



Amalgatome SK Tissue Processing System User Guide

RELEASED

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PN: X100894, REV. F

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Instructions for Use



Exsurco Medical
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NOTICE TO USERS

Read this manual thoroughly before using the Exsurco Medical Amalgatome SK System. It is designed for use by qualified and trained tissue bank professionals. Review this user guide, paying attention to all warnings and precautions, prior to any procedure. Improper system set up and operation or failure to follow this user guide can cause injury or damage that is not covered under the warranty.

NOTE: THIS PRODUCT IS APPROVED FOR CADAVERIC USE ONLY

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Preface

Purpose

This user guide provides directions to help users safely and effectively operate the Amalgatome SK Tissue Processing System. This guide also includes material such as appropriate use and troubleshooting information.

Exsurco Medical

Exsurco Medical's mission is to redefine excision science across the continuum of care through delivery and advancements in clinical solutions, strategic healthcare partnerships, and deep customer understanding. We are committed to improving patients' lives and outcomes by advancing the healing power of skin through innovation, product development, and the marketing of medical instruments for healthcare professionals in the surgical and tissue bank markets.

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System Overview

This section provides general information about the Amalgatome SK Tissue Processing System.

Indications for Use

The Amalgatome SK tissue processing instrument is specially designed for quick, precise full-thickness tissue processing for **Cadaveric Use** only.

Description

Amalgatome SK (ASK) tissue processing instrument is specially designed for quick and precise full-thickness tissue processing and for use only in the cadaveric environment. It greatly simplifies the tissue recovery operation by eliminating the excessive, repetitive dissection motion required when using a scalpel, forceps, and razors. The unique, flat cutting surface of the circular blade dramatically reduces the chance for skin breakthroughs. The Amalgatome SK tissue processing instrument is available in electric configuration.

Compliance

Amalgatome SK complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This instrument may not cause harmful interference.
- This instrument must accept any interference that may cause undesired operation. This instrument was tested after assembly.

The Amalgatome SK tissue processing instrument (Drive Unit) is a Class A, Group 1 instrument. The instrument generates conductively coupled radio-frequency energy necessary for internal functioning.

EC Declaration of Conformity documentation is on file.

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Amalgatome SK Tissue Processing System: Part #: X100431

Components: Exsurco Universal Drive Unit & Handle Assembly

1. Handle assembly: Handle Drive, Adapter, and Set Screw
2. Flexshaft and Casing
3. Foot Pedal
4. Universal Drive Unit (UDU)
5. Disposable Blade Head(s)

Operating Instructions and Parts List (sent with purchase and available online)



NOTE: Disposable Blade Head Assembly Kits sold separately



Part #: X101835- 10/box, sterile disposable blade head

General Warnings and Precautions

This section provides general warnings and precautions about the Amalgatome SK Tissue Processing System.

Warnings:

- Any use in applications other than those for which the Universal Drive Unit and Amalgatome SK tissue processing instrument was designed and built, may result in serious injuries.
- 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. 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.
- For continued protection against risk of equipment damage and fire, ensure that the correct fuse is used. Replace only with Exsurco fuse Part # X100276.
- To avoid personal injury, always disconnect the power cord before performing any adjustments, disassembly/assembly, troubleshooting or cleaning. Sharp blades may cause cut injury.
- All electrical repairs should be completed by an approved service provider.
- Avoid use of this instrument while standing in water.
- This product can expose you to chemicals including lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to “www.P65Warnings.ca.gov”.
- This instrument is intended to be used only by trained personnel.
- The disposable blade heads are intended for one-time use. Do not re-use or re-sterilize the Amalgatome SK disposable head.
- Any unused, single-use blade head that has been exposed to blood, tissue, body fluids or bone must not be reprocessed or resterilized and must be discarded. Blade heads are single use.
- Discard contaminated used sharps per facility protocol. Disease may occur from contact or injury. Dispose of in puncture resistant biohazard sharps container. Refer to AATB, AORN, CDC, OSHA or local standards setting organizational guidelines for handling and disposal of sharps.
- If at any time this instrument does not appear to operate normally or exhibits a marked change in performance, it should be immediately shut down, unplugged, and tagged as “Service Required” until such time as proper repairs are made, and the machine again operates normally.
- After service of the unit, always check to ensure that the blade inside the blade head is free to rotate prior to starting. If the blade does not rotate freely, it may cause the handpiece to rotate in the hand.
- Long or repeated use of vibrating instruments 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 may need replacement.
- Performance of the Universal Drive Unit can degrade in the presence of other activated electrical equipment.

