpiece.

CAUTION 9.2 Be certain to clear debris from all internal passages by brushing. Failure to do so may hinder sterilization of units during autoclaving.

CAUTION 9.3 Do not immerse ultrasonic console, handpiece, irrigation pump, remote footswitch or electric cables. These items are not sealed against liquids and damage to equipment will result.

CAUTION 12.1 Use only genuine replacement parts from Aesculap. Use of parts furnished by other sources may result in patient or operator injury or system malfunction and will void any applicable warranty.

CAUTION 12.2 Before using loose packing materials, such as foam pellets, shredded paper or similar, be sure to wrap the component(s) separately in plastic bags, film or other protective wrapping.

List Of Notes

NOTE 4.1 After extended periods of operation, the bottom of the console housing may become warm to the touch. This is normal. Do not touch the bottom of the console housing while in operation or shortly after operation.

NOTE 4.2 Loose tip/tissue contact upon an initial bone incision can cause a thin tip to resonate not only longitudinally but also transversely. This can cause a thin tip to break. It is necessary to engage bone actively and with a minimal tip pressure greater than zero in order to prevent the shattering.

NOTE 4.3 Contact of the ultrasonic tip or the exposed extension with metal, surgical instruments or other objects during ultrasound use must be avoided. Such contact can damage the ultrasonic components very easily and may result in compromised performance, including failure. Discard any extensions or tips that show signs of damages like gouges, nicks or fractures. External aspiration may be used but it is recommended that a plastic suction tip should be used when in proximity with the probe tip.

NOTE 7.1 Adequate air circulation is needed to cool electronic components inside of the unit. Do not block the cooling fan at the console rear or the air vents on the console bottom. Do not place the unit on a towel, foam or other soft surface since the material may block the air vents. Blocking these vents may cause unit to overheat and malfunction or create a shock hazard. A clear drape can be used to protect the console front panel but do not cover the pump housing or other console portions.

NOTE 8.1 The handpiece must be placed into the counter wrench. Do not attempt to tighten or loosen handpiece components by holding the handpiece case or endcap. Always use the T-wrench wrench when tightening or un-tightening the tip or an extension. Never apply a pipe or strap wrench to the handpiece case. Do not over-tighten the tip or the extension.

NOTE 8.2 Always tighten or un-tighten the probe cover by hand and without using any wrenches. Do not over-tighten the probe cover.

NOTE 8.3 Always hold the handpiece at its metallic endcap when tightening or un-tightening the irrigation tubing. Always tighten or un-tighten the irrigation tubing by hand and without using any wrenches. Do not over-tighten the tubing connector.

NOTE 9.1 Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage.

NOTE 9.2 The reuse life given takes into account wear and tear due to cleaning and sterilization only. Damage or wear caused by actual use in treatments will affect life of components.

1.5. Trademark Information

Aesculap® is a registered trademark of Aesculap, Inc.
Misonix® is a registered trademarks of Misonix, Inc., Farmingdale, NY
BoneScalpel™ is a pending trademark of Misonix, Inc., Farmingdale, NY
ASP Enzol® and Prolystica® are registered trademarks of STERIS Corporation, Mentor, OH

1.6. Explanation Of Symbols

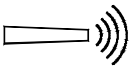
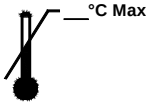
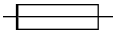
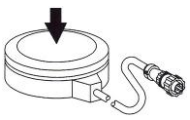
Console Related Symbols					
Symbol	Description	Symbol	Description	Symbol	Description
	Enable / Standby Ultrasound		Caution: Dangerous voltage		Mains Power ON
	Scroll through menu pages		Caution: Consult accompanying documents		Mains Power OFF
	Amplitude setting		Caution: Pinch hazard		Protective earth ground
	Pulse setting		Consult Instructions for Use		Equipotentiality connection
	Flow setting		Type B equipment		Disposal to be compliant with EN 50419 (WEEE directive)
	Do not reuse	STERILE EO	Sterilized using Ethylene Oxide	R_X ONLY	Restricted to sale by or on the order of a physician only
	Do not use if packaging is damaged	STERILE R	Sterilized using Gamma Irradiation	EC REP	Authorized representative
	Contents are latex-free		Use by date indicated	REF	Catalog number
	Do not expose to temperatures greater than indicated	LOT	Lot or batch code	~	AC Voltage
	Must use hospital grade power cord only		Fuse		Manufacturer
	Contains DEHP and/or Phthalates		Classified by UL		Footswitch connector

Table 1.7 Explanation of symbols

2. Indications And Contra Indications

2.1. Indications

The BoneScalpel system is indicated for use in the fragmentation and aspiration of both soft and hard (e.g.: bone) tissue as used in the following surgical specialties:

- Orthopedic Surgery
- Plastic and Reconstructive Surgery
- Thoracic Surgery
- NeuroSurgery
- General Surgery

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2.2. Contra Indications

The BoneScalpel system is contra indicated for cardiac surgery and any procedure in the proximity of the heart.

The irrigation pump is contra indicated for the administration of parenteral fluids, infusion of drugs or for any life sustaining purposes

3. Adverse Effects

CAUTION 3.1 The BoneScalpel system and its accessories may emit harmful acoustic pressure if exposure exceeds recommended limits.

Limits For Airborn Acoustic Exposure		
Minimum Operating Distance From operator's or patient's ear		Maximum Exposure Period Within a 24hour period
3" - 12"	8 cm – 30 cm	Not to exceed 30 minutes
12" - 24"	30 cm – 60 cm	Not to exceed 90 minutes
> 24"	60 cm	Not to exceed 240 minutes

WARNING 3.1 Tip and irrigant temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal , set the irrigation flowrate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 7, a minimum flow setting of 70% should be used. Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures.

WARNING 3.2 Tissue necrosis may result if tip is not moved relative to tissue. A continuous tip motion is recommended in order to minimize contact duration with the ultrasonic tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert tip frequently.

4. Considerations During Clinical Use

4.1. Hand position

Recommended Hand Positions

The following illustrations demonstrate safe positions for holding the handpiece.

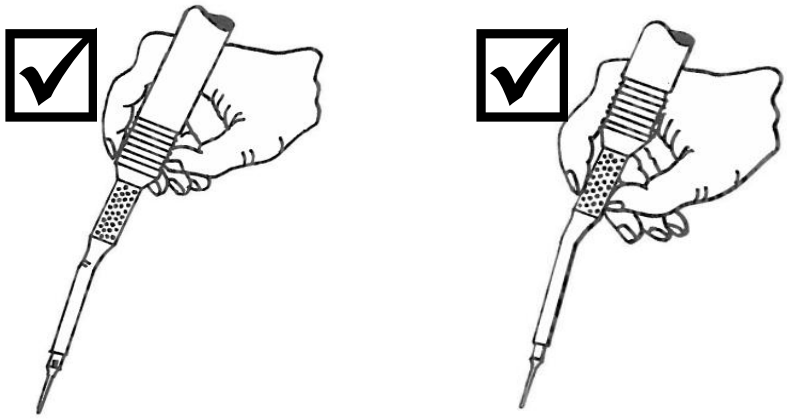


Figure 4.1 Correct hand position

Holding the handpiece at the silicone sleeve should be avoided or kept brief with minimal amount of contact pressure.

Figure 4.2 Incorrect hand position

WARNING 4.1 Contact to vibrating elements like extension and ultrasonic tip may cause burns and should be avoided by all means. The handpiece should only be held at the black housing area. A protective silicone sleeve, included with certain tips, reduces the risk of thermal damage but does not eliminate it. Contact with the silicone sleeve should be avoided or kept

brief with minimal amount of contact pressure. Pressure and extended exposure can still result in excessive frictional heat and cause burns.

NOTE 4.1 After extended periods of operation, the bottom of the console housing may become warm to the touch. This is normal. Do not touch the bottom of the console housing while in operation or shortly after operation.

4.2. HARD Tissue Use

Recommended Settings For Hard Tissue Use

The following settings are general guidelines and should be adjusted based on indication, anatomy, pathology and surgeon's preference.

	Amplitude	Pulse	Flow
Highest	10	100%	100%
Very High	9	100%	90%
High	8	100%	80%
Standard (Default)	7	100%	70%
Moderate	6	100%	60%
Low	5	100%	50%

Table 4.1 Recommended settings for hard tissue removal

- A high amplitude setting results in more aggressive tissue removal, a low setting in less aggressive tissue removal.
- A higher amplitude setting in combination with lower irrigation could result in increased tissue necrosis. A lower amplitude setting in combination with higher irrigation would minimize or eliminate tissue necrosis.
- Bone shaving tips tend to require a lower amplitude than cutting blades.

WARNING 3.1 Tip and irrigant temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal , set the irrigation flowrate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 7, a minimum flow setting of 70% should be used. Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures.

