



**Operation & Instruction Manual
Amalgatome® Debridement Devices &
Exsurco® Drive Unit**

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Operating Instructions in other languages are available on request. Additional copies of Operating Instructions are available by calling or writing your Sales Manager, or by contacting:



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The Information Provided In These Operating Instructions Is
Important To Your Health, Comfort And Safety.

For Safe And Proper Operation, Read This Entire Manual
Before Using This Equipment.

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Original Instructions

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Section 1

Safety

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The information provided in these operating instructions is important to your health, comfort and safety. For safe and proper operation, read this entire manual before using this equipment.



Please read and save these instructions. Read carefully before attempting to assemble, install, operate or maintain this product. Protect yourself, others and equipment by observing all safety information. Failure to comply with instructions could result in personal injury and/or damage to the equipment. Any use in applications other than those for which the equipment was designed and built may result in equipment damage and/or serious injuries.

Retain this manual for future reference. Be thoroughly familiar with the controls and proper use of this equipment.

SIGNAL WORD PANELS



Indicates a hazardous situation that, if not avoided, will result in death or serious injury.
(The signal word **Danger** is in white letters on a safety red background)



Indicates a hazardous situation that, if not avoided, could result in death or serious injury.
(The signal word **WARNING** is in black letters on a safety orange background)



Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.
(The signal word **CAUTION** is in black letters on a safety yellow background)



Indicates information considered important, but not hazard-related (e.g. messages relating to property damage).
(The signal word **NOTICE** is in italicized white letters on a safety blue background)

The signal word definitions provided comply with the American National Standard for Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials (ANSI Z535.6-2011).

This technical manual is printed in black and white.

SAFETY SYMBOLS



The safety alert symbol indicates a potential personal injury hazard. It is not used for messages related to property damage. The safety alert symbol may be used alone or in conjunction with a signal word in a signal word panel



Danger of electrical shock



Blade hazard, keep hands clear



Biohazardous waste also known as medical waste by the Environmental Protection Agency. Proper disposal and care is necessary to prevent illness.



Fuse of specified type, current, and voltage rating



Read operator's manual



Protective safety gloves must be worn

Symbols are harmonized with ANSI Z535.4 and ISO 3864-2 standards. Warning symbols are presented on a safety yellow background. Mandatory action symbols are presented on a safety blue background.

This technical manual is printed in black and white.

SAFETY SYMBOLS (CONTINUED)



Not sterilized



Do not reuse



Do not resterilize

Medical Device Symbols comply with ISO 15223.1 standards and are presented in black on a white background.

GLOSSARY OF TERMS

STERILIZATION: Validated process used to render a device free from all forms of viable microorganisms. *NOTE: In a sterilization process, the nature of microbiological death is described by an exponential function. The presence of microorganisms on any individual item may be expressed in terms of probability. While this probability may be reduced to a very low number, it can never be reduced to zero. This probability can only be assured for validated processes.*

DISINFECTION: A process used to reduce the number of viable microorganisms on a product to a level previously specified as appropriate for its further handling or use.

NOT USED: The term not used refers to those single-use components that have not been in contact with blood, tissue, body fluids or bone.

SAFETY RECOMMENDATIONS AND WARNINGS

 **WARNING**

If you have any pre-existing medical conditions or implanted medical devices, consult a physician before using the Exsurco[®] Drive Unit and Amalgatome[®] debridement device.

 **WARNING**

The manufacturer assumes no liability for any unauthorized changes in operating procedures or for unauthorized changes or modifications made to the design of the machine or any factory-installed safety equipment, whether these changes are made by the owner of this equipment, by his employees, or by service providers not previously approved by Exsurco[®] Medical.

 **WARNING**

Use only replacement parts manufactured by Exsurco[®] Medical. Use of substitute parts will void the warranty and may cause injury to operators and damage to equipment.

 **WARNING**

Use Correct Fuse. For continued protection against risk of equipment damage and fire, replace only with fuse of the specified type, current, and voltage rating.

 **WARNING**

The use of parts other than those listed in the parts list for the specific model may cause blade lock-up, resulting in an unsafe operating condition.

 **WARNING**

Sharp blades may cause cut injury!

For proper protection of hands, a protective glove should be used when operating this equipment and during the handling of disposable heads.



A metal mesh safety glove is recommended in addition to the surgical glove for the free hand.

Keep hands away from moving blade.

SAFETY RECOMMENDATIONS AND WARNINGS (CONTINUED)

 **WARNING**

To avoid personal injury, always disconnect the power cord before performing any adjustments, disassembly/assembly, troubleshooting or cleaning.



All electrical repairs should be completed by a qualified electrician or approved service provider.

Avoid use of this machine in standing water.

 **WARNING**

Always disconnect the power and remove the tool from the flexshaft casing prior to servicing.



 **WARNING**

Do not install or change disposable heads while motor his running. This could cause serious cut injury.



SAFETY RECOMMENDATIONS AND WARNINGS (CONTINUED)

 **WARNING**

The Amalgatome[®] Handle Assembly and Non-sterile Disposable Head Assemblies require sterilization prior to use. Follow your organization's protocol for sterilization of surgical equipment.



 **WARNING**

DO NOT REUSE OR RESTERILIZE Amalgatome[®] heads after they have been used for tissue and/or bone debridement.



These devices are single-use but can be reprocessed if *not used*.

NOTE: The term *not used* refers to those single-use components that have not been in contact with blood, tissue, body fluids or bone.

Any unused, single-use device that has been exposed to blood, tissue, body fluids or bone must not be reprocessed or resterilized and must be discarded.

 **WARNING**

Used sharps are contaminated. Disease may occur from contact or injury. Dispose of in puncture resistant biohazard sharps container. Refer to AORN, CDC, OSHA or local standards setting organizational guidelines for handling and disposal of sharps.



SAFETY RECOMMENDATIONS AND WARNINGS (CONTINUED)

! WARNING

If at any time this machine does not appear to operate normally or exhibits a marked change in performance, it should be immediately shut down, unplugged, and tagged as “UNSAFE” until such time as proper repairs are made and the machine again operates normally.

! WARNING

After service of the unit, always check to ensure that the blade is free to rotate in the machine prior to starting. If the blade does not rotate freely, it may cause the handpiece to rotate in the hand.

**! WARNING**

Long or repeated use of various power tools vibrating excessively is suspected of contributing to certain hand, wrist or forearm disorders in susceptible individuals. If excessive vibration occurs, it is an indication that there are worn parts that need replacement.

! WARNING

If your Amalgatome[®] debridement device develops unusual vibration, do not continue to use it without first undertaking corrective action as outlined in the fault detection and correction section guide in this manual.

! WARNING

Surgical accessories like drill bits, blades, burs, chisels, rasps, taps and reamers are intended to be used only by trained medical professionals who are familiar with their use and application. Verify that the surgical accessories have been properly inserted and tightened before instrument activation to avoid possible injury.

! CAUTION

Correct installation is extremely important to achieve maximum efficiency for both the Amalgatome[®] debridement device being used and the operator. Incorrect installation may possibly hamper the operator's movements and cause undue wear or damage to the flexshaft and flexshaft casing parts of the unit.

SAFETY RECOMMENDATIONS AND WARNINGS (CONTINUED)**NOTICE**

Casings, flexshaft, and handpieces should be removed prior to area cleanup.

NOTICE

Do not use hydrocarbon solvents on or in the casing as these will cause casing to shrink in length and become brittle.

NOTICE

Before installing the handpiece on the casing assembly, ensure that the flexshaft extends beyond the end of the casing at least 5/8" but not more than 7/8". If incorrect, this distance can be adjusted by adding or removing flexshaft washers under the collar of the flexshaft. There must be at least ONE washer under the collar but no more than FOUR at any time. If proper adjustment cannot be obtained as described above, change the flexshaft and/or flexshaft casing.

