

MEDCO

MANUFACTURING

Innovators of Lipoplasty
Since 1979



ASPIRATOR IV MANUAL & PRIMARY MEDICAL DEVICE LABEL

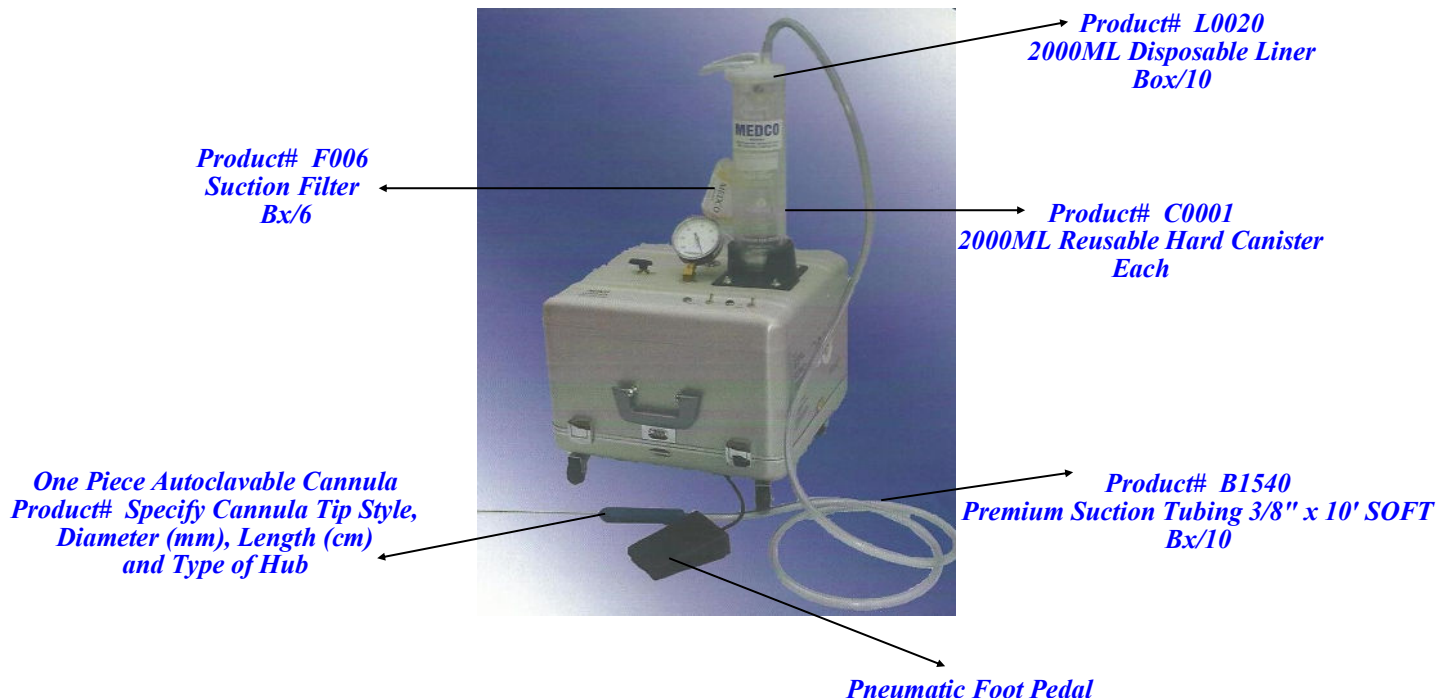
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MEDCO

ASPIRATOR IV

The MEDCO ASPIRATOR IV utilizes two advanced, state of the art positive displacement pumps. These dual headed pumps relive back pressure to allow each individual pump to pull against the patient so that a deep vacuum is quickly reached and maintained. If one pump should go down, the other three will continue to function independently.

The positive displacement pumps used in MEDCO ASPIRATORS are the QUIETEST on the market! The Aspirator is made even quieter with 1" shock mounts to eliminate vibration. This, combined with a super quiet muffler and insulation system, make the MEDCO ASPIRATOR IV the QUIETEST Aspirator on the market today!



✱ *MEDCO ASPIRATORS come with a limited* ✱
5 year warranty on all parts and labor

Specifications

Voltage	110V or 220V
Weight	64 pounds
Dimensions	17"x 18"x 18"
Max Vacuum	29+ inches Hg
Max Flow	7.5= CFM
Sound Level	29+ -3db
Pump	2x2 Piston
Horsepower	2/3 hp
MAINTENANCE FREE, OILLESS	

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General Description:

The Medco Aspirator IV is a high powered suction system with two oil-less piston vacuum motors and four pump heads. The system is designed to pull a vacuum on any closed container or any open process system. Vacuum is accomplished by mounting the vacuum pumps parallel.