WARNING 3.2 Tissue necrosis may result if tip is not moved relative to tissue. A continuous tip motion is recommended in order to minimize contact duration with the ultrasonic tip and minimize heat build-up. When lateral motion is not possible withdraw and re-insert tip frequently.

WARNING 4.2 Additional external irrigation, e.g. by administering sterile saline with a syringe over the distal tip portion, may be necessary for removal of very dense, hard osseous structures of the skull, when using the BoneScalpel accessories.

CAUTION 4.1 Ultrasonic energy is inhibited if excessive physical force is applied to the ultrasonic tip; use only enough force to guide the tip to the surgical site and to advance it through the tissue. Do not force the tip; allow the ultrasonic action to do the work.

Tip Limitations During Bone Removal

Both the ultrasonic tip and the extension are vibrating at high frequency and are thus exposed to extreme mechanical stresses, especially when cutting bone.

WARNING 4.3 Ultrasonic tips can break under excessive use in extreme conditions, e.g. when cutting for extended duration in tight cavities with limited lateral motion. The tip could break into two or more fragments with the main fragment remaining attached to the handpiece. All fragments must be retrieved immediately from the surgical site. The fragments should be checked to ensure that no further pieces are missing. It is possible that a fragment is propelled outside of the surgical cavity. Diagnostic imaging, such as X-ray, must be used if a fragment cannot be found to confirm that the broken piece is outside of the surgical cavity.

WARNING 4.4 Breakage of ultrasonic tips will result in sharp edges that can be harmful to soft tissue even without activation of ultrasound. Tips can bend or deform before they actually brake. Tips showing signs of deformation or cracking should be replaced immediately since tip breakage is otherwise imminent. Do not bend or twist the ultrasonic tips since it reduces the structural integrity and can result in tip breakage during use. Dispose of deformed or broken tips immediately in a sharps container.

CAUTION 4.2 Insufficient irrigation and high tip pressure (loading) under extended exposure, e.g. in tight cavities, are to be avoided in BoneScalpel hard tissue removal. It is recommended to withdraw and re-insert the ultrasonic tip repeatedly to re-establish adequate cooling and lubrication.

NOTE 4.2 Loose tip/tissue contact upon an initial bone incision can cause a thin tip to resonate not only longitudinally but also transversely. This can cause a thin tip to break. It is necessary to engage bone actively and with a minimal tip pressure greater than zero in order to prevent the shattering.

NOTE 4.3 Contact of the ultrasonic tip or the exposed extension with metal, surgical instruments or other objects during ultrasound use must be avoided. Such contact can damage the ultrasonic components very easily and may result in compromised performance, including failure. Discard any extensions or tips that show signs of damages like gouges, nicks or fractures. External aspiration may be used but it is recommended that a plastic suction tip should be used when in proximity with the probe tip.

5. System Overview

5.1. Principle Of Operation

The BoneScalpel system is designed to ultrasonically dissect and fragment hard (osseous) tissues. The system consists of an ultrasonic console with handpiece and accessories. The console features an integrated irrigation pump.

Figure 5.1 BoneScalpel Console

Figure 5.2 BoneScalpel Handpiece

The console produces an electrical signal that is fed into the handpiece and its piezoelectric transducer. The transducer converts the electrical signal into mechanical vibrations. The vibratory motion is amplified all the way down to the tip's distal end. Various tip shapes and sizes are available to achieve desired tissue effects.

- Hard Tissue Applications: Specialized hard tissue tips are utilized to cut hard, osseous structures.
    - BoneScalpel blades, typically used for performing osteotomies, are usually flat and have a blunt active edge. A compression cut is achieved through repetitive impacts on the bone at an ultrasonic frequency.
    - Bone shaving tips are used for sculpting bone. They have an abrasive surface for bone removal through abrasion under ultrasonic oscillation.
    - BoneScalpel multi-function tips can have a combination of blunt and abrasive cutting surfaces.

A peristaltic pump, integrated into the BoneScalpel console, provides irrigant to the operative site during use.

5.2. Reusable System Components

The following system components represent the minimum requirements for performing hard tissue procedures. They can be ordered as a system or individually.

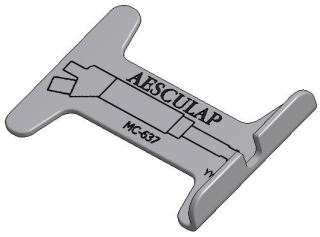
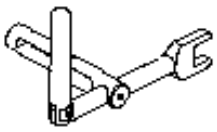
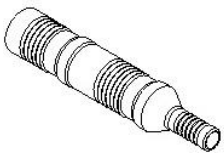
Required System Components			
MC634	BoneScalpel console  Includes IV pole, power cord, footswitch, peristaltic pump and instructions for use		1 ea.
MC632	BoneScalpel handpiece  		1 ea.
MC637	Counter wrench  	Compatible with MC632	1 ea.
MC628	T-Wrench 	Compatible with MC922 MC923 MC925 MC926 MC927	1 ea.
MC631	Probe cover 	Compatible with MC922 MC923 MC925 MC926 MC927	1 ea.

Table 5.1 Required system components

Components and quantities included with the system may change over time, please check with your Aesculap USA representative for the most current configuration.

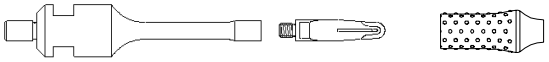
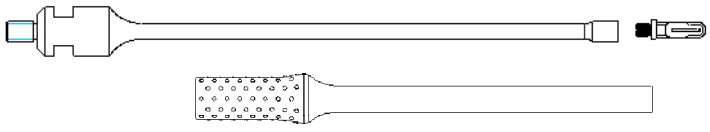
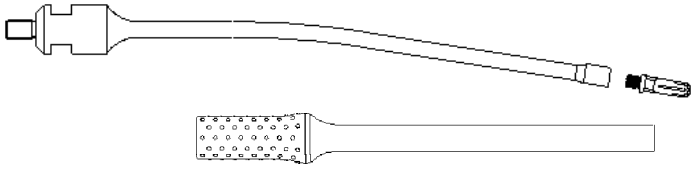
5.3. Single-use, Sterile Components

At least one irrigation tubeset must be available for each surgical procedure.

Irrigation Tubeset		
MC924	Irrigation Tubeset	1 ea.

Table 5.2 Irrigation tubeset

Ultrasonic tips are supplied sterile and are for single use only. At least one of the following tips must be available for each surgical procedure.

Hard Tissue Tips All tips requires MC631 probe cover		
MC922	Bone Scalpel – 10mm, Blunt  Includes blade, short extension, and silicone sleeve	1 ea.
MC923	Bone Scalpel – 20mm, Blunt  Includes blade, short extension, and silicone sleeve	1 ea.
MC928	BoneScalpel –20mm, serrated blade  Includes blade, short extension, and silicone sleeve	1 ea.
MC925	Bone Shaver – Micro Hook  Includes shaver tip, short extension and silicone sleeve	1 ea.
MC927	Bone Scalpel – 10mm, Blunt, Long Straight  Includes blade, long curved extension, and silicone sleeve	1 ea.
MC926	Bone Scalpel – 10mm, Blunt, Long Curved  Includes blade, long curved extension, and silicone sleeve	1 ea.

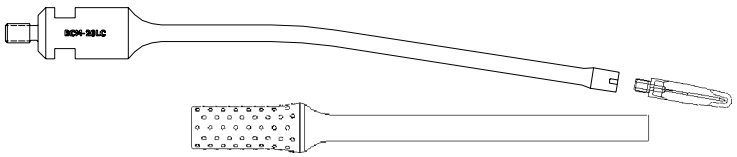
MC929	Bone Scalpel – 20mm, Blunt, Long Curved  Includes blade, long curved extension and silicone sleeve	Requires BCM-SS probe cover

Table 5.3 Tips

6. Console

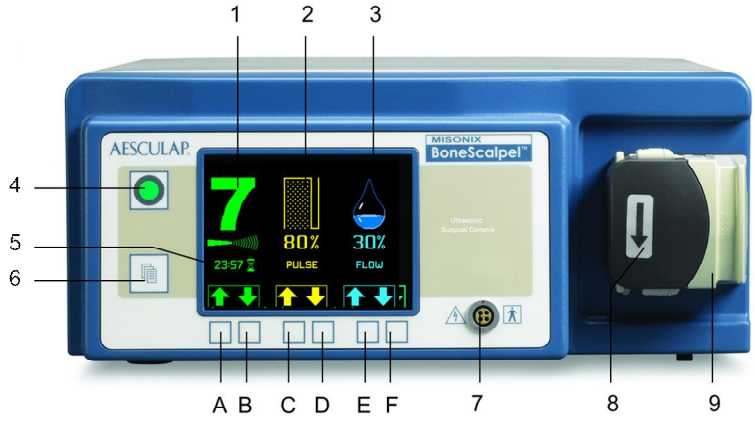
6.1. Receptacles, Controls And Indicators

The rear of the console features receptacles for the power cord, fuses, footswitch cable and IV-pole as well as a switch for mains power.

