Amalgatome® MD Split Thickness Tissue Recovery System and Sterilization Tray User Guide

EXSURCO MEDICAL
10804 GREEN ROAD
WAKEMAN, OH 44889

PN: X100573 REV. H

This page intentionally left blank.

AMALGATOME® MD & STERILIZATION TRAY USER GUIDE

Instructions for Use

REDEFINING EXCISION SCIENCE

Exsurco Medical
10804 Green Road
Wakeman, OH 44889
1-800-243-6049
www.exsurco.com

NOTICE TO USERS

Read this user guide thoroughly paying attention to all warnings and precautions before using the Exsurco Medical Amalgatome MD System and Sterilization Tray. It is designed for use by trained tissue recovery and processing technicians. 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

This page intentionally left blank.

Table of Contents

Preface

Purpose

This user guide provides directions to help users safely and effectively operate the Amalgatome MD System. This guide also includes material such as indications for use, best practices, 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 power-operated excision equipment, used in the Tissue Bank, Processing, and Surgical markets. For more information contact Exsurco Medical at 1-800-243-6049 or via e-mail at info@exsurco.com.

This page intentionally left blank.

System Overview

This section provides general information about the Amalgatome MD System and Sterilization Tray.

Indications for Use

The Amalgatome MD is a split thickness tissue recovery product that is intended to provide variable graft thickness and width capabilities for Cadaveric Use only.

Description

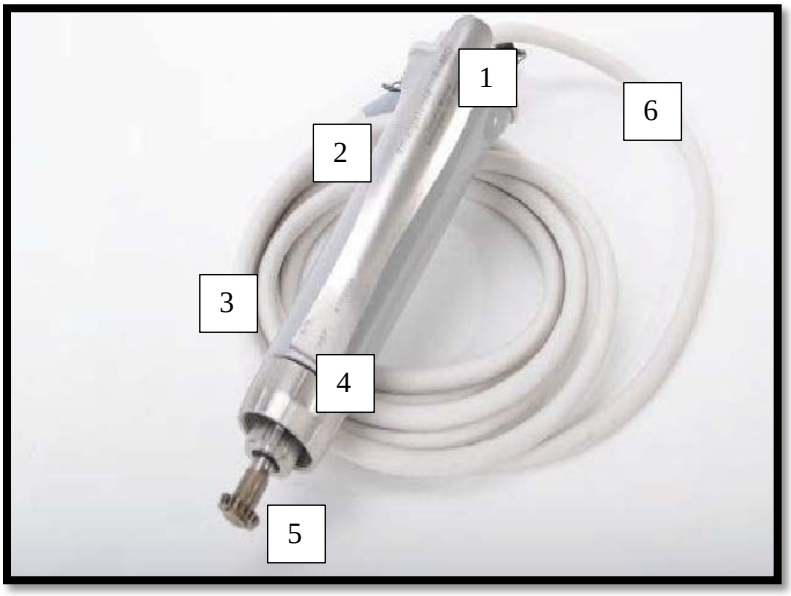
The Amalgatome MD Split Thickness Tissue Recovery system is electrically powered designed specifically for cadaveric tissue recovery procedures. It is intended for use on donors for recovery of allograft skin only by trained and/or certified professionals in tissue recovery. This instrument is designed for retrieving Split-Thickness Skin Grafts ranging between 0.005 inches to 0.040 inches (0.127 mm to 1.016 mm) in tissue recovery procedures.

Components

The Amalgatome MD Skin Recovery System and Sterilization Tray is comprised of the following components when you purchase an X100556 Amalgatome MD System:

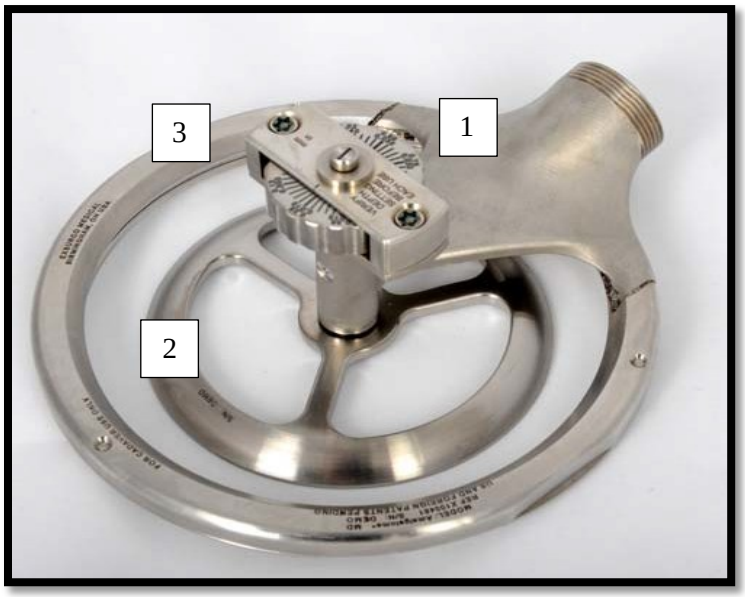
X100460 Handpiece Assembly

1.) Handle
2.) Activation Lever
3.) Locking Knob
4.) Locking Nut
5.) Pinion
6.) Handpiece Power Cord with Protective Cap



X100461 Head Assembly

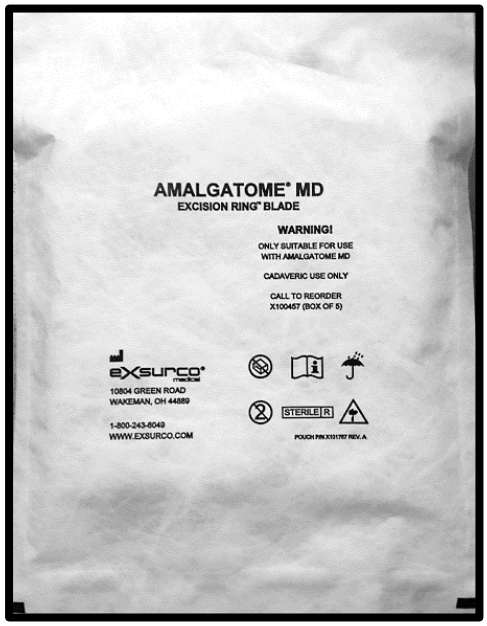
1.) Housing Frame
2.) Depth Gauge Assembly
3.) Blade Locking Ring with Three (3) Screws (screws to be left on ring always)

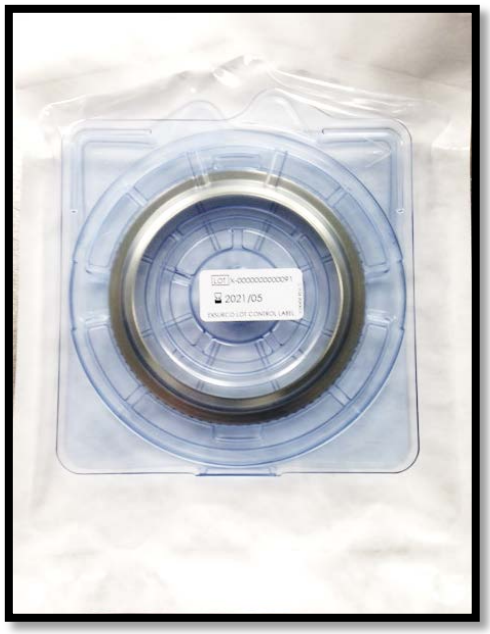


X100380 Power Supply

X100626 AMD Sterilization tray

X100457 Disposable Blade





This page intentionally left blank.

General Warnings, Precautions & Safety Features

This section provides general warnings and precautions about the Amalgatome MD System and Sterilization Tray.

Amalgatome MD Power Supply

- Front Panel: Caution: For Cadaveric Use Only. Do Not Autoclave.
- Rear Panel: Specification Plate Fuse 1.25 AMP Slow-Blow.
- Always disconnect the power cord before installing / removing disposable blades.
- Electrical shock may occur! Use only 3-wire ground type connector and grounded mains supply. Avoid use of or placement of power supply in standing water.
- Correct installation is extremely important to achieve maximum efficiency and skin recovery thickness for both the Amalgatome MD Split Thickness Tissue Recovery (Amalgatome MD) and the operator. Incorrect installation may possibly affect the operator's movements and cause undue wear or damage to equipment.
- Ensure the instrument is disconnected from the power supply before placing into the sterilizer. NEVER steam sterilize the power supply.
- Ensure cleaning cap is still in place on the power cord when removing from the power supply.

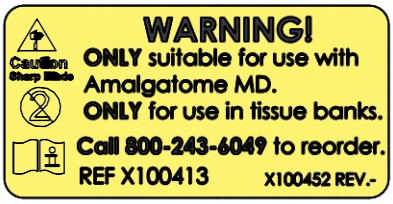
Amalgatome MD Head Assembly and Handpiece

- The Amalgatome MD Skin Recovery Instrument will not turn on unless the activation lever is held down, and the activation button depressed. If the activation lever is held down for 4-7 seconds with no press of the activation button, the instrument will deactivate, and the activation lever must be released to reset the instrument.
- Releasing the activation lever will deactivate the instrument.

Amalgatome MD Head Assembly Depth Gauge

- Verify depth setting before each use.
- Always set depth gauge to the position where the dial reads 0.005 inches (0.127 mm) before installing or removing disposable blade.
- Verify that the disposable blade has been properly inserted and tightened before Instrument activation to avoid possible injury.

Amalgatome MD Disposable Blade and Blade Package



- Caution Sharp Blade Symbol
- Do not reuse Symbol
- Read instructions Symbol
- Sharp blades may cause cut injury. Use extreme caution when handling.
- Always set depth gauge to the position where the dial reads 0.005 inches (0.127 mm) before installing or removing disposable blade.
- Verify expiration date and package integrity prior to opening sterile blade

Amalgatome MD Sterilization Tray

- Do not add other instruments to the Amalgatome MD Sterilization Tray. Areas designated for specific components shall contain only components specifically intended for these areas.
- The sterilization tray is only compatible with the Amalgatome MD Skin recovery product and has not been validated for use with any other product.
- Do not use the sterilization tray that is damaged or has signs of cracking, flaking, peeling is fractures, brittle or deformed in any manner.
- Do not load filled sterilization container into sterilizer on sides or upside down. Lid should always face upwards and do not stack trays.
- Do not place more than 1 Amalgatome MD product into sterilization tray at a time.
- Do not use the product if the external CSR Wrapping has been compromised, ripped, torn. etc.
- Do not use a sterilization tray if the lid does not securely latch to the base.
- Always follow this user guide for safe handling of the Amalgatome MD and container.
- The sterilization tray is intended to be used with approved, legally marketed, FDA approved sterilization wrap.
- After sterilization, do not immerse in liquid to cool. Cool tray with product inside by exposure to room temperature or cover with a cold, sterile towel until cool to the touch for use.
- Do not use the Amalgatome MD Sterilization Tray as a shipping container. Use approved transportation case provided at the original shipment of the system or contact Exsurco Medical Technical Service Department to have packaging materials sent. Refer to Section for Instrument Requiring Technical Service.