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Unpacking & Assembly

Set-up

1. Connecting the power

- a. Connect the Universal Drive Unit power cord to the prescribed voltage on the drive unit nameplate. The drive unit must be connected to a grounded outlet. Use only approved type connector.

WARNING: Electrical shock may occur. Use only 3-wire ground type connectors of proper rating. This must be connected to a plant ground via a suitable grounded three conductor receptacle. See Technical Specifications for approved power cord ratings. Avoid use of this machine in standing water.

2. Placement of Universal Drive Unit

CAUTION: Correct installation is extremely important to achieve maximum efficiency for both the Amalgatome tissue processing system 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.



Figure a

- a. Place the Universal Drive Unit on a table or cart in the clean room for use. **WARNING:** Never cover the back of the unit and ensure the ventilation fan is not blocked. **WARNING:** Do not disassemble the Universal Drive Unit. Refer to the Troubleshooting section of this manual or return drive unit to Exsurco Medical.

3. Installation of Flexshaft Assembly



Figure b

- a. Install the Flexshaft Casing assembly to the Universal Drive Unit. Disconnect assembly by pushing the disconnect collar button 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.
- b. Release the disconnect button on the collar to secure the casing to the drive unit assembly. After installation, lightly pull casing to ensure connection is secure.

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Figure c: Drive end of Casing Assembly

- c. The casing assembly should swivel freely.



Figure d

- d. Draping Flexshaft and Casing. Drape the Amalgatome Flexshaft and Casing using a sterile probe/sleeve drape (available from a medical distributor). Insert the squared end of the Flexshaft into the sterile probe/sleeve drape where indicated by an arrow.



Figure e

- e. 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.

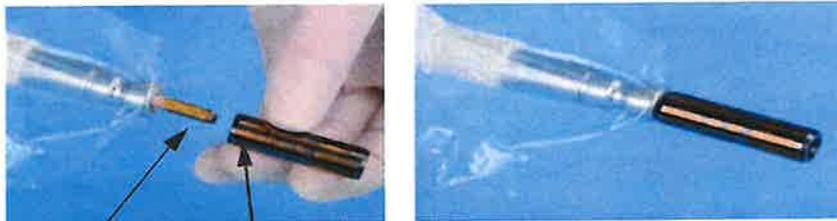
NOTE: If an assistant is available, the non-sterile area indicated with the hand symbol is where the assistant should pull the drape. This end is towards the motor. Mark the drape where the line of sterilization remains on the sterile field, or tape/secure the drape to keep from falling off the sterile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



Figure f

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4. Installation of Handpiece (Handle)



Square End of Flexshaft Assembly Drive Adapter *Figure g*

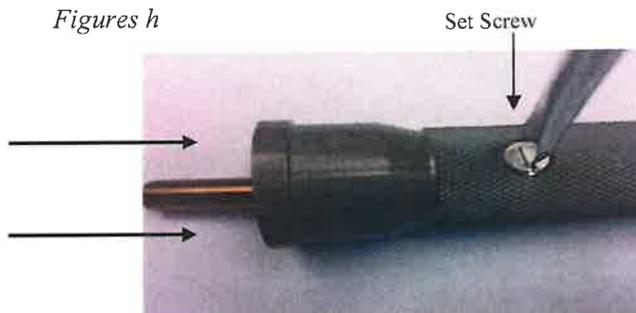
- a. Puncture through drape using the square end of the Drive Adapter. Align and place the square end of the Drive Adapter onto the square end of the Flexshaft Assembly.



Figures h

- b. Loosen set screw. 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.



5. Installation of Disposable Heads



Figure i

- a. 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.

NOTE: The Amalgatome Handle Assembly requires sterilization prior to use. Follow your organization's protocol for sterilization of surgical equipment.

