Amalgatome® SD
User Guide

EXSURCO MEDICAL
10804 GREEN ROAD
WAKEMAN, OH 44889

PN: X101456 REV. C

This page intentionally left blank.

AMALGATOME® SD USER GUIDE

Instructions for Use

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

NOTICE TO USERS

Read this manual thoroughly before using the Exsurco Medical Amalgatome SD System. It is designed for use by qualified and trained medical professionals where the patient is under supervision of trained personnel. Review this user guide, paying particular attention to all warnings and precautions, prior to any surgical 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.

This page intentionally left blank.

Table of Contents

Preface

Purpose

This user guide provides directions to help users safely and effectively operate the Amalgatome SD System. This guide also includes material such as indications for use, contraindications, 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 devices for healthcare professionals in the surgical and tissue bank markets.

The Amalgatome SD is designed to excise tissue utilizing an innovative excision ring blade technology and is indicated for skin grafting and wound debridement. This new advancement and design incorporates the ability to excise tissue with one device in a precise and efficient manner.

Contact Information

Contact Exsurco Medical at 1-800-243-6049 or via e-mail at support@exsurco.com.

This page intentionally left blank.

System Overview

This section provides general information about the Amalgatome SD System.

Indications for Use

The Amalgatome SD System is designed to excise soft tissue in varying widths and thicknesses for skin grafting and wound debridement. It is indicated for open wounds, including wound site preparation (debridement and sharp debridement), removal of necrotic tissue and eschar, and tissue harvesting (autograft harvesting).

Description

The Amalgatome SD System is a pneumatically powered surgical skin grafting instrument capable of producing varying thicknesses of skin grafts from 0.005 to 0.045 inches in increments of 0.001". Single-use disposable, excision ring blades provide precision cutting and are available in 2-inch and 4-inch diameters, depending on the size of the graft needed or debridement site.

The Amalgatome SD is also capable of soft tissue excision (removal of necrotic tissue and eschar) and wound site preparation of the surgical site in applications (acute, chronic wounds, and burns) that in the physician's clinical judgment require debridement and sharp debridement.

Components

Figure 1. Components

1. Pneumatic hose
2. 4-inch Lock Ring
3. 4-inch Cutting Head (excision ring blade head)
4. 2-inch Cutting Head (excision ring blade head)
5. 2-inch Lock Ring
6. Hand Piece (Drive Unit)
7. Lock Nut Wrench
8. Lock Ring Removal Tool

Disposable Excision ring blades, 2-inch and 4-inch (sold separately, not shown) and sterilization Tray (not shown)

For additional part number information, refer to Appendix B: Parts Information.

How Supplied

- The Amalgatome SD System consists of the following components as shown on previous page:
  - Hand Piece (Drive Unit): Consists of the motor and pneumatic hose which powers the system.
  - Interchangeable cutting heads with lock ring and assembly accessories.
  - The single-use disposable surgical excision ring blades are supplied separately.
- The complete system is shown and is sold with the custom-made sterilization tray, which should be utilized with this system only.
  - SDSYSTEM024 contains the 2-inch and 4-inch cutting heads.
  - SDSYSTEM04 contains the 4-inch cutting head.
  - SDSYSTEM02 contains the 2-inch cutting head.
- The system is provided non-sterile and is reusable after cleaning and sterilization prior to use according to the procedures outlined in this document.
- Each piece of the system is shipped individually contained in protective suspension or retention boxes and each must be opened, visually inspected, cleaned and then placed in the sterilization tray for sterilization.
- The single-use, disposable excision ring excision ring blades are provided sterile and should be considered sterile unless the sterile packaging has been opened or damaged.

  WARNING: Re-sterilization or reuse of the disposable excision ring blades can result in serious physical harm to the patient. Excision ring blades are for single use and must not be reused.

Contraindications

The Amalgatome SD System is not recommended for use on the following locations on the body or where surgeon determines due to health reasons:

- Eyelid(s)
- Post auricular region (behind the ear) and on the ear
- Inguinal region (groin)
- Genital region
- Forearm (underside of wrists up to the elbow)
- Supraclavicular area (above the collarbone)

General Warnings and Precautions

This section provides general warnings and precautions about the Amalgatome SD System.

Warnings

- The user of the Amalgatome SD System must be a surgically trained professional (e.g., a surgeon) and thoroughly familiar with the function, application, and instructions for use in order to avoid injury to the patient and operating staff.
- Each physician must evaluate the appropriateness of the technique for each patient based on his or her own medical training and expertise. Care should be taken in treating individuals with pre-existing conditions that might affect the success of the surgical procedure. Every patient is different and results can vary.
- This device can cut soft tissue. Apply only to tissues and debris intended to be excised from the wound.
- Only use the Amalgatome SD sterile, disposable, excision ring excision ring blades with the Amalgatome SD System.
- Do not use excision ring blades from other manufacturers.
- Do not reuse the excision ring blades as they are intended for single use. Serious injury can result from use of other manufacturer's excision ring blades or reuse of the Amalgatome SD excision ring blades. Dispose of the excision ring blades in accordance with facility protocol for sharps containment.
- Sharpening of the excision ring blade or removal of excision ring blade material will result in loss of calibration.
- Care should be taken when removing the excision ring from its packaging. The excision rings are extremely sharp.

Precautions

- The Amalgatome SD System operator and other clinical personnel should follow the universal protocol for aseptic technique as with all surgical procedures.
- As with all surgical procedures, the surgical team and clinical personnel should follow the universal precautions for infection control. (including the use of surgical gloves, facemask that covers the mouth and nose, protective eye wear or shield, protective clothing and anti-slip shoe covers.) Especially during debridement procedures due to possible tissue spray
- It is recommended prior to clinical use of the Amalgatome SD System, that all operators of the system be trained in its proper use. Contact your local Exsurco Medical Sales Representative for all details regarding Amalgatome SD training.
- United States of America (USA) federal law restricts this device to sale by or on the order of a physician.

This page intentionally left blank.

Setup Instructions

This section describes how to inspect and set up the Amalgatome SD System prior to each use.

Perform the following procedures before each use. Follow sterile field aseptic technique per the Association of periOperative Registered Nurses (AORN) guidelines and hospital protocol. Open, inspect, and set up the sterile Amalgatome SD and disposable excision ring blades within the sterile field.

Inspection

1. Inspect the disposable excision ring blade for possible damage, wear, or defects. Ensure that the excision ring blade is free of particulate and burrs. Discard the excision ring blade if it is damaged or defective.
2. Inspect all movable parts in order to ensure that the parts function through the intended range of motion. Do not use or reprocess damaged or defective parts. If the system does not function correctly, contact Exsurco Medical Customer Service at 1-800-243-6049, ext. 4, or email support@exsurco.com for repair or replacement.
3. Inspect the O-ring on the hand piece of the device. Wear on the O-ring is expected. During the annual preventative maintenance program the O-ring will be replaced. Do not use if the O-ring is cut or severed in half, or missing. Do not attempt to replace the O-ring.

Setup

Refer to Appendix D: Quick Reference Guide for a pictorial reference to this procedure.

1. Assemble the cutting head onto the hand piece.

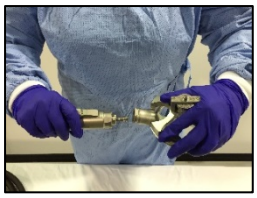


Figure 1a

a. Hold the hand piece in the upright position, with the protruding gear facing upward and the **ON/OFF** lever facing the user.

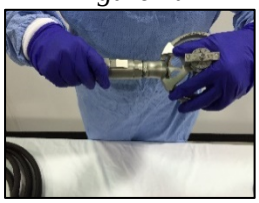


Figure 1b

b. Align key slot on the handle onto the pin on the head of the system.

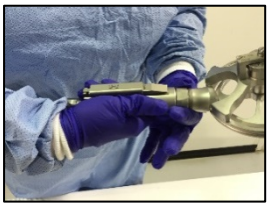


Figure 1c

c. Hand-tighten the locking knob clockwise until it stops; do not over tighten.

Figure 1d

d. Adjust the depth gauge to the preferred operating setting.

2. Open and install the disposable excision ring blade.

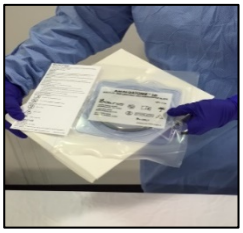


Figure 2a

a. Check the package integrity and the expiration date.

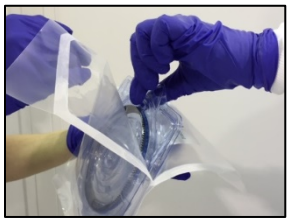


Figure 2b

b. Using the peel-pack end with peel corners, pull open the package, allowing the sterile operator to reach in and grab the clamshell. **WARNING SHARP**

NOTE: It is best practice to have the package opened for the sterile operator. It also best practice not to open the excision ring blade or change the excision ring blade over a patient.