Operator Safety

- Please read and understand these operating instructions before attempting to assemble, install, operate or maintain this instrument. Failure to comply with instructions could result in personal injury and/or damage to the equipment. Read this entire manual before using this equipment.
- Any use in applications other than those for which the equipment was designed and built may result in equipment damage, void the warranty and/or cause serious injuries.
- Retain this manual for future reference.
- This document in part or its entirety may not be reproduced in any form or means, for any purpose, without the express written permission of Exsurco Medical. Written permission to reproduce in whole or part is herewith granted to the legal owners of the Amalgatome MD Split Thickness Tissue Recovery System with which these operating instructions have been supplied.
- Information in this document is subject to change without notice. Check the Exsurco Website for most current revision @ www.exsurco.com
- Additional copies of operating instructions are available by visiting our website or contacting customer service by phone at (800) 243-6049 ext. 2 or email info@exsurco.com.

Physical Condition

- Do not operate equipment while under the influence of alcohol, medication, or any other substance that can impair judgment, reflexes, vision, or coordination. Operating a unit while impaired can result in serious injury to the operator and bystanders, or cause damage to property or equipment.

Training

- The Amalgatome MD Split Thickness Tissue Recovery System (Amalgatome MD) is to be used only by trained professionals who are familiar with its use and application. It is highly recommended that all users review the Amalgatome MD training video and document training.

Equipment

- After sterilization, do not immerse instrument in liquid to cool. Cool by exposure to room temperature or cover with a cold, sterile towel until cool to the touch for use.
- Process the Amalgatome MD system only one time in sterilization cycle after each use.
- It is the facility responsibility to follow the reprocessing procedure, including resources, materials and personnel, it suitable to achieve the required results. If the suggested cleaning, disinfection, and sterilization methods are not used, the user it obliged to validate their procedure accordingly.
- The manufacturer assumes no liability for any unauthorized changes in operating procedures or for unauthorized changes or modifications made to the design of the instrument or any factory-installed safety equipment, whether these changes are made by the owner of this equipment, by the employees, or by service providers not previously approved by Exsurco Medical. Any unauthorized changes will void the warranty.
- Correct installation is extremely important to achieve maximum efficiency for both the Amalgatome MD System being used and the operator. Incorrect installation may possibly hamper the operator's movements and cause undue wear or damage to equipment.
- Any use in applications other than those for which the Instrument is designed and built, may result in serious injuries
- Never connect the Amalgatome MD Handpiece to any source other than the Amalgatome MD Power Supply. It is specifically designed to optimize the performance of the Instrument.
- Never use the power supply cords or power supply for any other Instrument or Instrument. It is designed specifically for use with the Amalgatome MD only.
- Never connect the Amalgatome MD Head Assembly to any other source other than the Amalgatome MD Handpiece.
- Always inspect entire system prior to use.

Accessories

- Exsurco products are specifically designed and manufactured for use only with Exsurco accessories and disposables.
- Accessories designed by other manufacturers have not been tested by Exsurco and are not recommended for use with our product.

Operation

- Personal Protective Equipment (PPE) should be worn and follow facility protocol.
- Do not use this instrument in standing water.
- If at any time this Instrument does not appear to operate as intended or exhibits a marked change in performance, it should be immediately powered down, unplugged, and taken to returns/ facility designated area for a return to Exsurco for inspection.
- 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.
- If the Amalgatome MD System develops unusual vibration, refer to Troubleshooting. If that does not satisfy the problem, return to Exsurco for inspection.
- Sharp blades may cause cut injury. Use extreme caution when handling.
- To avoid personal injury, always disconnect the power cord before installing / removing disposable blade, disassembly / assembly, troubleshooting or cleaning.
- Amalgatome MD System Disposable Blades are single-use only. Do not reuse or resterilize.
- Used sharps are contaminated. Disease may occur from contact or injury. Dispose of Amalgatome MD Blades n puncture-resistant bio-hazard sharps container. Refer to AORN, CDC, OSHA or local standards setting organizational guidelines for handling and disposal of sharps.
- No other blade can be used with this Instrument. Only part number X100457, sterile blade is approved for use with the Amalgatome MD.

Replacement Parts

- 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 provided by Exsurco Medical may cause blade lock-up, resulting in an unsafe operating condition.
- Exsurco Medical 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 equipment, by facility, or by service providers not previously approved by Exsurco Medical. This will void the warranty.
- 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”.

Unpacking & Assembly

Inspection of Instrument

- After receiving the Amalgatome MD System, examine for external signs of damage. Keep transportation case to ship instrument to Exsurco Medical for repair. Retain all packing material until the contents have been verified and an initial operational check has been performed. If the instrument has been damaged, contact Exsurco Medical for return authorization information.

Sterilization of Contents

- New and used Amalgatome MD Systems must be thoroughly processed according to the disassembly, cleaning, and sterilization instructions in this manual.
- Systems are supplied visually clean, but not are not sterilize. The customer is responsible for cleaning and sterilization of the System prior to use. Refer to section on Disassembly, Cleaning & Sterilization (p.27).

Set-up Handpiece and Head Assembly

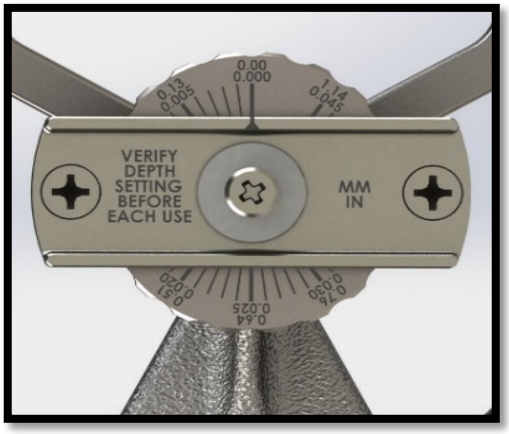
The Amalgatome MD System will be shipped with the handpiece and head assembly individually pre-assembled. Once received, detach the head assembly for sterilization. Refer to section on Disassembly, Cleaning and Sterilization. When unit is sterilized and ready for use, open sterilization tray containing the Amalgatome MD on the sterile field to prepare the set-up of the product. The operator will need to assemble the handpiece and head assembly to operate the instrument.

1.) Insert the pinion end of the handpiece into the housing / frame on the head of the instrument, making sure to align the key and slot.

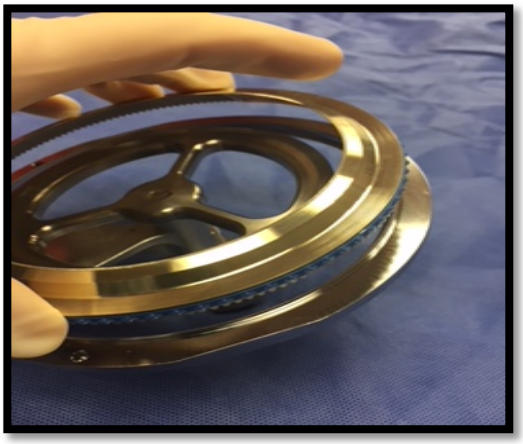
2.) With the handpiece in an upright position (direction shown below), hand tighten the locking knob until it stops.

Disposable Blade Installation

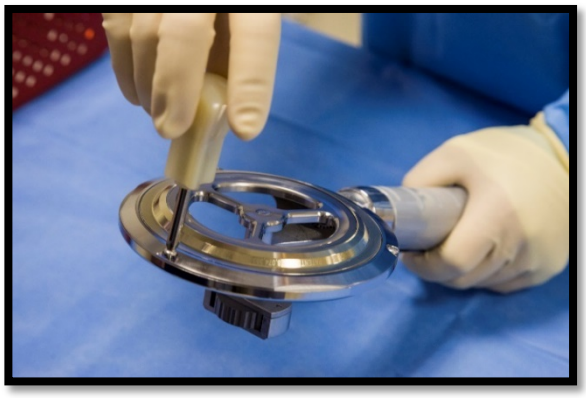
1.) Set depth gauge to the closed position (0.005 inches, (0.127 mm)) before installing disposable blade.



2.) Turn the instrument lever side down, then place the disposable blade into the housing / frame. Follow facility protocol for opening and loading blade into frame. Slightly turn the blade to ensure proper seating and gear tooth engagement.



3.) Place the blade locking ring onto the housing frame, lining up the screws with the screw holes on the housing / frame. Tighten into place using the provided screwdriver. **NOTE:** Do not over tighten screws. Finger tight only. **NOTE:** The three (3) screws should remain captive in the blade locking ring always.



Amalgatome MD Power Supply

1.) Place the Amalgatome MD Power Supply on a table or cart outside of the sterile field. Ensure the power supply is on a stable, secure surface to prevent dropping onto the floor.

2.) Make sure cord is not pulled taut to prevent dropping unit. It can be draped with a sterile cover, but not required.

3.) Connect the power supply power cord to the prescribed voltage on the specification plate.

4.) The power supply must be connected to a ground. Use only approved type connector. Make certain the power switch is in the "OFF" (0) position.

Connecting the Amalgatome MD Power Supply to the Handpiece Power Cord

5.) Remove the protective cap from the end of the handpiece power cord and plug it into the power supply by aligning the red dots.

6.) Turn the power supply power switch to the "ON" (I) position. The Amalgatome MD System is ready for use.

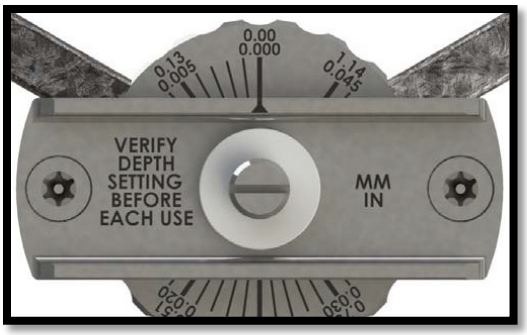
Operating Instructions

Depth Gauge Settings

The depth gauge allows the user to control skin thickness. Adjust the depth setting to the desired thickness by turning the depth adjustment knob. Settings on the depth adjustment knob indicate increments of 0.001 inches (0.0254 mm) and will cover a range of 0.005 inches to 0.040 inches (0.127mm to 1.016mm).

The Amalgatome MD Depth Gauge is designed to have a functional range of 0.000 inches to 0.045 inches (0.00mm to 1.14mm). However, the recommended allograft recovery depth range settings are 0.005 inches to 0.040 inches (0.127mm to 1.016mm). Recovering allograft skin grafts within the 0.005 inch to 0.040-inch (0.127mm to 1.016mm) depth range ensures allograft skin graft accuracy to the setting reflected on the depth adjustment knob. Always set depth gauge to the closed position (0.003 inches, 0.0762mm) before installing or removing disposable blade.

NOTE: It is the user's responsibility to be properly trained. User must understand depth gauge settings and know the depth adjustment knob controls the depth of the allograft skin graft.

