MicroAire® LipoFilter®
Fat-Transfer System
Instructions for Use

Look for the hand symbol to remove the top tray.

MICROAIRE®

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INSTRUCTIONS FOR USE

MicroAire® LipoFilter®
ASP-CAN-2S Fat-Transfer System

Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.

TABLE OF CONTENTS

APPLICABLE PART NUMBERS

REF Number	Description
REF ASP-CAN-2S	LipoFilter - Clinical Pack
REF ASP-CAN-2R	LipoFilter Stand
REF ASP-CAN-2C	LipoFilter Clamp
REF ASP-ADP-2	Adapter - Toomey Syringe-to-Luer Syringe
REF ASP-ADP-3	Adapter - Toomey Syringe-to-Luer Needle

PRODUCT DESCRIPTION

The MicroAire LipoFilter System consists of a single use, closed loop tissue collection system comprised of a medical grade canister, vacuum port, collection port, tissue port and lid intended to be used with a standard liposuction aspiration system pump to collect fatty tissue for aesthetic body contouring. As the tissue is harvested from the patient, it enters the canister via the collection port in the canister lid. Unwanted waste is removed from the collection system via the vacuum port by closing a valve. This process leaves fatty tissue that can be transferred to syringes via the tissue port for autologous fat re-injection.

INTENDED USE

Single-use collection canister used in the harvesting and transferring of autologous adipose tissue.

INDICATIONS

The MicroAire LipoFilter System is used in the aspiration, harvesting, filtering and transferring of autologous adipose tissue for aesthetic body contouring. If the harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

COMPATIBILITY

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.

TERMS

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 equipment.

WARNINGS AND CAUTIONS

WARNING: This device will not, in and of itself, produce significant weight reduction.

WARNING: This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes; heart, lung, or circulatory system disease; or obesity.

WARNING: The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

WARNING: Do not use device if sterile packaging is damaged or opened.

WARNING: Do not reuse LipoFilter. This device is for single-patient use only. Reuse may result in infection.

CAUTION: This device is designed to contour the body by removing localized deposits of excess fat through small incisions.

CAUTION: Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.

CAUTION: Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.

CAUTION: Results of this procedure may or may not be permanent.

CAUTION: The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

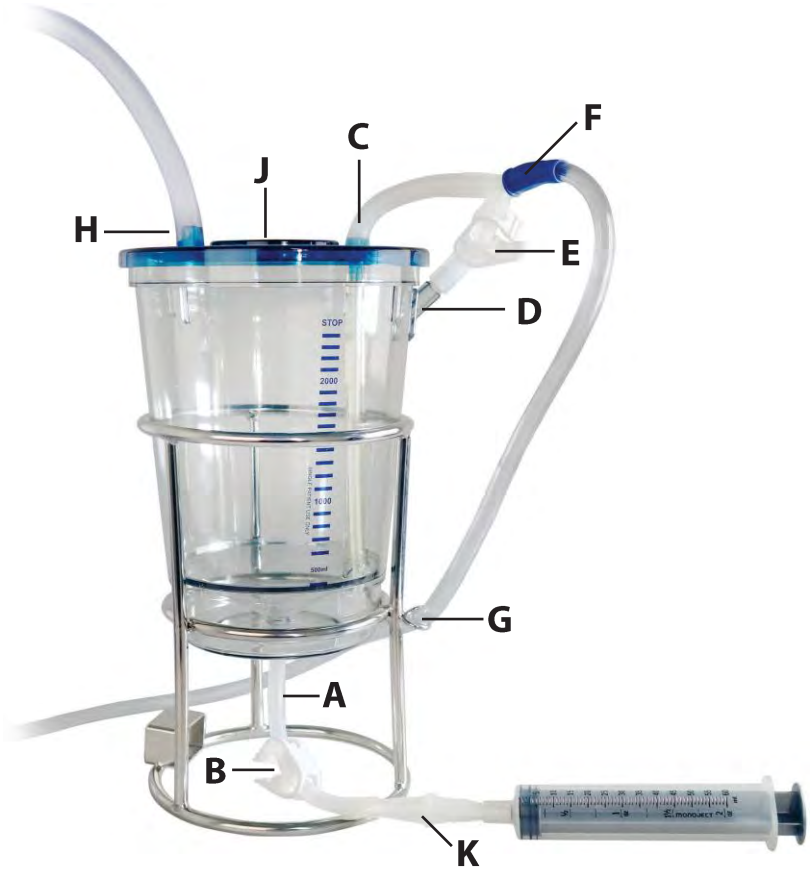
CAUTION: All reusable components of the device must be sterilized and all disposable components replaced before using the device system on another patient.