1 IV-pole receptacle
2 Mains power on/off
3 Power cord receptacle with fuse block
4 Voltage selector switch
5 Cooling fan
6 Equipotentiality connection
7 Footswitch receptacle

Figure 6.1 Console rear

The front of the console features a receptacle for the handpiece cable and an irrigation pump head, in which the irrigation tubing is inserted. A large color LCD screen provides information on system status and set points for ultrasound amplitude, pulse rate and irrigant flow rate with respective controls on the panel below. Additional controls for ultrasound enable/standby and menu access are provided on the left of the display panel. An ultrasound timer indicates the elapsed time, in which the ultrasound was on.



1 Amplitude setting
2 Pulse setting
3 Flow setting
4 Enable/standby button
5 Ultrasound timer
6 Menu button
7 Handpiece cable receptacle
8 Indicator for flow direction
9 Irrigation pump head
A-F Custom buttons

Figure 6.2 Console front

Buttons A-F perform various functions, depending on the information displayed on the screen. The display screen shown is the Main Screen used for all major control functions.

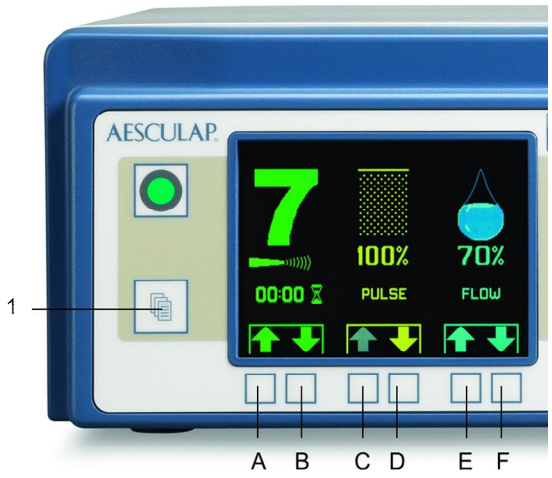
The handpiece receptacle is keyed in order to facilitate connection. The red dot on top of the receptacle must be in line with the corresponding red dot on the handpiece cable.

6.2. Menu Functions

The standard screen is the Main Screen. Additional screens are the Options and the Help Screen. Both the Options and Help screens can be accessed by pressing the menu button to toggle through the three main screens; Main Menu, Options and Help.

Main Screen

The Main Screen allows control of the main system functions such as Amplitude, Pulse, and Flow .



1 Menu Button
A-E Custom Buttons

Figure 6.3 Main screen

Amplitude Control

The amplitude can be set between 0 and 10. Press A to increase and B to decrease the amplitude. The default setting for amplitude is 7. Refer to section 6.3 for further details on the Amplitude feature.

Pulse Control

The pulse can be set between 50% and 100%. Press C to increase and D to decrease the pulse. The default setting for pulse is 100%. Refer to section 6.3 for further details on the Pulse feature.

Flow Control

The flow can be set between 20% and 100%. Press E to increase and F to decrease the flow. The default setting is 70%. Refer to section 6.3 for further details on the Flow feature.

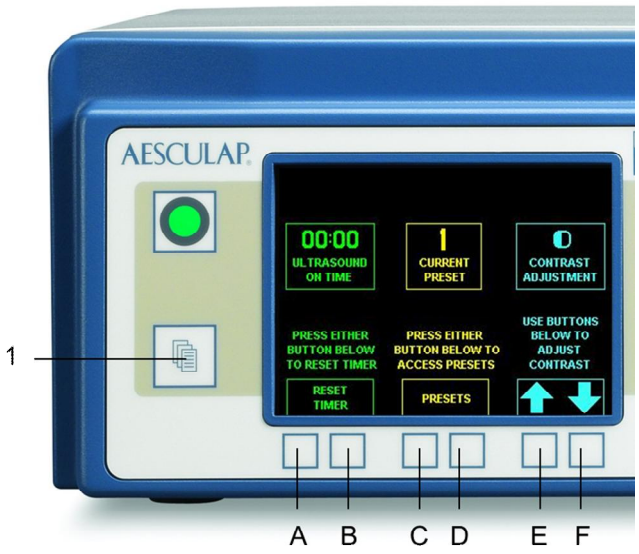
Ultrasound Timer

The ultrasound timer records the elapsed time, in which the ultrasound was activated with the footswitch. The timer can be re-set to zero via the secondary screen.

In the event of error, such as a Mechanical Limit or an Electrical Fault, the main screen is replaced by alert screens. Refer to section 6.4 for a description of these warnings.

Options Screen

The Options Screen allows the user to do the following; re-set the elapsed ultrasound time, save and choose presets and adjust the display contrast.



1 Menu Button
A-E Custom Buttons

Figure 6.4 Options screen

Ultrasound timer

The elapsed ultrasound time can be re-set to 00:00 by pressing either A or B.

Presets

Preferred settings for amplitude, pulse and flow can be saved as two presets. A third preset features the default settings, which can not be customized. A sub-screen for presets 1, 2 and 3 can be accessed by pressing either C or D.

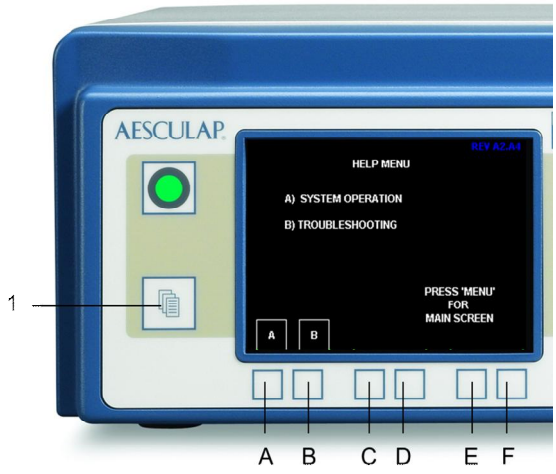
Contrast

The display contrast can be adjusted. Press E to increase and F to decrease contrast.

Pressing the menu button toggles from the options to the help screen.

Help Screen

The Help Screen provides access to a quick guide on system operation and troubleshooting.



1 Menu Button
A-E Custom Buttons

Figure 6.5 Help screen

System Operation

Press A to access the quick reference guide on system operation.

Troubleshooting

Press B to access the quick reference guide on troubleshooting.

Pressing the menu button toggles from the help to the main screen.

6.3. Main Functions

Amplitude

The ultrasonic tip engages the target area in linear strokes at a rate of approximately 22,500 cycles per second. During each cycle the tip elongates from resting to maximum position, contracts back over resting and to minimum position and elongates back to its resting point. The peak-to-peak amplitude or stroke distance can be adjusted by changing the Amplitude from setting 1-10. This is the main parameter to control the rate of tissue removal. A high amplitude setting results in more aggressive tissue removal, a low setting in less aggressive tissue removal. Amplitude and thus removal rate may alter with size and geometry of the ultrasonic tip.

Pulse

The ultrasonic energy output over time can be reduced by using the pulse mode, in which a resting period is inserted within the duty cycle. This results in an active period, followed by a resting period during each duty cycle. The total period is a ¼ second (250ms). The pulse can be set between 50% and 100%.

Pulse Setting 100% [Continuous]

The default setting is 100% or continuous, which refers to 100% energy output or zero resting period. This is the recommended setting for hard tissue applications.

Pulse Setting 50-90% [Pulsed]

The Pulse function minimizes exposure to ultrasound over time.

The Pulse setting corresponds to the duration of the active period of the ultrasound output. For example, a Pulse setting of 60% corresponds to an active period of 60% of ¼ second (150ms). The resulting resting period is 40% of ¼ second (100ms). The ultrasonic energy output over time is reduced by 40% with this setting. Note that the ultrasound timer will only advance during the active period and not during the resting period. For most applications, the recommended pulse setting is 100%.