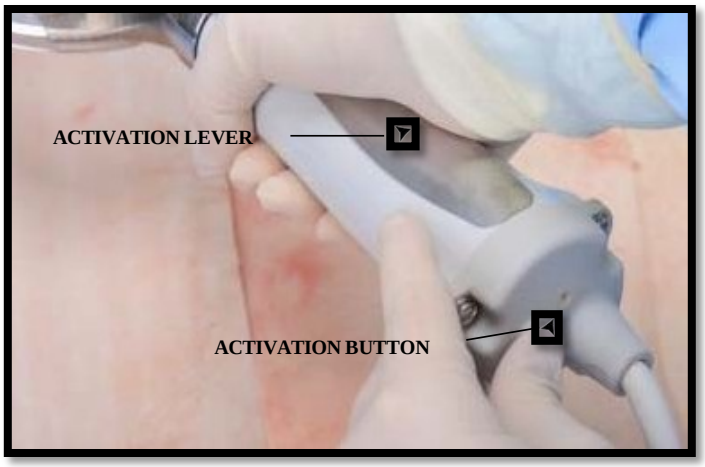


Activating the Amalgatome MD

1. Place the power supply switch into the **"ON** "position.

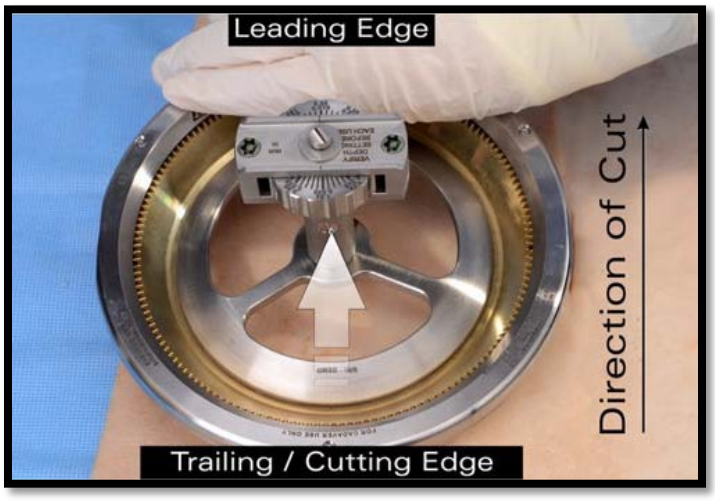
2. When ready to operate the Amalgatome MD, press the "Activation Lever" down onto the handle. This will put the instrument in "READY" mode.

3. While the "Activation Lever" is depressed and a firm grip is kept on the instrument, press the "Activation Button" located on the end of the handpiece next to the power cord. This will cause the blade to rotate. **NOTE:** If the instrument is not activated within 4-7 seconds, the lever must be released and re-engaged to reset the "READY" timer. This is for safety purposes and does not allow the Instrument to be accidentally activated if set lever-side down. Releasing the lever will deactivate the instrument.



Allograft Skin Graft Recovery

1. Lubricate the donor skin graft site with sterile mineral oil to decrease blade drag through the tissue. **NOTE:** There is a 15° angle built into the handle, so the operator does not need to hold the Amalgatome MD Head Assembly at an angle to recover an allograft skin graft. **NOTE:** The instrument cuts with the trailing edge of the blade. Pressing down on the leading edge may lift the cutting edge away from the desired recovery site.

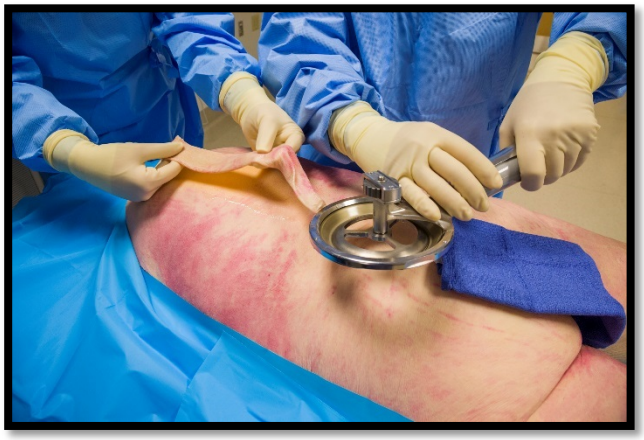


2. Place the head of the instrument at the desired starting point, using a slight downward pressure to ensure the cutting edge of the blade maintains contact with the recovery site. Only light pressure is required

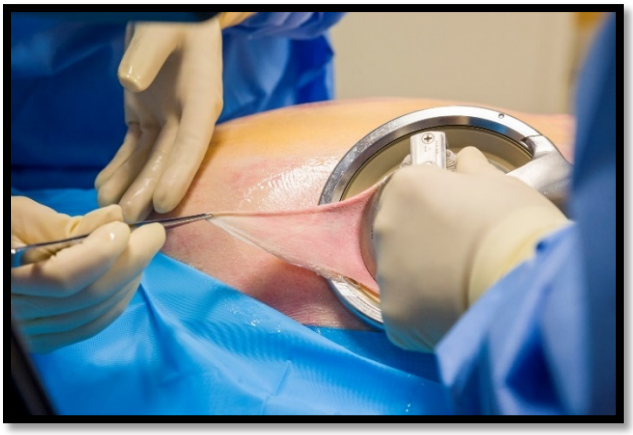
3. Once the cutting starts, move the instrument head in the desired direction. Maintain a steady speed to ensure desired graft thickness and width is recovered.

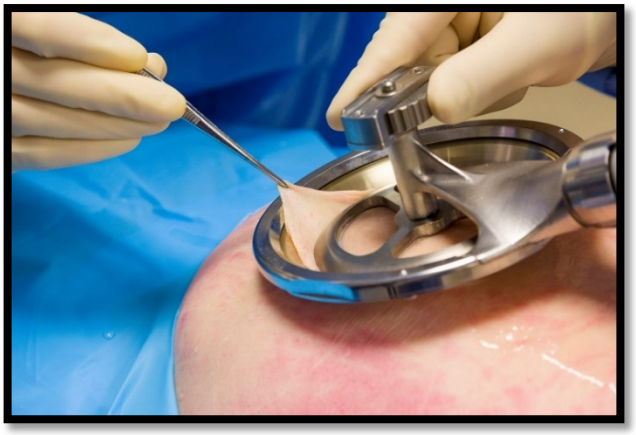
4. As the allograft skin graft emerges from the instrument head, the following options can be used to collect the recovered graft:

OPTION #1: Allow the allograft skin graft to lie along the recovery site. When recovery is complete, lift the instrument head off the site. Lift the graft away and place into appropriate collection container.



OPTION #2: Use forceps to gently lift the allograft skin graft as it emerges from the instrument head. Do not stretch or pull the graft.





5. Lift the instrument head off the recovery site once the desired graft is obtained.
6. Repeat steps until all desired grafts are recovered.
7. At the completion of the procedure, refer to section on Disassembly, Cleaning, & Sterilization.

This page intentionally left blank.

Maintenance & Inspection

Amalgatome MD Inspection Checklist

- ✓ Inspect system prior to each use.
- ✓ Do not attempt to disassemble or lubricate the handpiece. It is a factory sealed unit.
- ✓ Inspect for cuts or nicks on the cord insulation from mishandling and if present do not use.
- ✓ Inspect the instrument for mechanical defects that could affect performance or processing.
- ✓ Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
- ✓ Check to ensure that the depth gauge on the head assembly has not been taken apart for any reason. If disassembled, it will affect the ability of the instrument to cut at the specified donor skin thickness.
- ✓ If damage or wear is noted that may compromise the function of the system, do not use. Return to Exsurco Medical for inspection and repair.

Amalgatome MD Power Supply

- ✓ Inspect prior to each use.
- ✓ Do not attempt to disassemble the power supply. It is a factory sealed unit.
- ✓ Always inspect the power cord for cuts or nicks in the cord insulation from mishandling and if present do not use the power supply.
- ✓ Do no attempt to adjust or repair power supply. If damage or wear is noted that may compromise the function of the power supply, do not use. Return to Exsurco Medical for inspection and repair.
- ✓ Do not attempt to remove the cover from the power supply. Doing so will expose the components that are considered hazardous live when power supply is plugged into supply mains.

This page intentionally left blank.

Troubleshooting Guide

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

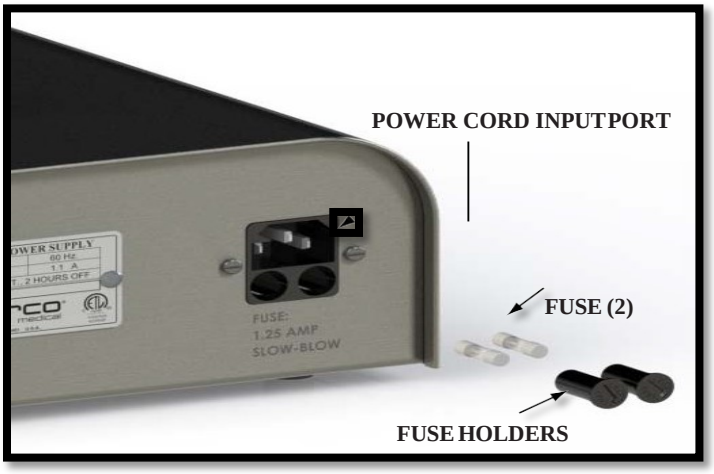
Use the following assessment steps to confirm proper operation of the Amalgatome MD System. If you discover a problem with any of these components, do not use the system; return it to Exsurco Medical for service. For additional information, refer to the Warranty, Service, and Returns section.

Exsurco also offers a comprehensive video library containing step by step operation and troubleshooting information. This training tool is available online https://www.exsurco.com/amalgatome-md-training-instructions/.

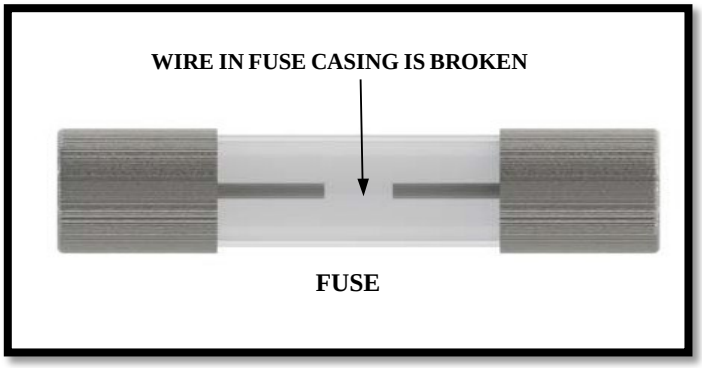
Problem	Possible Solution
Power supply not operating:	• Check power cord connections
	• Turn power supply OFF (O) for 10 seconds then turn back ON (l)
	• Check power supply for blown fuse
	• Return for service
Handpiece not operating:	• Check blade fit
	• Check handpiece connection to power supply
	• Attempt with another Amalgatome MD Blade
	• Return for service
Handpiece will not turn on	• Ensure all connections are in place and power is switched “ON” (I)
	• Release and re- engage the Activation Lever, pressing the Activation Button within 5 seconds of re-engagement
	• Examine the Instrument for defects
	• Return for service
Operating “too slow”	• Check handpiece connection to power supply
	• Lubricate the recovery site with mineral oil to decrease blade drag through the tissue
	• Return for service
Blade will not fit into housing/frame	• Attempt with another Amalgatome MD Blade
	• Notify Exsurco Medical
Blade cutting poorly	• Attempt with another Amalgatome MD Blade
Blade locking ring does not fit flush against housing / frame	• Check parts for defects
	• Return for service
Vibration	• Return for service

Amalgatome MD Power Supply Fuse Replacement

1. Turn power switch to the “OFF” (0) position and unplug the power supply from the electrical outlet.
2. Unplug the handpiece power cord from the power supply.



3. Locate fuse holders (2) below the power cord input port on the back of the power supply.
4. Insert flat bladed screwdriver into fuse holder slot and turn counter-clockwise until fuse holder ejects from power supply.
5. Pull fuse from the fuse holder.
6. Inspect both fuses to see if they are blown. Verify that the very fine wire in the fuse casing is broken.