Spring clip

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Figure j

- b. Press spring clip into external groove of disposable head.

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

CAUTION: Keep hands away from moving blade.

6. Installation of Foot Pedal



Figure k

- a. Attach foot pedal to Exsurco Universal Drive Unit by pressing foot pedal fitting onto the foot pedal outlet located on the front panel of the Universal Drive Unit.



Figure l

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

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c. Turn drive unit switch to the “ON” position. The green, Power LED will illuminate. GREEN means unit is on.

Figure m



d. Press foot pedal to activate Universal Drive Unit and operate tool.

Figure n

7. Transporting the Universal Drive Unit (UDU)

a. To properly transport the UDU, use the handle on the top of the unit

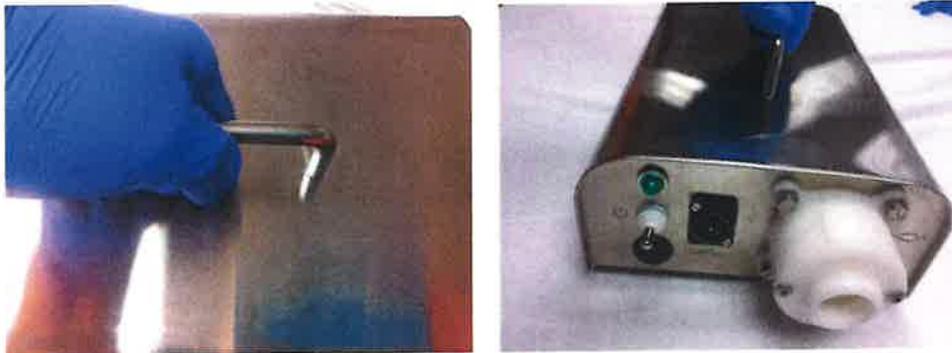


Figure o

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Operating Instructions

1. Operating Procedure



Figure p

- a. With the handpiece held in your operating hand and proper safety gloves on the other (the recommended safety glove is a chain mail/ mesh type cut resistant design), 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.
- b. Hold the handpiece naturally in the palm of the hand in a relaxed manner. You are now ready to put the Amalgatome SK Tissue Recovery Processing System into operation.
- c. Using the instrument 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.

NOTE: The Universal Drive Unit is suitable for use in a basic electromagnetic environment. Performance of the Universal Drive Unit could be degraded in the presence of other activated electrical equipment

NOTE: 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



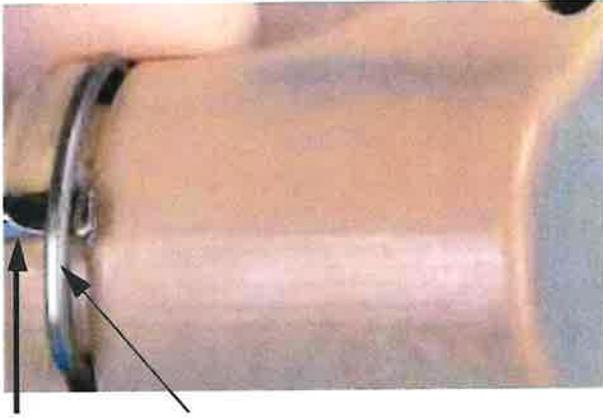
Figure q

- d. Turn on the drive unit switch. The green Power LED will illuminate. Press the foot pedal to activate drive unit and operate tool. Drive unit will stop when foot pedal is released. **CAUTION:** Keep hands away from moving blade.
- e. Move your hand and handpiece over your normal work area to ensure that there are no binds or sharp bends in casing. **WARNING:** Blades may cause serious injury. Never hold the allograft skin graft being processed in your hand. Always lay it flat on the work surface.