SAFETY FEATURES OF DRIVE UNIT

User protected from electrical hazard.

User protected from moving parts.

SAFETY FEATURES OF AMALGATOME[®] DEBRIDEMENT DEVICES

Disposable heads are single use to prevent cross contamination. Simply remove the disposable head and discard after use.

SPECIFICATIONS

The Exsurco[®] Drive Unit and Amalgatome[®] debridement devices are highly effective for use in the bone and tissue processing industry. They are designed with the highest possible standards for safety, ergonomic design, and productivity.

The Exsurco[®] Drive Unit described in this Operation Instruction has been tested by an independent and certified body, Intertek Testing Services, Twinsburg, OH and complies with UL standard #61010-1 and CAN/CSA C22.2 #61010-1, Electrical Equipment for Measurement, Control and Laboratory Use.



General Exsurco[®] Drive Unit Information

Weight	17.5 lbs. (7.9 kg)
Overall Size	6 3/4" High x 7 5/8" Wide x 11" Deep (170mm) x (190mm) x (280mm)

Power Requirements

115VAC	1 Phase, 1.8 A	60Hz
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Duty Cycle

20 minutes on / 150 minutes off

Environmental Condition

This unit is rated safe for use under Normal Environmental Conditions.

- Indoor use
- Altitude up to 2000m
- Temperatures 5°C to 40°C
- Maximum relative humidity 80% for temperatures up to 31 °C decreasing linearly to 50% relative humidity at 40°C
- Mains supply voltage fluctuations up to 10±% of nominal voltage
- Temporary over voltages occurring on the mains supply
- Pollution Degree 2 (Only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is expected)

MATERIALS
Amalgatome[®] Disposable Heads

ITEM	MATERIALS
Frame	PPS with 20% Glass Fiber, Medical Grade
Pinion Shaft	Peek RTP 220If, Stainless Steel 300 series
Spring Clip	Stainless Steel 300 Series 1/2 hard
Blade Ring	Stainless Steel 300 Series 1/2 hard
Blade	Zirconium Nitride Coating over Alloy Steel

Handpiece

ITEM	MATERIALS
Handle, Electric	SustaPEEK MG
Set Screw, Handpiece	Stainless Steel 300 Series
Drive Adapter	17-4 PH Stainless Steel

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Section 2

Designated Use

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DESIGNATED USE



Any use in applications other than those for which the Exsurco[®] Drive Unit and Amalgatome[®] debridement devices were designed and built, may result in serious injuries.

Exsurco[®] Drive Unit

- The Exsurco[®] Drive Unit has been designed for use with electric Amalgatome[®] debridement devices.
- This drive unit features a 1/7 HP motor which will drive all current electric Amalgatome[®] debridement devices.

Non-sterile SK and Sterile SK Amalgatome[®] Skin Debridement Devices

- Non-sterile SK and Sterile SK Amalgatome[®] skin debridement devices are specially designed for quick, precise full-thickness skin defatting.
- The Non-sterile SK and Sterile SK Amalgatomes greatly simplify the debriding operation by eliminating the excessive, repetitive dissection motion required when using a scalpel, forceps, and osteotome.
- The unique, flat cutting surface of the circular blade dramatically reduces the chance for skin breakthroughs. Non-sterile SK and Sterile SK Amalgatome[®] debridement devices are available in electric and pneumatic configurations.

RECOMMENDED OPERATION

The Exsurco® Drive Unit has been designed for use with the following electric Amalgatome® debridement devices.

MODEL	INTENDED USE
Non-sterile SK Amalgatome®	Skin Debridement / Defatting
Sterile SK Amalgatome®	Skin Debridement / Defatting

FUNCTION

The Exsurco® Drive Unit or the pneumatic power unit will drive all current Amalgatome® debridement devices with all the advantages, power, and performance to improve debridement.

The force required to cut through the gross debridement is now provided by the tool and no longer by the technician. Forces applied by the technician are greatly reduced and limited to guiding the rotating knife blade.

The Exsurco® Drive Unit drives a flexible shaft. The flexible shaft drives a rotating blade in the handpiece via a gear and pinion.

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Section 3

Unpacking and Installation

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Surgical accessories like drill bits, blades, burs, chisels, rasps, taps and reamers are intended to be used only by trained medical professionals who are familiar with their use and application. Verify that the surgical accessories have been properly inserted and tightened before instrument activation to avoid possible injury.

CONTENTS

The Amalgatome[®] is available in both electric and pneumatic configurations. Please check when unpacking and advise your local Exsurco[®] Medical representative if the delivery is incomplete.

Electric Amalgatome[®] Complete

Includes:

Exsurco[®] Drive Unit

Amalgatome[®] Handle Assembly

- Handle
- Drive Adapter
- Set Screw

Flexshaft and Casing

Foot Pedal

Operating Instructions and Parts List

NOTE: Disposable Head Assembly Kits sold separately.

STERILIZATION OF CONTENTS

 **WARNING**

The Amalgatome[®] Handle Assembly and Non-sterile Disposable Head Assemblies require sterilization prior to use. Follow your organization's protocol for sterilization of surgical equipment.



Exsurco[®] Drive Unit

NOTICE

Do not immerse in cleaning solution.

Do not autoclave drive unit.

These procedures will cause damage to the drive unit.

The Exsurco[®] Drive Unit should be disinfected using a hospital grade disinfectant cleaning solution on a cloth or towel before and after each use. Completely wipe the outside of the drive unit. **NOTE:** *Do not immerse drive unit in cleaning solution or sterilize drive unit in an autoclave.*

STERILIZATION OF CONTENTS (CONTINUED)

Flexshaft and Casing

NOTICE

Do not use hydrocarbon solvents on or in the casing.

Do not immerse in cleaning solution.

Do not autoclave.

These procedures will cause casing to shrink in length and become brittle.

The flexshaft and casing are not sterilized when delivered. Flexshaft and Casing should be disinfected using a hospital grade disinfectant cleaning solution before and after each use.

NOTE: Do not immerse in cleaning solution or sterilize flexshaft and casing in an autoclave.

When used, flexshaft and casing should be draped with a sterile probe/sleeve cover prior to use in a clean room.

Handle Assembly (With Set Screw and Drive Adapter)

The handle assembly is not sterilized when delivered. The handle assembly requires sterilization prior to use. Package and sterilize handle, set screw, and drive adapter following your organization's protocol for sterilization of surgical equipment. All materials will withstand conventional sterilization using steam, ethylene oxide (ETO), and gamma.

Foot Pedal

NOTICE

Do not immerse in cleaning solution.

Do not autoclave.

These procedures will cause damage to the foot pedal.

Using a hospital grade disinfectant cleaning solution on a cloth or towel, completely wipe the outside of pedal and electrical cord. *Do not autoclave.*

STERILIZATION OF CONTENTS (CONTINUED)

Non-Sterile Disposable Head Assembly Kit

 **WARNING**

DO NOT REUSE OR RESTERILIZE Amalgatome[®] heads after they have been used for tissue and/or bone debridement.



These devices are single-use but can be reprocessed if *not used*.

NOTE: The term *not used* refers to those single-use components that have not been in contact with blood, tissue, body fluids or bone.

Any unused, single-use device that has been exposed to blood, tissue, body fluids or bone must not be reprocessed or resterilized and must be discarded.

The Non-sterile SK blade support structures are not sterilized when delivered. They require sterilization prior to use. Package and sterilize head assemblies following your organization's protocol for sterilization of surgical equipment. **WARNING! DO NOT REUSE OR RESTERILIZE Amalgatome[®] heads after they have been used for tissue and/or bone debridement.**

CONNECTING THE POWER



Electrical shock may occur!



Use only 3 wire ground type connector. This must be connected to a plant ground via a suitable grounded three conductor receptacle. Avoid use of this machine in standing water.