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

SYMBOL DEFINITIONS

Name	Ref# (ISO 7000)[2]	Symbol	Description	Use Standard
Consult Instructions For Use (IFU)	1641		Indicates the need for the user to consult the Instructions For Use (IFU).	ISO 15223-1:2021[1]
REF (Catalog #)	2493		Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1:2021[1]
Do Not Use if Package is Damaged	2606		Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1:2021[1]
Do Not Reuse	1051		Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	ISO 15223-1:2021[1]
Date of Manufacture	2497		Indicates the date when the medical device was manufactured.	ISO 15223-1:2021[1]
Manufacturer	3082		Indicates the medical device manufacturer.	ISO 15223-1:2021[1]
Use-By Date	2607		Indicates the date after which the medical device is not to be used.	ISO 15223-1:2021[1]
Lot / Batch Code	2492		Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021[1]
Prescription	N/A		**CAUTION:** Federal Law (U.S.A.) restricts this device to sale by or on the order ofa physician (or properly licensed practitioner).	FDA Title 21, Ch. 1, Subchapter H, Part 801.15(F)
Sterilized using Irradiation (gamma)	2502		Indicates a medical device that has been sterilized using irradiation (gamma).	ISO 15223-1:2021[1]
Importer	3725		Indicates the entity importing the medical device into the locale.	ISO 15223-1:2021[1]
Medical Device	N/A		Medical Device	ISO 15223-1:2021[1]
Contains or Presence of Phthalate	2725		Indicates the presence of phthalate (DEHP) as a material of construction within the medical device or the packaging of a medical device.	EN 15986:2011
Sterile Barrier: Single	3707		Indicates that there is a single sterile barrier system.	ISO 15223-1:2021[1]

[1] ISO 15223-1:2021 – "Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements"
[2] ISO 7000 – "Graphical symbols for use on equipment – Registered symbols"



SETUP INSTRUCTIONS

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

2. Place the stand onto the sterile field. Secure the stand to the table with the clamp.

3. Open the box and inspect contents.

WARNING: Do not use device if sterile packaging is damaged or opened.

4. Open the sterile packaging and locate the grip with the hand symbol to remove the top tray. Transfer the components and LipoFilter canister onto the sterile field.

WARNING: Do not reuse LipoFilter. This device is single-patient use only. Reuse may result in infection.

5. Attach the fat evacuation tube (A) to the bottom of the LipoFilter *(fig 1)*. If the five-way connector (K) is not already attached to the fat evacuation tubing, attach the connector by pushing either end securely into the bottom of the fat evacuation tubing. Make sure the tubing (A) is pushed fully onto the canister, and the lower pinch-clamp is closed.

6. Place the canister into the stand *(fig 2)*. Make sure it is seated properly and not tilted.

7. Attach the Y-connector tubing by 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)*. The top pinch-clamp (E) must remain completely open during aspiration.

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

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

10. Pre-load the canister with a cushion of fluid by pouring 500ml of sterile saline or Lactated Ringer's solution through the open port in the top center of the canister, then secure the center cap (J) *(fig 8)*.

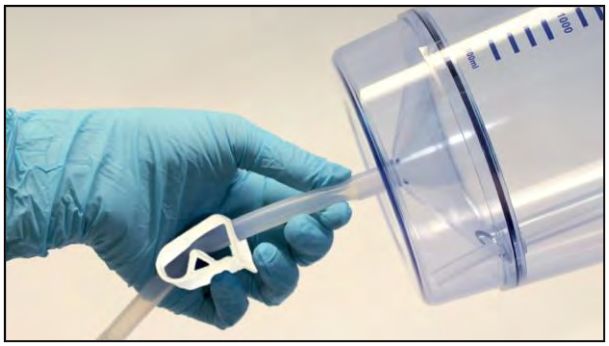


Figure 1. Attach fat evacuation tubing.