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

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2. Changing Disposable heads



Screwdriver Spring clip

Figure r

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

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

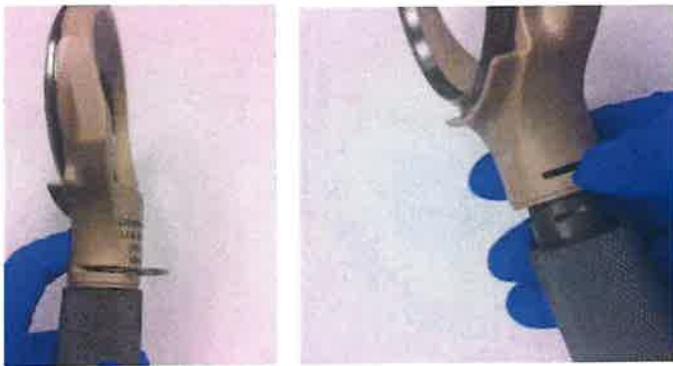


Figure s

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

3. Training requirements for user

- a. All technicians using the Amalgatome SK and Universal Drive Unit system for tissue processing must be familiar with operating the device and receive instruction from trained operators.
- b. All users should be familiar with the user guide provided with the purchase and accessible online on the Exsurco Website: www.exsurco.com.

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Cleaning & Sterilization Instructions

The Amalgatome Handle Assembly Assemblies require sterilization prior to use. Follow your organization's protocol for sterilization of surgical equipment.

1. Universal Drive Unit (UDU)
 - a. Ensure the unit is unplugged.
 - b. Using a hospital grade disinfectant cleaning solution on a cloth or towel, completely wipe the outside of the UDU.

NOTE: Do not immerse drive unit in cleaning solution and sterilize Drive Unit in an autoclave. Do not clean unit with saline solution. These procedures will cause damage to the drive unit.

- c. After disinfection is complete and drive unit is dry, check for any malfunction and place in appropriate storage area.

2. Flexshaft and Casing



Figure 1

- a. The casing should be cleaned and inspected before each use.

- b. Make sure the unit is unplugged.

NOTE: Flexshaft and Casing are not to be immersed in liquid at any time.

- c. Using a hospital grade disinfectant cleaning solution on a cloth or towel, completely wipe the outside of the casing.

- d. After disinfection is complete and Flexshaft and Casing are dry, check for any malfunction and place items in appropriate storage area.

NOTE: 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. When used, Flexshaft and Casing should be draped with a sterile probe/sleeve cover prior to use in a clean room.

- e. Interior casing may be cleaned if needed. Tie a small piece of dry cloth to a thin wire and pull through.

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

3. Handle Assembly (With Set Screw and Drive Adapter)
 - a. Make sure the instrument is completely disassembled.
 - b. The handle, set screw, and Drive Adapter can be immersed. Using a hospital grade disinfectant cleaning solution, follow your organization's protocol for surgical equipment.
 - c. After washing is complete and handle, set screw, and Drive Adapter are dry, check for any malfunction.

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Package and sterilize handle, set screw, and Drive Adapter following your organization's protocol for sterilization of surgical equipment.

4. Foot Pedal
 - a. Make sure that unit is unplugged.
 - b. 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. These procedures will cause damage to the foot pedal and electrical cord.

- c. After the washing is complete and pedal and electrical cord are dry, check for any malfunction and place items in appropriate storage area.
5. Disposable Head Assembly Kit
 - a. Do not reuse or resterilize the Amalgatome SK disposable heads after they have been used.
 - b. The Amalgatome SK Head Assembly is single-use.

NOTE: Any unused, single-use instrument must be discarded.

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Maintenance & Inspection Instructions

1. Flexshaft Maintenance

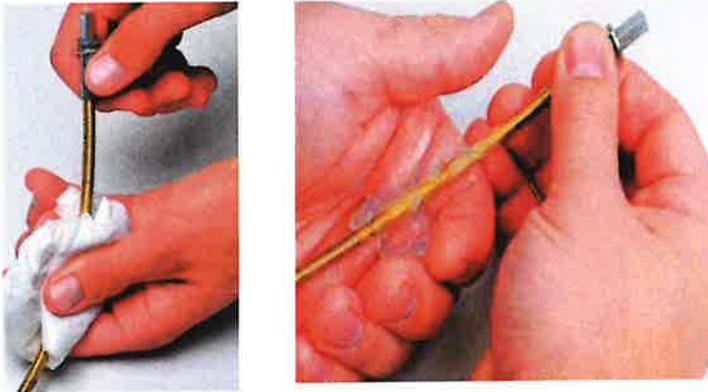
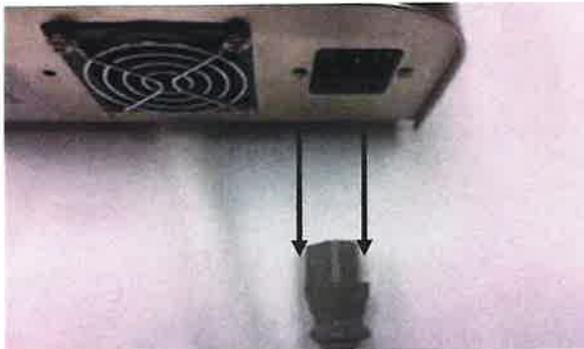