Connect the Exsurco[®] Drive Unit power cord to the prescribed voltage on the drive unit nameplate. The drive unit must be connected to a ground. Use only approved type connector.

PLACEMENT OF EXSURCO[®] DRIVE UNIT

⚠ CAUTION

Correct installation is extremely important to achieve maximum efficiency for both the Amalgatome[®] debridement device being used and the operator. Incorrect installation may possibly hamper the operator's movements and cause undue wear or damage to the flexshaft and flexshaft casing parts of the unit.

Place the Exsurco[®] Drive Unit on a table or cart in the clean room for use. This motor can be draped with a sterile cover, but not required.



INSTALLATION OF CASING ASSEMBLY

Install the casing assembly to the Exsurco® Drive Unit disconnect assembly by lifting the disconnect collar and inserting the drive end of the casing into the disconnect body. It may be necessary to rotate the casing assembly to align the square drive of the flexshaft with the square in the flexshaft/drive unit adapter. Release the disconnect collar to secure the casing to the drive unit assembly.



Disconnect Collar



Drive End of Casing Assembly

The casing assembly should swivel freely.



INSTALLATION OF CASING ASSEMBLY (CONTINUED)

Draping Flexshaft and Casing

Drape the Amalgatome[®] Flexshaft and Casing using a sterile probe/sleeve drape. Insert the squared end of the flexshaft into the sterile probe/sleeve drape where indicated by an arrow.



Once the flexshaft and casing end is inside the drape, hold that end firmly and slide the remaining excess drape along the length of the flexshaft and casing.

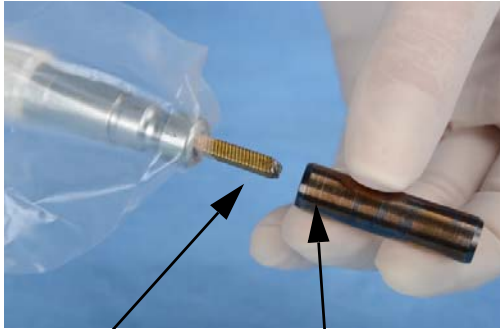


NOTE: If an assistant is being used, the non-sterile area indicated with the hand symbol is where the assistant can pull the drape. This end is towards the motor. Mark the drape where the line of sterilization remains on the sterile field, or tape/secure the drape to keep from falling off the sterile field.



INSTALLATION OF HANDPIECE (HANDLE)

Puncture through drape using the square end of the drive adapter. Align and place the square end of the drive adapter onto the square end of the flexshaft assembly.

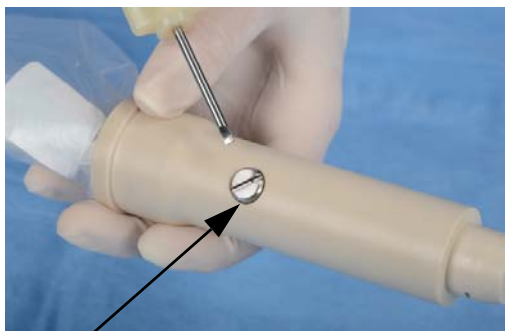


Square End of
Flexshaft Assembly

Drive Adapter



Install the handle by inserting the proper end of the flexshaft assembly into the handle. When proper alignment is achieved, tighten handpiece set screw using a flathead screwdriver. **NOTE:** *Do not over tighten.*



Set Screw

INSTALLATION OF DISPOSABLE HEADS

Safety First

 **WARNING**

The Amalgatome[®] Handle Assembly and Non-sterile Disposable Head Assemblies require sterilization prior to use. Follow your organization's protocol for sterilization of surgical equipment.



 **WARNING**

DO NOT REUSE OR RESTERILIZE Amalgatome[®] heads after they have been used for tissue and/or bone debridement.



These devices are single-use but can be reprocessed if *not used*.

NOTE: The term *not used* refers to those single-use components that have not been in contact with blood, tissue, body fluids or bone.

Any unused, single-use device that has been exposed to blood, tissue, body fluids or bone must not be reprocessed or resterilized and must be discarded.

 **WARNING**

Sharp blades may cause cut injury!

For proper protection of hands, a protective glove should be used when operating this equipment and during the handling of disposable heads.



A metal mesh safety glove is recommended in addition to the surgical glove for the free hand.

Keep hands away from moving blade.

 **WARNING**

Surgical accessories like drill bits, blades, burs, chisels, rasps, taps and reamers are intended to be used only by trained medical professionals who are familiar with their use and application. Verify that the surgical accessories have been properly inserted and tightened before instrument activation to avoid possible injury.

 **WARNING**

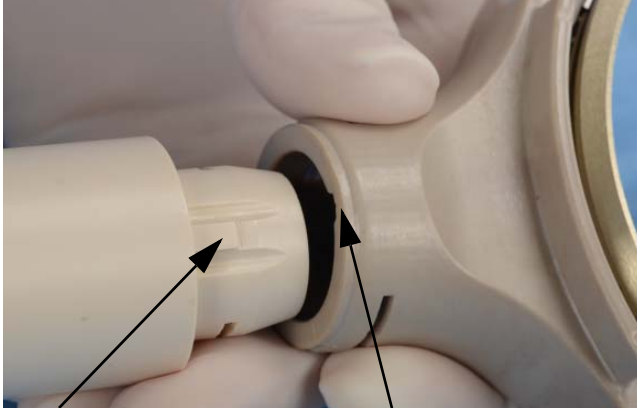
Used sharps are contaminated. Disease may occur from contact or injury. Dispose of in puncture resistant biohazard sharps container. Refer to AORN, CDC, OSHA or local standards setting organizational guidelines for handling and disposal of sharps.



INSTALLATION OF DISPOSABLE HEADS (CONTINUED)

Non-Sterile SK and Sterile SK Head Assemblies

Locate the raised key on the handle and align the key with the notch on the disposable head. Slide into place. Place spring clip in external groove of disposable head.



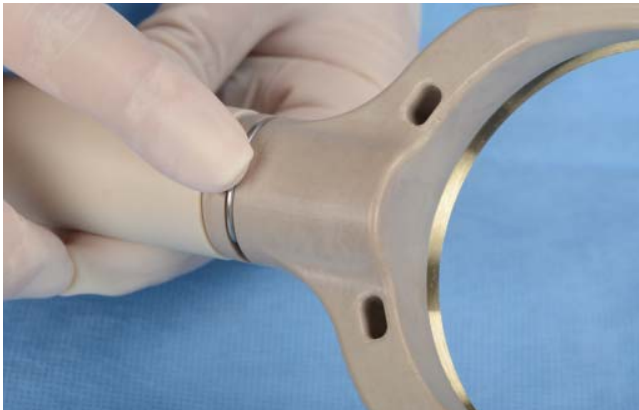
Raised Key

Notch on Disposable Head



Spring Clip

Press spring clip into external groove of disposable head.



FOOT PEDAL INSTALLATION

Attach foot pedal to Exsurco[®] Drive Unit by pressing foot pedal fitting onto the foot pedal outlet located on the front panel of the drive unit.



Foot Pedal



Foot Pedal Outlet

FOOT PEDAL INSTALLATION (CONTINUED)

Plug drive unit power cord into power outlet specified on the specification plate. Drive unit must be connected to a ground approved type connector.



Power Cord

Turn drive unit switch to the “ON” position. The green, Power LED will illuminate.



ON/OFF Switch

Press foot pedal to activate drive unit and operate tool. The green, Blade Activated LED will illuminate. Drive unit will stop when foot pedal is released and Blade Activated LED will turn off.

Section 4

Instructions for Operation

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SAFETY FIRST**! WARNING**

The Amalgatome[®] Handle Assembly and Non-sterile Disposable Head Assemblies require sterilization prior to use. Follow your organization's protocol for sterilization of surgical equipment.