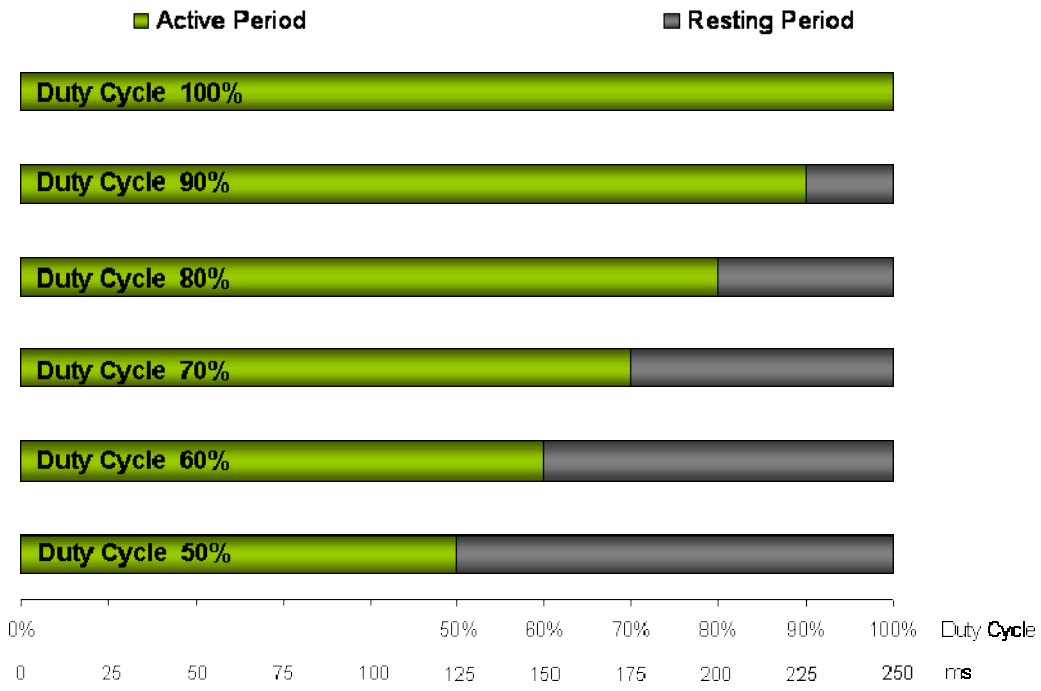


Figure 6.6 Illustration of pulse setting

Irrigation

Proper irrigation with sterile saline ensures:

1) Cooling of handpiece and vibrating elements
2) Cooling and lavage of the surgical site
3) Lubrication of bone/tip interface for BoneScalpel hard tissue removal

The active ultrasonic probe remains cold when not in contact with tissue. However, when a tip contacts tissue heat is generated. The heat increases with applied tip pressure or amplitude. Irrigant needs to be applied at the tip/tissue interface to mitigate this temperature rise.

Most ultrasonic tips and probes feature an integrated irrigation channel. The irrigant is expelled through a jet nozzle at the tip. Active tip surfaces are being cooled directly.

Enable/Standby

The Enable/Standby button on the console's front panel can be used to block accidental ultrasound activation during longer periods of inactivity following set-up or during surgery.

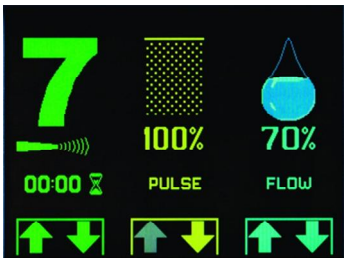
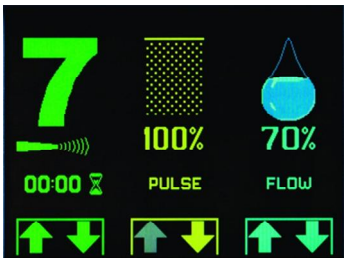
Standby Mode	Enable Mode
	
Amplitude setting is GREY and HOLLOW	Amplitude setting is GREEN and SOLID
Footswitch activates ▫ Irrigation only. Irrigation can be used for lavage or priming.	Footswitch activates ▫ Ultrasound output and irrigation. A bell chime is emitted briefly.

Table 6.1 Enable/standby function

6.4. Alerts And Alarms

Mechanical Limit Alert

The console monitors the ultrasonic output at all times and alerts in cases of overload or malfunction of the vibrating elements (handpiece, extension and ultrasonic tip).

A "Limit" alert is displayed together with a pulsed audible alarm as long as the footswitch is depressed. Ultrasound and Irrigation are deactivated temporarily.

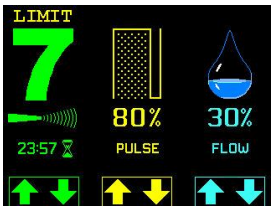
Mechanical Limit Alert		
Alert Type	Alert Screen	Alert Action
Mechanical Limit		Displays "LIMIT" alert located above amplitude setting display. Triggers a pulsed, audible alarm upon footswitch activation. Temporarily deactivates ultrasound and irrigation functions.
Possible Cause	Corrective Action	
1. Tip overload	Release footswitch. Reduce tip pressure and/or use higher amplitude setting as required. Continue procedure.	
2. Loose or damaged component	Release footswitch. Set ultrasound to STANDBY. Remove silicone sleeve (if applicable) and probe cover. Inspect extension probe and ultrasonic tip for damage. Replace if necessary. Otherwise re-tighten extension probe and tip using the correct wrenches. Set ultrasound to ENABLE. Continue procedure.	
3. Defective Handpiece	If corrective action steps above are followed and alert continues, the handpiece may need to be replaced.	

Table 6.2 Mechanical limit alert and recommended corrective actions

Tip overload can occur during hard tissue removal when applying excessive tip pressure or facing strong tissue resistance, e.g. from thick cortical bone. This can lead to stalling of the ultrasonic tip. A pulsed audible signal alerts of the stalling and the ultrasound is deactivated. Release the footswitch briefly and reduce the tip pressure, e.g. by retrieving the ultrasonic tip. Depress the footswitch again and continue with reduced tip pressure. Consider using higher amplitude setting or reduced loading if stalling persists.

Electrical Fault Alert

The console monitors the electrical output at all times and alerts in cases where the handpiece is not properly connected to the console, when an output short or open circuit is detected or electrical safety is compromised.

An Electrical Fault Screen is displayed together with a steady audible alarm. Ultrasound and Irrigation are deactivated. Requires recycling of mains power switch to re-set.

WARNING 6.1 Immediately suspend operation if Electrical Fault appears on display and/or an Electrical Fault audible alarm sounds. Remove ultrasonic tip from surgical site. Turn Mains Power OFF. Do not touch any metallic parts of handpiece, extension, ultrasonic tip or generator while fault is indicated.

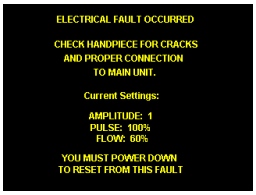
Electrical Fault Alert		
Alert Type	Alert Screen	Alert Action
Electrical Fault		Displays Electrical Fault Screen. Triggers steady audible alarm. Permanently deactivates ultrasound and irrigation. Requires recycling of mains power switch to re-set.
Possible Cause	Corrective Action	
1. Handpiece not connected	Turn mains power OFF. Check handpiece cable connection. Restart console.	
2. Defective Handpiece	Turn mains power OFF. Replace handpiece and restart console. If problem persists replace console.	
3. Defective console	Turn mains power OFF. Replace console.	

Table 6.3 Electrical fault alert and recommended corrective actions

7. System Set-up

7.1. Installation

Upon delivery perform a visual inspection of the shipping containers and all system components for obvious shipping damage. Retain the shipping container and immediately notify the shipping carrier of any damages found.

CAUTION 7.1 All reusable system components like handpiece, probe covers, counter wrench, and T-wrench are supplied industrially cleaned, but NON-STERILE. All items intended for use in the sterile field must be cleaned and sterilized as per the indicated instructions before first clinical use and before every subsequent clinical use.

The BoneScalpel system is designed and tested to comply with IEC EN60601-1-2: 2001 guidelines for EMC. See section 1 for general safety statements.

WARNING 1.5 Connecting the console to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or to create a shock or fire hazard. Confirm that the voltage selector switch on the console rear panel is set to the local voltage setting and ensure that the correct fuses are being used. Refer to section 12.1 on fuse replacement.See section 12.1 for instructions on adjusting to local electrical requirements.

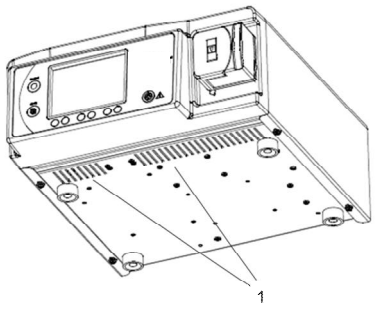
Care should be taken to stay within the general operating conditions.

Operating Conditions	
Operating conditions	• Temperature 55-95°F (13-35°C) • Relative humidity 20-90% (non condensing) • Standard atmospheric pressure

Table 7.1 Operating conditions

The console can be placed on an appropriate table or cart outside of the sterile field. Ensure that the pump head on the console right is installed. Refer to section 12.2 if the pump head is not yet installed.

The console features air vents on the bottom. When installing the unit, ensure that these vents are not blocked in a way that would prevent the circulation of air around the unit.