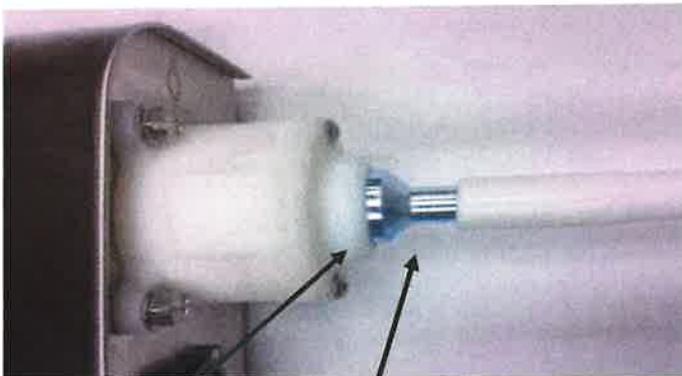
Figure u

- a. Clean the Flexshaft after 20 hours of operation by wiping with a dry cloth to remove any grease.
- b. Ensure that the Flexshaft washer is installed under the ferrule during reassembly.
- c. Place a small quantity of 100% pure petroleum jelly in the palm of your hand and pull the shaft through your clenched hand.
- d. Inspect the casing support for wear, cracks or chips.

2. Universal Drive Unit Maintenance



- a. Remove the power cord from the power source, then remove the power cord from the unit.



Disconnect Assembly Flexshaft Casing

Figure w

- b. Periodically check the condition of the Flexshaft Casing to motor disconnect location.
- c. Ensure the balls move freely and the casing rotates freely in the disconnect location and the shaft disconnect button fully rebounds after being pressed.

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3. Replacement of the Main Power Cord

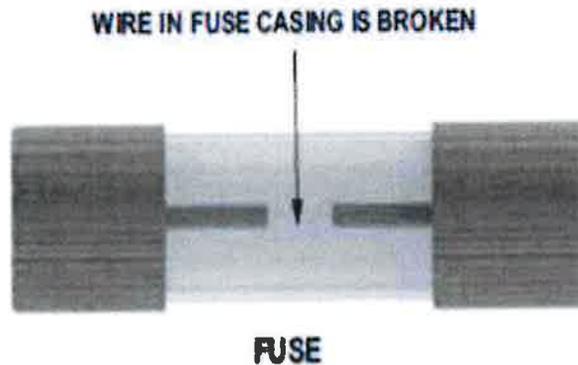
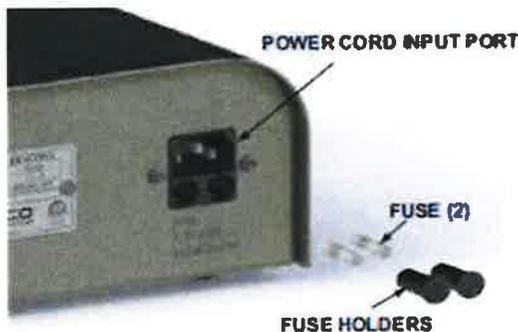
- a. Inspect the outer cord casing prior to every use.



Figure x

NOTE: If the outer cord casing has nicks that expose internal wires, cord must be replaced.

