

SURGI FRESH[®] Mini TURBO 120V PN 906500

SAFETY PRECAUTIONS

This manual contains information that is important to your safety and preventing damage to your smoke evacuator

CAREFULLY READ THIS INSTRUCTION MANUAL BEFORE ATTEMPTING TO OPERATE THIS SMOKE EVACUATOR

Model #
Serial #
Purchase Date / /

SMOKE EVACUATION SYSTEM

SAFETY PRECAUTIONS



This symbol is intended to alert the user to the presence of uninsulated “dangerous voltage” within the product’s enclosure that may be of sufficient magnitude to constitute a risk of electric shock to persons.



This symbol is intended to alert the user to the presence of important operating and maintenance instructions in the literature accompanying the product.

Warning -- indicates that a condition may exist which could adversely affect the operator or patient.

Caution -- indicates that a condition may exist which could damage the smoke evacuation system.

This Owner's Manual and the equipment discussed herein are to be used only by qualified and properly trained medical personnel who are skilled in the particular technique and surgical procedure to be performed.

Notice: Federal (USA) law restricts this device to sale by or on the order of a physician.

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WARNING



Warning: To prevent electric shock

- Do not connect a wet power cord to the wall receptacle.
- Do not expose to moisture.
- Do not use extension cords, adapter plugs, or a non approved hospital grade grounded polarized receptacle. Be sure electrical plug blades are fully inserted in receptacle.
- Do not remove covers from the unit. The unit is non serviceable except for component replacement. Refer to qualified service personnel.
- Unplug the unit from the wall receptacle before cleaning.
- Unplug the unit from the wall receptacle if it is not to be used for several days or more.
- To disconnect the power cord, pull it out by firmly grasping the plug, never pull the cord itself.



WARNING

Warning: The smoke evacuator produces a strong vacuum force. Properly adjust the suction control and the position of the inlet end of the suction tubing or wand to prevent injury to the patient or inadvertent damage to surgical materials prior to turning power on.

Warning: Laser and electrosurgical plume are potentially hazardous. Used filters, tubing, and accessories should be handled according to your institution's procedures for biohazardous materials.

Warning: To prevent a fire or explosion hazard, do not use the unit in the presence of flammable or potentially flammable materials.

Warning: Some cannulas, valves, or other instruments combined with suction may cause rapid reduction of the pneumoperitoneum in laparoscopic procedures.



CAUTION

Caution: Use the unit in a well-ventilated area.

Caution: Introduction of fluids into the filters could damage them and the smoke evacuation system.

Caution: Occlusion of the smoke evacuation system air can overheat the unit.

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Made in U.S.A.

INTRODUCTION

1.0 INTENDED USE

The SurgiFresh® Mini Turbo Smoke Evacuation System is intended to be used to evacuate plume / smoke created during electrosurgery, laser surgery, and laproscopic or power tool surgical procedures.

Do not use the SurgiFresh® Mini Turbo for applications other than its intended use.

Use only Surgimedics accessories with the SurgiFresh® Mini Turbo

Contact Surgimedics with questions concerning features, performance, and intended use of this device.

Surgimedics
2950 Mechanic Street
Lake City, PA 16423

800-645-7418

www.surgimedics.com

2.0 DESCRIPTION OF SYMBOLS

The following is a description of the symbols located on the SurgiFresh® Mini Turbo



Danger, explosion risk if used in presence of flammable anesthetics.



Medical Electrical Equipment Classified with respect to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 and CAN/CSA C22.2 No. 601.1 61CB

OPERATING INSTRUCTIONS

1.0 FEATURES AND CONTROLS

Figure 1 User controls

- A) Power Switch, Suction Control Knob, Filter Test Switch, and Replace Filter Lamp.
- B) Footswitch Tubing Port and Footswitch Control -- connection and control for remote footswitch.

