



INSTRUCTIONS FOR USE

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中文 (Chinese)

本明的中文本可在网上 www.microaire.com/resources/instructions-for-use

LipoFilter - INSTRUCTIONS FOR USE

APPLICABLE PART NUMBERS:

<i>REF Number</i>	<i>Description</i>
REF ASP-CAN-1S	LipoFilter - Hospital Pack (Reduced-Component Kit)
REF ASP-CAN-2S	LipoFilter - Clinic Pack (Standard Kit)
REF ASP-CAN-2R	LipoFilter Stand
REF ASP-CAN-2C	LipoFilter Clamp
REF ASP-ADP2	Adapter - Toomey-to-Luer Syringe
REF ASP-60CC	60cc Toomey Syringe

INTENDED PURPOSE:

Single-use collection canister used in the aspiration of adipose tissue.
















TERMS:

NOTE - Used to point out the easiest means of carrying out the techniques.

WARNING - Used to indicate that the safety of patients and hospital personnel could be involved.

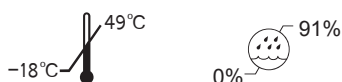
CAUTION - Used to point out special procedures or precautions that must be complied with to avoid damaging an instrument.

SYMBOL DEFINITIONS:

	Product catalog number
	Do not reuse
	Manufacturer
	Date of manufacture (YYYY-MM)
	Use by date (YYYY-MM)
	Attention, see instructions for use
	Batch code
	Non-sterile
	Relative humidity limits
	Atmospheric pressure limits
	Temperature limits
	Authorized European Representative
	European Conformity Mark
	Sterilized using irradiation
	Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner)

COMPATABILITY: This device has been designed to be compatible with standard liposuction tubing and cannulas.

STORAGE: Device should be stored in a designated, limited-access area that is well ventilated and provides protection from dust, moisture, insects, vermin and temperature/humidity extremes.



CAUTIONS AND WARNINGS:

CAUTION: Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

CAUTION: DO NOT utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.

CAUTION: Make sure stand and clamp are secured to table.

WARNING: Proper setup of device is critical to safe operation.

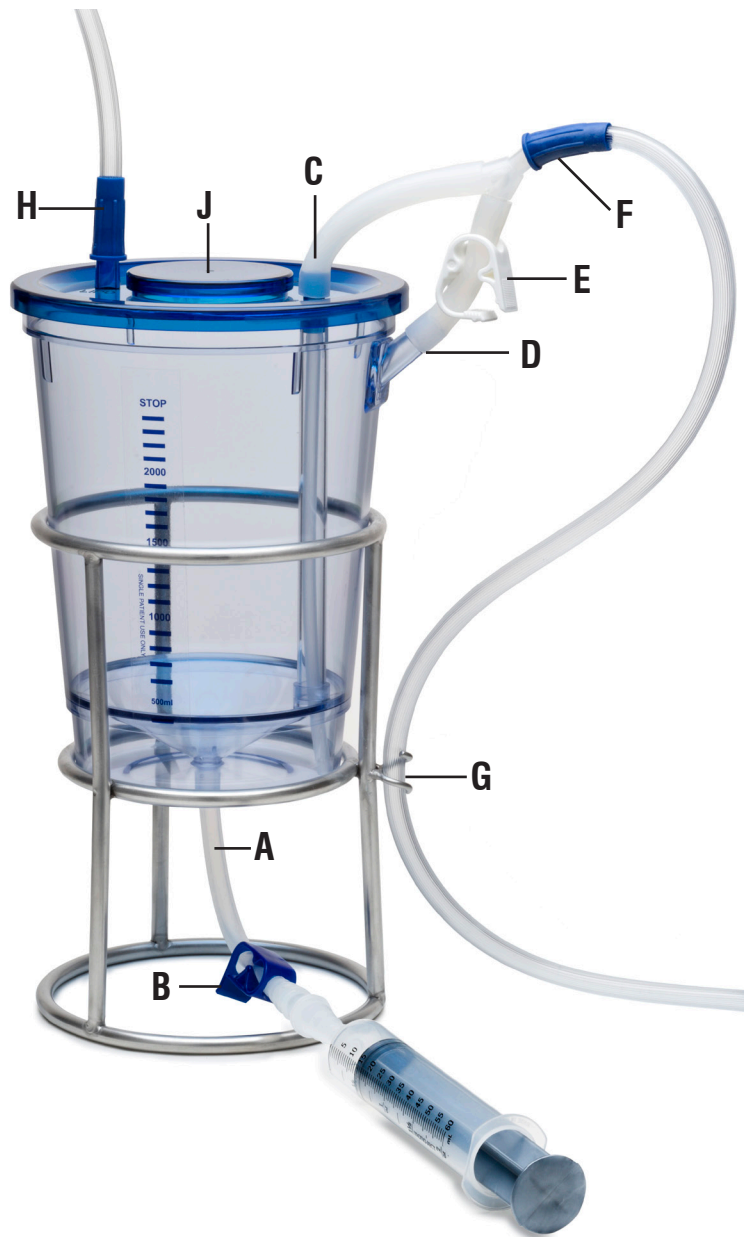
WARNING: This device is single-patient use only. Reuse may result in infection.