4. Replacement of fuses



- a. Turn power switch to the OFF” position and unplug the power supply from the electrical outlets.
- b. Locate the fuse holders (2) below the power cord input port on the back of the power supply.
- c. Insert flat bladed screwdriver into fuse holder slot and turn counter-clockwise until fuse folder ejects from power supply.
- d. Pull fuse from the fuse holder.
- e. Inspect both fuses to see if they are blown. Visually check if the fuse is blown by checking if the wire in the fuse case is broken.
- f. If it is confirmed the fuse if broken, insert new fuse (Part #: X100276) into fuse holder and install into power supply. Insert flat bladed screwdriver into fuse holder slot and turn clockwise.

5. Disposal of Universal Drive Unit

- a. If the Universal Drive Unit is being discarded, it cannot be discarded in the trash. The UDU must be taken to an approved Electronics Disposal Facility for disposal.

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Troubleshooting

This section describes general troubleshooting information, including solutions to potential problems.

Use the following assessment steps to confirm proper operation of the Amalgatome SK Tissue Processing System. If you discover a problem with any of these items, do not use the system; return it to Exsurco Medical for service. For additional information, refer to the Warranty, Service, and Returns section.

NOTE: UDU is an abbreviation for: Universal Drive Unit.

1. Visually inspect the system for any signs of physical damage or wear:
 - a. Loose parts
 - b. Missing or loose screws
 - c. Signs of being dropped or bent
 - d. Areas with corrosion or pitting

Problem	Probable Cause	Possible Solution
Handpiece Vibration	<ul style="list-style-type: none"> • Inside of Flexshaft Casing worn • No lubrication on Flexshaft or casing 	<ul style="list-style-type: none"> • Replace Casing • Clean and lubricate Flexshaft and Casing as described in the Maintenance and Inspection section of this manual.
	<ul style="list-style-type: none"> • Improper cleaning and lubrication of Flexshaft and Casing • Mechanical bind in handpiece 	<ul style="list-style-type: none"> • See Maintenance and Inspection Section of this manual. • With handpiece removed from Flexshaft, blade should rotate freely by hand. Correct any mechanical bind.
Blade Skips or Will Not Rotate	<ul style="list-style-type: none"> • Casing not fully engaged or inserted 	<ul style="list-style-type: none"> • Make sure the casing is fully inserted to the drive position
	<ul style="list-style-type: none"> • Flexshaft worn 	<ul style="list-style-type: none"> • Replace Shaft
	<ul style="list-style-type: none"> • Motor Adapter worn 	<ul style="list-style-type: none"> • Replace Adapter
	<ul style="list-style-type: none"> • Loose ferrule on shaft • Blade not cutting or fitting properly 	<ul style="list-style-type: none"> • Replace Shaft • Replace with new blade
Motor Will Not Run	<ul style="list-style-type: none"> • No power to motor 	<ul style="list-style-type: none"> • Check fuses. If fuses are ok, return UDU to Exsurco for service.
Motor Operating with Excessive Noise	<ul style="list-style-type: none"> • Bad bearing in motor 	<ul style="list-style-type: none"> • Return UDU to Exsurco for service.

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Warranty, Service, and Returns

This section describes the limited warranty, service requirements, and returns policy.

Limited Warranty

Exsurco Medical (“Exsurco”) warrants that each new Amalgatome SK Tissue Processing System and its components have been tested and inspected and have left the facility in proper working condition.

- The Amalgatome SK Tissue Processing System is guaranteed to be free from defects in material and workmanship when maintained by the customer, properly cleaned, and used under normal circumstances for its intended purpose. Exsurco warrants the product for a period of one year from date of delivery to the customer.
- The sterile, disposable product is not warranted beyond the expiration date stated on the product labeling.

During the warranty period, Exsurco shall repair, or at its sole opinion, replace the defective product or part without cost incurred to the customer. Defective parts replaced under this warranty shall become the property of Exsurco. This warranty does not cover damage caused by misuse, abuse (dropped or damaged), accident, neglect, or any use not prescribed in this user guide. If the system becomes defective because of misuse or abnormal conditions of operations, these repairs shall be charged to the customer. All products returned for warranty or non-warranty repair must be through the Exsurco return procedure. For more information, refer to the Returns section below. In no event shall Exsurco be liable for any incidental, indirect, consequential, or punitive damages in connection with the acquisition or use of Exsurco product. Further, this warranty shall not apply to, and Exsurco shall not be responsible for, any loss or damage arising in connection with the purchase or use of Exsurco product that has been repaired by anyone other than Exsurco, or altered in any way so as to, in the judgment of Exsurco Medical, affect the usability or reliability of the product. If this happens, the product repairs shall be charged to the customer. This limited warranty is exclusive and in lieu of all other warranties, express or implied, and of all other obligations or liabilities on Exsurco’s part, and Exsurco neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with this product.