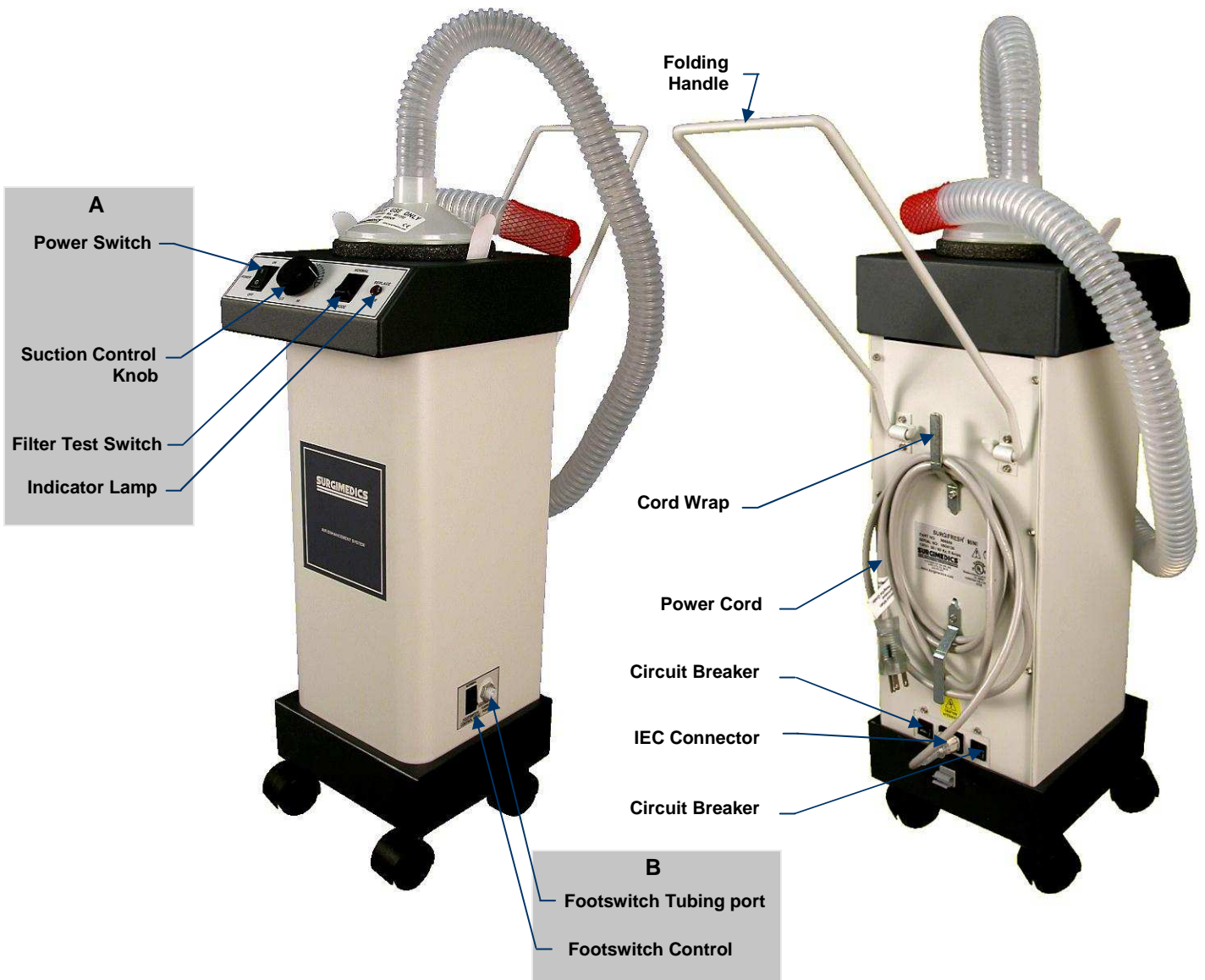


FIGURE 1

OPERATING INSTRUCTIONS

2.0 SYSTEM SET-UP

2.1 Installation

The SurgiFresh® Mini Turbo with manual will arrive in a single carton. Inspect the carton and the product for any scratches, dents or damage which may have occurred during shipment. If any damage is noted, follow the instructions per the Warranty section. Smoke evacuation disposable filters, tubing and accessories may be shipped separately. The same shipping damage instructions apply to these items as well.

After removal from the carton, the SurgiFresh® Mini Turbo is set up as follows:

Note: Save carton and packing for future use.