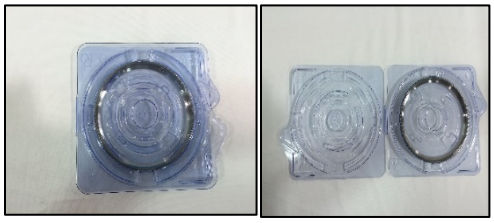


Figure 2c

c. Open the clamshell containing the excision ring blade – (similar to opening a book – right to left), following the **THIS SIDE UP** arrow.

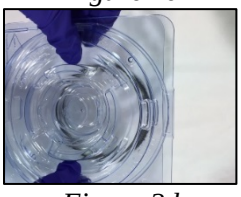


Figure 2d

d. Fold the left (empty) side of the clamshell under the excision ring blade side, and then turn the clamshell over.

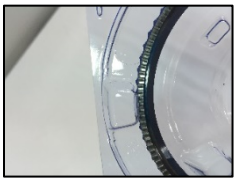


Figure 2e

e. While standing close to the table or sterile surface, use the thumb notches on the tray to release the excision ring blade out of the clamshell onto the sterile surface.

CAUTION: At this time the excision ring blade is lying teeth side down on the sterile surface. Do not touch the inner ring of the excision ring blade. It is the sharp cutting surface.

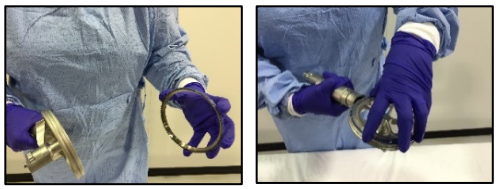


Figure 2f

f. Hold the outer edge of the excision ring blade by grasping the blue strip and load the excision ring blade into the hand piece. While nesting the excision ring blade, turn its outer edge slightly in order to ensure proper seating.

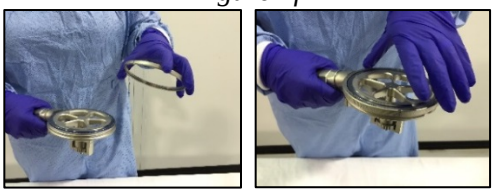


Figure 2g

g. Place the excision ring blade lock ring over the excision ring blade and twist it in a clockwise motion until it stops. Do not over tighten.

3. Attach the pneumatic hose.

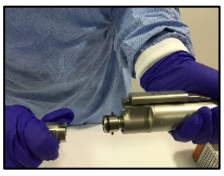


Figure 3a

a. Connect the female end of the pneumatic hose to the male end of the hand piece, securing with the twist-lock feature.

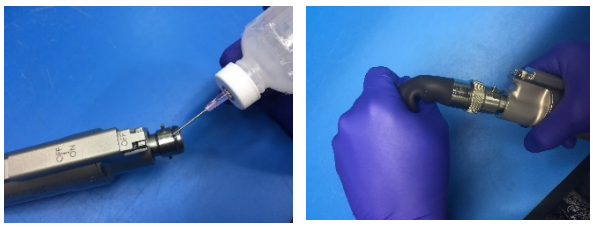


Figure 3b

b. Lubricate the O-ring prior to connecting the air hose with sterile mineral oil. This will help make the female end of the air hose easier to attach to the male end of the hand piece using the toggle barbs. Do not bend hose at a 90o angle at the connection site. Do not use excessive force during the process.

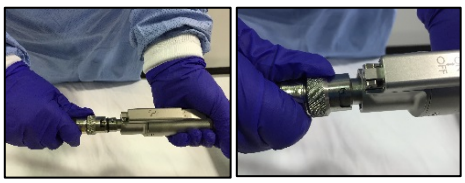


Figure 3c

c. Grasp the hose and attach the hose to the swivel connector on the hand piece. Turn the hose clockwise to secure.

NOTE: If the connection seems difficult to attach it is acceptable to place a few drops of

sterile mineral oil on the O-ring to help engage the connection.
NOTE: Use caution not to drop the hose prior to assembly.

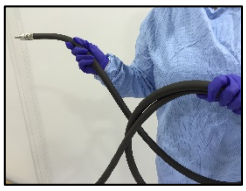


Figure 3d

d. Pass the other end of the pneumatic hose to the circulator. Using a non-perforated holder, clip or secure the pneumatic hose to the sterile field, taking care not to compress the hose.

Figure 3e

e. Connect the male end of the pneumatic hose to the appropriate air source in the operating room designated for the procedure.

NOTE: The male end of the hose connects to a Schrader® style quick connect female coupler indexed for air.

f. Turn on the air or gas supply, and then verify the pressure while the system is running.

CAUTION: Use hospital grade compressed air or nitrogen at the recommended setting of 100 psi.

System Check

This section describes the process for checking the system and setting the depth gauge.

NOTE: This process must be performed over a sterile surface.

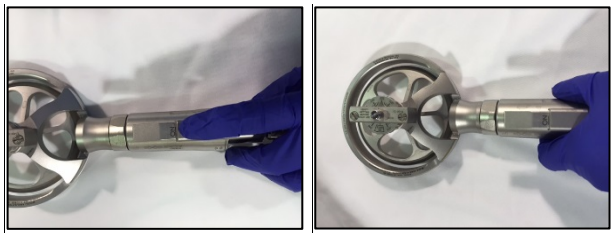


Figure 1

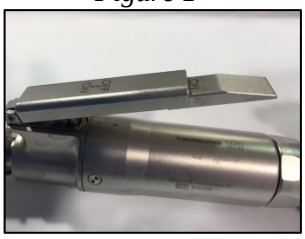


Figure 2

1. Slide the **ON/OFF** lever on the hand piece to the **ON** position.

2. Press down on the **ON/OFF** lever to activate the system. It is now ON.

   When the system activates, the disposable excision ring blade spins.

3. Verify that all connections are secure and that the air pressure is set correctly while the system is running.

   NOTE: The required air pressure setting is 100 psi.

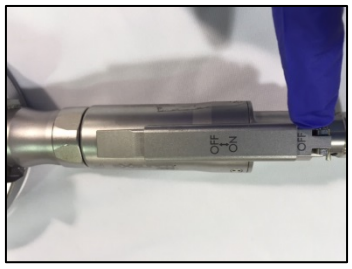
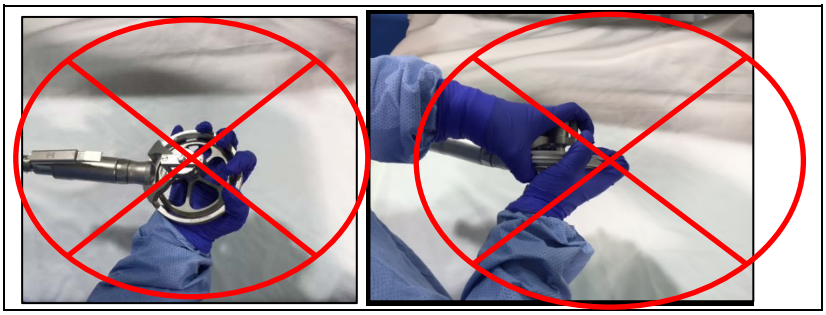


Figure 4

4. Release the **ON/OFF** lever, and then slide it to the **OFF** position.

   The system deactivates and the disposable excision ring blade stops spinning. The system is now ready to be used for the procedure.

CAUTION: Always pass the hand piece from one person to another with the **ON/OFF** lever in the **OFF** position. Do not grab or pass the hand piece by the cutting head due to the risk of contact with the excision ring blade.



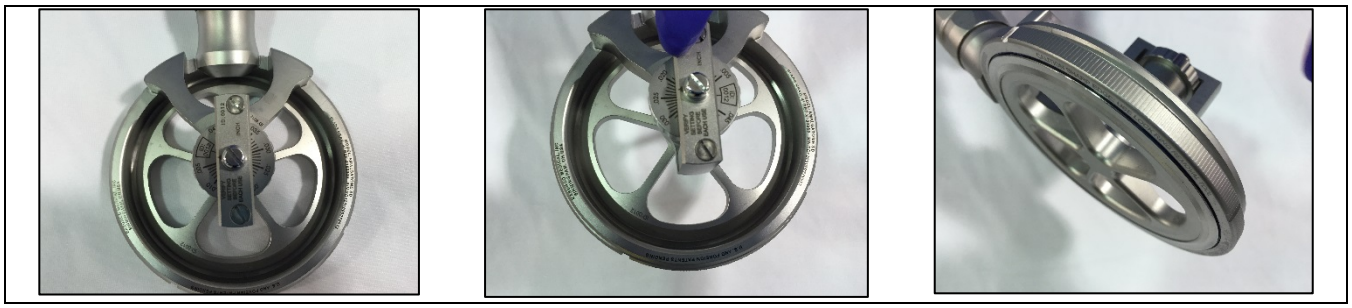
Passing the Hand Piece

Depth Gauge Setting

The settings on the depth adjustment knob indicate increments of 0.001 inches (0.0254 mm) and cover a range of 0.005 to 0.045 inches (0.127 to 1.143 mm).

