



Amalgatome[®] SD Sterilization Tray User Guide

**EXSURCO MEDICAL
10804 GREEN ROAD
WAKEMAN, OH 44889**

PN: X101489 REV. B

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AMALGATOME® SD STERILIZATION TRAY 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 Sterilization Tray. It is designed for use by qualified and trained medical professionals. Review this user guide, paying particular attention to all warnings and precautions, prior to any sterilization 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.

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Preface

Purpose

This user guide provides directions to help users safely and effectively use the Amalgatome SD Sterilization Tray. The guide also includes material such as indications for use and troubleshooting information.

Exsurco Medical

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

Contact Information

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

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System Overview

This section provides general information about the Amalgatome SD Sterilization Tray.

Indications for Use

The Amalgatome SD Sterilization Tray is only intended for use to contain and protect the Amalgatome SD System (SDSYSTEM024/ SDSYSTEM02/ SDSYSTEM04). This is the only sterilization tray validated to contain the Amalgatome SD system for steam sterilization. This sterilization tray should not be used to sterilize any other instrument.

The maximum product load per sterilization tray includes one each of the following Amalgatome SD System components:

- Hand Piece (Drive Unit)
- Pneumatic Hose
- 4-inch Cutting Head (Blade Head)
- 2-inch Cutting Head (Blade Head)
- 4-inch Lock Ring
- 2-inch Lock Ring
- Lock Ring Removal Tool
- Lock Nut Wrench
-



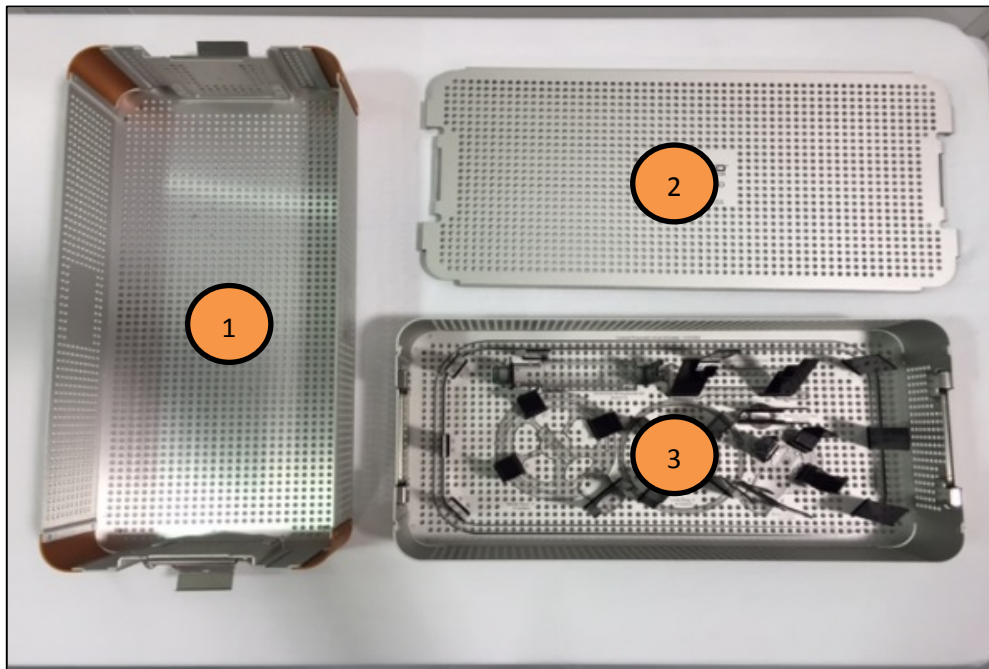
Figure 1: Fully Assembled Amalgatome SD Sterilization Tray

Description

The Amalgatome SD Sterilization Tray consists of an anodized aluminum base, nylon coated instrument brackets, internal instrument tray with component placement identifiers, handles, and a lid. The inserts to hold the individual components are configured within the sterilization tray specifically for securing the Amalgatome SD System components.

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Components



1. Base
2. Lid
3. Internal Instrument Tray

Figure 2: Components

How Supplied

- The Amalgatome SD Sterilization Tray is supplied non-sterile and is usable after cleaning and sterilization prior to use according to the procedures in the Operating Instructions section.
- It is packaged one per box.
- The sterilization tray must be inspected prior to cleaning and sterilization for any damages upon receipt.
- It carries a one-year warranty on all parts.
 - Customer is not to service the sterilization tray, including but not limited to performing maintenance on any of its components.
 - The warranty will be voided if the customer performs any maintenance on the sterilization tray.

Sterilization

The Amalgatome SD System has only been validated for steam sterilization using the Amalgatome SD Sterilization Tray and a United States (US) Food & Drug Administration (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 sterilization tray 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*.

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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 upon 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: For more information, refer to Appendix D: References for Sterilization and Details of Validation Report.