Exsurco disclaims all other warranties, express or implied, including any implied warranty of merchantability or of fitness for a purpose or application or warranty of quality as well as any express or implied warranty to patients.

The Exsurco Medical Amalgatome SK Tissue Processing System is intended for use only with the Amalgatome SK disposable head assembly. Using another manufacturer’s blades in conjunction with the Amalgatome SK voids the product warranty.

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Service

The Amalgatome SK Tissue Processing System contains no serviceable parts, only individual replacement parts as defined in Appendix B. The system must be returned to Exsurco Medical for servicing. Exsurco Medical performs all repairs in-house by our trained Technical Service team.

NOTE: Exsurco Medical cannot be held liable for any system malfunctions resulting from repairs or service performed by anyone other than Exsurco Medical.

Do not attempt to open or disassemble the Universal Drive Unit. It is a factory-sealed unit with no user serviceable parts inside. If this occurs the warranty is voided, and the customer must return the Universal Drive Unit to Exsurco Medical for repair that shall be charged to the customer.

Exsurco Medical performs all service of the Amalgatome SK Tissue Processing System.

Our Technical Service Department can be contacted at 1-800-243-6049, or email support@exsurco.com to answer any general questions that relate to the operation, warranty, and service of the system.

Returns

When it is necessary to return the Amalgatome SK Tissue Processing System for warranty service, or non-warranty service, please contact Customer Service at 1-800-243-6049, or email support@exsurco.com to receive a Return Material Authorization (RMA) or Service Repair Order (SRO).

Product will not be accepted without an RMA/SRO. Exsurco Medical shall provide the customer with the approved return shipping container. The customer is responsible for the return freight.

When the customer is returning the system, we require proof of cleaning documents upon receipt of the RMA or SRO. If proof of cleaning is not included with the product, the product shall be returned to the user. Exsurco Medical does not accept product that has been used without being cleaned first or has not been shipped with the appropriate documents. If it is a new product or has not been used, then Customer Service shall note that on the RMA/SRO documentation.

While the system is at Exsurco Medical for repair, a loaner if available can be requested and shipped to the customer. Please confirm this with Customer Service at time of the return request.

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Upon receiving returned product at Exsurco Medical, the product is reviewed by our Technical Service Department. Customer Service shall provide the customer with a service estimate for any repairs not covered under warranty or extended warranty. Exsurco Medical performs all product service on-site in our Technical Service Department.

When product is ready for shipment back to the customer, Exsurco Medical covers the freight and returns the product in an approved protective shipping container.

Exsurco Medical is committed to the quality of our products. Should you have a complaint or not be completely satisfied with your product, please call our Customer Service team to register a complaint. Our Customer Service team is available Monday through Friday, 8 am to 5 pm ET and is here to assist you in any way. Email support@exsurco.com or call 1-800-243-6049. To help investigate the event further, we require the following information:

- Name, address, and account number
- Phone number and email address
- Part/product that the complaint is being filed on
- Serial number (equipment) or lot number (disposable)
- A description of the event. Be as descriptive as possible and provide pictures, if available.
- Loaner requirements if available upon request

Once a complaint is received, we may contact you for more information. When the product is returned, a preliminary evaluation is conducted, and the product is repaired (if required) and restored to conformance prior to being shipped back. A closure letter shall be provided advising you of the outcome of the investigation regarding the complaint.