1. Connect the footswitch tube to the side tubing port on the smoke evacuator. Place the footswitch control in the footswitch mode. If the footswitch is not desired for use, override the footswitch by placing the footswitch control in the normal mode.
2. Install an ULPA filter in the central core of the unit. Note the air flow direction arrow on the ULPA filter. The arrow should be pointing downward. Be sure the filter is seated squarely and all the way down.

Note: Fill out the *date sticker* (included with filter) and apply it to the top of the unit. Use it to determine when the ULPA filter must be replaced. Early replacement when used heavily as determined by odor is not uncommon.

3. Connect the power cord to the unit and an appropriate electrical receptacle.
4. Perform the ULPA filter test per the procedure in Section 4.2.

Note: The ULPA filter test is performed with no pre-filter or tubing in place. After testing is satisfactorily completed, turn the motor speed knob to approximate $\frac{1}{4}$ speed to ensure that the unit will not be activated at high speed.

5. Install a pre-filter to the top of the ULPA filter.

Caution: Be sure both the ULPA filter and pre-filter are securely seated to ensure proper suction flow.

6. Determine the type of procedure, select the appropriate tubing and accessories, and prepare the unit for use as described Section 3.1

Warning: Sterile tubing should be handled using your institution's sterile protocol.

2.2 Typical Setup Instructions

1. OPEN PROCEDURES -- EVACUATING DRY PLUME / SMOKE

- a. Ensure an ULPA filter and applicable pre-filter are installed per 2.1.
- b. Connect an adapter if required and/or tubing appropriate for the procedure to the pre-filter.

OPERATING INSTRUCTIONS

2. OPEN PROCEDURES -- EVACUATING SMOKE WITH INCIDENTAL FLUIDS

- a. Ensure ULPA filter / pre-filter are installed and tested per 2.1
- b. Secure a disposable suction canister near the unit.
- c. Attach a 1 1/3" diameter hose from the suction canister to the pre-filter.

Note: Hose attaches to the 'vacuum' port on a suction canister.

- d. Connect the adapter and/or tubing appropriate for the procedure to the 'patient' port of the suction canister.

Caution: If 3/8" tubing is used, avoid dislodging from the suction canister by using a sufficient length for the procedure.

If desired, connect an optional suction wand to the tubing distal end (7/8" or 1 1/3" only).

Remove the red plastic sponge guard, connect the wand, and replace the sponge guard on the wand.

3. CLOSED PROCEDURES

Note: Closed procedure set up for dry smoke or smoke with incidental fluid is the same as the corresponding open procedure set-up.

Warning: Some cannulas, valves, or other instruments combined with suction may cause rapid reduction of the pneumoperitoneum in laparoscopic procedures.

OPERATING INSTRUCTIONS

3.0 SYSTEM OPERATING INSTRUCTIONS

3.1 Pre-op preparation

1. Choose the appropriate set-up per Section 2.2 for the intended procedure.
2. Verify the power cord is plugged into the unit and an appropriate electrical receptacle.
3. Verify the footswitch cord is attached to the unit. Uncoil the footswitch cord and place the footswitch near the operator's station.
4. Turn on the power switch. **Note:** On is the "I" position. Off is the "O" position.
5. Rotate motor speed control knob slightly to verify that the motor speed varies.
6. Press the footswitch to ensure that the unit starts and stops using the footswitch.
7. Turn off the power switch until the smoke evacuator is required.

3.2 Operative Use

Warning: The smoke evacuator produces a strong vacuum. Properly adjust the suction control and the position of the inlet end of the suction tubing or wand to prevent injury to the patient or inadvertent damage to surgical materials.

Warning: Some cannulas, valves, or other instruments combined with suction may cause rapid reduction of the pneumoperitoneum in laparoscopic procedures.