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

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

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

²Drying time: Period during which steam is removed from the chamber and 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 and the wrapping method and material. It is the hospital's responsibility to validate the appropriate drying time with the sterilization equipment used.

CAUTIONS:

- Do not load the sterilizer tray into a sterilizer so that the sterilizer tray lies on its side or upside down; always load it on the cart or shelf in a way so that the lid of the sterilization tray is facing upward.
- Do not stack Amalgatome SD System components on the internal instrument tray; the sterilization tray is intended for use with one Amalgatome SD System and each component has a designated location on the internal instrument tray.
- Do not stack multiple sterilization trays in a sterilization chamber because this has not been validated and might adversely affect the effectiveness of the sterilization process.
- After sterilization and prior to use, inspect the external wrapping for sterile integrity; do not use if it has been compromised, ripped, torn, or any other visual observations per facility protocol.
- The Amalgatome SD Sterilization Tray is intended to be used only with an FDA-approved sterilization wrap, in a double wrapped configuration, in order to maintain sterility of the enclosed system.

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General Precautions

This section provides general precautions about the Amalgatome SD Sterilization Tray.

The Amalgatome SD Sterilization Tray is only compatible with the Amalgatome SD System and has not been validated for any other instruments.

- Do not use any other sterilization tray for the Amalgatome SD System (including casket system); if any other sterilization tray is used, the facility is responsible for the internal sterilization validation.
- Do not use the sterilization tray if it is damaged or shows signs of cracking, flaking, peeling, or deformity in any manner.
- Do not use if any of the internal brackets are bent, damaged, or broken; sterility and integrity of the system could be compromised.
- Always follow the Amalgatome SD System User Guide (Part #: X101456) for safe handling of the system.
- Do not use if the lid does not securely attach to the base; damage to the Amalgatome SD System components inside the sterilization tray could occur.

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Operating Instructions

This section describes how to safely setup, use, and maintain the Amalgatome SD Sterilization Tray.

Prior to First Use

Upon receipt of the Amalgatome SD Sterilization Tray, the product must be cleaned and sterilized. For more information, refer to the Cleaning procedure below.

Setup

Perform the following procedure 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 Amalgatome SD Sterilization Tray within the sterile field.

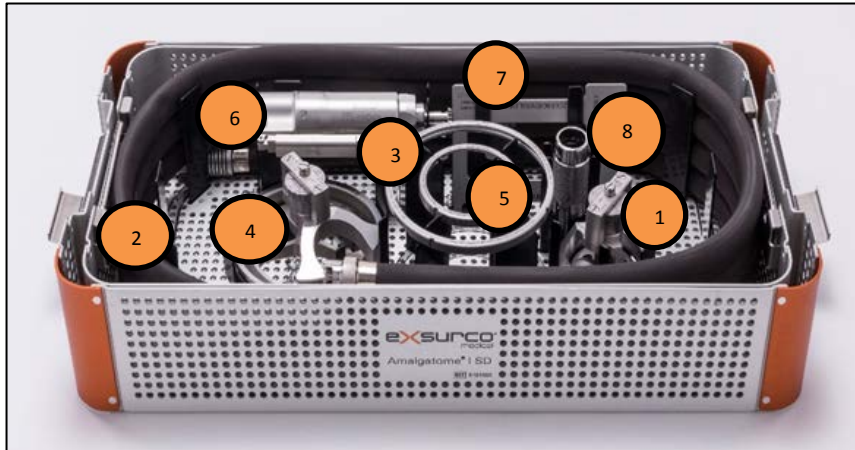
1. Verify that the Amalgatome SD Sterilization Tray is free of damage and particulate. If any contaminants are present, re-clean the sterilization tray. For more information, refer to the Cleaning procedure below.
2. Verify that all latches and inserts are secure and in working order.
3. If the sterilization tray is compromised in any way due to damage, contact Exsurco Medical Customer Service at 1-800-243-6049, ext. 4, or email support@exsurco.com to describe the malfunction and request a return for service.

Loading the Amalgatome SD Sterilization Tray

- The Amalgatome SD Sterilization Tray is designed to hold one set of Amalgatome SD System components.
- Prior to loading the Amalgatome SD System into the sterilization tray, disassemble and manually clean all of the components as directed in the Amalgatome SD User Guide.
- The facility is responsible for ensuring all their personnel are familiar with the cleaning and sterilization procedures for the sterilization tray. Failure to follow the procedures outlined in this section might affect sterility.
- If the recommended cleaning and sterilization methods described in this section are not followed, it is your responsibility to validate your own process. Exsurco Medical is not liable for outcomes resulting in personnel not following the procedures in this user guide.
- 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.*

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1. Secure the manually-cleaned Amalgatome SD System components into their proper locations in the previously cleaned sterilization tray. There are visual guides, including part number and description, marking the correct location for the placement of each component.