1 Air vents

Figure 7.1 Underside view of console with air vents

NOTE 7.1 Adequate air circulation is needed to cool electronic components inside of the unit. Do not block the cooling fan at the console rear or the air vents on the console bottom. Do not place the unit on a towel, foam or other soft surface since the material may block the air vents. Blocking these vents may cause unit to overheat and malfunction or create a shock hazard. A clear drape can be used to protect the console front panel but do not cover the pump housing or other console portions.

7.2. Console Set-up – Part I (Non-sterile)

Console Set-up | Part I	
Switch Mains Power OFF	Set Mains Power switch on console rear to OFF.
Connect IV-pole	Connect IV-pole to receptacle in console rear. Hang container with sterile irrigant into IV-pole hook. Irrigation tubing features IV-spike and is compatible with rigid bottles or flexible bags.
Connect Electrical Power	Connect power cord to receptacle on console rear and to wall outlet.
Connect Footswitch	Connect footswitch cable to receptacle on console rear. Footswitch connector and receptacle are keyed to ensure proper connection. Turn cable connector until keys match. Insert connector fully into receptacle. Turn outer connector ring clockwise to lock into position. Footswitch may be covered with clear drape during clinical use.
Switch Mains Power ON	Set Mains Power switch on console rear to ON. Front panel will display Main Screen upon completion of system start.

Table 7.2 Console set-up - part I

7.3. Handpiece Assembly (Sterile)

Handpiece assembly in the sterile field should be performed by trained and authorized OR staff only.

Please refer to section 8.0 for specifics on the handpiece assembly and disassembly for both hard tissue applications.

Once the handpiece has been assembled, continue with part II of the Console Set Up.

CAUTION 7.2 All items intended for use in the sterile field must be cleaned and sterilized as per indicated instructions before each clinical use.

CAUTION 7.3 The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.

7.4. Console Set-up – Part II (Non-sterile)

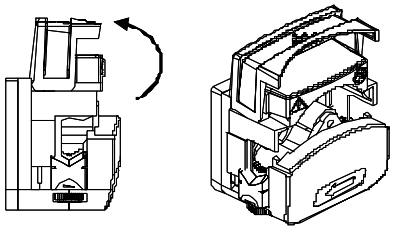
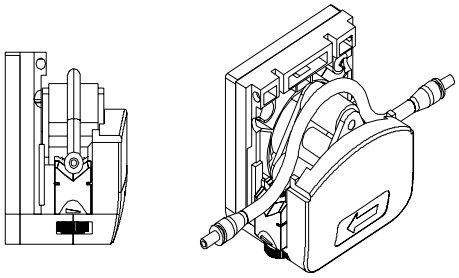
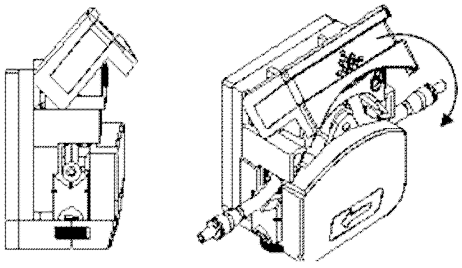
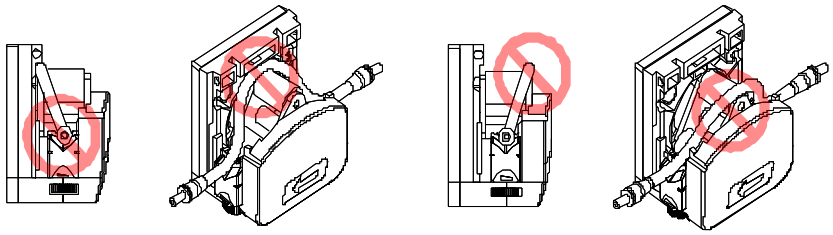
Console Set-up | Part II	
Connect Handpiece cable	Attach cable connector receptacle on console front panel. Align red dot on cable connector with red dot on front panel receptacle. Push cable connector into place.
Open pump cover	Open the latch of the irrigation pump  The arrow on the pump housing indicates the direction of flow.
Insert tubing	Insert the soft silicone section by placing it over the pump rollers.  Verify that the tubing enters the pump from fluid container and exits to handpiece and in direction of arrow on pump housing.
Secure tubing in V-notches	Place and hold the tubing's silicone section in the V-notches on both pump sides.  Apply slight pressure to ensure that tubing rests within both V-notches.
Close pump cover	Close the latch of the irrigation pump until it locks.
Adjust the grip of the V-notches	Evenly adjust the V-notches to their fully opened position by turning the adjustment wheel underneath the front and back of the pump assembly. Allow for tight grip to prevent the tubing from slipping but without pinching the tubing, which would obstruct the irrigation flow.
Connect Tubing to Fluid Container	Connect IV-Spike to fluid container following standard sterility protocol. Irrigation tubing features vented IV-spike and is compatible with rigid bottles and flexible bags.
Prime Tubing	Check that ultrasound is in Standby Mode. Set Flow rate to 10. Depress footswitch until fluid discharges at ultrasonic tip.

Table 7.3 Console set-up - part II

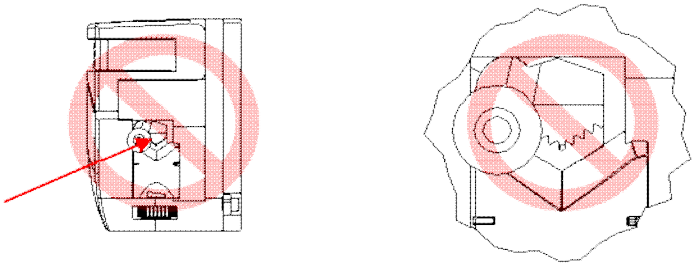
WARNING 7.1 Improper connection of the handpiece cable may present a shock hazard. Confirm that handpiece connector is dry prior to plugging it in.

WARNING 7.2 Do not operate pump with pump cover in raised position. Rollers might pinch loose clothing or fingers. Personal injuries may result. Cooling of the ultrasonic tip and irrigation at the treatment site will be inhibited.

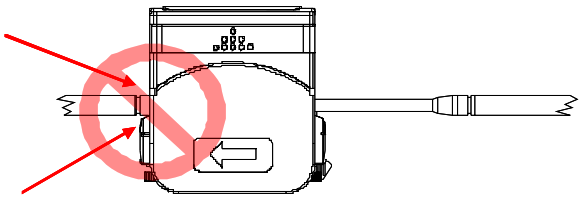
CAUTION 7.4 Do not place the soft silicone tube behind or in front of the rollers (latch removed in illustrations)



CAUTION 7.5 Do not pinch the soft silicone tube when the latch is locked.



CAUTION 7.6 Do not pinch barb fittings when closing the latch.



CAUTION 7.7 Prime the irrigation tubing prior to use. At all times ensure that the irrigant flows towards the handpiece when footswitch is depressed. If no irrigant is flowing, cease use until flow is restored.

WARNING 7.3 Tip and irrigation temperatures may exceed the tissue necrosis point with BoneScalpel accessories for hard tissue removal if insufficient irrigation flow rates are used. Always set the irrigation flowrate for hard tissue removal to a setting no less than the comparable vibration setting. For example, if the vibration setting is 7, a minimum flow setting of 70% should be used.

WARNING 7.4 Heat is being generated at the tip/tissue interface. A continuous, lateral sweeping motion is recommended for general bone/tissue removal in order to minimize contact duration with the ultrasonic tip and minimize the temperature increase.

The BoneScalpel System is now ready for the system check.

7.5. Perform System Check

System Check	
Enable Ultrasound	Switch to Enable Mode using enable/standby button. Confirm that Amplitude setting is FILLED GREEN.
Depress footswitch	Direct ultrasonic tip toward suitable reservoir to collect irrigant. Depress footswitch.
Confirm Function	Console emits a bell chime. Irrigant will be pumped from console towards handpiece. Ultrasonic tip emits buzzing sound and irrigant exits tip as fine spray. Ultrasound timer counts up in 1-second increments.
Release footswitch	Release footswitch. Ultrasound and Flow output stop. Ultrasound timer freezes at last reading.
Function Confirmed	Reset ultrasound timer as desired. System is now ready for use.
Function NOT confirmed	Console alerts of Mechanical Limit or Electrical Fault or does not respond as expected. Refer to troubleshooting section for next steps.

Table 7.4 System check

CAUTION 7.8 The system check should always be done in advance of preparing patient for surgery to minimize risk to patient in case of system malfunction.

The BoneScalpel System is now ready for use. Refer to section 1.0 for general safety statements, indications and adverse affects and section 4.0 for use of main system functions.

8. Handpiece Assembly And Disassembly

The BoneScalpel Ultrasonic Surgical System can accommodate different tip configurations to perform hard tissue applications.