1. Move the SurgiFresh® Mini Turbo into position near the procedure site.
2. Attach tubing per the instructions in Section 2.2.
3. Turn on the power switch.
4. The footswitch may be pressed by personnel in the operative area to start and stop the suction as needed during the procedure. Place the footswitch in a convenient location.
5. Rotate the motor speed control knob clockwise to increase air flow (suction) and counterclockwise to decrease air flow. Stop at desired setting.
6. Verify adequate air flow is set by inquiring with the surgeon. Adjust as necessary with the motor speed control knob.
7. When the procedure is finished, turn off the power switch.
8. Recover the footswitch and electrical cord.
Follow cleanup instructions per Section 3.4.

3.3 Maximizing Use Suggestions

1. Air flow
 - a. The distance of the tubing from the plume source affects capture and removal of the plume. The tubing end should be within several inches of the procedure site.
 - b. Larger tubing will permit a higher volume of flow for better plume removal. Do not occlude tubing.
2. Noise
 - a. Lower speed equals lower noise.
 - b. Larger tubing equals lower noise. Do not occlude tubing.
 - c. Use the footswitch to turn the suction on and off as it is needed during the procedure.
3. Incidental Fluids
 - a. Do not allow a suction canister to overfill.
 - b. Replace filters immediately if contaminated by fluids.
 - c. The SurgiFresh® MINI Turbo should not be used as the primary fluid suction system.

OPERATING INSTRUCTIONS

4. Filters
 - a. Ensure filters are securely seated.
 - b. Perform the ULPA filter test (Section 4.2) prior to the start of each surgical procedure.
5. Tubing
 - a. Check throughout the surgical procedure to be sure tubing is not occluded.

Caution: Ensure sponge guard is attached to prevent surgical materials or tissue from being aspirated into the tubing.

3.4 Clean-Up

After each surgical procedure, the SurgiFresh® MINI Turbo smoke evacuation system should be cleaned and prepared for future use.

1. Turn off the power switch and unplug the unit from the wall receptacle.
2. Remove the unit from the immediate surgical area.
3. Wipe the footswitch and footswitch cord with an appropriate hospital disinfectant. Coil the footswitch cord around the cord wrap at the back of the unit.
4. Wipe the power cord with an appropriate hospital disinfectant. Coil the power cord around the cord wrap.
5. Remove the tubing from the pre-filter or suction canister.
6. If a suction canister was used, securely close lids/caps and properly dispose canister.
7. Remove the pre-filter.
8. Dispose of all single-use operative waste materials according to your institution's procedures for biohazardous materials.
9. Check the ULPA filter to be sure no fluids are on top of the filter.
10. Install a new pre-filter.
11. Thoroughly wipe all external surfaces of the SurgiFresh® MINI with an appropriate hospital disinfectant. Follow the procedures approved by your institution.

Warning: Ensure the unit is completely dry before restoring power.

MAINTENANCE

4.0 MAINTENANCE

4.1 Power Cord

1. Prior to each use, check the power cord along its entire length and at both plugs to ensure no damage has occurred.
2. Do not use a power cord with exposed wires, cracks, or frayed areas.

4.2 Filter Test

Note: Perform the ULPA filter test with no pre-filter or tubing in place.

1. Ensure an ULPA filter is in the unit and seated properly.

MAINTENANCE

4. Turn on the POWER switch. Place the filter TEST SWITCH in TEST MODE. (See Figure 1.) Operate the unit for ten to fifteen seconds to assure the motor speed is stabilized.
5. Should the red REPLACE FILTER indicator lamp light, replace the ULPA filter with a new one. Note: An ULPA filter that tests OK but produces an abnormal odor or is over 90 days old requires replacement because the carbon life has been exceeded. Note: The filters design life is 12 hours of smoke/plume removal.
6. Move the TEST SWITCH to the NORMAL mode after the test is completed.

4.3 Replacing the ULPA filter

1. Unplug the power cord from the electrical receptacle before replacing the ULPA filter.
2. Obtain a new ULPA filter. Remove its outer storage bag and dispose of the bag and twist tie properly.

Note: Fill out *date sticker* and apply to the unit for future reference.

3. Open the biohazard bag provided with the new ULPA filter and prepare to dispose of the old filter.
4. Grasp the used ULPA filter tabs. Carefully lift the used ULPA filter out of the unit, dispose of the ULPA filter in the biohazard bag, and seal the bag.

