

MicroAire® LipoFilter®

Fat-Transfer System

Instructions for Use



MICROAIRE®
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INSTRUCTIONS FOR USE

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

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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

INTENDED PURPOSE:

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

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:

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.

WARNINGS, CAUTIONS AND NOTES:

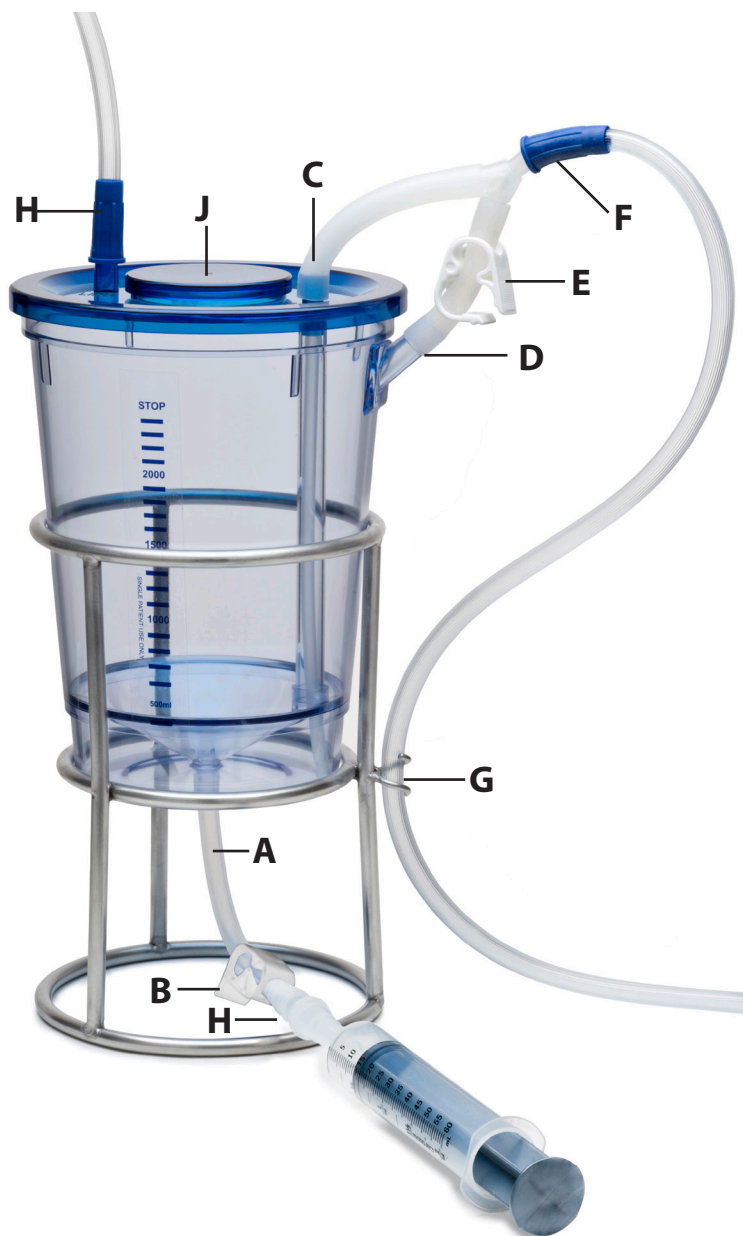
- WARNING:** Proper setup of device is critical to safe operation.
- WARNING:** Do not reuse LipoFilter. This device is for single-patient use only. Reuse may result in infection.
- WARNING:** Do not exceed 559 mmHg (22inHg) of vacuum as failure could occur.
- WARNING:** Universal precautions for handling contaminated materials should be observed at all times.
- WARNING:** Sterilizers vary in design and performance parameters. Verify cycle parameters against the written instructions of the sterilizer and container manufacturers.
- WARNING:** Do not use device if sterile packaging is damaged or opened.
- CAUTION:** Federal Law (U.S.A.) 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 as these are corrosive to stainless steel.
- CAUTION:** Make sure stand and clamp are secured to table.
- CAUTION:** This device is for single-patient use only. Reuse may result in device malfunction, device damage or failure, and damage to ancillary instruments.
- NOTE:** Make sure that tube is pushed fully onto canister, and pinch-clamp is closed.
- NOTE:** Depth scale is for general reference only.
- NOTE:** The top pinch-clamp must remain completely open during harvest mode.
- NOTE:** Make sure the tubing is not twisted or kinked.
- NOTE:** Do not use sterile water as this may damage fat cells.
- NOTE:** Harvesting at levels greater than 457mmHg (18inHG) may reduce cell viability.
- NOTE:** Do not fill canister past the 2500ml mark. This is indicated on the canister as "STOP".
- NOTE:** Remember to close the pinch clamp before removing the syringe.
- NOTE:** If concerns are noted that may compromise the function of the device, please contact your MicroAire representative.