**! WARNING**

Sharp blades may cause cut injury!

For proper protection of hands, a protective glove should be used when operating this equipment and during the handling of disposable heads.



A metal mesh safety glove is recommended in addition to the surgical glove for the free hand.

Keep hands away from moving blade.

! WARNING

Used sharps are contaminated. Disease may occur from contact or injury. Dispose of in puncture resistant biohazard sharps container. Refer to AORN, CDC, OSHA or local standards setting organizational guidelines for handling and disposal of sharps.



OPERATING PROCEDURE

With the handpiece held in your operating hand and proper safety gloves on the other, stand at your normal work position and move your hand and the handpiece over your normal work area to check that there are no binds or sharp bends in the flexshaft and casing assembly.



With your other hand, turn on the drive unit switch. The green Power LED will illuminate. Press the foot pedal to activate drive unit and operate tool. The green Blade Activated LED will illuminate when foot pedal is pressed. Drive unit will stop when foot pedal is released.



Drive Unit Switch

OPERATING PROCEDURES (CONTINUED)

Hold the handpiece naturally in the palm of the hand in a relaxed manner. You are now ready to put the Amalgatome[®] debridement device into operation.

Move your hand and handpiece over your normal work area to ensure that there are no binds or sharp bends in casing.

Press the foot pedal to activate the Amalgatome[®] debridement device. Release the foot pedal to deactivate the tool.

**WARNING**

Sharp blades may cause cut injury. Never hold the product being trimmed in your hand. Always lay the product flat on the work surface.



Skin Debridement

The Amalgatome[®] is used for the removal of adipose tissue from a full thickness skin graft. The rotating blade will cut through the adipose.

With the epidermis (outer layer of skin) laying completely flat on the working surface. The adipose tissue will be facing up towards the technician. **WARNING!** Sharp blades may cause cut injury. Never hold the product being trimmed in your hand. Always lay the product flat on the work surface.

Apply cutting surface of the blade directly onto the adipose tissue. Use a gliding motion from one edge of the skin graft to the other. Press the blade into the adipose to the dermis layer. The angle of the blade allows pressure onto the dermis to remove the adipose while not striking through the dermis.

OPERATING PROCEDURES (CONTINUED)

Skin Debridement (Continued)

Let the Amalgatome[®] Debridement Device do the work. Using the device does not require the technician to push hard or use force. The proper angle at which to hold the blade against the adipose will become easily identifiable.

Repeat the gliding motion across the entire skin graft until all adipose is excised and only dermis remains.

Bone Debridement

The Amalgatome[®] for bone debridement is used for gross debridement of donated bone grafts. The rotating blade will cut through the connective tissues such as adhered muscle, tendons, adipose and periosteum.

Apply cutting surface of the blade directly onto the bone. While holding one end of the bone, use a gliding motion along the area in which tissue need to be removed. **WARNING!** Sharp blades may cause cut injury. Keep hands away from moving blade.

Let the Amalgatome[®] debridement device do the work. Using the device does not require the technician to push hard or use force.

Rotate the bone until the Amalgatome[®] has excised all required tissues off the surface of the bone.

OPERATING PROCEDURE (CONTINUED)

Changing Disposable Heads

The Amalgatome[®] debridement tool has been designed in such a way as to allow the disposable head to be quickly removed and a sterilized replacement head to be easily installed.

 **WARNING**

To avoid personal injury, always disconnect the power source before changing disposable heads, performing any adjustments, disassembly/assembly, troubleshooting or cleaning.



 **WARNING**

The Amalgatome[®] Handle Assembly and Non-sterile Disposable Head Assemblies require sterilization prior to use. Follow your organization's protocol for sterilization of surgical equipment.



 **WARNING**

Sharp blades may cause cut injury!

For proper protection of hands, a protective glove should be used when operating this equipment and during the handling of disposable heads.



A metal mesh safety glove is recommended in addition to the surgical glove for the free hand.

Keep hands away from moving blade.

 **WARNING**

Used sharps are contaminated. Disease may occur from contact or injury. Dispose of in puncture resistant biohazard sharps container. Refer to AORN, CDC, OSHA or local standards setting organizational guidelines for handling and disposal of sharps.

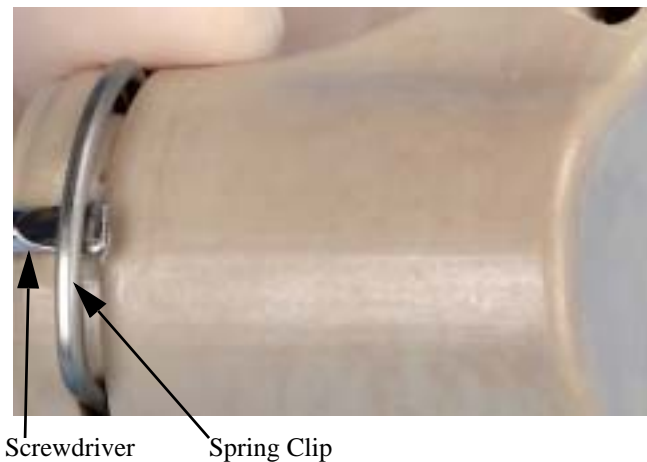


OPERATING PROCEDURE (CONTINUED)

Removing Disposable Head

WARNING! To avoid personal injury, always disconnect the power source before changing disposable heads.

Using a flathead screwdriver, lift the spring clip out of the external groove of the disposable head. The spring clip can be discarded.



Remove the disposable head from the handpiece. Dispose of in puncture resistant biohazard sharps container.



Refer to Section 3, Unpacking and Installation for disposable head installation.

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Section 5

Maintenance

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SAFETY **WARNING**

The information provided in these operating instructions is important to your health, comfort and safety. For safe and proper operation, read this entire manual before using this equipment.



Please read and save these instructions. Read carefully before attempting to assemble, install, operate or maintain this product. Protect yourself, others and equipment by observing all safety information. Failure to comply with instructions could result in personal injury and/or damage to the equipment. Any use in applications other than those for which the equipment was designed and built may result in equipment damage and/or serious injuries.

Retain this manual for future reference. Be thoroughly familiar with the controls and proper use of this equipment.

 **WARNING**

The manufacturer assumes no liability for any unauthorized changes in operating procedures or for unauthorized changes or modifications made to the design of the machine or any factory-installed safety equipment, whether these changes are made by the owner of this equipment, by his employees, or by service providers not previously approved by Exsurco[®] Medical.

 **WARNING**

Use only replacement parts manufactured by Exsurco[®] Medical. Use of substitute parts will void the warranty and may cause injury to operators and damage to equipment.

 **WARNING**

The use of parts other than those listed in the parts list for the specific model may cause blade lock-up, resulting in an unsafe operating condition.

 **WARNING**

To avoid personal injury, always disconnect the power cord before performing any adjustments, disassembly/assembly, troubleshooting or cleaning.



Always disconnect the power and remove the tool from the flexshaft casing prior to servicing.

All electrical repairs should be completed by a qualified electrician or approved service provider.

CASING MAINTENANCE

NOTICE

Do not use hydrocarbon solvents on or in the casing as these will cause casing to shrink in length and become brittle.

The casing should be cleaned and inspected before each use.

Exterior Of Casing

Cleaning should be done using a hospital grade disinfectant cleaning solution on a cloth or towel. Completely wipe the outside of the casing.



Interior Of Casing

NOTICE

Avoid the use of any liquids on the inside of the casing.

If needed, tie a small piece of dry cloth to a thin wire and pull through.

FLEXSHAFT MAINTENANCE

Clean the flexshaft after 20 hours of operation by wiping off the old grease with a dry cloth. Avoid the use of any liquids on the shaft. Be sure the flexshaft washer is installed under the ferrule during reassembly. Place a small quantity of 100% pure petroleum jelly in the palm of your hand and pull the shaft through your clenched hand. Inspect the casing support for wear, cracks or chips.