Warning: Follow instructions and procedures for biohazardous materials recommended by your institution.

5. Grasp the tabs of the new ULPA filter and insert it into the unit.
6. Replace the pre-filter to the top of the ULPA filter. Make sure the prefilter is not placed over a tab. Follow instructions in Section 2.0 as appropriate.

CUSTOMER SERVICE

5.0 CUSTOMER SERVICE

5.1 *Parts and Accessories:* Surgimedics
2950 Mechanic Street
Lake city, PA 16423
Phone: 800-645-7418

Service Department and Loaner Program:

1. If a problem is experienced, first review the troubleshooting section of this manual. For troubleshooting support, please contact Surgimedics Service (888)-606-9303
2. In the event your unit needs service or repair, do not attempt to repair. Please contact Surgimedics Service for assistance or to request a Loaner Program Fax Back form.

TROUBLESHOOTING

6.0 TROUBLESHOOTING

6.1 General

If the SurgiFresh® Mini Turbo smoke evacuation system is not functioning properly, review the items in this section for assistance.

1. Inspect the unit for visible signs of physical damage.
2. Verify all tubing and cords are connected properly.
3. Verify that the power cord has no exposed wires.
4. Ensure both filters are securely seated.
5. Check to see if the power cord is plugged into an appropriate electrical receptacle at the wall.
6. Check to see if the power switch is turned on.
7. Perform a filter test to verify the filter and motor are functioning.

6.2 Specific Conditions

If the solution is not readily apparent, these items may be of assistance:

Condition	Causes	Correction
Smoke evacuator does not operate when you turn on the power switch.	1. Disconnected or faulty power cord.	1. Check and correct power cord connections. Check cord for damage and replace as needed.
	2. No power from electrical receptacle.	2. Connect power cord to functional electrical receptacle.
	3. Footswitch control is in footswitch mode, was turned off with footswitch and no footswitch is installed.	3. Turn footswitch control to normal position or install footswitch and turn unit on.
	4. Circuit breaker needs to be reset.	4. Press the circuit breaker switch on the rear panel to reset the circuit breaker.
No suction when footswitch is depressed.	1. Improperly connected footswitch.	1. Check and correct footswitch cord connection.
	2. Damaged footswitch.	2. Check footswitch cord for damage and replace as needed.
	3. Kink in footswitch cord.	3. Straighten kinked section of cord
Smoke evacuator is operating but there is inadequate or no vacuum.	1. Improperly installed filter.	1. Turn the smoke evacuator off (O). Ensure pre-filter and ULPA filter are seated properly.
	2. Clogged or kinked tubing.	2. Unclog or replace tubing.
	3. Clogged pre-filter.	3. Replace pre-filter.
	4. Clogged ULPA filter.	4. Replace ULPA filter.
	5. Obstructed or malfunctioning motor and/or blower.	5. Refer to your Bio-Engineering Dept. or Surgimedics Service.
System does not adsorb Smoke.		
Odors.	1. The charcoal component of the ULPA filter has expired.	1. Replace the ULPA filter.
Above Normal Noise/Whining.	1. Poorly seated filters.	1. Check bottom of ULPA filter for condition of seal. Seat ULPA filter properly inside unit. Check seal around top of ULPA filter. Seat pre-filter securely into ULPA filter.
	2. Variation in line voltage.	2. Position motor speed control knob slightly lower than maximum to ensure controlled constant speed even with slight line voltage fluctuations.
	3. Motor brushes worn,	3. Return to Surgimedics for service.

SPECIFICATIONS

7.0 TECHNICAL SPECIFICATIONS

All specifications are nominal and subject to change without notice.