WARNING: DO NOT exceed 559 mmHg (22inHg) of vacuum as failure could occur.

WARNING: Universal precautions for handling contaminated materials should be observed at all times.

WARNING: Do not attempt to reuse LipoFilter.

WARNING: Sterilizers vary in design and performance parameters. Verify cycle parameters against the written instructions of the sterilizer and container manufacturers.



SETUP INSTRUCTIONS

WARNING: Proper setup of device is critical to safe operation.

1. Wash and sterilize stand and clamp (sold separately) according to washing and sterilization instructions located at the end of this instruction manual.

2. Place clean and sterilized stand onto sterile field. Secure stand with sterilized clamp.

CAUTION: Make sure stand and clamp are secured to table.

3. Open box and inspect contents. If the box or contents show any signs of damage, do not use.

4. Open sterile pouch containing canister and place contents onto sterile field.

WARNING: This device is single-patient use only. Reuse may result in infection.

5. Remove and discard four protective caps on tubing ports.

6. Attach fat evacuation tube (A) to bottom of LipoFilter (*fig 1*). **NOTE:** Make sure that tube is pushed fully onto canister, and pinch-clamp (B) is closed. **NOTE:** The fat evacuation tube in Model ASP-CAN-1S may appear different than the picture.

7. Place canister into stand (*fig 2*). Make sure it is seated properly and not tilted. **NOTE:** Depth scale is for general reference only.

8. Attach Y-connector tubing by first attaching the plain tube onto the canister's top port marked "EVAC" (C) (*fig 3*) and the clamped tube to the canister's side port marked "CLAMP" (D) (*fig 4*). **NOTE:** The top pinch-clamp (E) must remain completely open during harvest mode. **NOTE:** Make sure the tubing is not twisted or kinked.

9. Connect fluid evacuation tubing (F) to the Y-connector tubing (*fig 5*). Connect the other end to the waste canister. Secure fluid evacuation tubing in pigtail hook (G) to prevent accidental collapse of the Y-connector tubing (*fig 6*).

10. Connect liposuction tubing (H) to the port marked "LIPO" on the canister lid (*fig 7*). Connect other end of tubing to the cannula/handpiece.

11. Pre-load the canister with a cushion of fluid by pouring 500ml of sterile saline or Lactated Ringer's solution through open port in the top center of canister, then secure center cap (J) (*fig 8*). **NOTE:** Do not use sterile water as this may damage fat cells.

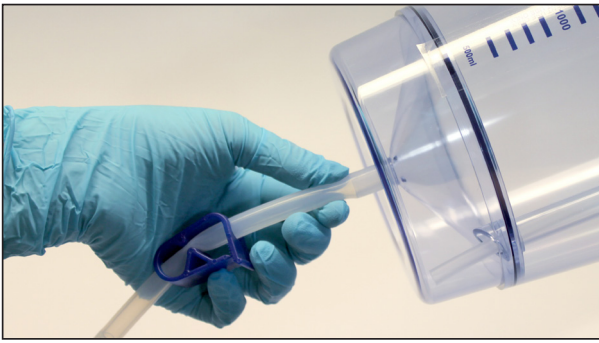


Figure 1. Attach fat evacuation tubing.

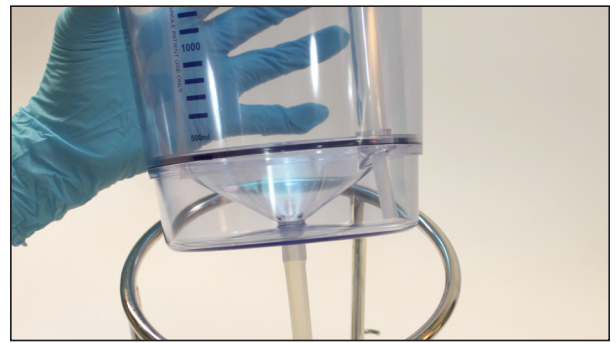


Figure 2. Place canister into stand.