7. Insert new fuse (Part Number X100525) into fuse holder and install into power supply. Insert flat bladed screwdriver into fuse holder slot and turn clockwise

This page intentionally left blank.

Disassembly, Cleaning, & Sterilization

Preparation at the Point of Use

- Follow recommended “Point of Use” practices. These practices should include keeping the instrument moist after use to prevent soil from drying, and removing gross soil from surfaces, crevices, and hinged/mating surfaces as soon as possible after use.
- Blades are SINGLE-USE ONLY.
- Discard disposable blade in a puncture-resistant bio-hazard sharps container with a wide opening (e.g., 2 gallons with a hinged lid).

Transport to Processing Area

- Universal precautions / facility protocol for handling contaminated / bio-hazardous materials should be observed. Minimize time before cleaning.

Disassembly Precautions for Amalgatome MD Disposable Blade

1. Sharp blades may cause cut injury! Use extreme caution when handling. Keep hands away from moving blade. Always disconnect the power cord before installing / removing disposable blades.
2. Amalgatome MD Disposable Blades are single-use only, do not reuse or re- sterilize
3. Used sharps are contaminated. Disease may occur from contact or injury. Dispose of in puncture-resistant bio-hazard sharps container. Refer to AORN, CDC, OSHA or local standards setting organizational guidelines for handling and disposal of sharps.
4. Always set depth gauge to the position where the dial reads 0.005 inches (0.127 mm) before installing or removing disposable blade.
5. Do not attempt to disassemble the handpiece. It is a factory sealed unit.
6. Do not disassemble the head assembly beyond removing the blade locking ring and the disposable blade. The head assembly (excluding the blade locking ring) has been validated for sterilization and will require factory re-calibration if disassembled.
7. Handle the instrument in a careful manner. Should any component of the instrument be dropped or damaged, return to Exsurco Medical for inspection and repair.

Manual Cleaning Warnings

- **NOTE:** If the mentioned chemicals and machines are not available, the user is obliged to validate their procedure accordingly. It is the obligation of the user to ensure that the reprocessing procedure, including resources, materials and personnel, is suitable to achieve the required results.
- **NOTE:** Universal precautions should be observed by all personnel that work with contaminated or potentially contaminated instruments. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated (or potentially contaminated) instruments.

Cleaning/Sterilization Precautions

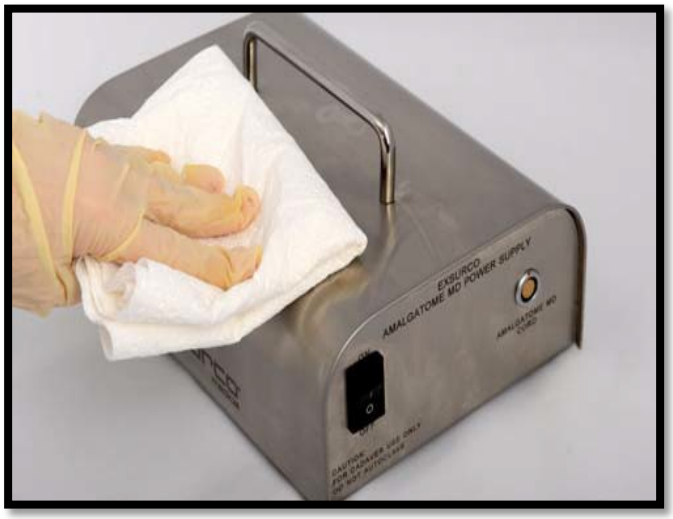
- The sterilization tray is considered a reusable instrument. It should be inspected for visible soil and must be cleaned prior to use. Clean manually. Use neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer of the cleaning agent.
- Do not add other components to the sterilization tray. Areas designated for specific components shall contain only coms specifically intended for these areas.
- The Amalgatome MD Disposable Blades shall be discarded in a puncture-resistant bio-hazard sharps container with a wide opening (e.g. 2 gallons with a hinged lid). The X100457, Amalgatome MD System, Disposable Blades are sold sterile and intended for single-use only.
- Handle the instrument in a careful manner. Should any component of the system be dropped or damaged, return to Exsurco Medical for inspection and repair.
- Do not process any component of the system in an automated wash system or ultrasonic cleaner. All components must be washed by hand to remove soil and debris.
- Ensure the instrument is disconnected from the power supply before placing into the sterilizer. Do not immerse the power supply or handpiece.
- Do not steam sterilize the power supply. This will cause damage to the power supply.

Amalgatome MD Power Supply

1. Turn power switch to the “OFF” (0) mode.
2. Unplug the power supply from the electrical outlet.

3. Unplug the handpiece power cord from the power supply and place a cleaning cap on the connector. **NOTE:** Do not immerse power supply.

4. Wipe down power supply with alcohol or other stainless-steel safe disinfectant. **NOTE:** Do not use bleach.

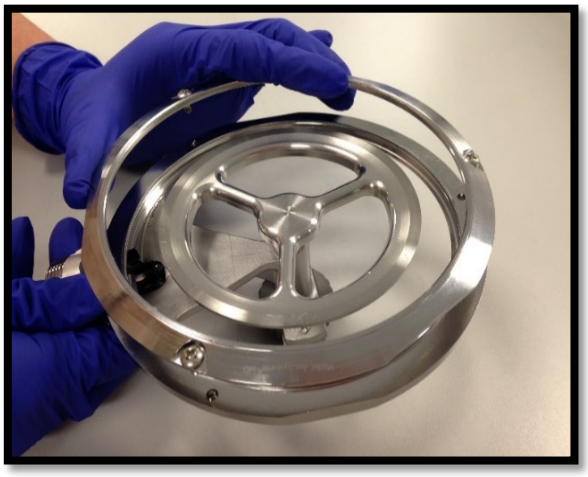


Re-Usable System Disassembly

1. Ensure the power cord has been disconnected from the power supply and ensure cleaning cap is placed on the connector.
2. Set depth gauge to the position where the dial reads 0.005 inches (0.127 mm) before removing disposable blade.

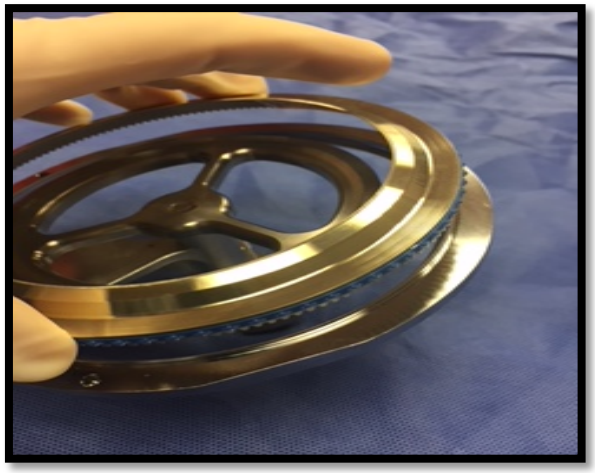
3. Turn the instrument lever side down. Loosen the three (3) screws to remove the blade locking ring. **NOTE:** The three (3) screws should remain captive in the blade locking ring always.

4. Slide the blade locking ring off the housing / frame.



Amalgatome MD Disposable Blade Removal

5. Remove the disposable blade and discard in a puncture-resistant bio-hazard sharps container. **NOTE:** Blades Are Single- Use.

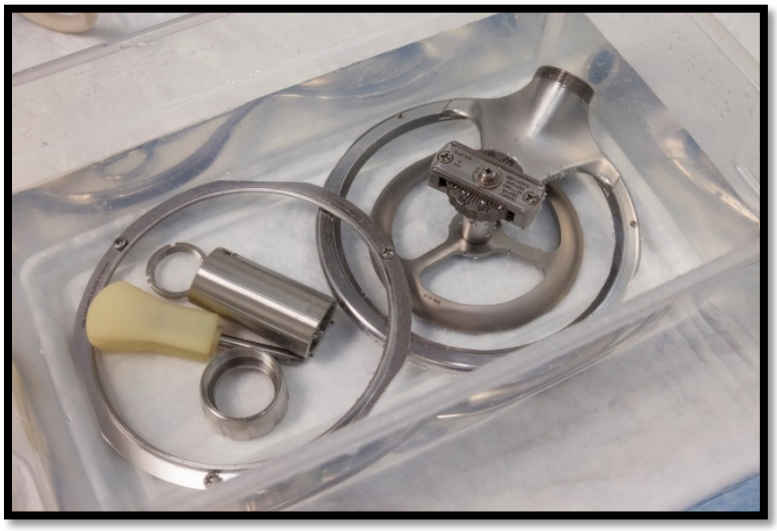


Housing / Frame Disassembly

1.) Detach the cutting head from the hand piece by holding the tool upright and turning the locking knob and then pulling the cutting head away from the hand piece counter-clockwise.

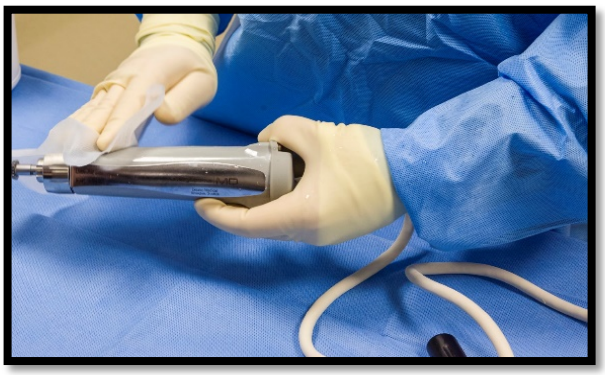
2.) Remove the locking knob (and locking nut) using the pin driver provided.
NOTE: This is a left-handed thread.

Manual Cleaning Instructions

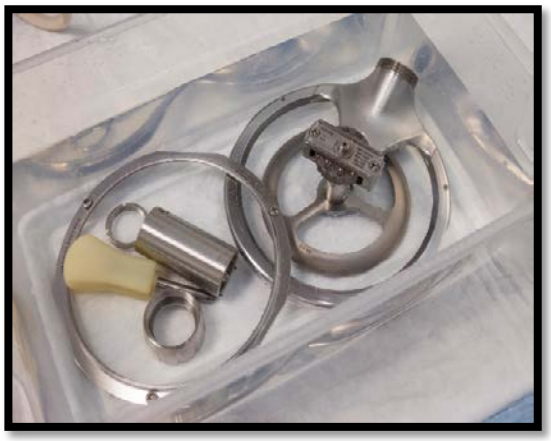


1.) Prepare a neutral pH or instrument safe enzymatic cleaning solution according to the cleaning solution manufacturer specification.
2.) Immerse the six (6) components: locking knob, locking nut, pin driver, screw driver, cutting head with adjustment knob, blade locking ring with screws (leaving out the handpiece with attached cord) into the cleaning solution and let soak for a minimum of two (2) minutes and then remove components from the solution. Soak for two (2) minutes.

3.) Using a lint free wipe moistened with the previously prepared cleaning solution, wipe the handpiece with attached cord or a minimum of one (1) minute. Do not immerse handpiece with attached cord. Wipe for one (1) minute.