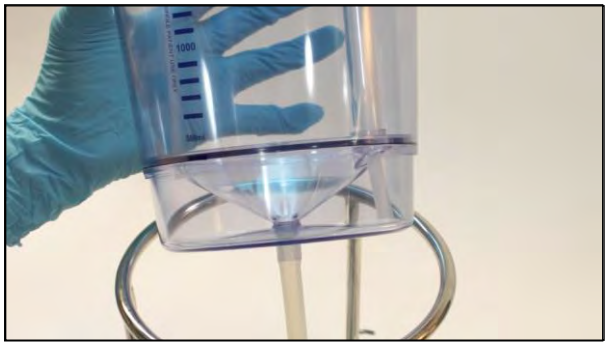


Figure 2. Place canister into stand.

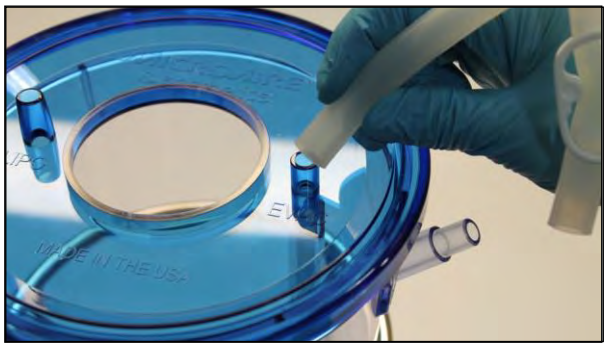


Figure 3. Attach plain side of Y-tube to "EVAC" port.

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

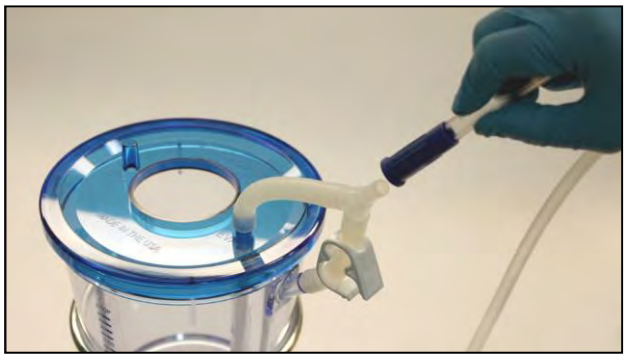


Figure 5. Attach fluid evacuation tubing to Y-tube.

Figure 6. Secure fluid evacuation tubing in pigtail hook.

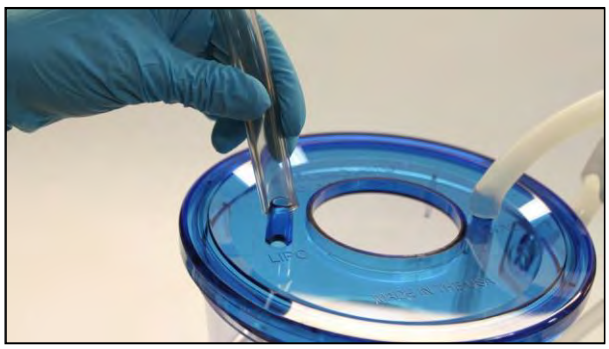


Figure 7. Attach liposuction tubing to "LIPO" port.

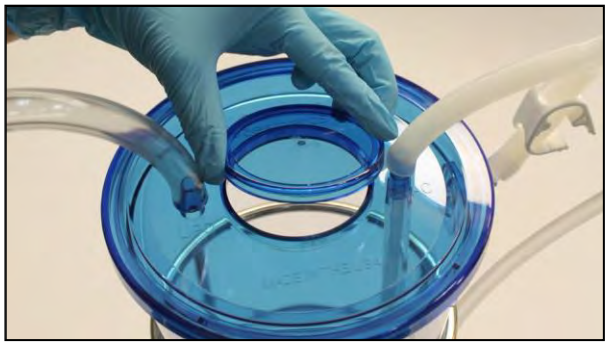


Figure 8. After pre-loading canister, attach center cap.