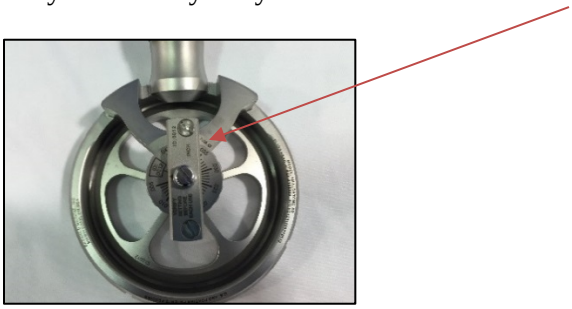
The depth gauge settings are a guide only and the resulting skin graft is dependent upon the individual patient demographics (e.g. age, weight, ethnicity, etc.).

Rotate the depth adjustment knob to the left (counterclockwise) for thinner settings and to the right (clockwise) for thicker settings. The depth gauge setting can be changed at any time during the procedure.



Setting the Depth Gauge

CAUTION: Do not disassemble the depth gauge. The gauge can lose calibration and must be returned to Exsurco Medical for recalibration. Never remove the screws or components on the gauge knob for cleaning or sterilization. They must always stay intact.



Operating Instructions

This section describes the process for graft harvesting and debridement, and post-operative procedures.

Graft Harvesting and Debridement

- The Amalgatome SD System is designed for use by qualified and trained medical professionals where the patient is under supervision of trained personnel.
- Each physician must evaluate the appropriateness of the technique used for each patient which should be based on his or her own medical training and expertise.
- Care should be taken in treating individuals with pre-existing conditions that can affect the success of the surgical procedure.
- Every patient is different and results can vary.
- It is recommended to always begin debridement and skin grafting procedures on a low depth setting and increase the depth gauge as necessary to the optimal setting. The surgical site should be selected per facility protocol for the surgical procedure as determined for skin grafting or wound debridement.
- Skin should be prepared per hospital protocol.

1. Lubricate the skin graft site with sterile mineral oil or sterile water in order to decrease excision ring blade resistance through the tissue.

   NOTE: Prolonged exposure to saline can damage the hand piece or cause pitting or corrosion.

2. Set the depth gauge to the desired setting.
3. Activate the system by sliding the **ON/OFF** lever to the **ON** position and pressing down on the lever.

   When the system activates, the disposable excision ring blade spins.

4. Position the cutting head at the desired starting point, and then apply a slight downward pressure to ensure the cutting edge of the disposable excision ring blade maintains contact with the recovery site. Only light pressure is required.

   NOTE: The system cuts with the trailing edge of the excision ring blade.

   The excision begins.

5. Move the cutting head in the desired direction, maintaining a slow and steady speed in order to ensure that the desired graft thickness and width is recovered.

   NOTE: At any point during the procedure the depth gauge setting can be adjusted by turning the depth adjustment knob on the gauge either to the left (counterclockwise) to decrease the thickness or to the right (clockwise) to increase the thickness.

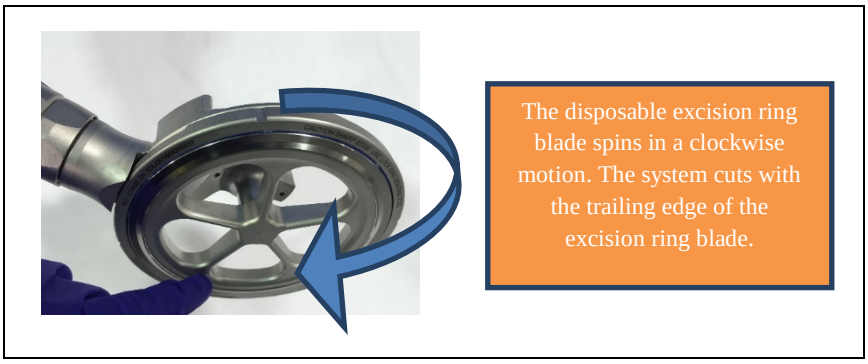


Figure 5

The excision continues and the skin graft and/or debrided tissue starts to emerge from the cutting head.

6. Use either of the following methods to collect the recovered graft or debrided tissue:
   - Method 1: Use tissue forceps to gently lift the graft as it emerges from the cutting head. Do not stretch or pull the graft as it emerges from the cutting head.
   - Method 2: When the graft emerges from the cutting head, allow the graft to collect in the cutting head.

   NOTE: There is a 15° angle built into the handle so you do not need to hold the hand piece at an angle to recover a skin graft or debrided tissue. For additional pictorial reference, refer to the figures on the following page.

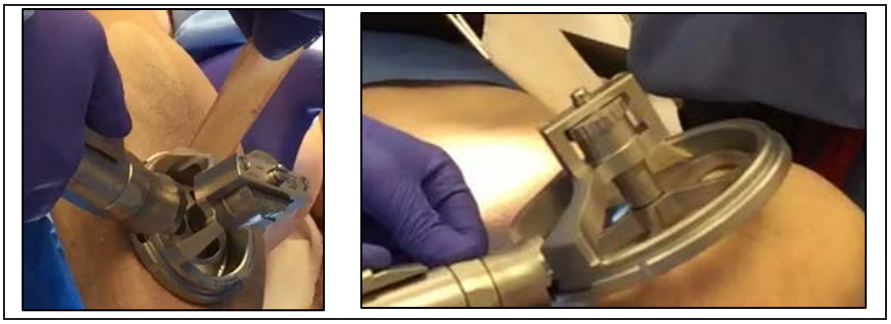


Figure 6a

Cross Section Diagrams

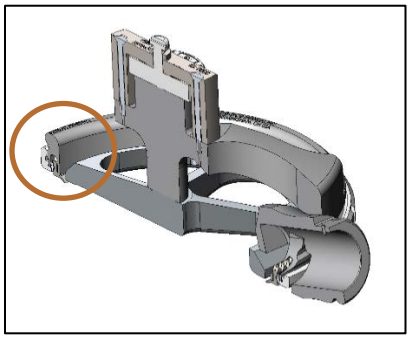


Figure 6b: Magnified view of cutting head

Direction of motion

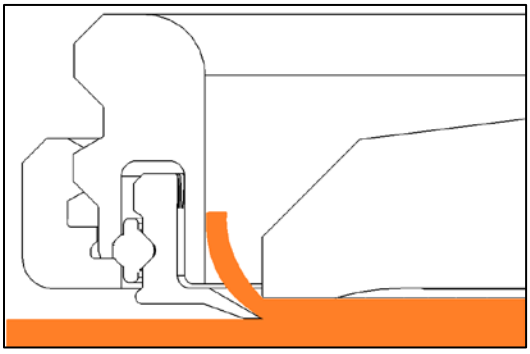


Figure 6c: Cutting portion or "trailing edge" of the instrument held parallel to the patient. Demonstrating good excision ring blade engagement.

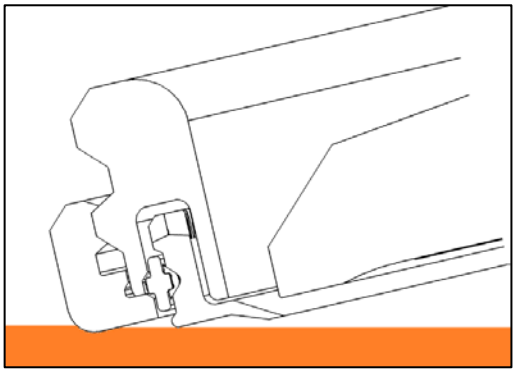


Figure 6d: Cutting portion or "trailing edge" of the instrument
Held at an angle to the patient.
Excision ring blade edge is not in contact.
As you collect the recovered graft, the excision continues.

7. To end the graft recovery, sever the graft, or stop procedure, move the hand piece in an angled, upward motion away from patient's body. This causes the excision ring blade to cut off the end of the graft.

   The disposable excision ring blade cuts off the end of the skin graft.

8. Release the **ON/OFF** lever, and then slide it to the **OFF** position.

   The system deactivates and the disposable excision ring blade stops spinning.

9. For wound debridement, once the surgical site is prepped and determined, begin to debride using techniques per hospital protocol until the wound bed is properly debrided and ready for the next step in the wound care protocol.
10. If the device seems to appear "sluggish" or the motor RPM seems to struggle or not perform as normal, it is acceptable to place a few drops of sterile mineral oil down into the pinion of the hand piece to lubricate the motor.
11. During the procedure, when the device is not being used and in the OFF position, it is recommended to place on back table or sterile field location NOT on top of patient or in the operating zone, but in an easy to accessible sterile location when needed.

Postoperative Procedure

Perform this procedure after the skin graft has been recovered or the wound debridement procedure is completed and the Amalgatome SD has been returned to the surgical back table or instrument table. Refer to Appendix D: Quick Reference Guides for a pictorial reference guide to this procedure.

