Operating and Maintenance Manual

Safety Trap

Amico

User Responsibility

READ ALL INSTRUCTIONS BEFORE USING

This manual is intended for trained individuals who have been adequately instructed to install and operate the Safety Trap. This is provided for your safety and to prevent damage to the Safety Trap. If you do not understand this manual, **DO NOT USE** the Safety Trap and contact your provider.

Symbols Glossary

WARNING - Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION - Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

Manufacturer - Indicates the medical device manufacturer (ISO 15223-1 5.1.1).

Batch Code - Indicates the manufacturer's batch code so that the batch or lot can be identified (ISO 15223-1 5.1.5).

Catalog Number - Indicates the manufacturer's catalogue number so that the medical device can be identified (ISO 15223-1 5.1.6).

MR Conditional - An item with demonstrated safety in the MR environment within defined conditions (ASTM F2503-23).

Receiving Inspection

Remove the Amico Patient Care Safety Trap from the packaging and inspect for damage. If there is any damage, **DO NOT USE** and contact your provider.

Intended Use

The Amico Patient Care Safety Trap is intended to prevent fluids from entering the vacuum regulator, in addition to the central suction system.

WARNING: Use the Safety Trap only for its' Intended Use as described in this manual.

Specifications

Capacity:	70 mL
Transport/Storage Temperature Range:	-4 ˚F to 140 ˚F (-20 ˚C to 60 ˚C)
Storage Relative Humidity Range:	Maximum 95% non-condensing
Height:	Approximately 4 inches
Width:	Approximately 2 inches

Specifications are subject to change without prior notice.

Safety Information - Warnings and Cautions

WARNING

- **DO NOT** use this device in the presence of flammable materials.
- **DO NOT** use if contaminants are present on or around Safety Trap.
- **DO NOT** use near any type of flame or flammable/explosive substances, vapors or atmosphere.

CAUTION

- Only personnel instructed and trained in its use should operate this Safety Trap.
- Handle the Safety Trap carefully at all times and use the device according to the instructions in this manual.
- Store the Safety Trap in a clean area when not in use.

MRI Safety Summary

THIS SECTION APPLIES TO MR CONDITIONAL LABELED SAFETY TRAPS ONLY.

Devices with this label indicates that it is MR Conditional and can be used in an MR Environment.

All products identified as MR Conditional have been observed to maintain proper functionality during exposure to static magnetic fields of not less than 300 Gauss in the fringe field area of a 3.0 Tesla MRI system.

As per ASTM F2052, the largest deflection measurement across all devices tested yield allowable maximum spatial gradients of 8.93 T/m (893 gauss/cm) for 1.5 T systems, and 4.46 T/m (446 gauss/cm) for 3.0 T systems.

MRI Safety Summary

WARNING:

- This product should not be used directly inside of the MR System (e.g., inside the bore of the scanner).
- The device must be securely connected to the vacuum regulator attached to the wall gas outlet.
- To ensure MR compatibility, only adapters and fittings tested and designated by Amico Patient Care for the configurations listed as MR conditional should be used. MR Conditional configuration options are available. Please contact customer service at sot-csr@amico.com for more information. Any substitution or change must be evaluated in accordance with your hospital policy.
- Device must be kept MR Conditional if serviced or replaced.
- This information must be kept with the device.

Operating Instructions

WARNING: Read this User Manual before installing or operating the Safety Trap.

1. Ensure the Safety Trap is in the upright vertical position to function as intended.
2. Connect the Safety Trap to the inlet of the Vacuum Regulator using the connection at the top of the device.
3. Attach the Tubing Nipple connection on the side of the Safety Trap to the vacuum port of a suction/collection canister.

CAUTION:

- The Cap must be disassembled from the PC Cup before any fitting can be assembled to the Cap. There is a risk of deforming the PC Cup and causing leakage when installing the fitting using a wrench while the Cap is attached to the PC Cup.
- Suction ceases when the overfill protection device is engaged. Shut off/disengage the vacuum to disconnect the Safety Trap from the equipment connected in series for reprocessing. Please follow the "Cleaning Instructions" section of this manual for more details.