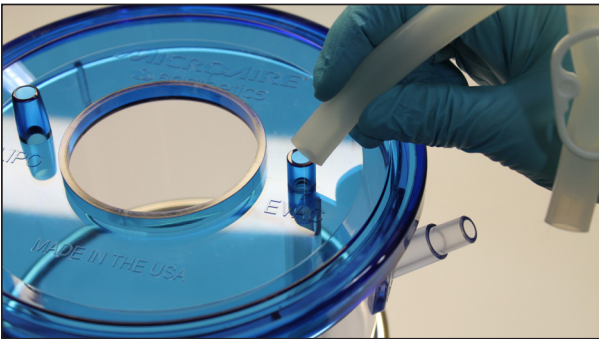


Figure 3. Attach plain side of Y-tube to "EVAC" port.



Figure 4. Attach clamp side of Y-tube to "CLAMP" port.

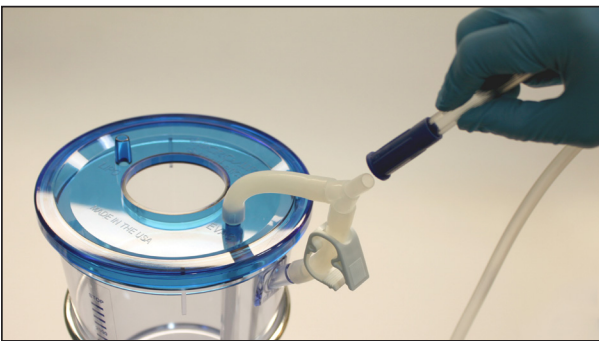


Figure 5. Attach fluid evacuation tubing to Y-tube.



Figure 6. Secure fluid evacuation tube in pigtail hook.

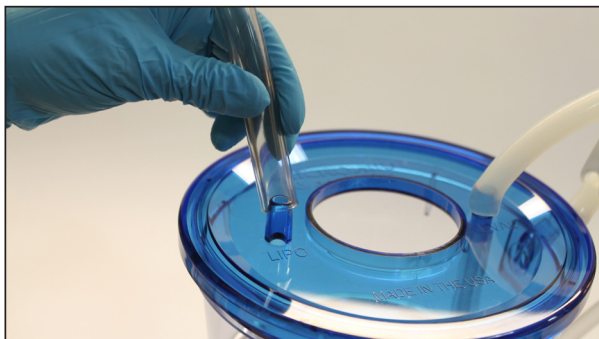


Figure 7. Attach liposuction tube to "LIPO" port.

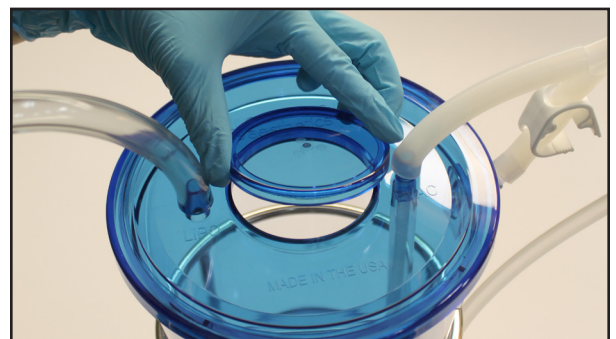


Figure 8. After pre-loading canister, attach center cap.

HARVEST INSTRUCTIONS

1. With aspirator on, manually crimp liposuction tubing to prevent airflow and set vacuum level to approximately 457 mmHg (18inHg). **NOTE:** Harvesting at levels greater than to 457 mmHg (18inHg) may reduce cell viability. **WARNING:** Do not exceed 559 mmHg (22inHg) of vacuum as failure could occur.

2. Begin harvesting. **NOTE:** Do not fill canister past the 2500ml mark. This is indicated on the canister as “STOP” (*fig 9*).

3. Allow fat to separate from fluids before attempting to evacuate the fluids. This normally takes about 12 minutes, but may take longer if the aspirate contains large amounts of blood.

4. To lower the fluid level: Remove cannula from patient and close the top pinch-clamp on the Y-connector tubing (*fig 10*). Fluid will transfer from the bottom of the LipoFilter through the fluid evacuation tubing to the waste canister.

5. To stop fluid evacuation, open the top pinch-clamp on the Y-connector tubing. If you are going to harvest more fat, do not reduce fluids below the 800ml mark. Open the top pinch-clamp on the Y-connector tubing and continue to harvest.