When the system is connected, the air flow will be from the tip of the cannulae through the tubing, collection system, bacterial filter and finally to the pumps that will evacuate the air from the lines, creating a vacuum pulling aspirated material in the same direction as the air flow. Aspirated material continues to the collection system under normal suction until the cannulae is exposed to air again.

Specifications:

Voltage:	110V or 220V
Weight:	64 lbs.
Dimensions:	17" x 18" x 18"
Maximum Vacuum:	29+ inches of Hg
Maximum Flow Rate:	7.5 cfm
Overflow Protection:	In-line Filter
Sound Level:	29 +/- 3db
Pump Type:	2 piston motors and 4 pump heads
Number of pumps:	4
Horsepower:	2/3 hp

Check List:

Carefully unpack the Aspirator IV. Check that the following accessories are included in the package and were received in good condition.

- Aspirator IV
- Canister Holder
- Vacuum Gauge
- Power Cord
- Foot Switch
- *Sterile, Disposable Tubing – Product #1540 (Box/10pcs)
- *Bacterial Filter -- Product #F006 (Box/10pcs)
- *Permanent Canister – Product #C0001 (Each)
- *Disposable Canister Liner – Product #L0020 (Box/10pcs)
- User's Manual
- *À la carte item(s) – NOT INCLUDED AS AN ACCESSORY. Listed for disposable(s) reorder reference.

Call Customer Service Immediately to report any damaged or missing items: 800.953.2555.

Component Description:

Vacuum Pumps

The Aspirator IV uses two (2) 1/3 hp piston pumps

- Oil-less, non-lubricated piston and cylinder.
- Permanently lubricated ball bearings
- Stainless steel valves
- Lightweight aluminum components
- Long-life, high performance piston seals
- Twin-fan cooling system
- UL recognized motors
- Thermal protected

- Balanced for low vibration operation
- Capacitor

Circuit Breaker:

To protect the equipment and reduce shock hazard, a re-settable circuit breaker is installed on the right-side, near the power cord outlet. If there is a voltage surge or the pump motor overheats, the circuit breaker will pop out. To reset, turn the Aspirator IV off, push in the circuit breaker, and turn the Aspirator IV on. If the unit fails to start, the Aspirator IV may require a cool-down period or technical repairs.

Note: DO NOT LET TECHNICIANS BY-PASS THE CIRCUIT BREAKER!!

Control Valves:

Vacuum Control

Operate Vacuum Control by turning pointer between High and Low (pressure is reduced). The vacuum gauge in the panel will indicate a pressure change.

Note: The Aspirator IV system has been calibrated at 160 feet above sea level to 29+ in Hg. For each additional increase of 1,000', the vacuum should drop by 1" Hg. And conversely, for each additional decrease of 1,000', the vacuum should increase 1" Hg.

Foot Switch:

OPERATION WITH FOOT SWITCH

Plug the foot switch cord into the unit. Turn the Foot Switch and Power switches to the **ON** position, press the pedal and the Aspirator IV will start. Press the pedal again to stop the power of the unit.

Overflow Bacterial Filter: Product #F006

The Overflow Filter is designed to catch aspirated material which has by-passed, or overflowed, from the main collection canister.

If there is a problem with the overflow, please check the following:

1. The liner may be collapsing, causing material to overflow into the filter.
2. The collection system may be full.
3. The collection system may not be set up properly.

NO ASPIRATED MATERIAL SHOULD BE ENTERING THE OVERFLOW FILTER AT ANYTIME.

Read the trouble shooting section of this material for instructions to correct an overflow situation.

SAFETY INFORMATION:

- Read all instructions carefully before opening equipment.
- Avoid ingesting aspirated material into the pumps. Severe damage can occur to the pumping system upon contact with aspirated material.
- Always disconnect the power supply to the Aspirator IV before servicing.
- Motors are thermally protected and will automatically restart when protector resets.
- Current leakage tests are performed and are certified within the AAMI maximum 300Ua limit for medical devices.
- Safety checks should be scheduled according to purchaser's policies.
- Additional warnings and power requirements, which are part of the labeling, are located on the side of the Aspirator IV.