Pre-use Check

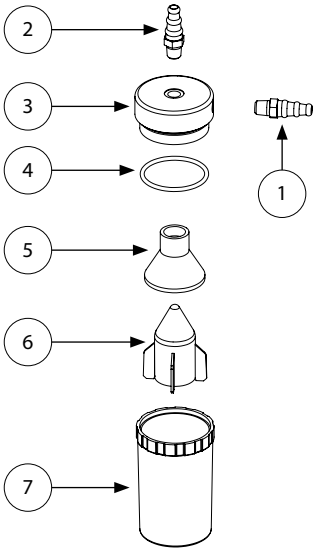
1. Turn the Selector Switch of the Vacuum Regulator to the REG position.
2. Block the Bottom Port of the Vacuum Regulator or kink the vacuum tubing.
3. Using the Regulator Knob, set the desired vacuum level of 80 mmHg. Don't adjust the Knob until all pre-check steps are complete.
4. Turn the Selector Switch of the Vacuum Regulator to the OFF position.
5. Perform the three steps within the "Operation Instructions" section of the manual.
6. Turn the Selector Switch of the Vacuum Regulator back to the **REG** position.
7. Occlude or kink the tubing between the Safety Trap and collection canister. Confirm the vacuum level reaches 80 mmHg within 10 seconds. If 80 mmHg cannot be reached within 10 seconds, there is a leak within the system of connection equipment. Do not use the Safety Trap if the presence of a leak is detected.

Reprocessing Instructions

CAUTION: Ensure cleaning agent is compatible prior to cleaning the equipment.

1. Disassemble the safety trap by unscrewing the Cap from the clear PC Cup. Remove the Cap and inner Float from the PC Cup, the Deflector from the Cap assembly, and O-ring from the Cap assembly.
2. Clean all parts of safety trap in running cold tap water to remove any foreign material.
3. Wipe all parts with a clean and dry low-linting cloth.
4. Disinfect the Cap by soaking it in 70% isopropyl alcohol for 15 minutes, then wipe it with a clean and dry low-linting cloth.
5. Disinfect the Float, Deflector and O-ring by wiping them with a low-linting cloth soaked in 70% isopropyl alcohol.
6. Steam sterilize the PC Cup for 15 minutes at 250 °F (121 °C).
7. Reassemble the components to the Cap and reassemble the Cap assembly to the bottle device by tightening it.
8. After dismantling and reassembly of the Safety Trap, please perform the steps within the "Pre-use Check" section of this manual to confirm for functionality.

Disassembly



Parts List	
1	Tubing Nipple
2	Regulator Connection
3	Cap
4	O-ring
5	Deflector
6	Float
7	PC Cup

Available Safety Trap Configurations

Part #	Description
SRX-TRP-F2	SR TRAP 1/8" FNPT CONNECTION
SRX-TRP-M2	SR TRAP 1/8" MNPT CONNECTION
SRX-TRP-DN	SR TRAP DISS HEX NUT CONNECTION
SRX-TRP-DO	SR TRAP LOCKING DISS HEX NUT CONNECTION
SRX-TRP-U-DH	SR TRAP - DISS HT CONNECTION
SRX-TRP-I-DH	SR TRAP DISS HANDTIGHT ISO

Note: Other configurations of the Safety Trap may be available.

Maintenance and Prevention

Before each use:

- Inspect the Safety Trap for damage. Do not use if damaged or visibly contaminated.
- Ensure all connections are tight and leak free.
- Confirm for functionality of device prior to use on patient.

CAUTION: DO NOT attempt to repair Safety Trap.

Warranty Policy - SOT Accessories and Fittings

This Product is sold by Amico Patient Care Corporation, a Richmond Hill Corporation (the "Company") under the express terms of the warranty set forth below.

For a period of one (1) year from the date the Company ships this Product to the customer, this Product is warranted to be free from functional defects in materials and workmanship and to conform in all material respects to the description of the Product contained in the operation manual, so long as this Product is properly operated under conditions of normal use, regular periodic maintenance and service is performed and repairs are made in accordance with the operation manual.

Within this period, Amico Patient Care Corporation will repair or replace any part which is proven to be defective at the Company's costs.

This warranty shall not apply if the Product has been repaired or altered by anyone other than the Company or an authorized dealer, or if the Product has been subjected to abuse, misuse, negligence or accidental damage. Should the parts be repaired or replaced by an authorized technician in accordance to the Company's operation manual, the warranty will continue to be applied.

This warranty is extended only to the initial customer with respect to the purchase of this Product directly from the Company or from an authorized dealer as new merchandise. Dealers are not authorized to alter or amend the warranty of any Product described in this agreement unless previously authorized in writing by the Company.

This warranty is expressly in lieu of any other warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. The Company shall not be liable for incidental, collateral, consequential or special damages including, but not limited to: lost profits or loss of use. The Company's liability, in the aggregate, shall not exceed the purchase price of the product.

As determined at the sole discretion of the Company, Products which qualify under the warranty will be repaired or replaced, at the Company's option, and returned to the Customer via ground delivery. The Company reserves the right to stop manufacturing any product or change materials, designs or specifications without notice.

All claims for warranty must first be approved by Amico Patient Care Corporation's Customer Service Department at: SOT-CSR@amico.com or 905.764.0800. Upon approval, the Customer Service Department will issue a Return Goods Authorization (RGA) number. An RGA must be obtained prior to commencement of any warranty claim.

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