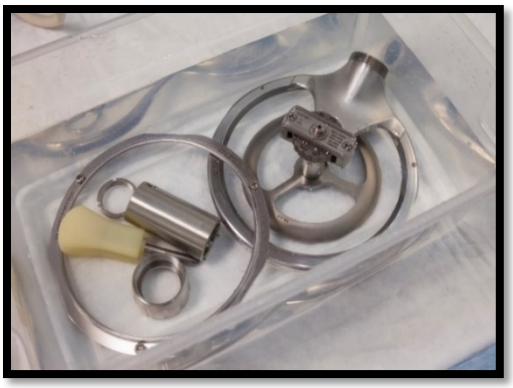


4.) Using a soft bristled brush, individually re-immerse and scrub all six (6) components: locking knob, locking nut, pin driver, screw driver, cutting head with adjustment knob, blade locking ring with screws (leaving out the handpiece with attached cord) in the previously prepared cleaning solution for a minimum of thirty (30) seconds each and until visibly clean. **NOTE:** Individually re-immerse each component during its individual scrubbing duration. Scrub each component for a minimum of thirty (30) seconds.

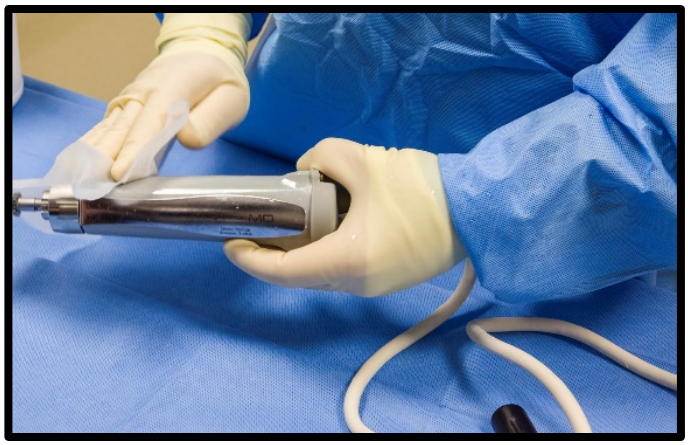


5.) Using a soft bristled brush, scrub the hand piece with attached cord for one (1) minute and until visibly clean. Do not immerse the handpiece with attached cord during scrubbing. Scrub for one (1) minute.

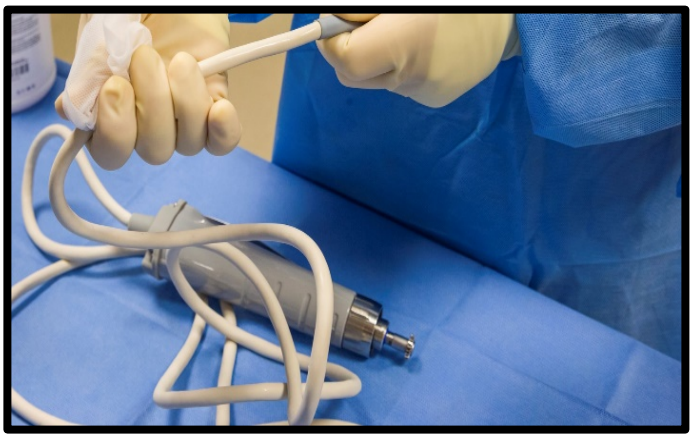
6.) Rinse the six (6) components: locking knob, locking nut, pin driver, screw driver, cutting head with adjustment knob, blade locking ring with screws (leaving out the handpiece with attached cord) under running tap water for a minimum of one (1) minute each. Rinse for one (1) minute.



7.) Moisten a wipe with tap water and wipe the handpiece with attached cord for a minimum of one (1) minute. Multiple sterile free lint wipes may be used as necessary. Do not rinse the handpiece with attached cord under running tap water. Wipe for one (1) minute.



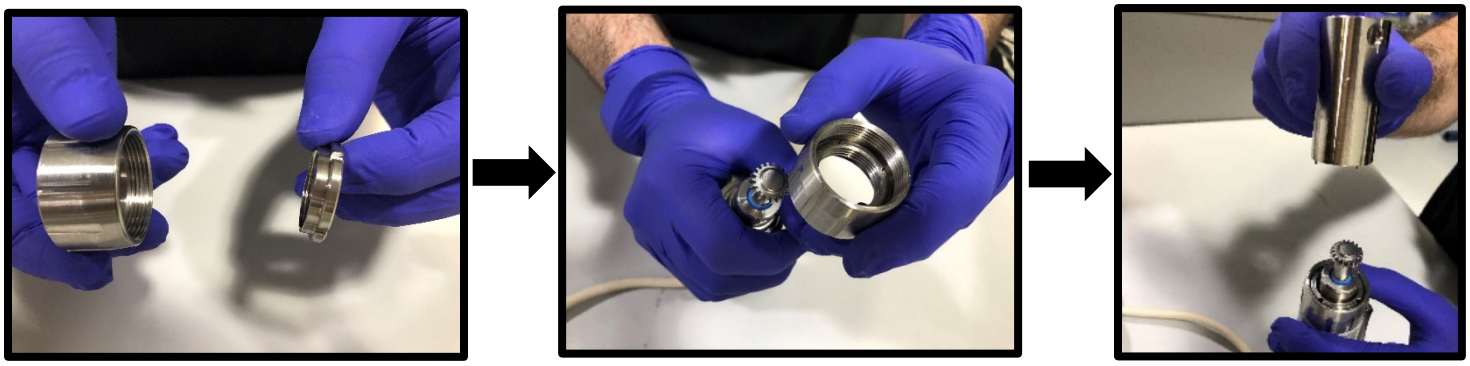
8.) Using a lint free wipe, dry all components: locking knob, locking nut, pin driver, screw driver, cutting head with adjustment knob, blade locking ring with screws and hand piece with attached cord. Visually inspect each component in a well-lit area to ensure all surfaces are clean and dry. Multiple sterile lint free wipes may be used as necessary.



9.) Inspect the sterilization tray for any damage and wipe with a neutral pH solution prior to loading in the components into the Amalgatome MD sterilization tray.

Assembly Prior to Sterilization

1. Connect the locking knob to the handpiece using the pin driver and locking nut.
   NOTE: This is a left-handed thread.

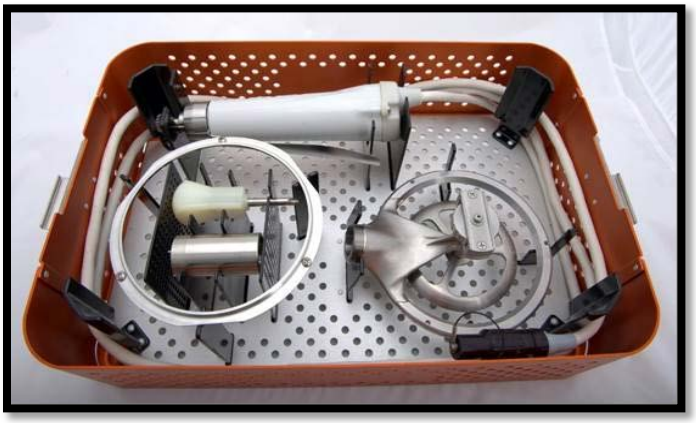


Functionality Testing

1. Visually inspect for damage and/or wear. If damage or wear is noted that may compromise the function of the instrument, follow the proper return authorization procedures and return sterilized instruction to Exsurco Medical for inspection and repair.

Sterilization Preparation

1. After cleaning, place the handpiece, head assembly, blade locking ring, screwdriver, and pin driver in the Amalgatome MD Sterilization Tray. The Exsurco Sterilization Tray (REF X100626) has been validated only for steam sterilization.



2. Place steam sterilization indicator strip inside tray (or per facility protocol). Wrap the sterilization tray in CSR wrap. Size 45” x 45” or bigger works best. Secure closed with steam indicator tape. Label as appropriate. Medical grade steam sterilization wrap must be used to wrap the instrument tray prior to sterilization. The package should be prepared using the AAMI double wrap or equivalent method.

Pre-Vacuum Steam Sterilization & Gravity Sterilization Parameters

Cycle Type	Prevacuum, Hospital
Set Point Temperature	132°C
Full Cycle Dwell Time	4 minutes
Dry Time	20 minutes

Cycle Type	Gravity, Hospital
Set Point Temperature	135°C
Full Cycle Dwell Time	10 minutes
Dry Time	30 minutes

NOTE: See References & Internal Validation details in Appendix E.

Limitations on Reprocessing

The limitation of the number of reprocessing procedures is determined by the function / wear of the instrument. In case of damage, the instrument MUST be sterilized prior to sending to Exsurco Medical for inspection and repair.

This page intentionally left blank.

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 MD System and its components have been tested and inspected and have left the factory in proper working condition. Exsurco warrants the product is free from manufacturing defects in material and workmanship under normal use and service for a period of one year from date of delivery by Exsurco to the customer. The sterile, disposable product is not warranted beyond the expiration date stated on the product labeling.

- The Amalgatome MD 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.
- Any Amalgatome MD System that is placed by Exsurco under an installment purchase agreement and requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement.

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 information 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 or 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 MD System is intended for use only with the Amalgatome MD disposable excision ring blade. Using another manufacturer's blades in conjunction with the Amalgatome MD voids the product warranty.

Service

The Amalgatome MD System contains no serviceable parts. 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 hand piece. It is a factory-sealed unit with no user serviceable parts inside. If this happens, it voids the warranty and the customer must return the hand piece to Exsurco Medical for repair that shall be charged to the customer.

Do not attempt to remove the screws and disassemble the depth gauge on the cutting head for any reason. It has been factory calibrated to provide optimum cutting performance. If this happens, it voids the warranty and the customer must return the system to Exsurco Medical for repair that shall be charged to the customer. All products returned for warranty or non-warranty repair must be through the Exsurco Medical return procedure. For more information, refer to the Returns information below. Exsurco Medical performs all service of the Amalgatome MD system.

Our Technical Service Department can be contacted at 1-800-243-6049, ext. 5, 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 MD System for inspection and preventative maintenance, warranty service, or non-warranty service, please contact Customer Service at 1-800-243-6049, ext. 4, 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. Customer is responsible for the return freight.

When the customer is returning the system, we require proof of sterilization documents upon receipt of the RMA or SRO. If proof of sterilization is not included with the system, the system shall be returned for sterilization. Exsurco Medical does not accept product that has been used without being sterilized first or has not been shipped with the sterilization 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.

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 stands behind 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, ext. 4. 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.
  - 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 generally 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 reported event.

Obtaining a Loaner System

Once an RMA is established, and upon request, Exsurco Medical will supply, at no charge to the customer, a loaner System to cover the period of the repair. The use of the loaner will be “no charge” to the customer for the amount of time required for any inbound and outbound shipping and all Exsurco Medical in-house processing time. System rental fees will apply for loaners kept beyond the defined period of repair.

Exsurco Medical must charge the System's daily rental rate for each day the loaner system has not been returned to Exsurco Medical. All loaner systems and associated equipment must be returned to Exsurco Medical in good working order and free of debris and bio-contaminant. Any components found to have suffered abuse or mistreatment will be repaired with all associated costs be charged to the customer.

This page intentionally left blank.

Appendix A: Technical Specifications

The Amalgatome MD described in this Operation and Instruction Manual has been tested by Intertek Testing Services NA, Inc. and conforms to UL 61010-1 and CSA C22.2 No. 61010-1 standards for electrical safety.