NOTICE

Before installing the handpiece on the casing assembly, ensure that the flexshaft extends beyond the end of the casing at least 5/8" but not more than 7/8". If incorrect, this distance can be adjusted by adding or removing flexshaft washers under the collar of the flexshaft. There must be at least ONE washer under the collar but no more than FOUR at any time. If proper adjustment cannot be obtained as described above, change the flexshaft and/or flexshaft casing.

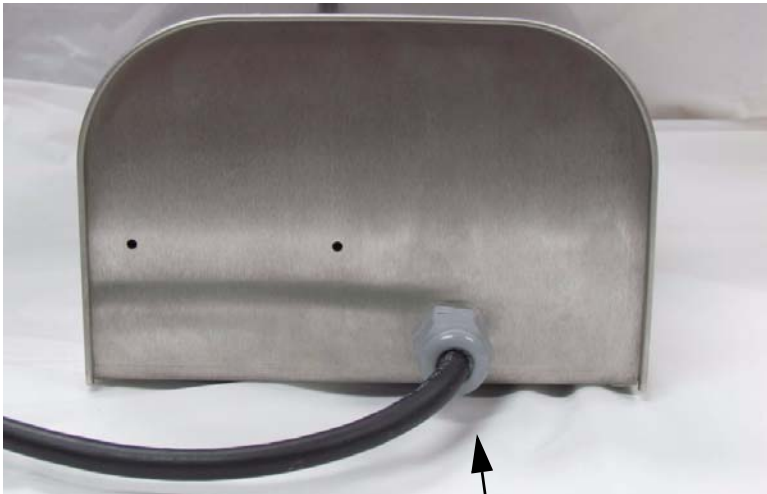
NOTICE

Casings, flexshaft, and handpieces should be removed prior to area cleanup.



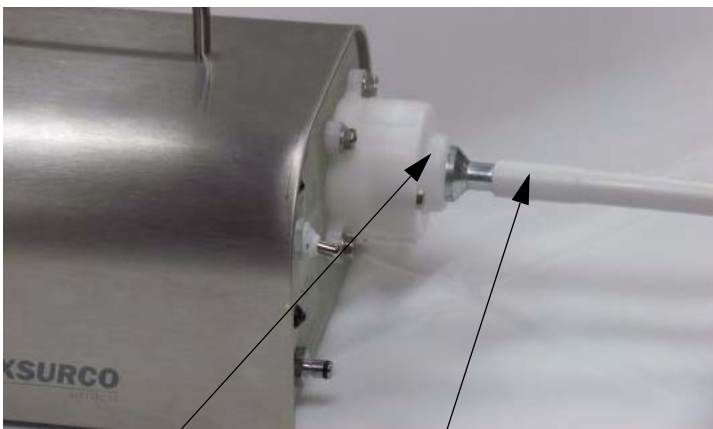
DRIVE UNIT MAINTENANCE

Make certain the power cord strain relief is tight against the motor enclosure. Tighten as required.



Strain Relief

Periodically check the condition of the flexshaft casing to motor disconnect. Make sure the balls move freely and the casing rotates freely in the disconnect. Make certain the shaft disconnect button fully rebounds after being pressed.



Disconnect Assembly

Flexshaft Casing

FAULT DETECTION AND CORRECTION**Handpiece**

PROBLEM	PROBABLE CAUSE	REMEDY
Handpiece Vibration	Inside of flexshaft casing worn	Replace casing
	No lubrication on flexshaft or casing	Clean and lubricate flexshaft and casing as described in Maintenance, Section 5 of this manual

FAULT DETECTION AND CORRECTION (CONTINUED)
Flexshaft and Disposable Heads

PROBLEM	PROBABLE CAUSE	REMEDY
Rapid Flexshaft Wear or Breakage	Improper cleaning and lubrication of flexshaft and casing	See Maintenance, Section 5
	Mechanical bind in handpiece	With handpiece removed from flexshaft, blade should rotate freely by hand. Correct any mechanical bind
Blade Skips or Will Not Rotate	Casing not fully engaged or inserted	Make sure the casing is fully inserted to the drive position
	Flexshaft worn	Replace shaft
	Motor Adapter worn	Replace adapter
	Loose ferrule on shaft	Replace shaft
	Faulty blade	Replace with new

FAULT DETECTION AND CORRECTION (CONTINUED)

Drive Unit

PROBLEM	PROBABLE CAUSE	REMEDY
Motor Will Not Run	No power to motor	Check line voltage. Make sure line voltage matches motor specification plate
	Bad power cord or plug	Check voltage at cord to switch point. Refer to Section 7 for proper schematic
	Loose wire connections	Tighten loose connections
	Bad switch	Check switch and replace if defective
Motor Noisy	Bad bearing in motor	Remove and replace
Handpiece Vibration	Machine not installed correctly in relation to operator position	Check installation procedures
	Flexshaft/motor adapter worn	Replace adapter

Section 6

Cleaning & Sterilization

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The Amalgatome[®] Handle Assembly, Amalgatome[®] Pneumatic Handle Assembly, and Disposable Head Assembly require sterilization prior to use. Follow your organization's protocol for sterilization of surgical equipment.



DO NOT REUSE OR RESTERILIZE Amalgatome[®] heads after they have been used for tissue and/or bone debridement.

These devices are single-use but can be reprocessed if *not used*.

NOTE: The term *not used* refers to those single-use components that have not been in contact with blood, tissue, body fluids or bone.

Any unused, single-use device that has been exposed to blood, tissue, body fluids or bone must not be reprocessed or resterilized and must be discarded.

CLEANING AND STERILIZATION

Exsurco[®] Drive Unit

NOTICE

Do not immerse in cleaning solution.

Do not autoclave drive unit.

These procedures will cause damage to the drive unit.

- Make sure the unit is unplugged.
- Using a hospital grade disinfectant cleaning solution on a cloth or towel, completely wipe the outside of the motor unit. **NOTE:** *Do not immerse drive unit in cleaning solution or sterilize drive unit in an autoclave.*
- After washing is complete and drive unit is dry, check for any malfunction and place in appropriate storage area.

Flexshaft and Casing

NOTICE

Do not use hydrocarbon solvents on or in the casing.

Do not immerse in cleaning solution.

Do not autoclave.

These procedures will cause casing to shrink in length and become brittle.

- Make sure the unit is unplugged.
- Flexshaft and casing are not to be immersed at any time.
- Using a hospital grade disinfectant cleaning solution on a cloth or towel, completely wipe the outside of the casing.
- After washing is complete and flexshaft and casing are dry, check for any malfunction and place items in appropriate storage area.

NOTE: *Do not sterilize flexshaft and casing in an autoclave. When used, flexshaft and casing should be draped with a sterile probe/sleeve cover prior to use in a clean room.*

CLEANING AND STERILIZATION (CONTINUED)

Handle Assembly (With Set Screw and Drive Adapter)

- Make sure the device is completely disassembled.
- The handle, set screw, and drive adapter are able to be immersed.
- Using FDA approved cleaning solution; follow your organization's protocol for surgical equipment.
- After washing is complete and handle, set screw, and drive adapter are dry, check for any malfunction.
- Package and sterilize handle, set screw, and drive adapter following your organization's protocol for sterilization of surgical equipment.

Foot Pedal

NOTICE

Do not immerse in cleaning solution.

Do not autoclave.

These procedures will cause damage to the foot pedal and electrical cord.