Caution: federal Law restricts this device to sale by or on the order of a physician.

SET UP AND OPERATION:

1. Carefully remove the Aspirator IV from the shipping carton. Be sure to save the box and packing material for convenient return to Medco.
2. Read all instructions carefully before operating the unit.
3. After you have removed the Aspirator IV, open the accessory box and locate the power cord and foot switch. Attach the foot switch to the Aspirator IV. Plug the power cord into the Aspirator IV and then into the power outlet.
4. Locate the vacuum gauge and screw into the gauge fitting on top of the Aspirator IV.
5. Turn the Power switch and the Foot Switch ON.
6. To test the unit, place a finger over the main suction hose coming directly out of the top of the Aspirator IV. Note the reading of the vacuum gauge. Keep in mind that vacuum changes according to elevation. After checking the vacuum, turn the Aspirator IV off.
7. Connect the HEPA Filter to the Aspirator IV using the 6" silicon tube. Connect the other end of the HEPA Filter to the permanent canister.

Note: Change the HEPA Filter after 10 procedures or every 24 hours use or replace Filter IMMEDIATELY if ANY Bodily Fluids/Blood/Fat/Residue is visual within the Filter.

Set up the collection system as describes.

At this point, the following accessories should now be connected:

1. Power cord and foot switch
2. Vacuum gauge – to quick connect
3. Bacterial filter-connected to the hose barb marked “**to filter**” and permanent canister.
4. Canister – placed in the canister holder with liner intact

The unit is now ready for operation.

Hospira Canister System Set-Up & Operation:

1. Place canister on the top panel of the Aspirator IV inside canister black base holder.
2. Insert a Quick Fit Liner into the canister and secure the lid.
3. Connect the piece of tubing that is connected to the liner lid to one end of the Tee connector.
4. Connect the piece of tubing from the filter to the bottom of the bracket on the Canister.
5. The sterile aspiration tubing will connect to the liner lid on the port labeled: **Patient**

The Canister System is now ready for operation.

Note: Aspirated material should not enter the overflow trap at anytime.

If an overflow situation occurs, please do the following:

1. Turn off the power immediately.
2. Check the connections between accessories to make sure the unit was set up correctly.
3. Check for a crack in the canister.
4. Check the vacuum and volume settings (should be on high).

A collapsing liner bag or Aspirated material going into the overflow trap does not mean that something is wrong with Aspirator IV. An overflow situation indicates there is an interference with the liner bag vacuum, such as an improper seal or a crack in the permanent canister.

Maintenance

- All Aspirators are thoroughly checked by the Quality Assurance Department before being released for shipping. Inspect the unit upon receipt to insure the equipment was not damaged during shipping. The vacuum power should also be checked.
- Do not lubricate pumps. The oil-less components are sealed and packed with optimum level of lubricant, requiring no lubrication.
- Do not let liquid or aspirated material enter the pumping system.
- The mufflers should be changed after approximately 80 hours of operation, or whenever the white filter inside the muffler becomes black.
- No scheduled maintenance is recommended. Follow the procedures established by your engineering department.
- Warnings are part of the labeling and are indicated on the Aspirator IV. The serial number is stamped on a small metal tag, located on the side of the Aspirator IV. Record the serial number.
- In-Services on new equipment can be provided by telephone with either your sales representative, or technical support staff. If additional information is needed, call Customer Service or technical support at 800.953.2555
- Change HEPA Filter after 10 procedures or after 24 hours of use or replace Filter IMMEDIATELY if ANY Bodily Fluids/Blood/Fat/Residue is visual within the Filter.**

Parts List:

Aspirator IV

Power Cord (AC 110V)

Power Cord (AC 22V)

Foot Switch (Single)

Vacuum Gauge

*HEPA Filters (Item # F006/bx of 6)

*Medco Holder (Black Base)

*Soft-Flexible Tubing 10ft. sterile (Item #B1540/bx of 10)

*Hospira Canister 2000cc (Item # C0001 each)

*Hospira Disposable Soft-Shell Liners (Item # L0020/bx of 10)

Vacuum Pump 1/3 hp, piston, hi-vac (2 ea.)

Vacuum Pump 1/3 hp, piston hi-vac (1 ea.)

Muffler (MIN)

Tubing (Internal PVC)

*À la carte item(s) – NOT INCLUDED AS AN ACCESSORY.
Listed for disposable(s) reorder reference.