OPERATION INSTRUCTIONS

1. With the aspirator on, manually crimp the liposuction tubing to prevent airflow and set the vacuum level to approximately 457 mmHg (18inHg). Do not exceed 559 mmHg (22inHg) of vacuum.

2. Begin aspiration. Do not fill the canister past the 2500ml mark. This is indicated on the canister as "STOP" *(fig 9)*. Volume scale is for general reference only.

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 the cannula from the 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. For additional fat aspiration, do not reduce fluids below the 800ml mark. Keep the top pinch-clamp open and continue to aspirate.

6. For 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, there may be an air break in the lower chamber. When 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. Connect the 60cc Toomey syringe to the fat evacuation tubing via the five-way connector. Push the syringe and the tubing together until they click into place.

8. Open the lower pinch-clamp on the fat evacuation tubing *(fig 11)* and draw out the small amount of fluid that remains in the tubing *(fig 12)*. Close the lower pinch-clamp, then remove the syringe and discard fluid.

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

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

11. To disassemble, disconnect all tubing from the canister. Remove the canister from the stand and loosen the clamp to remove from the table.

SYNTHETIC TISSUE SHOWN FOR REFERENCE ONLY

Figure 9. Do not fill canister past "STOP".

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

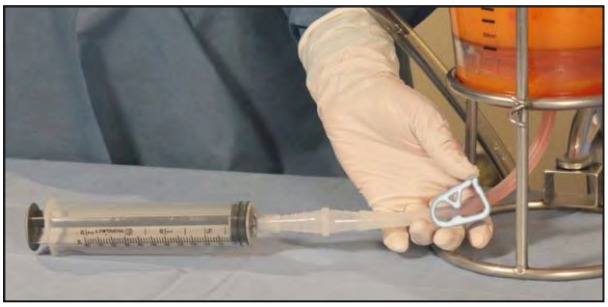


Figure 11. Open lower pinch-clamp.

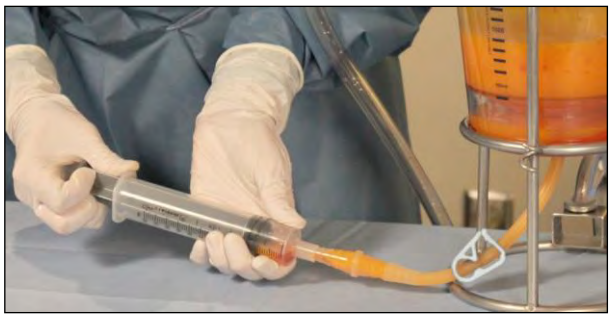


Figure 12. Remove excess fluid and discard.

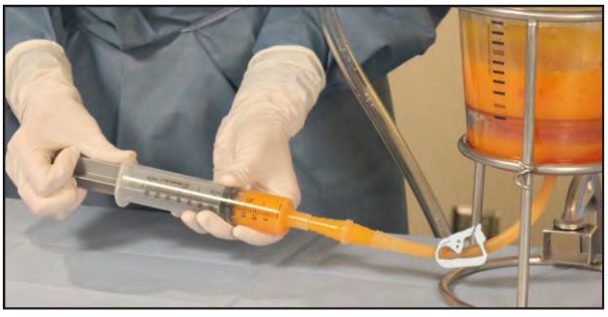


Figure 13. Draw out fat.

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

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 prior to cleaning.

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. DO NOT utilize cleaning agents with chlorine or chloride as the active ingredient as these are corrosive to stainless steel.

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

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

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

6. 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.

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

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

Pre-vacuum 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.

9. 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.

DISPOSAL

To reduce the risk of contamination by biological waste, it is recommended that all devices shall first be cleaned and sterilized. Disposal shall comply with all local, state, and federal laws and regulations.

LIMITATIONS ON REPROCESSING

Repeated processing of MicroAire multi-use instruments, according to the instructions above, has minimal effect on instruments. End of life is 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.

NOTES

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