- Make sure that unit is unplugged.
- Using a hospital grade disinfectant cleaning solution on a cloth or towel, completely wipe the outside of pedal and electrical cord. **NOTE:** *Pedal and electrical cord are not to be immersed in cleaning solution at any time.*
- After the washing is complete and pedal and electrical cord are dry, check for any malfunction and place items in appropriate storage area. **NOTE:** *Do not autoclave.*

CLEANING AND STERILIZATION (CONTINUED)

Disposable Head Assembly Kit

 **WARNING**

DO NOT REUSE OR RESTERILIZE Amalgatome[®] heads after they have been used for tissue and/or bone debridement.



These devices are single-use but can be reprocessed if *not used*.

NOTE: The term *not used* refers to those single-use components that have not been in contact with blood, tissue, body fluids or bone.

Any unused, single-use device that has been exposed to blood, tissue, body fluids or bone must not be reprocessed or resterilized and must be discarded.

Section 7

Service Parts

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 Top View of Drive Unit with Schematic7-6
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Use only replacement parts manufactured by Exsurco[®] Medical. Use of substitute parts will void the warranty and may cause injury to operators and damage to equipment.

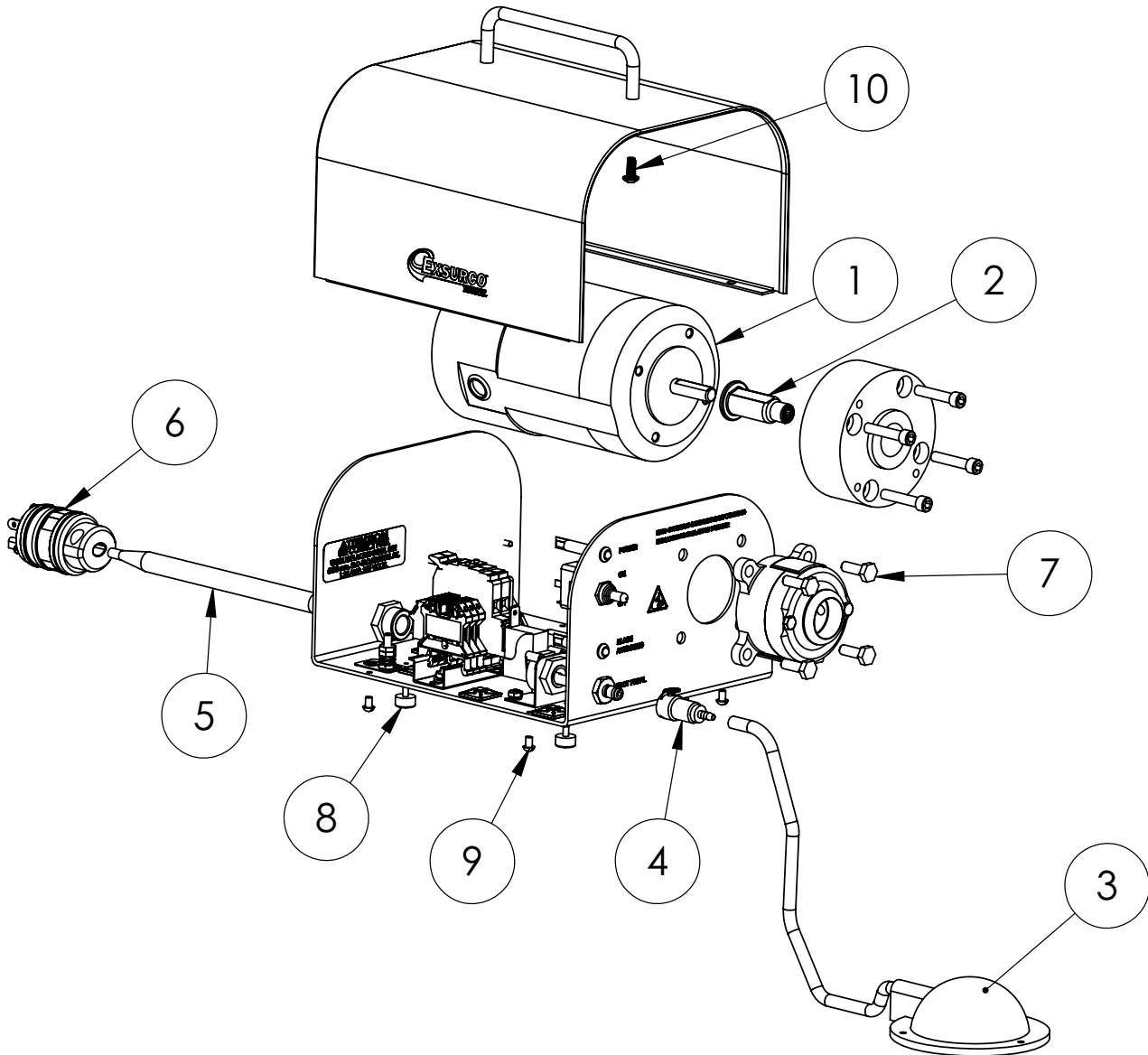
The use of parts other than those listed in the parts list for the specific model may cause blade lock-up, resulting in an unsafe operating condition.



Use Correct Fuse. For continued protection against risk of equipment damage and fire, replace only with fuse of the specified type, current, and voltage rating.



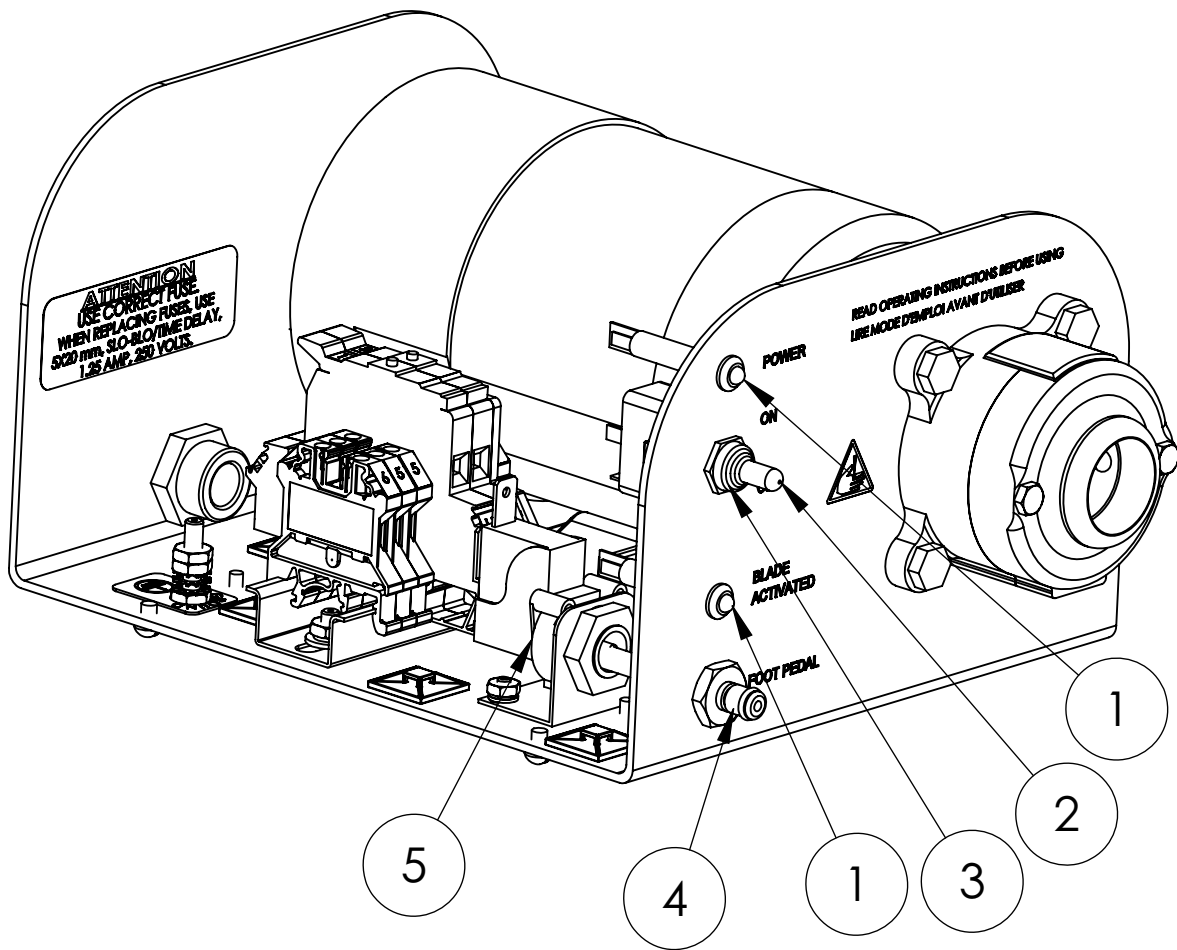
DRIVE UNIT ASSEMBLY



DRIVE UNIT ASSEMBLY (CONTINUED)