6. Final fluid evacuation: Allow enough time (12 minutes or longer) to get clear separation between fat and fluids. Turn on the vacuum and close the top pinch-clamp on the Y-connector tubing. When the fat reaches the filtering bilge at the bottom of the canister, you may observe an air break in the lower chamber. As soon as all the fluid is evacuated from the lower chamber, stop the evacuation by opening the top pinch-clamp on the Y-connector tubing and turning off the vacuum.

7. To extract fat: Remove the tubing from the port marked “LIPO” and leave this port open. If this port is closed you will have difficulty extracting the fat because of the vacuum lock. Connect the 60cc Toomey syringe to fat evacuation tube. Push syringe and tube together until they click into place.

8. Open the lower pinch-clamp on the fat-evacuation tube (*fig 11*) and draw out the small amount of fluid that remains in the tube (*fig 12*). Close the pinch-clamp and discard the fluid. **NOTE:** Remember to close the pinch clamp before removing the syringe.

9. Reattach the Toomey syringe, open the lower pinch-clamp, draw out fat (*fig 13*), close the pinch-clamp and remove the syringe. Continue process until desired amount of fat is collected. **NOTE:** Remember to close the pinch clamp before removing the syringe.

10. To harvest more tissue, reload the LipoFilter with 500ml of sterile saline or Lactated Ringer’s solution and repeat.



Figure 9. Do not fill canister past 2500ml.



Figure 10. Close top pinch clamp to evacuate fluid. Re-open clamp to stop fluid evacuation.



Figure 11. Open lower pinch clamp.



Figure 12. Remove excess fluid and discard.



Figure 13. Draw out fat.

CLEANING AND STERILIZATION INSTRUCTIONS FOR THE LIPOFILTER STAND, CLAMP AND ACCESSORIES

WARNING: Universal precautions for handling contaminated materials should be observed at all times.

CAUTION: DO NOT utilize cleaning agents with chlorine or chloride. The active ingredient is corrosive to stainless steel.

WARNING: Sterilizers vary in design and performance parameters. Verify cycle parameters against the written instructions of the sterilizer and container manufacturers.

1. At Point of Use. Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a cloth dampened with purified water. Body fluids and tissue should not be allowed to dry on stand prior to cleaning (MAXIMUM 30 minutes).

2. Preparation for Decontamination. Prepare mild-pH enzyme cleaning agents at the maximum use-dilution and temperature recommended by the manufacturer. Determination of cleaning agents shall be by local or country regulations.

3. Cleaning: Auto. Automatic cleaning is NOT recommended.

4. Cleaning: Manual. Pre-soak the stand for 20 minutes in enzymatic cleaner. Scrub the stand with a soft bristled brush while submerged in the enzymatic cleaner until all visible soil has been removed. If possible, use distilled water for the final rinse.

5. Disinfection. Disinfection is only acceptable as an adjunct to full terminal sterilization for multi-use surgical instruments. See sterilization section below.

6. Drying. Wipe off any water with a soft lint-free towel. An air gun can also be used.

7. Maintenance, Inspection and Function Testing. Carefully inspect to ensure that all visible blood and soil have been removed. Visually inspect for damage and/or wear. **NOTE:** If concerns are noted that may compromise the function of the device, please contact your MicroAire representative.

8. Packaging. A standard medical-grade steam sterilization wrap may be used.

9. Sterilization. Steam sterilize using one of the following cycles:

Prevacuum Steam Sterilization for a single device or in a sterilization tray:
4-minute Full Cycle at 132-135°C (270-275°F), 8-minute minimum heated dry time.

Gravity Displacement Steam Sterilization for a single device or in a sterilization tray:
35-minute Full Cycle at 132-135°C (270-275°F), 8-minute minimum heated dry time.

10. Storage. Device should be stored in a designated, limited-access area that is well ventilated and provides protection from dust, moisture, insects, vermin and temperature/humidity extremes.

LIMITATIONS ON REPROCESSING

Repeated processing of multi-use instruments, according to the instructions above, has minimal effect on MicroAire multi-use instruments. End of life is normally determined by wear and damage due to use.

WARRANTY

MicroAire Surgical Instruments LLC warrants its products to be free from defects in material and workmanship in their manufacture for a period of one year from the original purchase date by the end customer. The warranty is limited to the repair or replacement of the product without charge. This warranty is void in the event of abuse, misuse, or use in other than normal surgical environment, or in the event of disassembly, alteration, or repair of the product not authorized by the manufacturer, or in the event that the product has not been used in a reasonable manner and in compliance with the written instructions furnished by the Manufacturer. All other expressed or implied warranties of fitness and merchantability are excluded here from, and the manufacturer shall have no liability of any kind for incidental or consequential damages.

*LipoFilter*TM



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