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Appendix A: Technical Specifications

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



Specifications

Specification	Value
Supply Voltage, Frequency and Power Rating.	<ul style="list-style-type: none"> • 115VAC ±10%, 1 Phase, 1.6 A, 60Hz • 230VAC ±10%, 1 Phase, 0.8 A, 50Hz
Overall dimensions and weight	<ul style="list-style-type: none"> • (Including Power Cord and Foot Pedal) 12.4 lbs. (5.6 kg) • 4 1/4" High x 8" Wide x 12 3/4" Deep • (108mm) x (203mm) x (324mm)
Description of all input and output connections:	<ul style="list-style-type: none"> • Power Cord/Universal Drive Unit: Supply Power (VAC) • Foot Pedal/Universal Drive Unit: 24VDC • Driveshaft/Universal Drive Unit: Mechanical
Sound level during normal use	<ul style="list-style-type: none"> • Below 70dB
Level of vibration during normal use	<ul style="list-style-type: none"> • Less than 2.5 m/s²
Environmental Conditions for instrument operation	<ul style="list-style-type: none"> • 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 • Pollution Degree 2 (Only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is expected).
Foot pedal cord and Power cord insulation ratings	<ul style="list-style-type: none"> • Power Cord (North America): 60°C MIN, 10A-125V, SJT or SJTW • Foot Pedal Cord: 90°C, 300V, FT2
Duty Cycle	<ul style="list-style-type: none"> • Continuous
Fuse Information	<ul style="list-style-type: none"> • 5x20mm Cartridge Fuse, 1.25 A, 250 VAC, Time Delay/Slow Blow *Note: MUST USE Exsurco Fuse Part # X100276
Overvoltage Category	<ul style="list-style-type: none"> • Overvoltage Category II

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Appendix B: Parts Information

Description: Exsurco Amalgatome SK Tissue Processing System

Quantity	Part #	Description
X100431 Amalgatome SK Kit:		
1 each	X101453	Universal Drive Unit (including Foot Pedal and Power Cord)
1 each	X100060	Aluminum Handle Assembly (Including Drive Adapter & Handle Screw)
1 each	X100065	Flexshaft
1 each	X100064	Flexshaft Casing
1 each	X100894	Amalgatome SK User Guide
Individual Replacement Parts:		
1 each	X101440	Rubber Feet
2 each	X100276	Time Delay/Slow Blow Cartridge Fuse - 5x20mm Size, 1.25A, 250VAC
1 each	X100063	Handle Screw
1 each	X100062	Drive Adapter
1 each	X101421	Foot Pedal
1 each	X101719	9'10" Power Cord (North America)

Individual, Single Use Blade Cutting Heads Sold Separately:

Quantity	Part #	Description
10/box	X101835	Sterile, Single Use Blade Head

To place an order for the Amalgatome SK Tissue Processing System, please contact our Customer Service department at 1-800-243-6049, or email support@exsurco.com. For a price quote and all product-related questions, please contact your local Exsurco Medical sales representative or contact our Sales department at 1-800-243-6049, or email sales@exsurco.com

To order replacement components separately, please contact Customer Service at 1-800-243-6049, or email support@exsurco.com.

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Appendix C: Glossary of Symbols

Symbol	Definition	Symbol	Definition
	Serial Number	NON-STERILE	Symbol indication that the system has not been sterilized.
	Batch Code/Lot Number		Do not reuse. Single use, use only once.
	Manufacturer		Caution
	Use by date. This symbol is intended to indicate that the system should not be used after the end of the date shown.		Consult instructions for use
	Symbol for method of sterilization using radiation.		General warning sign
	Keep product dry		Fuse of specified type, current, and voltage rating
	Do not use if package is damaged		Presence of electricity
	This side up		Read operator's manual
	Sharp object		Protective safety gloves (like chain mail or mesh) must be worn

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Symbol	Definition	Symbol	Definition
	Product tested to FCC EMC requirements		Flexshaft input location
	Product to be discarded at an approved electronics disposal facility		Power standby switch. Power ON is up
	Product meets applicable safety requirements for EU market	CAN ICES-3 (A)/NMB-3(A)	Product tested to Canadian EMC requirements
	Normally open foot switch		

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Contact Information

Please refer to the information below for contacting Exsurco Medical directly for any of your questions, comments, or concerns about the Amalgatome SK.

Phone: 1-800-243-6049

Website: www.exsurco.com

Sales & Clinical Support: sales@exsurco.com

Marketing & Product Inquiries: info@exsurco.com

Customer Service or to Report a Quality Concern: support@exsurco.com.

System or Technical Service: support@exsurco.com

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