SYMBOL DEFINITION

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 15223-1:2012 ¹
REF (Catalog #)	2493		Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1:2012 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. This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".	ISO 15223-1:2012 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 15223-1:2012 ¹
Single sterile barrier system with protective packaging inside	3708		Aseptic presentation technique requires opening of the outer packaging by an assistant nurse. Sterile nurses or surgeons must not touch the surface of the outer packaging. The inner layer with the sterile product may be handled by sterile personnel. Product in inner layer can be placed on sterile surfaces.	ISO 15223-1:2012 ¹
Date of Manufacture	2497		Indicates the date when the medical device was manufactured. The date is expressed as YYYY-MM (e.g. 2015-11) or YYYY-MM-DD (e.g. 2015-11-29).	ISO 15223-1:2012 ¹
Manufacturer	3082		Indicates the medical device manufacturer.	ISO 15223-1:2012 ¹
Use-By Date	2607		Indicates the date after which the medical device is not to be used.	ISO 15223-1:2012 ¹
Authorized Representative in the European Community	N/A		Indicates the authorized representative in the European Community.	ISO 15223-1:2012 ¹
Lot / Batch Code	2492		Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2012 ¹
Non-Sterile	2609		<ul style="list-style-type: none"> Indicates a medical device that has not been subjected to a sterilization process. This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions. Also indicates a medical device that is provided non-sterile but must be sterilized prior to use. 	ISO 15223-1:2012 ¹
Prescription	N/A		Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a 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). Use of the Sterile symbol requires a use-by date (see Use-By Date symbol).	ISO 15223-1:2012 ¹
CE mark (with Notified Body #)	N/A		Indicates the European Conformity Mark with Notified Body Number. 0086 is the BSI-UK-registered Notified Body.	Council Directive 93/42/EEC
CE mark (with Notified Body #)	N/A		Indicates the European Conformity Mark with Notified Body Number. 2797 is the BSI-NL-registered Notified Body.	Council Directive 93/42/EEC

¹ISO 15223-1:2012 – "Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements"

²ISO 7000 – "Graphical symbols for use on equipment – Registered symbols"



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: Do not reuse LipoFilter. 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). If the Five-Way Connector (H) is not attached to the fat evacuation tubing, attach the connector by pushing either end securely into the bottom of the fat evacuation tubing.

NOTE: Make sure that tube is pushed fully onto canister, and pinch-clamp (B) is closed.

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 a 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.

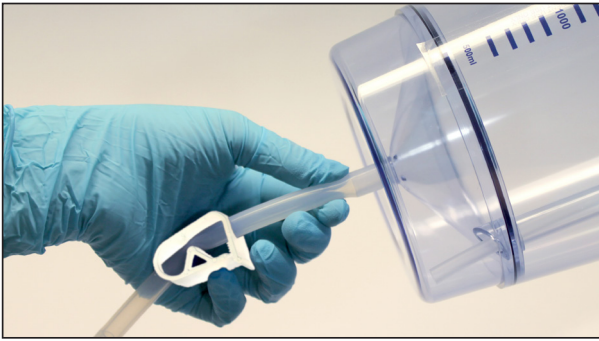


Figure 1. Attach fat evacuation tubing.

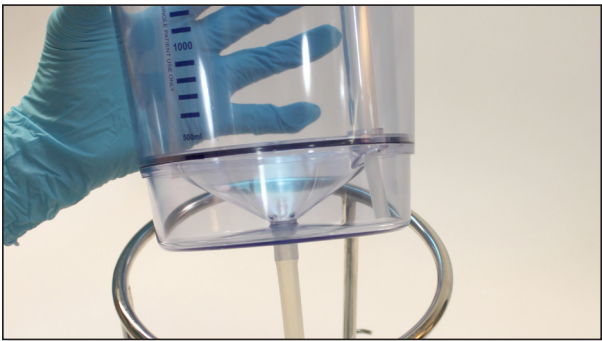


Figure 2. Place canister into stand.