ITEM	DESCRIPTION	PART NUMBER 115V	QTY
1	Drive Unit Motor	X100066	1
2	Motor Adapter	X100068	1
3	Pedal, Foot	X100086	1
4	Disconnect, Air Quick, Foot Pedal	X100085	1
5	Power Cord (10')	X100280	1
6	Male Plug, Power Cord	X100248	1
7	1/4-20 x .75 Hex Cap Screw	X100287	4
8	Rubber Feet	X100093	4
9	#8-32 x 1/4" Machine Screw	X100260	4
10	Screw, Self Seal / Self Lock	X100259	2

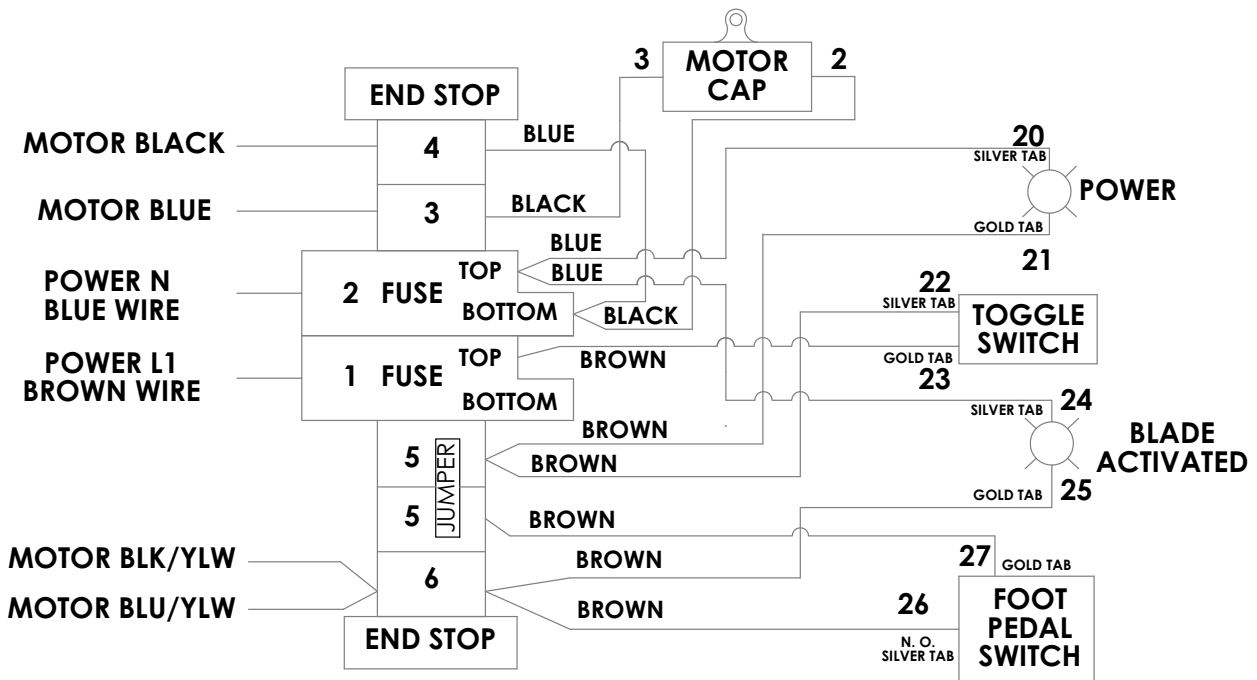
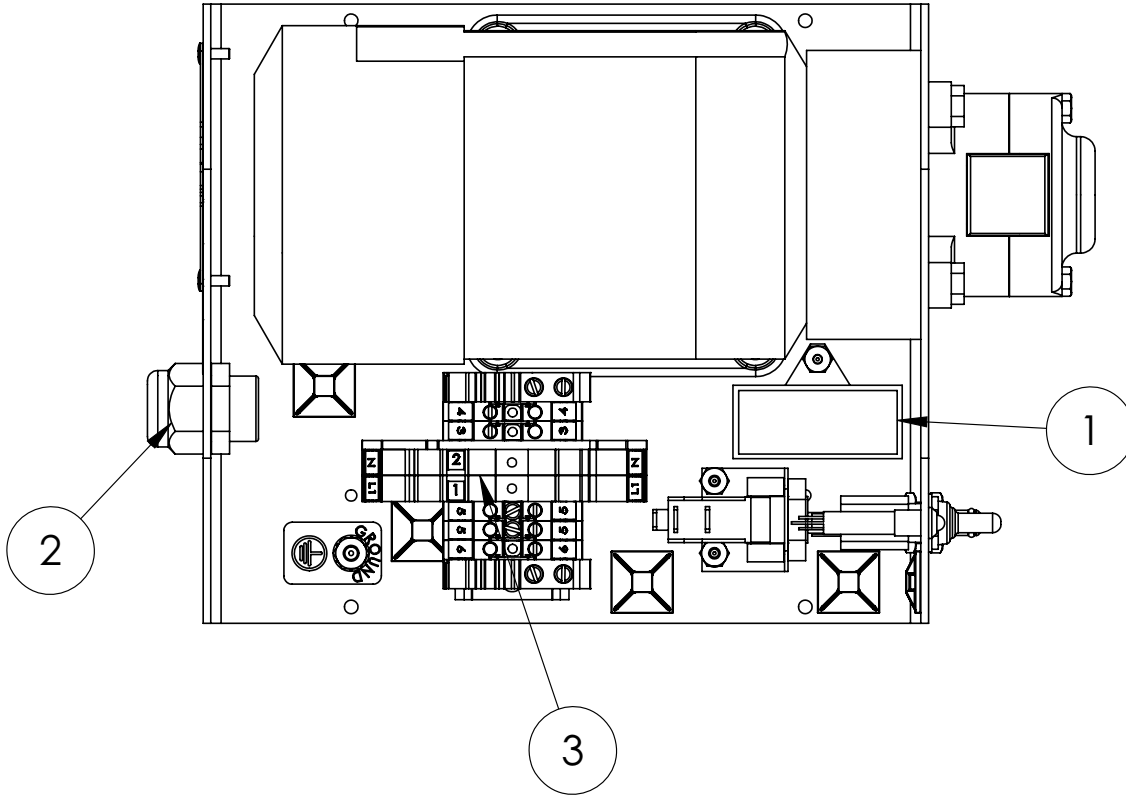
FRONT PANEL AND AIR SWITCH COMPONENTS



FRONT PANEL AND AIR SWITCH COMPONENTS (CONTINUED)

ITEM	DESCRIPTION	PART NUMBER 115V	QTY
1	Led Indicator, Green	X100088	2
2	Toggle Switch	X100089	1
3	Toggle Switch Seal	X100090	1
4	Disconnect, Air Quick, Panel Mount	X100084	1
5	Momentary Air Switch	X100087	1