1. 2-inch Cutting Head (Blade Head)
2. Pneumatic Hose
3. 4-inch Lock Ring
4. 4-inch Cutting Head (Blade head)
5. 2-inch Lock Ring
6. Hand Piece
7. Lock Nut Wrench
8. Lock Ring Removal Tool

Figure 1

- Do not stack the components onto the internal instrument tray; each component has a designated location.
 - Ensure that the pneumatic hose is coiled carefully around the outside, taking care as to not crimp it into the compartment.
2. Place the lid on top of the base, and then secure the side latches.
 3. Double wrap the sterilization tray with all components inside using FDA-cleared Center for Scientific Review (CSR)-type wrap per methods listed in *ANSI/AAMI ST79, A1, A2, A3, A4*, and adhere with chemical indicator autoclave tape.

The Amalgatome SD System is ready for sterilization.

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Cleaning and Sterilization

The Amalgatome SD Sterilization Tray is reusable and requires cleaning and sterilization prior to each use.

CAUTIONS:

- Do not allow blood, tissue, or disinfectants to dry on the sterilization tray.
- 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.
- Do not use saline as it has a corrosive effect on stainless steel and can result in physical damage to the sterilization tray.
- Always use cleaning agents that are safe for surgical instruments and stainless steel.

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



Figure 2

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

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 components 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 components 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 components 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 to ensure all surfaces are clean and dry.

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Troubleshooting

This section describes general troubleshooting information.

Check the Amalgatome SD Sterilization Tray for any evidence of having been dropped or damaged as this can affect the closure, insert brackets, and placement of the components on the internal instrument tray. If at any time damage is observed, the sterilization tray should be returned to Exsurco Medical for service and repair. All products returned for warranty or non-warranty repair must be through the Exsurco Return Procedure. For additional information, refer to the Warranty, Service, and Returns section. Exsurco Medical performs all Amalgatome SD Sterilization Tray service. Our Technical Service Department can be contacted at support@exsurco.com or 1-800-243-6049, ext. 5, to answer any general questions that relate to the operation, warranty, and service of the sterilization tray.

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Warranty, Service, and Returns

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

Limited Warranty

Exsurco Medical (“Exsurco”) warrants that each new Amalgatome SD Sterilization Tray has been tested and inspected, and has left the facility 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 sterilization tray is guaranteed to be free from defects in material and workmanship when maintained by customer and cleaned properly and used under normal circumstances for its intended purpose.
- Any sterilization tray that is placed by Exsurco under a lease, rental, or 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 guide. If the sterilization tray 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 of all other warranties, express or implied, and of all other obligations or liabilities on Exsurco’s part, and Exsurco neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with this product.

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

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Service

The Amalgatome SD Sterilization Tray contains no serviceable parts. The sterilization tray must be returned to Exsurco Medical for servicing. Exsurco Medical performs all repairs in house by our trained technical service team. 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. 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 sterilization tray.

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

Returns

The customer must obtain a Return Material Authorization (RMA) to return an item. Contact Customer Service at 1-800-243-6049, ext.4, or email support@exsurco.com to obtain an RMA or Service Repair Order (SRO).

Customer Service hours: Monday through Friday, 8:00 am to 5:00 pm, ET

When the customer is returning the sterilization tray, Exsurco Medical requires proof of sterilization documents upon receipt of the RMA or SRO. If proof of sterilization is not included with the sterilization tray, the product shall be returned to the customer 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. Failure to sterilize the sterilization tray might result in refusal of service and additional charges. 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 pays the freight and returns the product in an approved protective shipping container.

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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)
- 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 additional 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 will be provided advising you of the outcome of the investigation regarding the reported event.

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Appendix A: Technical Specifications

Specifications

Specification	Value
Sterilization	Steam sterilization only in validated Amalgatome SD Sterilization Tray
Cycle	Gravity or pre-vacuum steam sterilization
Wrap	FDA approved steam sterilization double wrap
Storage and Transport (Amalgatome SD System)	As per internal hospital procedure
Weight	Lid: 1.48 lb Base: 3.64 lb Internal Instrument Tray: 4.56 lb Complete Sterilization Tray: 9.7 lb Complete SDSYSTEM024 in sterilization tray: 17.8 lb
Dimensions	Length: 21 in., Width: 10.25 in., Height: 4 in.

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Appendix B: Parts Information

Part #: X101005

Description: Amalgatome SD Sterilization Tray






Ordering Information

The Amalgatome SD Sterilization Tray is only sold as a replacement product to current customers. To place an order, 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.

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Appendix C: Glossary of Symbols

Symbol	Definition
	Serial Number
	Manufacturer
NON-STERILE	Symbol indication that the sterilization tray has not been sterilized.
	Caution
	Consult instructions for use
	General warning sign

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Appendix D: 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 -154421
- Cleaning Efficacy Validation of the Amalgatome[®] SD Reusable Surgical Device and Sterilization Tray – Manual Cleaning Report- 154421 Part I.

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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 might 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.

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 Sterilization Tray.

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

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Exsurco Medical
10804 Green Road
Wakeman, OH 44889

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

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