Specifications

Specification	Value
Supply Voltage, Frequency and Power Rating.	• 115VAC ±10%, 1 Phase, 1.6 A, 60Hz
Overall dimensions and weight- MD Power Supply	• 6 lbs. (2.72 kgs) • 5 3/8" High x 7 7/8" Wide x 10 ¾" Deep
Overall dimensions and weight- MD Head Assembly	• 3.6 lbs. (1.63 kgs) • 2 ¾" High x 6" Wide x 14" Deep
Environmental Conditions for instrument operation	• Ambient temperature ranges.....-4°F to 110°F (-20°C to 43°C) • Relative humidity ranges..... 20% to 80% (non-condensing) • After sterilization, store the tool in the sterilization packaging (Exsurco Medical Sterilization tray, wrapped in Medical grade steam sterilization wrap). • The shelf life depends on the sterile barrier employed, storage manner, environmental and handling conditions. • A maximum shelf life for sterilized tools before use should be defined by each health care provider. • Prior to storage, the instrument must be cleaned and sterilized according to instructions in this manual. All sterilized parts are to remain in the sterilization tray for storage. All components of the Instrument must be stored in accordance with the storage conditions as defined. • Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature / humidity extremes. • Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.
Power cord insulation ratings	• 60 °C MIN, 300V, SJT
Duty Cycle	• 10 Minutes continuous, 2 hours off
Operating temperature range	• The Amalgatome MD System has an operating temperature range of -4°F to 104°F (-20°C to 40°C).

This page intentionally left blank.

Appendix B: Parts Information

Description: Exsurco Amalgatome MD

Quantity	Component #	Description
X100556 Amalgatome MD Kit:		
1 each	X100461	Head Assembly
1 each	X100460	Handpiece Assembly
1 each	X100495	Pin Driver
1 each	X100498	Screwdriver
1 each	X100402	Power Cord
1 each	X100380	Power Supply
1 each	X100626	Sterilization Tray
Individual Replacement Parts:		
1 each	X100495	Pin Driver
1 each	X100350	Lock Nut
1 each	X100351	Locking Knob
3 each	X100437	Captive Screw
1 each	X100332	Blade Lock Ring
1 each	X100498	Screwdriver
1 each	X100402	Power Cord
1 each	X100380	Power Supply
1 each	X100626	Sterilization Tray
1 each	X100607	Transportation Case

Individual, Single Use Excision Rings Sold Separately:

Quantity	Component #	Description
5	X100457	Amalgatome MD System, Disposable Blades

To place an order for the Amalgatome MD, please contact our Customer Service department at 1-800-243-6049, ext. 4, 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, ext. 1, or email sales@exsurco.com

This page intentionally left blank.

Appendix C: Glossary of Symbols

Symbol	Definition
	Serial Number
	Batch Code/Lot Number
	Manufacturer
	Use by date. This symbol is intended to indicate that the system should not be used after the end of the date shown.
	Symbol for method of sterilization using radiation.
	Symbol indication that the system has not been sterilized.
	Do not reuse. Single use, use only once.
	Caution
	Consult instructions for use

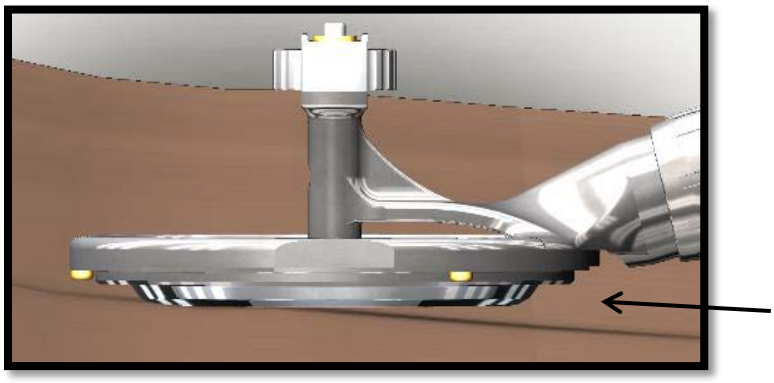
	Keep product dry
	Do not use if package is damaged
	This side up
	Sharp object
	General warning sign
	Presence of electricity
	Read operator's manual
	Power standby switch. Power ON is up

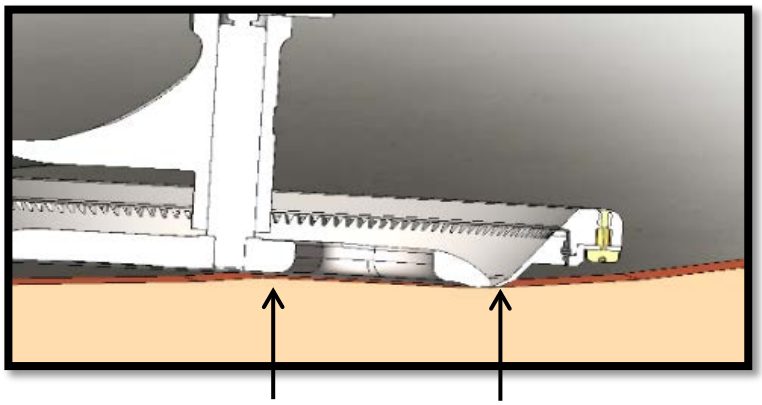
This page intentionally left blank.

Appendix D: Best Practices & Techniques

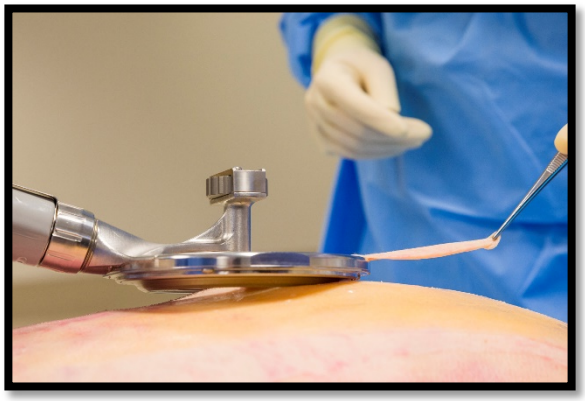
Proper Angle During Recovery

1. To ensure 3 to 4-inches (8 to 10 cm) recovery of an allograft skin graft ensure the diameter of the blade is in contact with the recovery area. The red arrow on the figure to the right indicates the blade edge. The green arrow indicates the center of the head assembly. The depth plate is flattening the skin surface, area between the two arrows, which is the surface of the 4" skin graft.

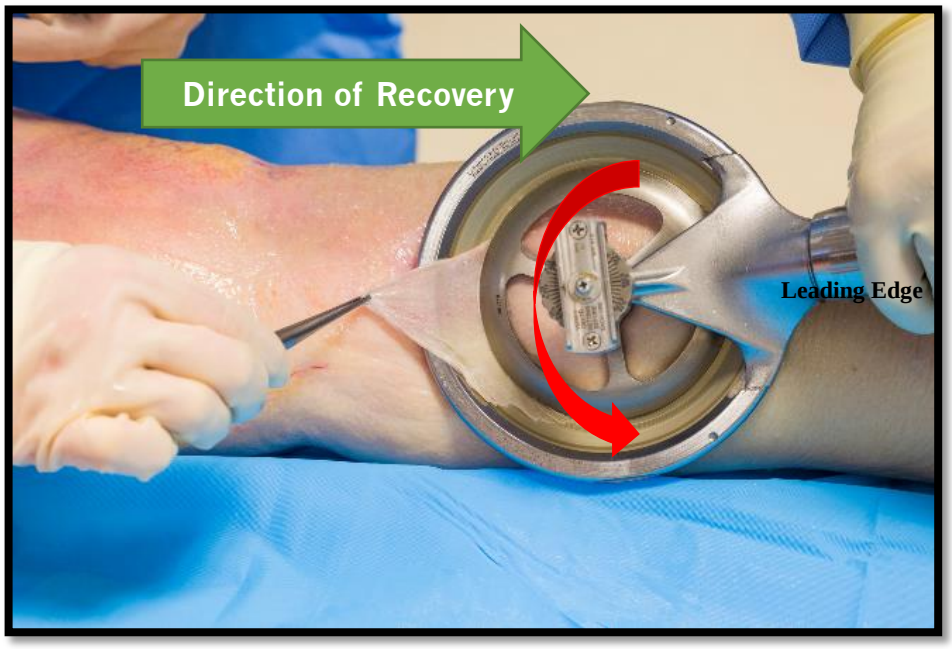




2. Operator should not apply pressure (i.e. pressing down with pressure). For best results glide the instrument over skin in a controlled motion. This technique also ensures the edges are uniform and not chattered.
3. If the Operator starts with a graft that does not meet the desired thickness and width, or recovery of the skin graft is inadequate it is best to stop recovering that graft and start a new graft.



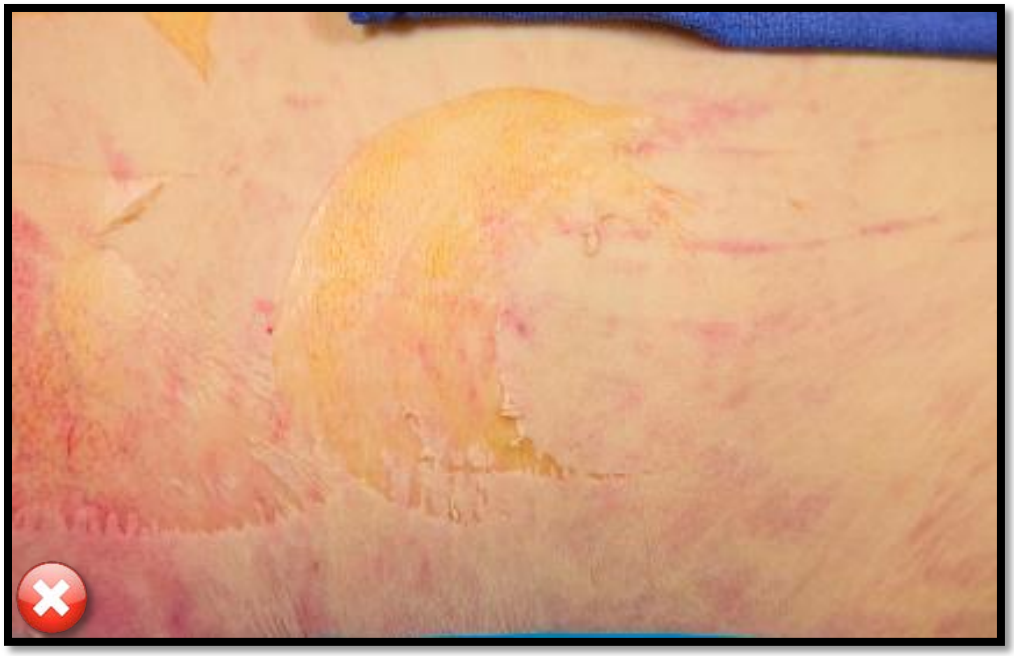
4. The red arrow indicates the direction of the blade spin or cut. This is the trailing edge of the blade.
   NOTE: The red arrow indicates the direction of the blade spin or cut. This is the trailing edge of the blade.