1. Disconnect the pneumatic hose from the wall source.
2. Use a "push in and twist" motion to unlock it from the security tab, and disconnect the pneumatic hose from the hand piece.
3. Place the pneumatic hose in the instrument tray.
4. Remove the disposable excision ring blade from the hand piece. NOTE: Surgical team MUST remove the excision blade from device and dispose of prior to sending device to SPD for reprocessing.
   a. Use the lock ring removal tool to loosen the excision ring blade lock ring by engaging the tool with the notches in the lock ring and using a counterclockwise motion to remove the ring.
   b. Turn the hand piece lever-side-up and allow the excision ring blade to release freely onto the table.

   CAUTION: At this time, the excision ring blade is lying gear teeth side down on the table. Do not touch the inner ring of the excision ring blade. It is the sharp cutting surface. Only handle the blue strip on the outside.

   c. Taking care as to not touch the inner ring, grasp the outer ring excision ring blade around the blue strip and dispose of properly in a designated sharps container per hospital protocol.
   d. Place the lock ring and lock ring removal tool back into the sterilization tray.

5. Disassemble the hand piece from the cutting head.
   a. Using a counterclockwise motion, loosen the cutting head from the hand piece.
   b. Using sterile water, remove any apparent debris from the Amalgatome SD components in order to prevent the drying of blood and body fluids.
   c. Place the cutting head into the sterilization container.
   d. Place the hand piece into the sterilization tray.

   CAUTIONS:

   - Do not allow blood, tissue, or disinfectants to dry on any part of the Amalgatome SD System.
   - Do not use cleaning agents with chlorine or chloride (e.g., saline or bleach) as the active ingredient as they are corrosive to stainless steel and can result in physical damage to the system, including rust and corrosion.
   - Do not use saline as it has a corrosive effect on stainless steel and can result in physical damage to the system.
   - Always use cleaning agents that are safe for surgical instruments and stainless steel.
   - Immediately disconnect the pneumatic hose once the surgical case is complete.
   - Do not lay device on patient when not in use, place on back table or accessible sterile field location.

6. Prepare the Amalgatome SD and sterilization tray for transport to the decontamination department per facility protocol.
7. Secure the instrument tray for transport.

This page intentionally left blank.

Cleaning and Sterilization Instructions

This section describes the Amalgatome SD System cleaning and sterilization requirements.

The Amalgatome SD is reusable and requires cleaning and sterilization prior to reuse. **Manual cleaning and Automated Cleaning have both been validated for use with the system.** It is important to exercise care when handling the components to protect them from physical damage. Only remove the components as instructed in the following procedures. Any further disassembly of the system can cause damage and/or loss of calibration and will void the warranty. The system contains no user-serviceable parts and must be returned to Exsurco Medical for repair and maintenance.

As with any decontamination procedure, follow the accepted guidelines for hand washing, use of personal protective equipment (PPE), etc., as recommended by the Association for the Advancement of Medical Instrumentation (AAMI) Standards and Recommended practice, *Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Non-Clinical Settings, current version of ANSI/AAMI ST35*.

CAUTIONS:

- Do not allow blood, tissue, or disinfectants to dry on any part of the Amalgatome SD System.
- Do not use cleaning agents with chlorine or chloride (e.g., saline or bleach) as the active ingredient as they are corrosive to stainless steel and can result in physical damage to the system, including rust and corrosion.
- Do not use saline as it has a corrosive effect on stainless steel and can result in physical damage to the system.
- Always use cleaning agents that are safe for surgical instruments and stainless steel.
- Never place the pneumatic hose in any kind of automated washing system.
- Always inspect instruments and devices for rust and corrosion per AORN and hospital protocols.

Manual Cleaning of the Sterilization Tray

1. Prepare a neutral pH or instrument-safe enzymatic cleaning solution according to the cleaning solution manufacturer specifications.

Figure 1

2. Disassemble the tray into its individual components:
   - Base
   - Lid
   - Internal instrument tray

   NOTE: For additional part number information, refer to Appendix B: Parts Information.

3. Rinse each component under running tap water for a minimum of one minute in order to remove excess soil.
4. Immerse the base, internal instrument tray, and lid into the cleaning solution and let soak for a minimum of five minutes. Do not immerse the unit overnight.
5. While still immersed in the cleaning solution, use a non-metal, soft-bristled brush moistened with cleaning solution to scrub each component for a minimum of two minutes each and until visibly clean.
6. Place each component in a tap water bath for a minimum of one minute, and then repeat one time using fresh tap water. Do not immerse the unit overnight.
7. Place each component in a critical water (e.g., deionized (DI), reverse osmosis (RO), or distilled water) bath for a minimum of one minute. Do not immerse the unit overnight.
8. Using a sterile, lint-free wipe, dry each component. Use multiple wipes as necessary.
9. In a well-lit area, visually inspect each component in order to ensure all surfaces are clean and dry.

Automated Cleaning of the Sterilization Tray

1. Prepare a neutral pH or instrument-safe enzymatic cleaning solution according to the cleaning solution manufacturer specifications.
2. Disassemble the tray into its individual components:
   a. Base
   b. Lid
   c. Internal instrument tray

NOTE: For additional part number information, refer to Appendix B: Parts Information.

3. Rinse each component under running tap water for a minimum of one minute in order to remove excess soil.
4. Immerse the base, internal instrument tray, and lid into the cleaning solution and let soak for a minimum of two minutes. Do not immerse the unit overnight.
5. While still immersed in the cleaning solution, use a non-metal, soft-bristled brush moistened with cleaning solution to scrub each component for a minimum of one minutes each and until visibly clean.

Place each component in a tap water bath for a minimum of one minute, and then repeat one time using fresh tap water. Do not immerse the unit overnight.

6. Follow the below automated wash instructions:

Table 1 (Automated Cleaning Instructions for Use- Sterilization Tray)

Cycle	Time (minutes: seconds)	Minimum Temperature	Type of Detergent/ Water
Prewash	2:00	Cold	Tap
Wash	4:00	Heated Tap (60°C)	Enzymatic Cleaner (per the manufacturer's instructions)
Neutralize	2:00	Hot Tap	Neutral Detergent (per the manufacturer's instructions)
Rinse	0:15	Hot or Heated	Tap
Thermal Rinse	5:00	Heated (90°C)	Heated Deionized or High Purity Water
Dry	15:00	High (98.8°C)	NA

7. Using a sterile, lint-free wipe, dry each component. Use multiple wipes as necessary.
8. In a well-lit area, visually inspect each component in order to ensure all surfaces are clean and dry.

Manual Cleaning of the Reusable System

1. Prepare a neutral pH or instrument-safe enzymatic cleaning solution according to the cleaning solution manufacturer specifications.
2. Using the lock nut wrench that is provided with the system, remove the locking knob and locking nut.

   NOTE: This is a left-handed thread. Turning the knob and nut clockwise loosens or removes them.

   NOTE: These are two separate components so keep them together with other components and take care not to misplace them.

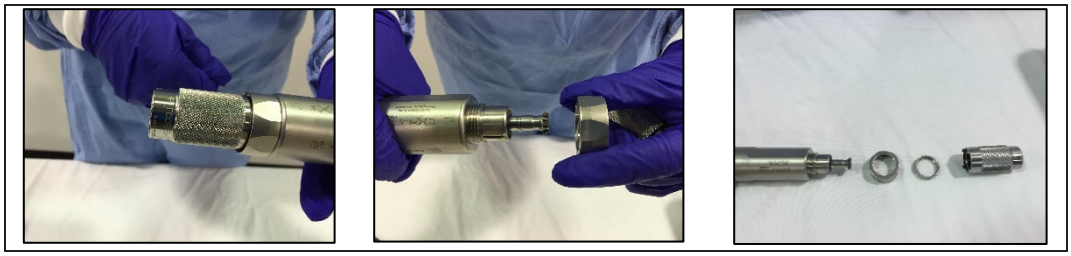


Figure 2

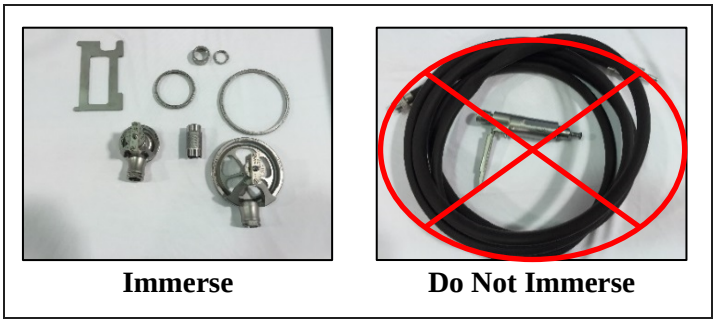


Figure 3

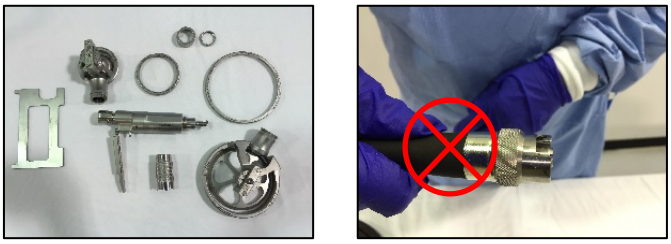
Figure 4

3. With the exception of the hand piece and pneumatic hose, immerse the components into the cleaning solution and let soak for a minimum of two minutes. Do not immerse the unit overnight.