8.1. Handpiece Assembly

Perform an inspection of handpiece and all components prior assembly.

Handpiece Inspection	
Inspect Handpiece	Inspect the black handpiece housing for any visual cracks. Inspect the front metallic portion probe for surface damage like nicks, gouges and cracks. Replace if damaged.
Inspect Mating Surface	Inspect mating face of handpiece to verify that it is clean and dry.

Table 8.1 Handpiece inspection

CAUTION 8.1 Ensure all connections and mating surfaces of handpiece, extension and ultrasonic tip are clean and dry before assembly.

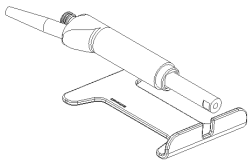
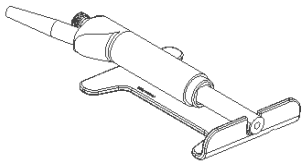
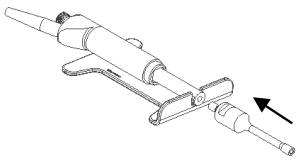
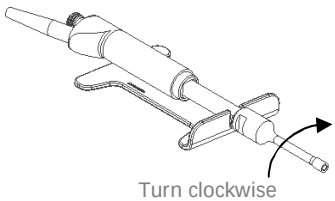
CAUTION 7.2 All items intended for use in the sterile field must be cleaned and sterilized as per indicated instructions before each clinical use.

CAUTION 7.3 The disposable items are intended for one procedure only (single use). Do not attempt to reuse or re-sterilize.

NOTE 8.1 The handpiece must be placed into the counter wrench. Do not attempt to tighten or loosen handpiece components by holding the handpiece case or endcap. Always use the T-wrench wrench when tightening or un-tightening the tip or an extension. Never apply a pipe or strap wrench to the handpiece case. Do not over-tighten the tip or the extension.

NOTE 8.2 Always tighten or un-tighten the probe cover by hand and without using any wrenches. Do not over-tighten the probe cover.

NOTE 8.3 Always hold the handpiece at its metallic endcap when tightening or un-tightening the irrigation tubing. Always tighten or un-tighten the irrigation tubing by hand and without using any wrenches. Do not over-tighten the tubing connector.

Handpiece Assembly		
Mount Handpiece Wrench	 Align wrench flats	
Mount Extension		 Turn clockwise

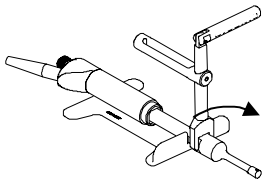
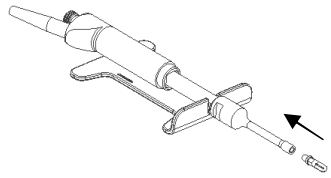
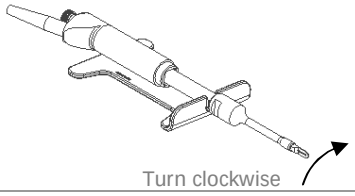
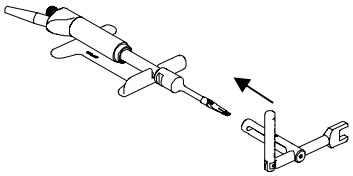
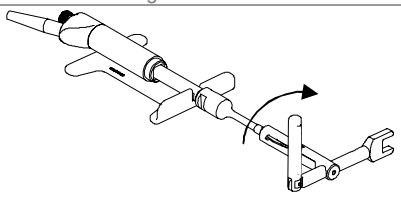
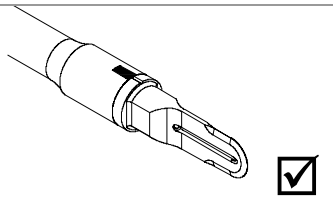
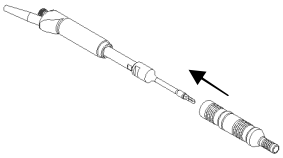
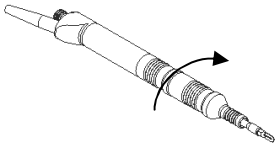
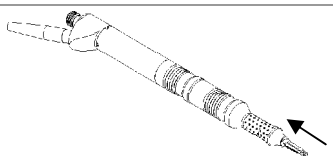
Tighten Extension	 Tighten clockwise	
Mount Ultrasonic Tip		 Turn clockwise
Mount Tip Wrench	 Align wrench flats	
Tighten Ultrasonic Tip	 Tighten clockwise	 Match alignment marks
Mount Probe Cover		 Turn clockwise
Mount Sleeve (if applicable)		Push sleeve over probe cover
Connect Irrigation Tubing	 Turn clockwise	

Table 8.2 Handpiece assembly

The handpiece is now ready for use and can be connected to the BoneScalpel System. Please refer to Section 7.0 for details.

Figure 8.1 Fully assembled handpiece

If desired, mount suitable sterile cable clips or sterile adhesive tape strips to attach irrigation tubing to handpiece cable.

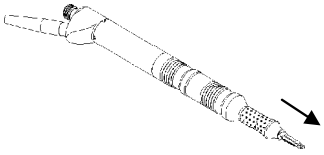
8.2. Handpiece Disassembly

WARNING 8.1 Remove probe cover, ultrasonic tip and extension from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.

NOTE 8.1 The handpiece must be placed into the counter wrench. Do not attempt to tighten or loosen handpiece components by holding the handpiece case or endcap. Always use the T-wrench wrench when tightening or un-tightening the tip or an extension. Never apply a pipe or strap wrench to the handpiece case. Do not over-tighten the tip or the extension.

NOTE 8.2 Always tighten or un-tighten the probe cover by hand and without using any wrenches. Do not over-tighten the probe cover.

NOTE 8.3 Always hold the handpiece at its metallic endcap when tightening or un-tightening the irrigation tubing. Always tighten or un-tighten the irrigation tubing by hand and without using any wrenches. Do not over-tighten the tubing connector.

Handpiece Disassembly		
Disconnect Irrigation Tubing	 Turn counter-clockwise	
Remove Sheath	 Pull sheath from probe cover	

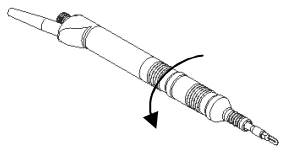
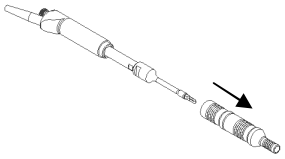
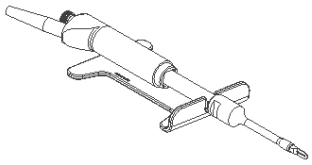
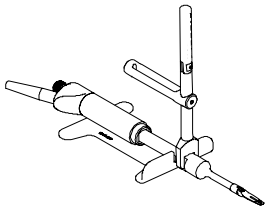
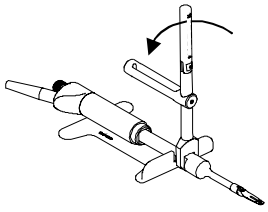
Remove Probe Cover	 Turn counter-clockwise	
Mount Handpiece Wrench	 Align wrench flats	
Mount Tip Wrench		
Remove Ultrasonic Tip		

Table 8.3 Handpiece disassembly

9. Cleaning And Sterilization

9.1. Disassembly

Console Tear-down	
Disable Ultrasound	Switch to Standby Mode using enable/standby button. Confirm that Amplitude setting is HOLLOW GREY.
Switch Console OFF	Set Mains Power switch on console rear to OFF.
Remove Handpiece Cable	Pull cable connector from receptacle on console front.
Remove Tubing	Open pump cover. Remove tubing from pump compartment. Disconnect tubing from irrigant container.
Wipe Down Console	Wipe down the console.

Table 9.1 Console tear-down

Handpiece Disassembly

Disassemble all handpiece components in reverse order of assembly. Please refer to Section 8.2 for disassembly.

Dispose Of Single-Use Items

The following items are considered single use items and must not be reused. Reuse of these items could result in severe patient injury or death.

- Irrigation tubeset
- Tips with extensions
- Silicon sleeves

Once used, dispose of above items in accordance with standard hospital procedures for disposal of biocontaminated wastes.

WARNING 8.1 Remove probe cover, ultrasonic tip and extension from the handpiece prior to cleaning and/or sterilization; otherwise proper cleaning/sterilization may be inhibited.

WARNING 9.1 Single-use items should be discarded following each surgical procedure according to hospital protocol for disposal of biocontaminated wastes. Do not attempt to reuse or re-sterilize any single-use items. Dispose ultrasonic tips in a sharps container.

9.2. Cleaning

Follow Standards For Decontamination, Cleaning And Sterilization

Follow ANSI/AAMI ST35, Good Hospital Practice: Handling and Biological Contamination of Reusable Medical Devices (1991), or other such guidelines as may be directed by Hospital or Clinic GHP's.