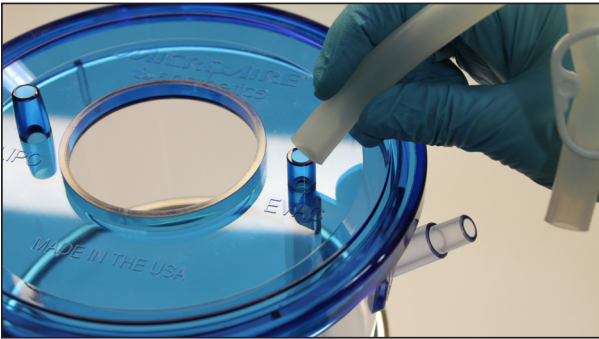


Figure 3. Attach plain side of Y-tube to "EVAC" port.



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

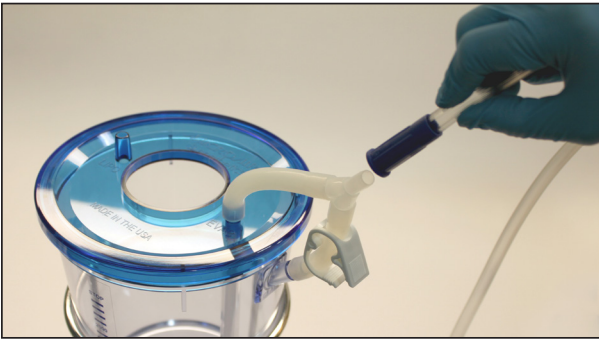


Figure 5. Attach fluid evacuation tubing to Y-tube.



Figure 6. Secure fluid evacuation tube in pigtail hook.

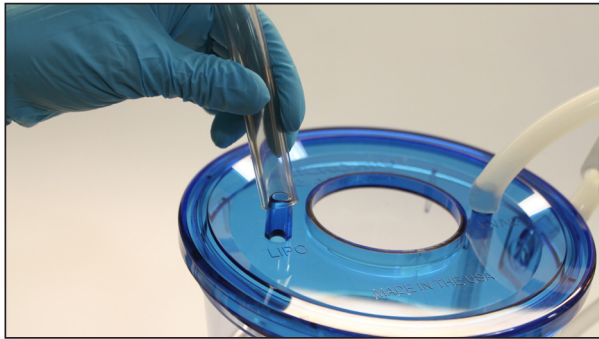


Figure 7. Attach liposuction tube to "LIPO" port.

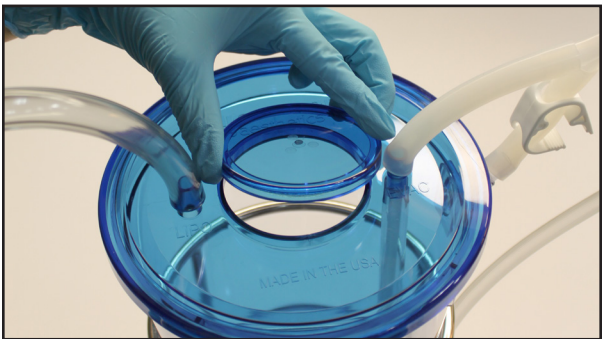


Figure 8. After pre-loading canister, attach center cap.

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 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.

SYNTHETIC TISSUE SHOWN FOR REFERENCE ONLY

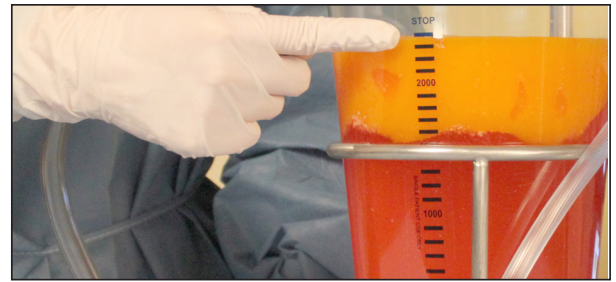


Figure 9. Do not fill canister past 2500ml.



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 as the active ingredient as these are 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.

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 OF REPROCESSING

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