   NOTE: For additional part number information, refer to Appendix B: Parts Information.

4. Using a lint-free wipe moistened with the cleaning solution, wipe the hand piece and the pneumatic hose for a minimum of one minute each.

   CAUTION: Do not immerse the hand piece or pneumatic hose into the cleaning solution.



Scrub

Do Not Scrub the Silicone Hose

Figure 5

Immerse

Do Not Immerse

Figure 6

Figure 7

5. Using a non-metal, soft-bristled brush moistened with the cleaning solution, scrub all of the components with the exception of the silicone portion of the tubing for a minimum of 30 seconds each and until visibly clean.

   NOTE: For additional part number information, refer to Appendix B: Parts Information.

   CAUTION: Do not scrub the silicone portion of the pneumatic hose. Never place hose in automated washing system.

   CAUTION: Do not immerse the hand piece or pneumatic hose into the cleaning solution.

6. With the exception of the hand piece and pneumatic hose, place the components into a fresh tap water bath for a minimum of one minute, and then repeat one time using fresh tap water. Do not immerse the unit in water. In the event the unit is immersed in water please hold with end where pneumatic hose attaches to allow for water to drain out.

   NOTE: For additional part number information, refer to Appendix B: Parts Information.

   CAUTION: Do not immerse the hand piece or pneumatic hose into the water.

7. Moisten a sterile, lint-free wipe with tap water, and wipe the hand piece and pneumatic hose for a minimum of one minute each. Use multiple wipes as necessary. Repeat this step one time using fresh wipes.

   CAUTION: Do not immerse the hand piece or pneumatic hose into the water.

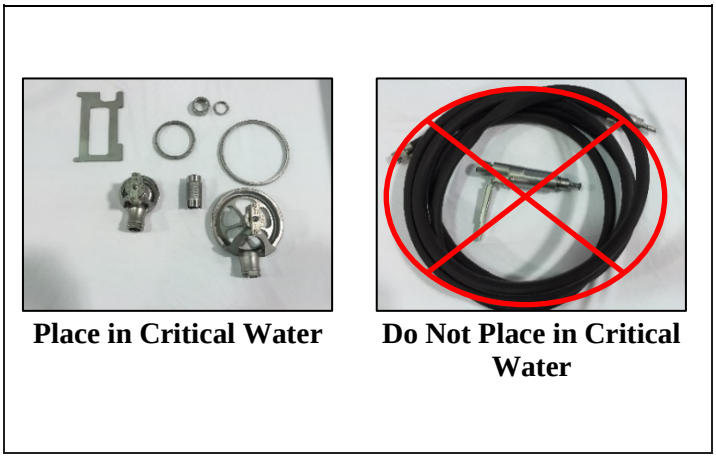


Figure 8

8. With the exception of the hand piece and pneumatic hose, place the components into a critical water (e.g., DI, RO, or distilled water) bath for a minimum of one minute. Do not immerse the unit overnight.

   NOTE: For additional part number information, refer to Appendix B: Parts Information.

   CAUTION: Do not place the hand piece or pneumatic hose into the critical water (e.g., DI, RO, or distilled water) bath.

Figure 9

9. Moisten a sterile, lint-free wipe with critical water, and wipe the hand piece and pneumatic hose for a minimum of one minute each. Use multiple wipes as necessary.

   CAUTION: Do not immerse the hand piece or pneumatic hose into the critical (e.g., DI, RO, or distilled water) water.

Figure 10

10. Using a sterile, lint-free wipe, dry each component. Use multiple wipes as necessary.

11. In a well-lit area, visually inspect each component in order to ensure all surfaces are clean and dry.

12. Using the lock nut wrench, replace the locking knob and locking nut back onto the hand piece.

    NOTE: This is a left-handed thread. Turning the knob and nut counterclockwise tightens or replaces them.

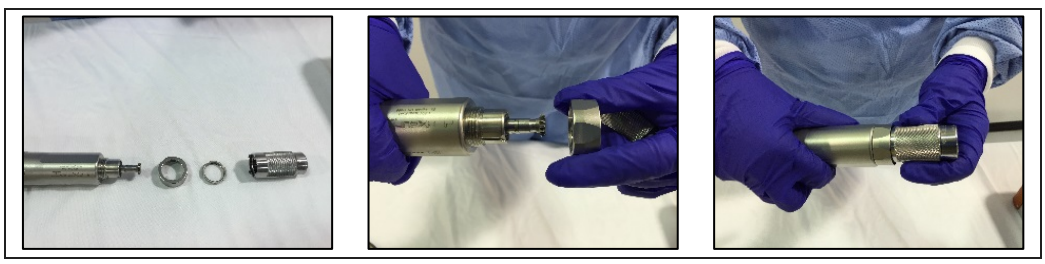
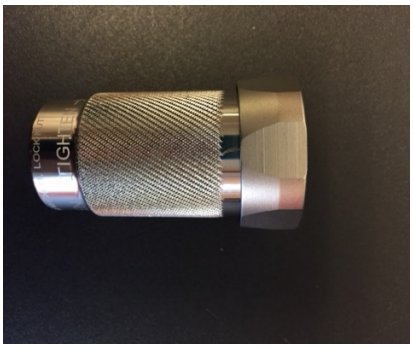


Figure 12

It is important when re-assembling the lock nut and locking knob back onto the handpiece the lock nut and locking knob are placed in the proper order and orientation on the hand piece. Below is a closeup showing the connection of the lock nut onto the wrench, and the locking knob onto the handpiece for ease in assembly:

Assemble lock nut onto wrench



Place lock knob over top of lock nut on wrench, the "U" facing UP.

Slide wrench (with lock nut and lock knob on) over the pinion of handpiece to engage at base of handpiece and screw on, finger tight, counter clockwise till secure. NOTE: the design on the handpiece should match the lock knob, and when looking down onto the handpiece the bottom of the U should be facing out.

Automated Cleaning of the Reusable System

Please follow the exact same steps outlined above in steps 1-7 for automated cleaning. It is the same pre-cleaning protocol for the components. When finished with step 7 above, stop (Do Not Follow Steps 8-10). Follow the automated cycle parameters validated below:

NOTE: Load the Hand piece, open end facing down, an angle (to allow for draining) into the washer-disinfector.

Table 1 (Automated Cleaning Instructions for Use- Reusable System)

Cycle	Time (minutes: seconds)	Minimum Temperature	Type of Detergent/ Water
Prewash	2:00	Cold	Tap
Wash	4:00	Heated Tap (60°C)	Enzymatic Cleaner (per the manufacturer's instructions)
Neutralize	2:00	Hot Tap	Neutral Detergent (per the manufacturer's instructions)
Rinse	0:15	Hot or Heated	Tap
Thermal Rinse	5:00	Heated (90°C)	Heated Deionized or High Purity Water
Dry	15:00	High (98.8°C)	NA

Upon completion of the automated cycle, inspect as outlined below:

9. In a well-lit area, visually inspect each component in order to ensure all surfaces are clean and dry.

10. Using the lock nut wrench, replace the locking knob and locking nut back onto the hand piece.

Visual Inspection

After cleaning and during and after reassembly, visually inspect all system components for visual contaminants. If any contaminants are present, re-clean following the appropriate cleaning instructions. Perform a component count in order to ensure that all components are present and none have been lost during the cleaning process. Check for any corrosion on the laser etching of the components. If present, contact Exsurco Medical Customer Service for a Service Repair Order at 1-800-243-6049, ext. 4, or email support@exsurco.com.

Sterilization Preparation

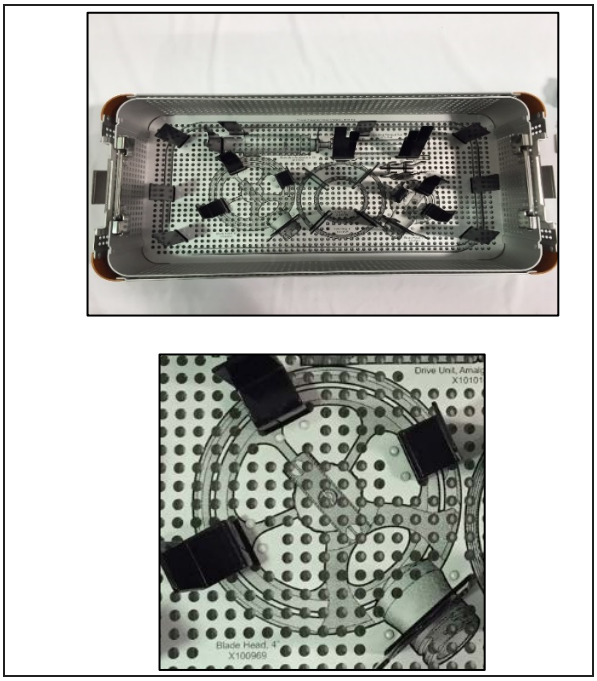


Figure 1

1. Place the clean components into their proper locations in the previously cleaned sterilization tray.

   NOTE: There are visual guides, including part number and description, marking the correct location for the placement of each component.