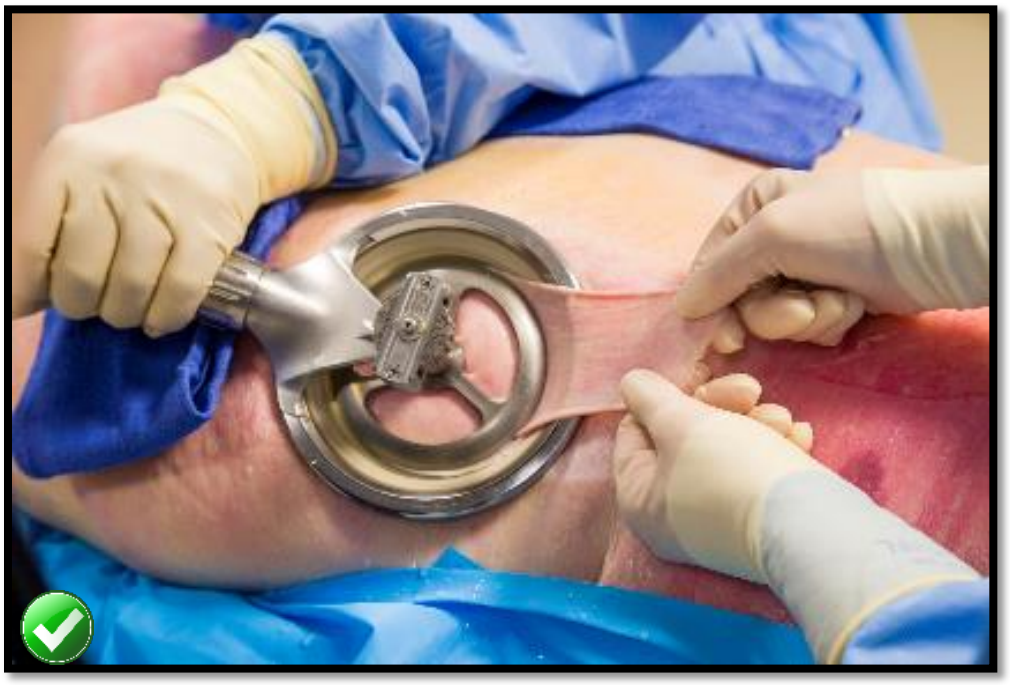


5. Pressing down on the leading edge may lift the cutting edge away from the desired recovery site.

Depth Setting

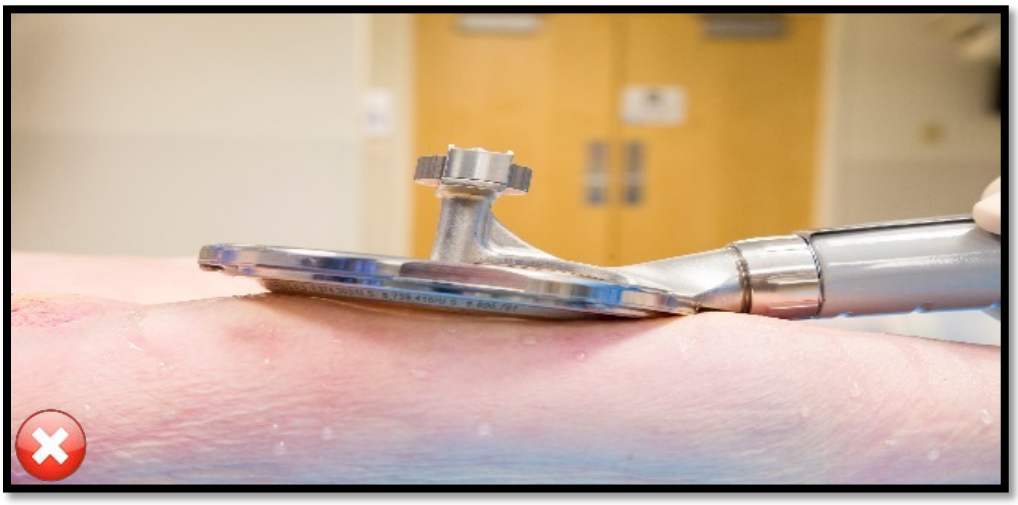
1.) If the Operator starts with a graft that does not meet the desired thickness and width, or recovery of the skin graft is inadequate it is best to stop recovering that graft and start a new graft.



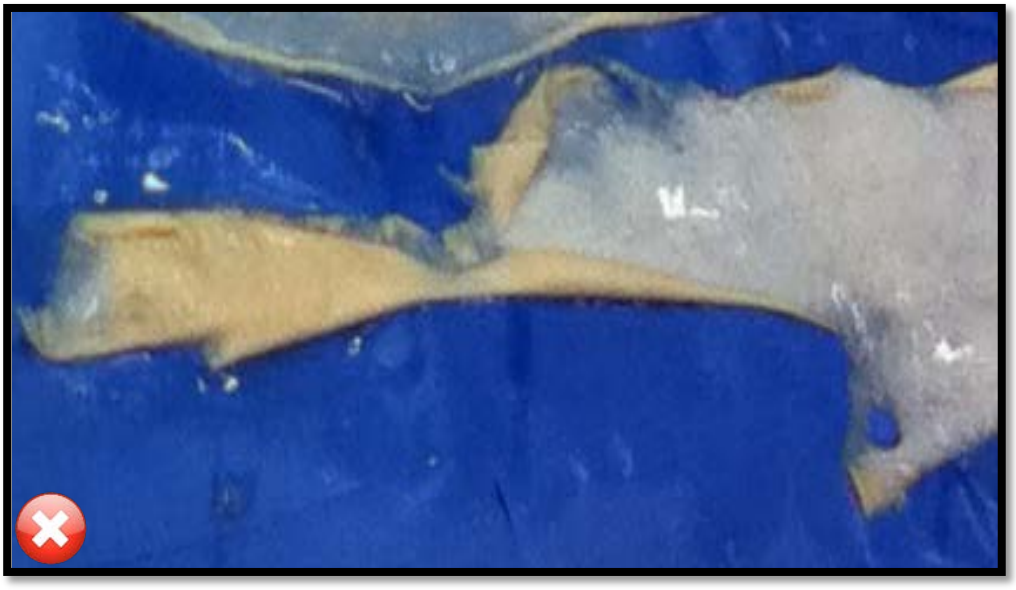


Prevent Dissected Skin Graft During Recovery

1. The instrument's Head Assembly cuts with the trailing edge of the blade.
2. If the Operator attempts to keep the Instrument "too flat", this may inadvertently cause the Operator to lift the cutting edge away from the recovery site, hence causing holes or tears or chattered edges.
3. If the Operator attempts to keep the instrument "too flat", the sound of the motor will change. The instrument will sound like it is over working or "bogged" down.



Incorrect method; Technique where instrument is laying too flat



Skin Graft Thickness and Uniformity

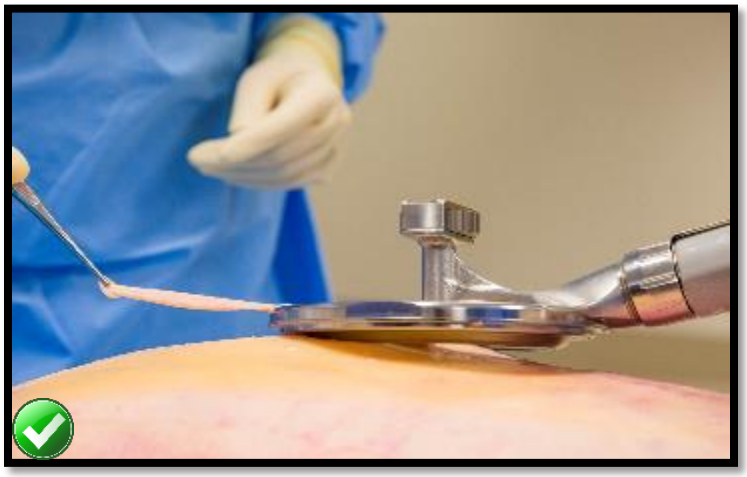
1. The depth gauge plate on the instrument is designed to flatten the skin as it approaches the cutting edge.
2. The operator does not need to provide additional pressure on the instrument.
3. This will cause the tissue to compress itself into the instrument, resulting in allograft skin grafts that are thick in the middle and thin on the edges.
4. Applying excess pressure will affect thickness of the graft.

Incorrect method: Technique where too much pressure is applied *Uneven, chattered edges*

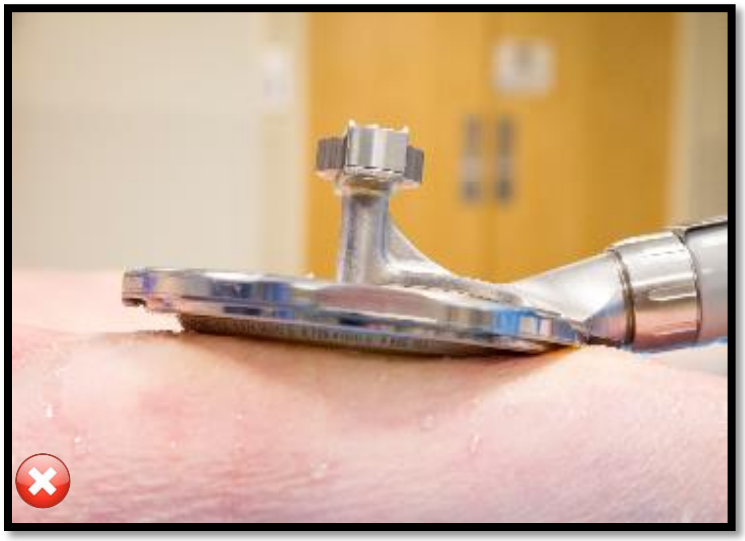
5. For best results the operator should glide the instrument steady and at a slow speed. Moving the instrument too fast does not allow the instrument to adjust to body contours, or irregularities in tissue during use. Notice the operator is ensuring the proper 3 to 4-inch (8 to 10 cm) recovery of the skin graft by ensuring the diameter of the blade is in contact with the recovery site. The operator also ensured the edges are uniform and not chattered.

Uniform, smooth edges

Applying too much angle

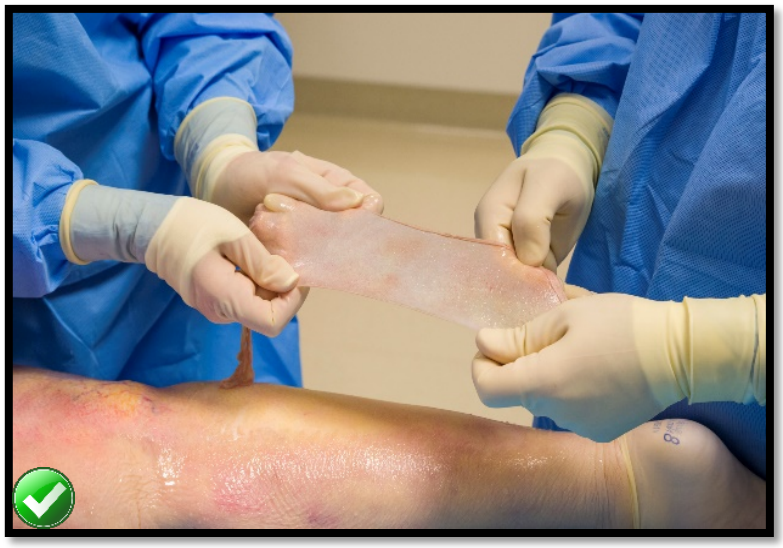


Correct Technique



Holding Instrument too flat

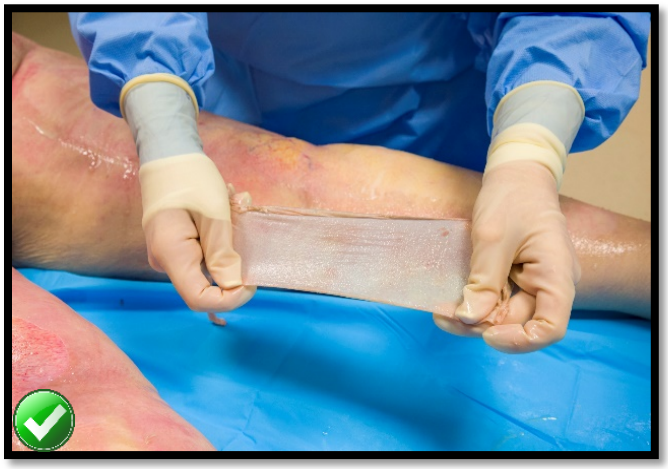
Crescent Shaped Appearance in Skin Graft



1. Steady/slow speed required.

2. For best results the operator should glide the instrument steady and at a slow speed. Moving the instrument too fast does not allow the instrument to adjust to body contours, or irregularities in tissue during use.