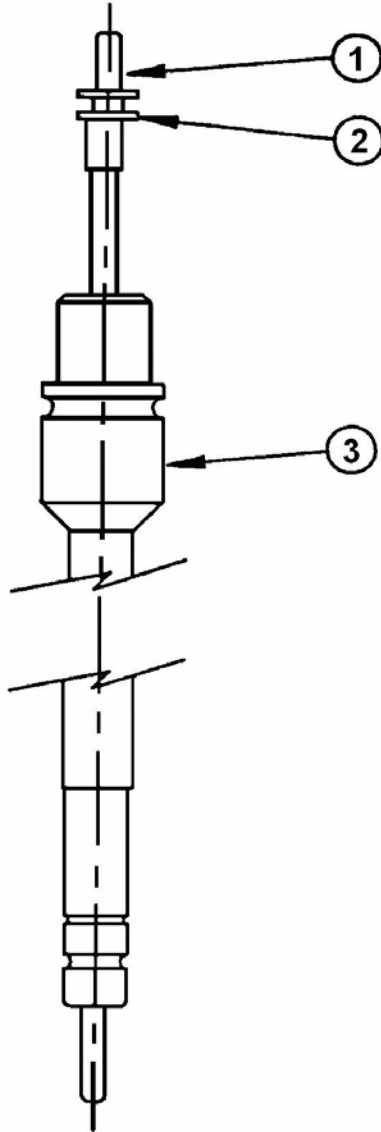
TOP VIEW OF DRIVE UNIT WITH SCHEMATIC



TOP VIEW OF DRIVE UNIT WITH SCHEMATIC (CONTINUED)

ITEM	DESCRIPTION	PART NUMBER 115V	QTY
1	Start Capacitor	X100083	1
2	Power Cord Strain Relief	X100275	1
3	Slo-Blo / Time Delay Fuse - 5 x 20mm Size, 1.25A, 250V (Not Pictured)	X100276	2

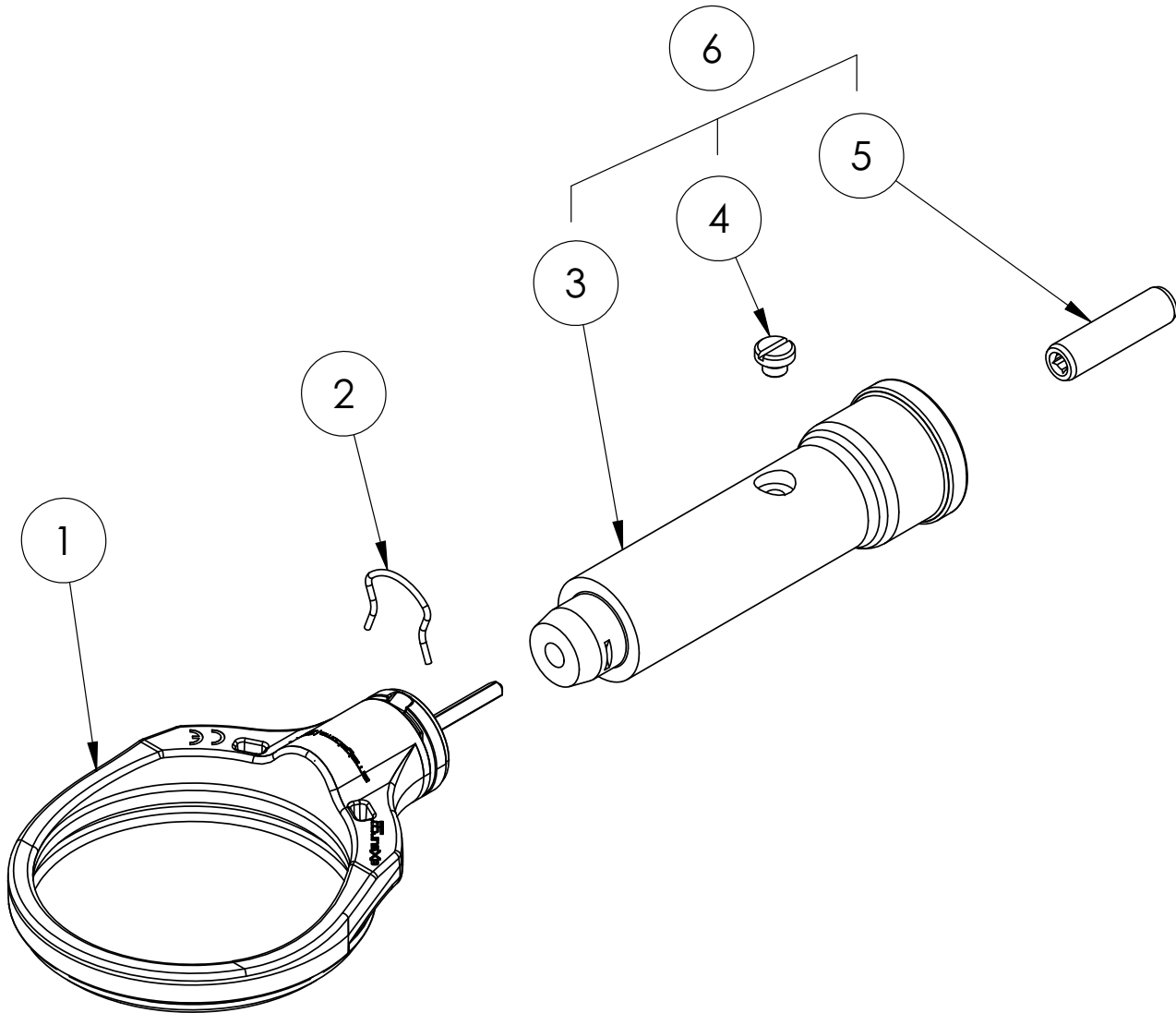
FLEXSHAFT AND CASING



FLEXSHAFT AND CASING (CONTINUED)

ITEM	DESCRIPTION	LONG 60"	QTY
1	Flexshaft with Washer	X100065	1
2	Flexshaft Washer (Included with item 1)	X100071	1
3	Casing	X100064	1

AMALGATOME[®] WITH DISPOSABLE HEAD



Model SK
Disposable Head

AMALGATOME[®] WITH DISPOSABLE HEAD (CONTINUED)

ITEM	DESCRIPTION	PART NUMBER	QTY
1	Head Assembly, SK Non-Sterile	X100044	REF
1A	Head Assembly, SK Sterile	X100593	REF
2	Spring Clip (Included in items 1 & 2)	X100050	1
3	Handle, Electric	X100061	1
4	Set Screw - Handle	X100063	1
5	Drive Adapter	X100062	1
6	Handle Assembly (Includes items 3, 4, and 5)	X100060	1

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Section 8

Contact and Document Information

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CONTACT ADDRESS AND PHONE

For additional information, technical support and spare parts, contact your Sales Manager, Distributor, or Exsurco® Representative:

Exsurco® Medical

10804 Green Road

Birmingham, Ohio 44889

USA

Tel: +1 440-752-9134

Fax: +1 440-328-4535

DOCUMENT IDENTIFICATION

Copies of this Operation Instruction may be ordered by quoting the Document ID as listed below:

Document ID:	Manual #X100894
Document Description:	Operating Instructions and Spare Parts List For Exsurco® Drive Unit & Amalgatome® Debridement Devices
Issued:	April 29, 2014

Operating Instructions for Exsurco® Drive Units and Amalgatome® debridement devices may be requested by quoting the model designation of the tool.

SOFTWARE AND DUPLICATION

For more information, contact your local Representative or:



Administrative Assistant/Engineering Department

10804 Green Road | Birmingham, OH 44889 USA

Tel. 440-752-9134 | Toll-Free: 800-243-6049

Fax: 440/328-4535

<http://www.exsurco.com>