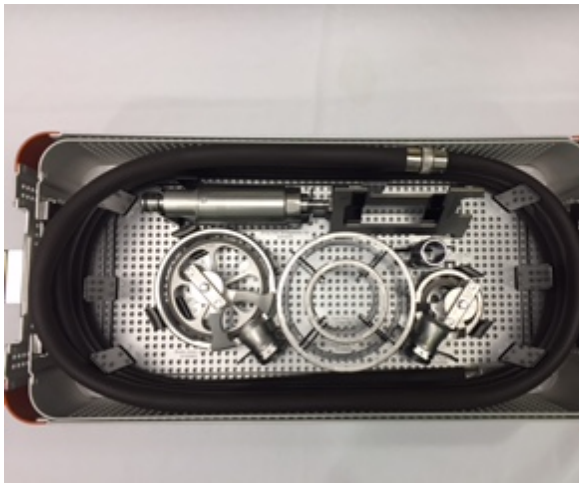


Figure 2

2. Place each component into the sterilization tray.
   - Do not bend or damage any of the components.
   - Ensure that the pneumatic hose is coiled carefully around the outside, taking care as to not crimp it into the compartment.
   - Place the hand piece into the sterilization tray.
   - Ensure that the lock nut and lock knob have been previously assembled to the hand piece.
   - Use the lock nut wrench to properly tighten the knob and nut into place if necessary.
   - Do not disassemble the depth gauge.
   - Do not disassemble any screws, washers, the pinion, or the lever from the hand piece.
   - Do not remove the end connectors from the pneumatic hose.

3. Double wrap the sterilization tray with all components inside using United States (US) Food & Drug Administration (FDA)-cleared Center for Scientific Review (CSR)-type wrap per methods listed in current version of *ANSI/AAMI ST79, A1, A2, A3, A4* and adhere with chemical indicator autoclave tape.

Sterilization

The Amalgatome SD System has only been validated for steam sterilization using the sterilization tray and FDA-cleared wrap. Should any other method or sterilization tray be used, it is the sole responsibility of the facility to validate any sterilization parameters that are not provided directly by the manufacturer. The Amalgatome SD System is provided non-sterile and must be sterilized prior to use.

The wrapped sterilization tray shall be placed inside an autoclave validated in compliance with current version of *AAMI ST8, Hospital Steam Sterilizers*.

Utilize one of the two validated steam sterilization methods listed below to provide a sterility assurance level of 10^{-6}. Upon completing sterilization, store the Amalgatome SD System in the sterilization packaging in a dry and dust-free place. The shelf life is dependent on the sterile barrier employed, manner in which product is stored, environment and handling conditions. A maximum shelf life for sterilized medical devices before use should be defined by each healthcare facility.

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

Cycle Type	Pre-vacuum
Pulses	4
Set-Point Temperature	135°C/ 275°F
Exposure Time [1]	3 minutes
Drying Time [2]	16 minute in chamber

Cycle Type	Gravity
Set-Point Temperature	135°C/ 275°F
Exposure Time [1]	10 minutes
Drying Time [2]	30 minute in chamber

[1] Exposure time: Period for which the load and entire chamber is maintained at the sterilization temperature.

[2] Drying time: Period during which steam is removed from the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. The drying time varies due to load configuration, wrapping method and material. It is the hospital's responsibility to validate the appropriate drying time with the sterilization equipment used.

Troubleshooting

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

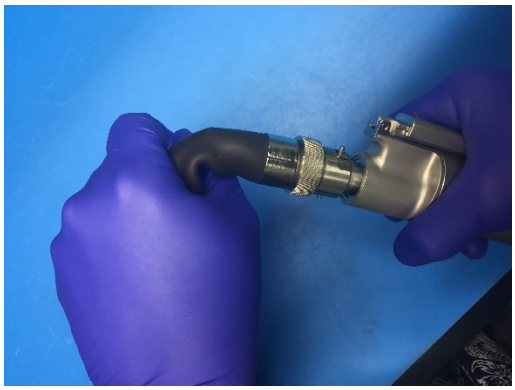
Use the following assessment steps to confirm proper operation of the Amalgatome SD System. If you discover a problem with any of these items, do not use the system; return it to Exsurco Medical for service. For additional information, refer to the Warranty, Service, and Returns section.

- Visually inspect the system for any signs of physical damage or wear:
  - Loose parts
  - Missing or loose screws
  - Signs of being dropped or bent
  - Areas with corrosion or pitting
- Check for the proper turning of the depth adjustment knob and depth gauge.
- Verify proper connection and fit of the pneumatic hose, ensuring that both ends of the pneumatic hose (to the hand piece and the air or gas supply) fit properly to their mating receptacles.
- Verify that the air supply is turned on and set to 100 psi and that the wall indicator or pressure gauge is reading correctly while the system is running.
- If no issues are observed during this assessment but performance issues are experienced, refer to the troubleshooting table below.

Problem	Possible Solution
System fails to spin excision ring blade when activated hand piece when engaged with the disposable excision ring blade and lock ring installed	• Verify that the excision ring blade and its mating surfaces are free of lint and other particulate which can hinder free movement of the excision ring blade. • Check the condition of the excision ring blade lock ring for any distortion or rough edges that might prevent the excision ring blade from moving properly. In this case, return the system to Exsurco Medical for service and repair. • Verify that the on/off button is working properly by sliding the **ON/OFF** lever to the **ON** position, and then pressing down on the lever to engage the motor. If the lever does not press down on the on/off button, the system will not operate. • Check the system for any evidence of being dropped or damaged as this can affect the operation and calibration of the depth gauge. In this case, return the system to Exsurco Medical for service and repair. • Check pneumatic air hose for any potential leaks or cuts in it that would prevent the proper pressure required to power device. • Remove the excision ring blade, cutting head, and hose from the drive unit. Turn the pinion (gear) and check for free rotation. Rotation should feel smooth and consistent. Otherwise it can indicate particulate in the motor or damaged bearings. If this is observed, return the unit to Exsurco Medical for servicing or repair.

Problem	Possible Solution
Actual graft thickness varies from the thickness guide on the depth setting	• Note that the actual thickness of the graft is dependent upon operator technique, the pressure applied to the hand piece and onto the skin, and the location and condition of the tissue being harvested. For more information, refer to the Operating Instructions section. • Note that the depth gauge – the mechanism that controls the graft thickness – is set and calibrated at the factory prior to shipment. Removal of the screws controlling the depth gauge can affect how the depth gauge performs. If the screws have been removed, return the system to Exsurco Medical for service and repair. • Check the system for any evidence of having been dropped or damaged as this can affect the operation and calibration of the depth gauge. In this case, return the system to Exsurco Medical for service and repair.
Variation in graft thickness is observed during the procedure	• Note that the actual thickness of the graft is dependent upon operator technique, the pressure applied to the hand piece and onto the skin, and the location and condition of the tissue being harvested. For more information, refer to the Operating Instructions section. • Check all connections and ensure that the system is assembled correctly and the disposable excision ring blade is engaged with the pinion to allow free and uniform movement of the excision ring blade. • Check the air connection to ensure the pressure setting is 100 psi with the system running, allowing the motor to provide continuous operation to the excision ring blade without interruptions in power. An interruption can cause random bursts of power that might affect the graft thickness. • Verify that the graft site is lubricated with sterile water or sterile mineral oil in order to decrease any excision ring blade resistance. • Check the system for any evidence of having been dropped or damaged as this can affect the operation and calibration of the depth gauge. In this case, return the system to Exsurco Medical for service and repair.
Graft quality	• Verify that the graft site is lubricated with sterile water or sterile mineral oil to decrease any excision ring blade resistance. • Check to make sure there is no debris or defects on the excision ring blade. • Note that the actual thickness of the graft is dependent upon operator technique, the pressure applied to the hand piece and onto the skin, and the location and condition of the tissue being harvested. For more information, refer to the Operating Instructions section. • Note that the depth gauge—the mechanism that controls the graft thickness—is set and calibrated at the factory prior to shipment. Removal of the screws controlling the depth gauge can affect how the depth gauge performs. If the screws have been removed, return the system to Exsurco Medical for service and repair. • Check the system for any evidence of having been dropped or damaged as this can affect the operation and calibration of the depth gauge. In this case, return the system to Exsurco Medical for service and repair.