WARNING 9.2 All reusable handpiece parts and accessories must be properly decontaminated, cleaned and sterilized before each use

as per instructions contained in this manual. Failure to do so may lead to infections, which can ultimately cause patient death.

WARNING 9.3 The manufacturer has validated all cleaning and sterilization cycles given in this manual. It is highly recommended that the procedures given in this manual for cleaning and sterilizing the BoneScalpel System and related accessories be followed. It is the responsibility of the user of this device or any accessories used with it to validate procedures for cleaning and/or sterilization if they differ from the procedures as outlined in this manual.

Clean And Disinfect/Sterilize Reusable Items

The following items are considered reusable items and should be cleaned as recommended:

- Handpiece
- Counter wrench
- T-wrench
- Probe cover

Probe Cover and Wrenches	
Wash & Brush	• Wash items with hot water mixed with an enzymatic detergent such as ASP Enzol® or Steris Prolystica® according to standard hospital protocol. Follow manufacturer's directions for preparing solutions. • Probe cover and wrenches may be fully immersed. • Brush all passages at least four (4) times from FRONT to REAR, rotating the brushes during insertion and inserting the brushes fully. This ensures clearing of debris from the internal passages. • Item's exterior surface can be cleaned using a standard soft bristle cleaning brush.
Rinse	• Rinse item under warm running water for a minimum of 1 minute to clear soap residue.
Dry	• Dry item fully with absorbent towel or paper. Dispose of cloth or paper in accordance with Hospital or Clinic practices for contaminated wastes.

Table 9.2 Cleaning of probe cover and wrenches

Handpiece	
Wipe Cable	• Wipe cable with cloth or absorbent paper moistened with an enzymatic detergent such as ASP Enzol or Steris Prolystica. Follow manufacturer's directions for preparing solutions. Clean all surfaces of bloodstains and obvious signs of decontamination.
Wash & Brush	• Wash and brush handpiece item with hot water mixed with an enzymatic detergent such as ASP Enzol or Steris Prolystica. Follow manufacturer's directions for preparing solutions. • The handpiece cannot be immersed. • Brush all passages at least four (4) times from FRONT to REAR, rotating the brushes during insertion and inserting the brushes fully. This insures clearing of debris from the internal passages. • The item's exterior surface can be cleaned using a standard soft bristle cleaning brush.
Rinse	• Rinse item under warm running water for a minimum of 1 minute to clear soap residue.
Dry	• Dry item fully with absorbent towel or paper. Dispose of cloth or paper in accordance with Hospital or Clinic practices for contaminated wastes.
Inspect	• Inspect handpiece and cable and remove any item which shows signs of damages (cracks, gouges, fractures etc.). Mark damaged items clearly to prevent future use before disposal.

Table 9.3 Cleaning of handpiece

CAUTION 9.1 Use manual cleaning techniques only. Do not use ultrasonic cleaners or automated washers to clean the handpiece as both methods could damage handpiece.

CAUTION 9.2 Be certain to clear debris from all internal passages by brushing. Failure to do so may hinder sterilization of units during autoclaving.

CAUTION 9.3 Do not immerse ultrasonic console, handpiece, irrigation pump, remote footswitch or electric cables. These items are not sealed against liquids and damage to equipment will result.

Console and Footswitch	
Wipe Surfaces	• Wipe footswitch and console, including irrigation unit, with cloth or absorbent paper moistened with an enzymatic detergent such as ASP Enzol® or Steris Prolystica®. Follow manufacturer's directions for preparing solutions. Clean all surfaces of bloodstains and obvious signs of decontamination. • Dispose of cloth or paper with contaminated waste.

Table 9.4 Cleaning of console and footswitch

9.3. Sterilizing By Steam Autoclave

Reusable, autoclavable Components	
MC632	Handpiece
MC628	T-Wrench
MC637	Handpiece/Counter Wrench
MC631	Probe Cover for hard tissue applications
MC638	Brush Set, Small
MC639	Brush Set, Large

Table 9.5 Autoclavable components

Validated Steam Sterilization Cycles		
Sterilizer Type	Pre-Vacuum at 132 °C | 270 °F	Gravity at 134 °C | 273 °F
Preconditioning pulses	3	None
Minimum Temperature	132 °C | 270 °F	134 °C | 273 °F
Full Cycle Time	8 min	20 min
Minimum Dry Time	5 min	5 min
Cooling Time	Allow items to cool gradually to room temperature prior use.	
Sample configuration	Wrapped	Wrapped

Table 9.6 Steam sterilization cycles

NOTE 9.1 Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage.

9.4. Expected Life, Reusable Components

All handpiece components need to examined regularly, prior each use and be replaced if damaged.

The estimated sterilization life of handpiece components is listed below. All sterilization life estimates are approximate and may be affected by rough handling, damage, wear due to vigorous cleaning, etc.

Estimated Sterilization Life	
Item	Number Of Steam Sterilization Cycles
Handpiece with attached cable	> 200 cycles
Probe cover	> 300 cycles
Wrenches: Handpiece/counter wrench and T-wrench	> 300 cycles

Table 9.7 Estimated re-use life

NOTE 9.2 The reuse life given takes into account wear and tear due to cleaning and sterilization only. Damage or wear caused by actual use in treatments will affect life of components.

NOTE 9.1 Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage.

9.5. Deviations From Decontamination, Cleaning And Sterilization Instructions

The manufacturer has validated all cleaning, disinfection and sterilization cycles given in this manual. It is highly recommended that the procedures given in this manual for cleaning and sterilizing the BoneScalpel System and related accessories be followed. It is the responsibility of the user of this device or any accessories used with it to validate procedures for cleaning and/or sterilization if they differ from the procedures as outlined in this manual.

Technical Assistance

Should the user wish further information or instructions regarding any aspect of cleaning or sterilizing procedures, please contact Aesculap USA or an Authorized Representative.

10. Troubleshooting

The BoneScalpel system provides both visual and audible alert signals when the system is not functioning properly.

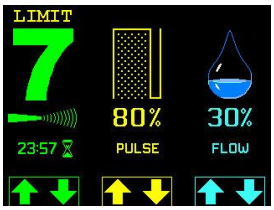
Mechanical Limit Alert		
Alert Type	Alert Screen	Alert Action
Mechanical Limit		Displays “LIMIT” alert located above amplitude setting display. Triggers a pulsed, audible alarm upon footswitch activation. Temporarily deactivates ultrasound and irrigation functions.
Possible Cause	Corrective Action	
1. Tip overload	Release footswitch. Reduce tip pressure and/or use higher amplitude setting as required. Continue procedure.	
2. Loose or damaged component	Release footswitch. Set ultrasound to STANDBY. Remove silicone sleeve (if applicable) and probe cover. Inspect extension probe and ultrasonic tip for damage. Replace if necessary. Otherwise re-tighten extension probe and tip using the correct wrenches. Set ultrasound to ENABLE. Continue procedure.	
3. Defective Handpiece	If corrective action steps above are followed and alert continues, the handpiece may need to be replaced.	

Table 6.2 Mechanical limit alert and recommended corrective actions

Tip overload can occur during hard tissue removal when applying excessive tip pressure or facing strong tissue resistance, e.g. from thick cortical bone. This can lead to stalling of the ultrasonic tip. A pulsed audible signal alerts of the stalling and the ultrasound is deactivated. Release the footswitch briefly and reduce the tip pressure, e.g. by retrieving the ultrasonic tip. Depress the footswitch again and continue with reduced tip pressure. Consider using higher amplitude setting or reduced loading if stalling persists.

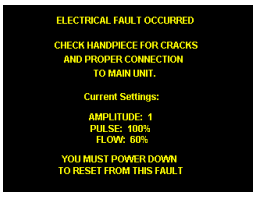
Electrical Fault Alert		
Alert Type	Alert Screen	Alert Action
Electrical Fault		Displays Electrical Fault Screen. Triggers steady audible alarm. Permanently deactivates ultrasound and irrigation. Requires recycling of mains power switch to re-set.
Possible Cause	Corrective Action	
1. Handpiece not connected	Turn console OFF. Check handpiece cable connection. Restart console.	
2. Defective Handpiece	Turn console OFF. Replace handpiece and restart console. If problem persists replace console.	
3. Defective console	Turn console OFF. Replace console.	

Table 6.3 Electrical fault alert and recommended corrective actions

WARNING 6.1 Immediately suspend operation if Electrical Fault appears on display and/or an Electrical Fault audible alarm sounds. Remove ultrasonic tip from surgical site. Turn Mains Power OFF. Do not touch any metallic parts of handpiece, extension, ultrasonic tip or generator while fault is indicated.

WARNING 1.4 Proper system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the console. Never pull on the power cord to remove it from the receptacle.