3. This results in crescent moon shaped patterns.

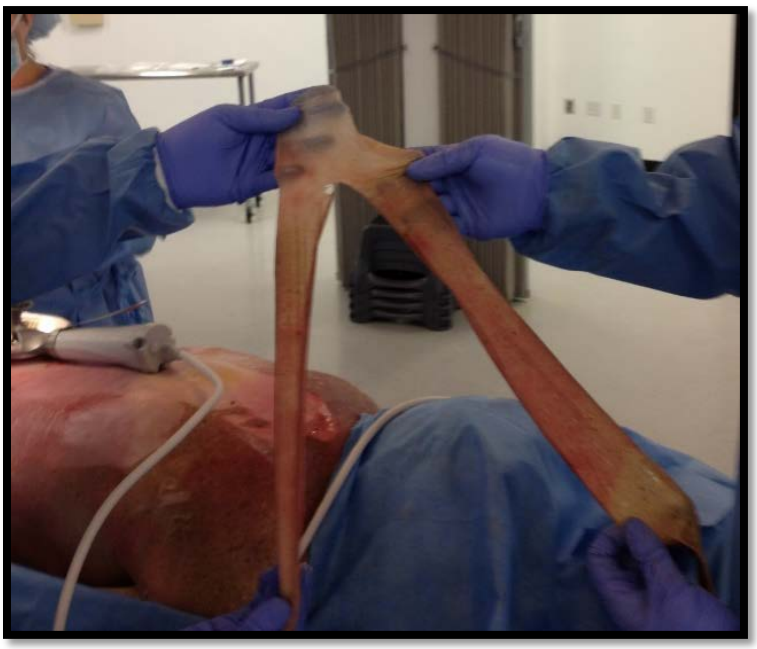


Uniform Graft

Crescent Shaped Graft

Instrument Direction: Turning Instrument in Multiple Directions Results in Odd Shaped Grafts

1. The operator may, while a good graft is in motion, to turn a corner or move in another direction, resulting in an “S”, “L” or “V” shaped graft. It is possible that the recovered yield will be lost.
2. The picture to the right identifies red circles and this area would not be able to be processed according to the length and width requirements for the end user.
3. Our recommendation is to avoid this way of recovery. Recovering grafts in one straight strip is best.



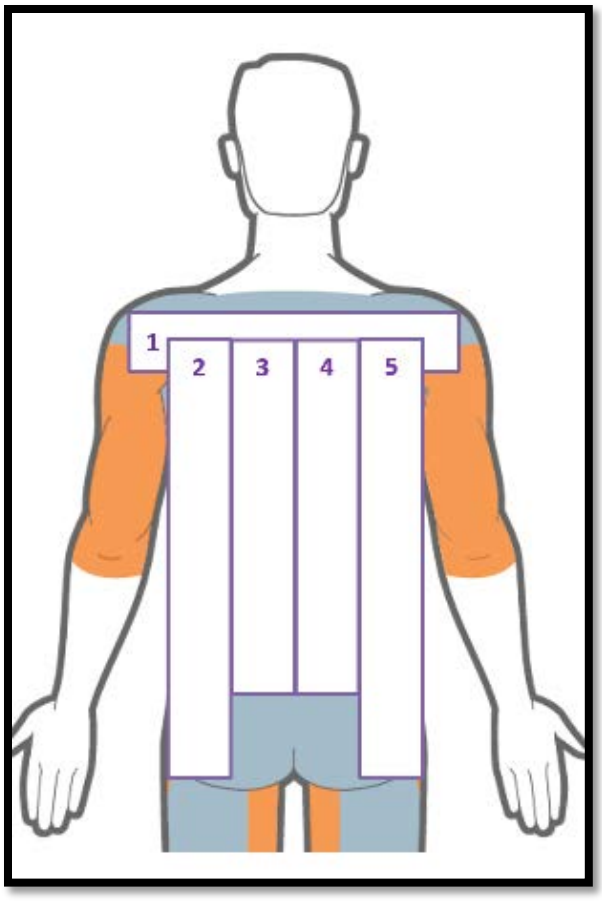
Posterior Torso

1. Notice the operator is allowing the depth gauge to flatten the skin prior to the blade cut.
2. The operator can change the depth during the recovery without stopping.

3. It can be helpful to recovery the first strip across the donors back from right to left in the opposite direction as illustrated in the image below, indicated by #1. Followed by recovering strips #2 to #5.

4. When recovering the strips #2 to #5, start the recovery into the exposed dermis that remains after recovering strip #1 as shown.

5. The start of the strip is often the crescent or half-moon shape of the blade is the section that will be trimmed in processing to create rectangular skin grafts, so starting within the exposed dermis can maximize the length of the rest of the recovered strips form the posterior torso.

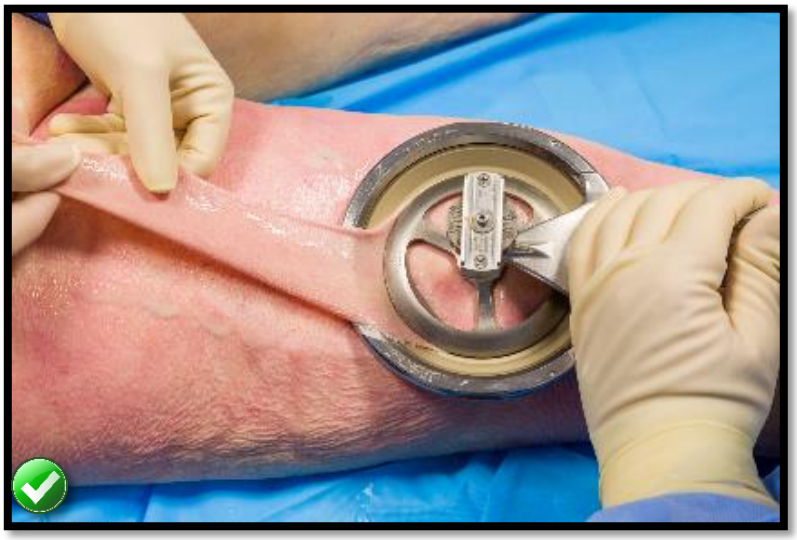


Anterior Torso and Buttocks

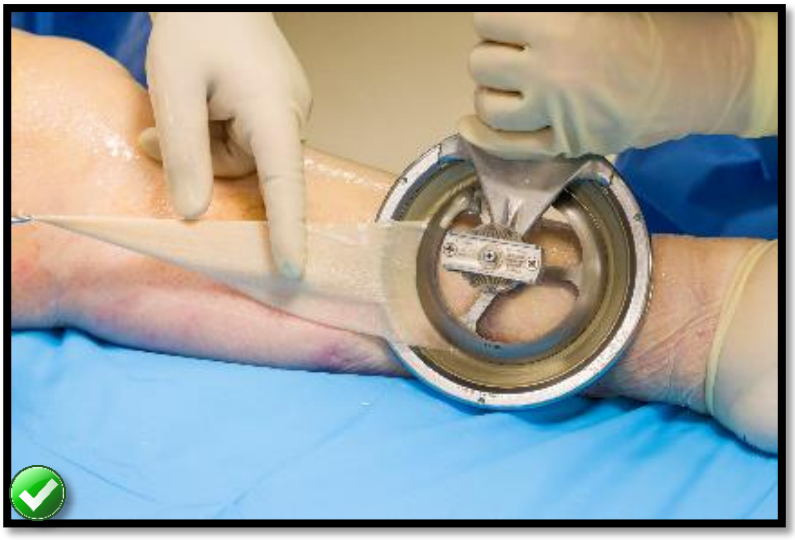
1. Notice the operator is ensuring the proper 4-inch (10 cm) recovery of the skin graft by ensuring the diameter of the blade is in contact with the recovery area.

Legs

1. Notice the operator is not applying too much pressure and using different areas on the head to recover great skin grafts.



2. The assist recovery technician is not pulling too tight on the recovered skin graft.



This page intentionally left blank.

Appendix E: References for Sterilization and Details of Validation Report

References

- The Guidance for industry and FDA staff, reprocessing medical Instruments in a healthcare setting: March 17, 2015.
- ANSI/AAMIST8 Hospital Steam Sterilizers
- ANSI/AAMIST79 Comprehensive Guide to Steam Sterilization and Sterility assurance in healthcare facilities
- AAMITRI 12 Designing, testing and labeling reusable medical Instruments for reprocessing the health care facilities
- AAMI TIR12:2010 – Designing, testing, and labeling reusable medical Instruments for reprocessing in health care facilities.
- A guide for medical Instrument manufacturers, AAMI TIR30:2011 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical Instruments.
- Reprocessing Medical Instruments in Health Care Settings: Validation Methods and Labeling, Document issued on March 17, 2015, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Instruments and Radiological Health, Office of Instrument Evaluations. ANSI/AAMI/ISO 17665 1 and 2.

Information on the Validation of the Re-Usable Amalgatome MD

The following testing Instruments, materials, and machines were used in these validation studies:

- Steris Prolystica 2X Concentrate Enzymatic Presoak and Cleaner
- FDA cleared wrap [Cardinal Health, Convertors Brand BioShield Regular Sterilization Wrap, Part Number 4040, Lot Number 14BDD044, 510(k) reference number K770933] using the sequential envelope wrapping method per
- ANSI/AAMIST79:2010/A1:2010/A2:2011/A3:2012/A4:2013/(R)2014.
- FDA cleared chemical indicator autoclave tape [SPS Medical Steam Indicator Tape, Part Number ST-048, Lot Number S11705, 510(k) reference number K890755].
- Steris LAB250

Cleaning Protocol

- Cleaning Efficacy Validation -NAMSA Summary Report 154261

Steam Sterilization Protocol

- Steam Sterilization Efficacy Study - Reusable Instruments - 132°C Pre-Vacuum Cycle EXS040213STM.01F
- Steam Sterilization Efficacy Validations-NAMSA Summary Part II Report 154261

This page intentionally left blank.

Contact Information

Contact Information

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

Phone: 1-800-243-6049
Website: www.exsurco.com

Press the number below for the following departments or email at:

1 – Sales & Clinical Support: sales@exsurco.com

2 – Marketing & Product Inquiries: information@exsurco.com

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

5 – System or Technical Service: support@exsurco.com

This page intentionally left blank.

REDEFINING EXCISION SCIENCE

Exsurco Medical
10804 Green Road
Wakeman, OH 44889

Exsurco Medical
P.O. Box 376
Vermillion, OH 44089

PN: X100573 Rev. H

Date Issued: July 24, 2019