Problem	Possible Solution
Disposable excision ring blade does not seem to be working properly	• Verify that the excision ring blade and its mating surfaces are free of lint and other foreign objects which can hinder free movement of the excision ring blade. • Verify that the excision ring blade is not clogged with debris, skin, or fabric from the Operating Room (OR) towels, sponges, or drape material, which can hinder free movement of the excision ring blade. • Check for any visible nicks or dings in the excision ring blade caused by running over metal objects. Do not attempt to cut exposed bone, tendon, or similar material. The system is intended to cut skin only.
Uneven or chattered edges on the skin graft	• Operate the system with a slow and steady speed. Moving too fast does not allow the user to adjust to body contours or irregularities in tissue. • Reduce speed and review proper angle and pressure to ensure that the correct technique is being used.
Crescent shaped appearance in the skin graft	• Operate the system with a slow and steady speed. Moving too fast does not allow the user to adjust to body contours or irregularities in tissue. This results in crescent moon shaped patterns or uneven thickness of grafts. • Reduce speed and review proper angle and pressure to ensure that the correct technique is being used.
Skin graft is not uniform or too thick/narrow in the middle	• Note that the depth gauge plate on the hand piece is designed to flatten the skin as it approaches the cutting edge. • Do not apply additional pressure or too much angle on the hand piece because it causes the tissue to compress itself into the hand piece, resulting in skin grafts that are thick in the middle and thin on the edges, and too narrow. • Reduce speed and review proper angle and pressure to ensure that the correct technique is being used.
Inadvertently dissected skin graft during harvesting	• The excision ring blade cuts with the trailing edge. Attempting to keep the instrument too flat can inadvertently lift the cutting edge away from the recovery site. • Reduce speed and review proper angle and pressure to ensure that the correct technique is being used.
Gradual loss of rpm or power	• Re-lubricate the drive unit by placing 1-3 drops of sterile mineral oil in the air inlet, and run the device for 2 minutes to ensure even internal distribution.  **NOTE** it is NOT recommended that this be performed after every use due to the risk of mineral oil buildup in the hose. It is not recommended that this be performed in the operating room due to potential for oil misting from the hose exhaust.

Problem	Possible Solution
Instant loss of function of the drive unit (device no longer capable of performing an operation)	• Return the device to Exsurco Medical for service and repair
Lever depression feels "tacky" or the lever does not freely rebound after release of pressure	• Re-lubricate the activation plunger using 1 drop of sterile mineral oil, and exercise the lever in the ON position until it is no longer "tacky" 
O-Ring on Hand Piece appears worn	• Normal wear of the O-ring is expected. The O-ring will be replaced during the annual Preventive Maintenance.
Pneumatic Hose difficult to connect to hand piece	• Lubricate the O-ring prior to connecting the air hose with sterile mineral oil. This will help make the female end of the air hose easier to attach to the male end of the hand piece using the toggle barbs. Do not bend hose at a 90° angle at the connection site. Do not use excessive force during the process.  

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 SD 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 SD 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 SD 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 particular purpose or application or warranty of quality as well as any express or implied warranty to patients.

The Exsurco Medical Amalgatome SD System is intended for use only with the Amalgatome SD disposable excision ring blade. Using another manufacturer's excision ring blades in conjunction with the Amalgatome SD voids the product warranty.

Service

The Amalgatome SD 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 SD 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.

The Amalgatome SD System must be returned every 12 months for inspection and preventative maintenance. The pneumatic hose must be replaced every 12 months or sooner if there is evidence of wear (holes/ cuts/ tears). A review of the hose from Exsurco Medical will determine warranty replacement. Annual factory calibration is strongly recommended in order to ensure consistent operation and accuracy.

Returns

When it is necessary to return the Amalgatome SD 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. The 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.

This page intentionally left blank.

Appendix A: Technical Specifications

Specifications

Specification	Value
Maximum Graft Width	2-inch Cutting Head: 2 in. (5.08 cm) 4-inch Cutting Head: 4 in. (10.16 cm)
Air Consumption	11 cfm
Input Air Pressure	100 psi, with system running (6.2 bar) Hospital Grade Air (compressed air, nitrogen)
Storage and Transport (Amalgatome SD System)	As per internal hospital procedure.
Weight and Measurement	Assembled 2-inch hand piece: 3.1 lb. Assembled 4-inch Unit: 3.7 lb. Hand Piece and Pneumatic Hose weight: 2.7 lb., length: 15 feet Complete SDSYSTEM024 in sterilization tray: 17.8 lb. Weight of Empty Sterilization Tray: 9.7 lb. Dimensions of the fully assembled tray: 21 x 10.25 x 4 in.
Sterile, Single-Use Excision ring blades Environmental Conditions	It is recommended these materials be stored in the provided packaging in a cool (under 32°C (90°F)), clean and dry area. Humidity Condition Storage Range: 30-70%

This page intentionally left blank.

Appendix B: Parts Information

Part #: SDSYSTEM024
Description: Exsurco Amalgatome SD Skin Grafting and Wound Debridement System (2-inch and 4-inch)

Quantity	Part #	Description
1 each	X101016	Amalgatome SD Hand Piece (Drive Unit)
1 each	X101005	Amalgatome SD Sterilization Tray
1 each	X101489	Amalgatome SD Sterilization Tray User Guide
1 each	X101004	Amalgatome SD Pneumatic Hose (length: 15 ft)
1 each	X100968	Amalgatome SD 2-inch Cutting Head
1 each	X100969	Amalgatome SD 4-inch Cutting Head
1 each	X100768	Amalgatome SD 2-inch Lock Ring
1 each	X100825	Amalgatome SD 4-inch Lock Ring
1 each	X100966	Amalgatome Lock Ring Removal Tool
1 each	X101133	Amalgatome Lock Nut Wrench
1 each	X101456	Amalgatome SD User Guide
1 each	X101491	Amalgatome SD Intro Letter

Sterile, Disposable Excision ring blades sold separately. Use only the excision ring blades listed below for this product. Failure to do so voids the warranty and can cause injury:

- Part #: X101006 - 2-inch ASD Excision ring blade (1 each)
- Part #: X101007 - 4-inch ASD Excision ring blade (1 each)

Exsurco also offers the following Amalgatome SD System configurations in just one size:

Part #: SDSYSTEM02
Description: Exsurco Amalgatome SD Skin Grafting and Wound Debridement System (2- inch)

Quantity	Part #	Description
1 each	X101016	Amalgatome SD Hand Piece (Drive Unit)
1 each	X101005	Amalgatome SD Sterilization Tray
1 each	X101489	Amalgatome SD Sterilization Tray User Guide
1 each	X101004	Amalgatome SD Pneumatic Hose
1 each	X101968	Amalgatome SD 2-inch Cutting Head
1 each	X100768	Amalgatome SD 2-inch Lock Ring
1 each	X100966	Amalgatome Lock Ring Removal Tool
1 each	X101133	Amalgatome Lock Nut Wrench
1 each	X101456	Amalgatome SD User Guide
1 each	X101491	Amalgatome SD Intro Letter

Part #: SDSYSTEM04
Description: Exsurco Amalgatome SD Skin Grafting and Wound Debridement System (4-inch)

Quantity	Part #	Description
1 each	X101016	Amalgatome SD Hand Piece (Drive Unit)
1 each	X101005	Amalgatome SD Sterilization Tray
1 each	X101489	Amalgatome SD Sterilization Tray User Guide
1 each	X101004	Amalgatome SD Pneumatic Hose
1 each	X100969	Amalgatome SD 4-inch Cutting Head
1 each	X100825	Amalgatome SD 4-inch Lock Ring
1 each	X100966	Amalgatome Lock Ring Removal Tool
1 each	X101133	Amalgatome Lock Nut Wrench
1 each	X101456	Amalgatome SD User Guide
1 each	X101491	Amalgatome SD Intro Letter

Ordering Information

To place an order for the Amalgatome SD System, 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

To order replacement components separately, please contact Customer Service at 1-800-243-6049, ext. 4, or email support@exsurco.com.

This page intentionally left blank.