WARNING 10.1 If a Mains Power fuse fails after replacement when the unit is reactivated, discontinue use of the device and contact an authorized Aesculap USA representative.

Lack of Irrigant		
Symptons • No spray from tip when ultrasound is engaged • No flush fluid available • Unexpected temperature rise at operative site • Unexpected temperature rise of handpiece		
Alert Type	Alert Screen	Alert Action
None	None	None
Possible Cause	Ultrasound Mode	Corrective Action
1. Closed or empty fluid bag	Set ultrasound to STANDBY.	Check fluid bag and tubing clamp. Replace fluid bag if necessary.
2. Tubing not connected	Set ultrasound to STANDBY.	Check tubing connections. Check mounting in pump head. Close pump cover until locked.
3. Tubing obstructed or defective	Set ultrasound to STANDBY.	Check tubing for kinking, restrictions or leaks. Replace tubing if necessary. Check mounting in pump head. Close pump cover until locked.
4. Tubing installed in reverse	Set ultrasound to STANDBY.	Open pump cover. Reposition the tubing in direction of flow. Close pump cover until locked.
5. Tubing slides through pump	Set ultrasound to STANDBY.	Open pump cover. Adjust the grip of the tubing by turning the adjustment wheel underneath the front and back of the pump assembly.
6. Pump defect	Set ultrasound to STANDBY.	Open pump cover. Check if pump rollers are rotating when depressing footswitch. Replace console if they don't.

Table 10.1 Troubleshooting – Insufficient Irrigation

WARNING 3.1 Tip and irrigant temperatures may exceed the tissue necrosis point if insufficient irrigation flow rates are used. For hard tissue removal , set the irrigation flowrate to a setting no less than the comparable vibration setting. For example, if the vibration setting is 7, a minimum flow setting of 70% should be used.

WARNING 7.1 Improper connection of the handpiece cable may present a shock hazard. Confirm that handpiece connector is dry prior to plugging it in.

WARNING 7.2 Do not operate pump with pump cover in raised position. Rollers might pinch loose clothing or fingers. Personal injuries may result. Cooling of the ultrasonic tip and irrigation at the treatment site will be inhibited.

For all other malfunctions please contact Aesculap USA or an Aesculap USA authorized representative for service.

11. Specifications

Console Specifications	
Power input	• 120VAC, 4 Amps, 60Hz • 220 VAC, 2.5 Amps, 50/60Hz • 230/240VAC, 2.5 Amps, 50Hz
Operating frequency	22.5 kHz
Ground leakage current	300 µA (max.)
Output power	130 Watts (max.)
Mode of Operation	• Continuous Wave • Pulse Wave
Controls	• Mains Power on/off switch (rear panel) • Footswitch control for ultrasonic and irrigation on/off • Ultrasound enable/standby button • Amplitude control • Pulse control • Flow control • Ultrasonic timer with reset • Menu button • Six screen-specific buttons
Irrigation pump	Peristaltic pump
Pump flow rate	Max flow > 67 ml/min.
Irrigation tubing	• Dedicated tubeset, sterile, single-use • Vented IV-spike, compatible with fluid bags and bottles • Dedicated handpiece connection
Handpiece cable	• 15 ft | 4.6m
Footswitch cable	• 14 ft | 4.3m
Power cord	• 10 ft | 3.0m
Operating conditions	• Temperature 55-95°F (13-35°C) • Relative humidity 20-90% (non condensing) • Standard atmospheric pressure
Shipping/storage conditions	• Temperature: 35-120°F (2-49°C) • Relative humidity: 10-95% (non condensing) • Ambient pressure extremes: 40,000 ft | 14,125m
Dimensions	7” H x 16” W x 19” D | 180mm H x 410 mm W x 485mm D
Weight	25.6 Lb. | 11.6 kg

Table 11.1 Console specifications

12. Service, Repair And Technical Correspondence

WARNING 1.4 Proper system grounding can only be ensured when an approved, hospital-grade receptacle and matching power cord are used. Install plug and receptacles as per local regulations before operating the unit. Power cord, plug and receptacle should be examined to verify that they are in good working condition before connecting the console. Never pull on the power cord to remove it from the receptacle.

12.1. Fuse Replacement

WARNING 12.1 Connecting the console to a power outlet with inadequate voltage or frequency may cause the unit to malfunction or to create a shock or fire hazard. Confirm that the voltage selector switch in the console rear is set to the local voltage setting and ensure that the correct fuses are being used. Refer to section 12 on fuse replacement

Fuse Specifications				
Line Voltage	Manufacturer	Manufacturer P/N	Rating	Description
120 VAC, 60 Hz	Cooper/Bussman	GDB-4	250V @4 A	Fast Acting, Low Breaking
220/230/240 VAC, 50/60 Hz	Littlefuse	021702.5	250V @ 2.5A	Fast Acting

Table 12.1 Console fuse specifications

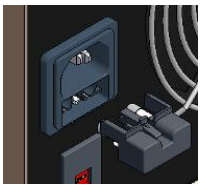
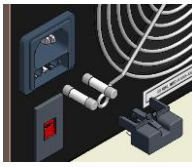
Fuse Replacement (The fuse holder is located on the console rear)		
Disable Ultrasound	Switch to Standby Mode using enable/standby button. Confirm that Amplitude setting is HOLLOW GREY.	
Switch Console OFF	Switch console OFF and disconnect power cord.	
Remove Fuse Holder	 Pinch tab on fuse holder.	 Pull fuse holder out.
Replace Fuses	 Replace both fuses as specified above.	
Mount Fuse Holder	Push fuse holder back into receptacle.	
Switch Console ON	Connect power cord and switch console ON	
Check Function	Confirm that console powers up and that Main Settings respond to activation of buttons A-F.	

Table 12.2 Fuse replacement

12.2. Pump Head Replacement

The pump head may not be connected to the unit for shipping purposes.

Mount Pump Head		
Position Pump Head	 Shaft recess and bayonet fitting on pump head rear	 Pump drive shaft on console front
	 Turn pump head 45°clockwise.	Align drive shaft on console front and shaft recess on pump head rear. Drive shaft and recess must engage easily. Rotate pump head slightly back and forth to check engagement.
Lock pump head in place	Turn pump head clockwise until it locks in place. Arrow should be in the vertical position pointing down.	

Table 12.3 Assembly of pump head

Remove Pump Head		
Disable Ultrasound	Switch to Standby Mode using enable/standby button. Confirm that Amplitude setting is HOLLOW GREY.	
Switch Console OFF	Switch console OFF and disconnect power cord.	
Remove Tubing	Open pump cover. Remove tubing. Close pump cover.	
Release Pump Head	 Press and hold lock lever on pump head bottom.	 Turn pump head 45° counter clockwise.
Remove pump head	Pull pump head away from console until pump drive shaft clears. Release lock lever.	

Table 12.4 Disassembly of pump head

12.3. Repair, Service and Replacement Parts

All requests for repairs and replacement parts should be directed to Aesculap USA or an authorized Aesculap USA representative. Always provide model and serial number of malfunctioning items.

When returning items include model, serial and RMA number as well as purchase order number on all documents. Always prepay return shipping and specify method of shipment.

CAUTION 12.1 Use only genuine replacement parts from Aesculap. Use of parts furnished by other sources may result in patient or operator injury or system malfunction and will void any applicable warranty.

CAUTION 12.2 Before using loose packing materials, such as foam pellets, shredded paper or similar, be sure to wrap the component(s) separately in plastic bags, film or other protective wrapping.

12.4. Important Notice

Please contact Aesculap USA with any questions regarding the specifications, use, sterilization, limitations or maintenance of the BoneScalpel System:

Aesculap, Inc.

Web	www.aesculapusa.com
Email	info@aesculap.com
Phone	+1-800-258-1946
Customer Service:	1-800-282-9000
Technical Service:	1-800-214-3392
Address	3773 Corporate Parkway Center Valley, PA 18034 U.S.A.

By returning any material to Aesculap USA the customer or the customer's agent must certify that any and all materials so returned are or have been rendered free of any hazardous or noxious matter or radioactive contamination and are safe for handling under normal repair shop conditions.

Do not return any material for which such certification cannot be made without prior approval from Aesculap USA.

The correct return address should read as follows:

Aesculap, Inc.
615 Lambert Pointe
RMA#: _____
Hazelwood, MO 63042
Phone: 1-800-258-1946
U.S.A.

Distributed in the U.S.A. by:	Aesculap, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Phone: 1-800-258-1946
Manufactured by:	Misonix, Inc. 1938 New Highway Farmingdale, NY 11735 Phone: 1-800-694-9612

Customer Service: 1.800.282.9000, Technical Service: 1.800.214.3392
3773 Corporate Parkway, Center Valley, PA 18034, U.S.A.