Filters

Pre-filter: captures medium and large particles > 0.3 microns; single use only

ULPA filter: 0.1 micron particulate size at 99.9995% efficiency; activated high grade carbon for gas and odor adsorption

Air Flow

Motor Speed Setting	1 1/3 in. X 6 ft. (3.4 cm)	7/8 in. X 6 ft. (2.2cm)	3/8 in. X 6 ft. (1 cm)
0%	45 cfm	30 cfm	5 cfm
25%	50 cfm	35 cfm	6 cfm
50%	55 cfm	37 cfm	8 cfm
75%	60 cfm	40 cfm	9 cfm
100%	65 cfm	43 cfm	10 cfm

Maximum Static Suction

92 inches H₂O (172mm Hg) suction pressure motor fan rating (sealed)

Safety

Circuit breakers: 8 amps / ea

Power cord: 3 - prong hospital grade plug

Leakage Current (50 / 60 HZ): 300µA max.

Power

Input mains voltage (nominal): 120VAC

Mains frequency (nominal): 60 Hz

Mains frequency range: 50 to 60 Hz

Mains current: 6.5 amps maximum during normal operation

Physical Characteristics

Height: 25 1/4 inches (57.8 cm)

Depth: 10.5 inches (28 cm)

Width: 9 1/8 inches (23.2 cm)

Weight: 26.25 pounds (9.7 kg) without filters, hoses or box

8.0 TRANSPORT AND STORAGE

Ambient temperature range -40°F to 158°F (-40°C to 70°C)

Relative Humidity: <75%, noncondensing

Use original packaging materials when shipping or transporting via carrier

WARRANTY

Warranty Limitations

Surgimedics makes no express guarantees, warranties, or other representations as to its products, other than those appearing in its written form in its own trade literature or written proposals. **Surgimedics expressly disclaims the implied warranties of merchantability, fitness for a particular purpose, and noninfringement in relation to any of its products. In no event shall Surgimedics be liable to the purchaser of any product for consequential, incidental, or special damages irrespective of whether such damages are alleged to arise in tort, contract, law, equity, or by statute.** The above provisions relating to the exclusion of consequential, incidental, and special damages shall survive and remain in force notwithstanding a finding by a court of competent jurisdiction that the exclusive remedy provided below to a product purchaser has failed of its essential purpose.

For a period of one year, Surgimedics will repair or replace, at its option, any product, or part thereof, that fails because of a material or manufacturing defect; provided that (1) the defect is not caused by the purchaser or its customer, (2) the product was not custom manufactured to the specifications of the purchaser, and (3) the product has not been damaged, altered, or defaced. This limited warranty shall be the sole and exclusive remedy of the purchaser, irrespective of whether the claims of purchaser are made in contract, tort, warranty, law, equity, or by statute. In the event that a court of competent jurisdiction determines that the exclusive remedy set forth above has failed of its essential purpose, such a failure shall entitle the purchaser to a return of the purchase price of the product involved.

Shipping Damage

Title and risk of loss will pass to purchaser upon delivery at the (Ex-Works) point. Delivery shall be (Ex-Works Lake City, Pennsylvania). Surgimedics will, as an accommodation to purchaser unless otherwise directed in writing, ship product to purchaser at its address, freight prepaid and insured at purchaser's risk and expense. Purchaser should (1) inspect all packaging for external damage, (2) report the same to the carrier, (3) obtain an inspection report from the carrier within 15 days, and (4) file a claim with the carrier.

Returned Goods Policy

A request for return authorization must be submitted to Surgimedics Customer Service Department prior to the return of any product. The request for return authorization must include the product catalog number, product lot number, quantity, and specific reason for the return. No product may be returned after 90 days from the original date of purchase, unless defective.

Where a return of any product is authorized, Surgimedics will provide a return authorization number. Each shipping container must be marked with the return authorization number or it will not be accepted. All product must be returned freight prepaid except returns due to our shipping error, material or manufacturing defects, or damage during shipment that renders the product unsalvageable upon receipt. Unsalvageable product must be returned via the original carrier.

Credit may be issued to the original purchaser for authorized returns of salable, unused product in unopened boxes in Surgimedics current catalog, subject to a 25% restocking fee. Surgimedics Quality Assurance Department will inspect returned product to determine whether it is in salable condition. Credit, including transportation costs, will be issued to the original purchaser for authorized returns within 90 days for product discovered upon inspection to be unsalvageable or shipped in error. Except for defective products, no credit will be issued for unauthorized returns, returns after 90 days from original date of purchase, custom manufactured product, or unsalable product.