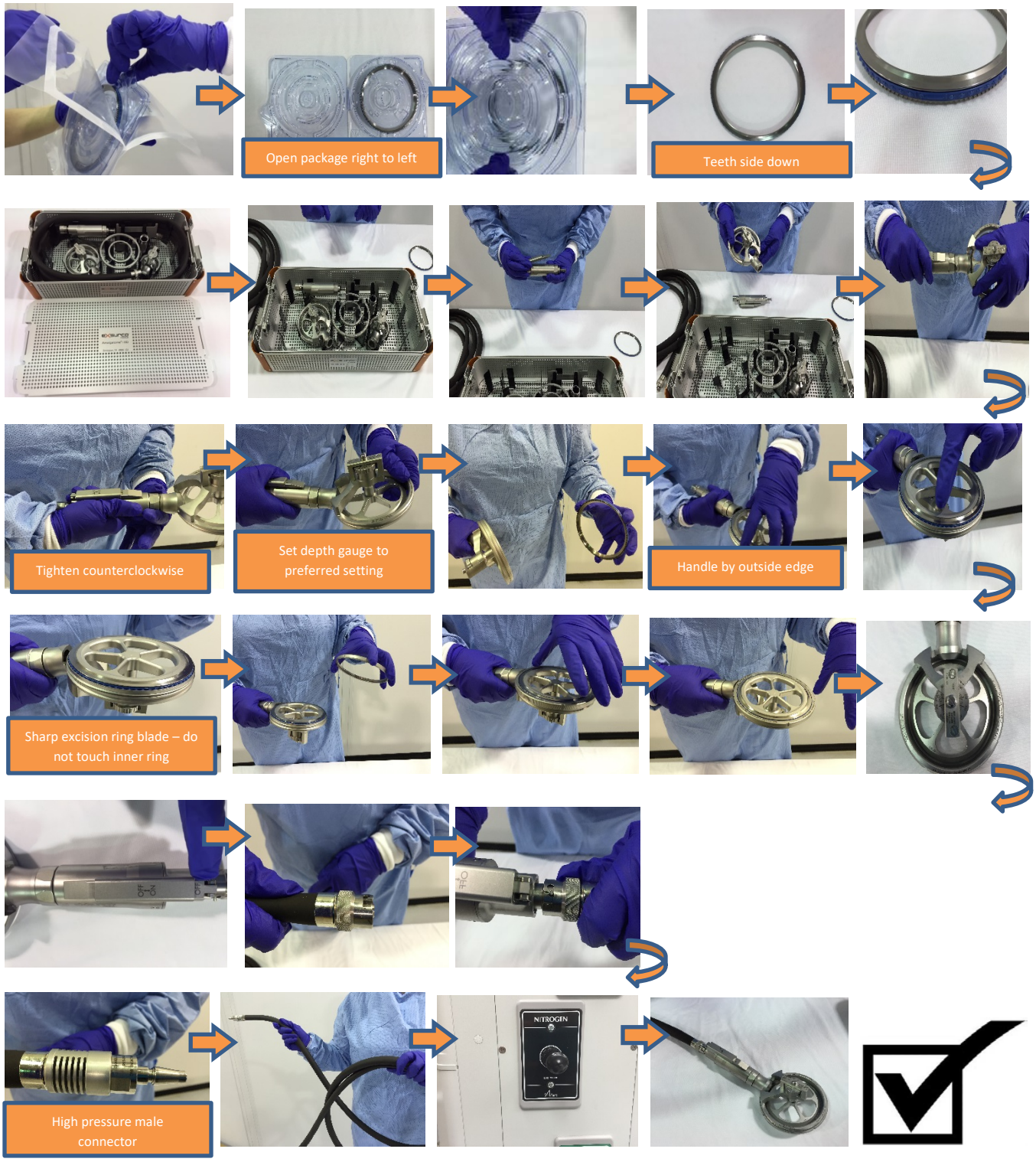
Appendix C: Glossary of Symbols

Symbol	Definition
	Serial Number
	Batch Code/Lot Number
	Manufacturer
	Caution: USA federal law restricts this system to sale by or on the order of a physician.
	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.

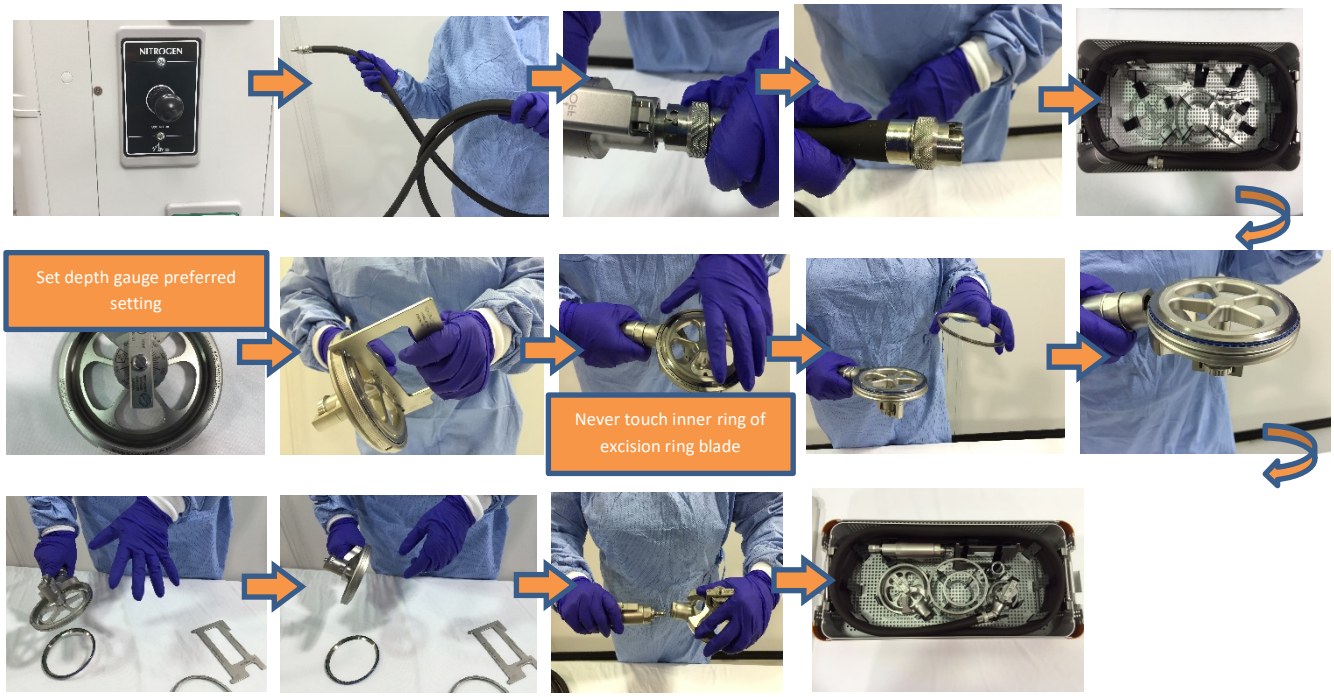
Symbol	Definition
	Caution
	Consult instructions for use
	Keep product dry
	Do not use if package is damaged
	This side up
	Sharp object
	General warning sign

Appendix D: Quick Reference Guides

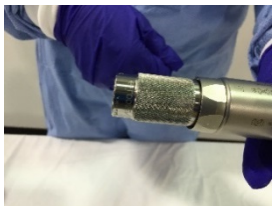
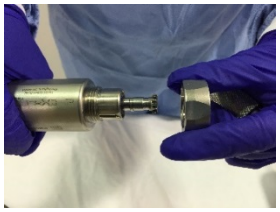
Setup



Postoperative Procedure



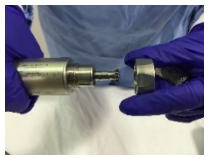
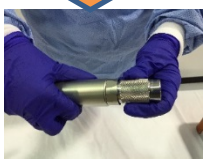
Manual Cleaning of the Reusable System


Clean with a soft-bristle brush


Lint-free wipe


Dry



Reassemble lock nut onto hand piece



Load ASD into Sterilization Tray

This page intentionally left blank.

Appendix E: References for Sterilization and Details of Validation Report

References

- Current version of ANSI/AAMI/ISO 17665-1 – Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of sterilization process for medical devices
- Current version of AAMI TIR12 – Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- Current version of ANSI/AAMI ST81 – Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- Current version of ISO 17664 – Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- Based on guidelines outlined in AAMI TIR12 – Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- Current version of AAMI TIR30 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, and Office of Device Evaluations (March 17, 2015). Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Document Guidance for Industry and Food and Drug Administration Staff
- Current version of ANSI/AAMI ST8 – Hospital steam sterilizers
- Current version of ANSI/AAMI ST79/A1/A2/ A3/A4 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities (Consolidated text)

Internal Validation Reports

- Steam Sterilization Efficacy Validation of the Amalgatome® SD Reusable Surgical Device Report - Project 154421.
- Cleaning Efficacy Validation of the Amalgatome® SD Reusable Surgical Device and Sterilization Tray – Manual Cleaning Report- Project 154421 Part I.
- Cleaning Efficacy Validation of the Amalgatome® SD Reusable Surgical Device and Sterilization Tray – Automated Cleaning Validation Summary Report- 165647
- The cleaning agents listed below were used by Exsurco Medical when validating the instructions for processing provided in this document.

Supplier	Designation	Comment
Steris	Prolystica® 2X Concentrate Enzymatic Presoak	neutral pH or instrument safe enzymatic cleaner

- Exsurco Medical does not recommend these products in preference to others that are available. Other products may perform equally in conjunction with the equipment being used. The instructions provided by the supplier of the detergents should be followed. Personal protection for operators should be provided in accordance with the supplier´s instructions and safety data sheets. Suitability of alternative agents should be checked by reference to the supplier's information and/or physical testing.

This page intentionally left blank.

Help 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 SD.

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

6 – Quality Department: support@exsurco.com

7 – Accounting Department:
support@exsurco.com

This page intentionally left blank.

Exsurco Medical
10804 Green Road
Wakeman, OH 44889

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

PN: X101456, Rev. C

Date Issued: January 31, 2018