Trouble Shooting:

No Suction or Trips Breaker

1. Turn vacuum and volume control knobs to High. If one or both knobs are on Low, there will be no noticeable suction.
2. Check for a collapsing liner.
3. Remove bacterial filter and place a finger over the main suction hose. If there is no suction, turn the unit off, remove finger from hose, wait a moment, then turn the unit on again.

4. If pump is under pressure and is turned off by the Foot Switch or Pedal, the pump WILL NOT turn back on without removing the Cannula from the Patient and/or bleeding Gauge COMPLETELY DOWN TO ZERO(0). Pressure must be FULLY RELIEVED before it will restart!

NOTE: Before starting any suction procedure, let the aspirator IV go to full vacuum when switched on, during operation, if the Aspirator IV is momentarily turned off, let the vacuum gauge indicator return to ZERO(0) before restarting the machine. All the air must clear from the vacuum lines before all the pumps will start again. Failure to follow this procedure can result in the loss of vacuum.

Overflow Situation:

1. Monitor the collection system for fluid level. Do not overflow.
2. A collapsing liner can cause aspirated material to overflow into the overflow trap.
3. Check for a crack in the canister. This can cause the liner to collapse, resulting in an overflow situation. A collapsing liner bag does not mean that there is something wrong with the Aspirator IV.

NOTE: With proper operation and monitoring, at no time during any procedure, should an overflow situation occur.

Broken Canister:

1. Do not use a damaged canister. A damaged canister will cause the liner bag to collapse, causing the aspirated material to overflow into the overflow trap.

WARNING:

Ingesting aspirated material into the pumping system can severely damage the pumps and void the warranty. If material is going into the overflow filter, check the collection system immediately to see if the Liner bag is collapsing or is too full, if further assistance is needed, call technical support at 800.953.2555.

Refer to the collection system section and instructions for proper set up.

WARRANTY

MEDCO MANUFACTURING will void Warranty on any Products indicating negligence, or noncompliance with Operation Maintenance Instructions.

Products are warranted against defect in Material and Workmanship for a period of five (5) years from date of purchase.

If repair or adjustment is necessary, and are not the result of abuse or misuse, please return, freight prepaid and correction will be performed without charge.

- *Five (5) year on parts and labor from the date of shipment.**
- *Unauthorized handling of the Aspirator IV will void warranty of the unit.**
- *Any aspirated material found to have been ingested into the pumping system will void the warranty.**
- *Retain the custom-made packing box with foam for returns.**
- *For questions regarding the warranty, call the Quality Assurance Department: 800.953.2555.**

**For Technical Assistance, contact MEDCO MANUFACTURING
Customer Service or Technical Support:**

(800)953-2555 • (281)379-3100

Or email: Service@MedcoManufacturing.com

**All returns require prior Authorization from
MEDCO MANUFACTURING
Quality Assurance Department.**

MEDCO POLICY ON RETURNED GOODS

1. No returns or exchanges will be accepted unless you have received a return of goods authorization number from Medco. This number must be in the return box and all written communication.
2. Return numbers will expire if items are not returned within **30 days**.
3. Credit will only be issued if the merchandise is in salable condition, if the product(s) has been used in surgery, the product must be **CLEANSED and STERILIZED** and a **written statement confirming such must accompany the product(s)**.
4. Full credit will be issued for any item returned in **15 days** that is undamaged and salable condition.
5. A restocking charge of **25%** will be charged to any product returned between **15-45 days**. A credit memo, based on the dollar amount, will be issued to the account.
6. OPENED PACKAGES OR BOXES containing disposable are not returnable for credit or exchange. Each package or sales unit specifically states "Not Returnable if Package Seal is Broken".
7. **Custom products are NOT RETURNABLE**. Since special tooling and time are dedicated to these products which are manufactured to the precise specifications of the surgeon, they cannot be sold to another customer.
8. **NO CREDIT WILL BE ISSUED ON ANY ITEM RETURNED AFTER 45 DAYS.**
9. COMPLIANCE WITH FDA REGULATIONS ON STERILE AND IMPLANTABLE PRODUCTS ACCEPTED FOR RETURN REQUIRE MORE EXTENSIVE CONTROLS AND ARE SUBJECT TO REFUSAL AND HIGHER HANDLING CHARGES.
10. ALL DISCREPANCIES BETWEEN THE PRODUCTS RECEIVED MUST BE REPORTED WITHIN **48 HOURS** OF RECEIPT OF THE PACKAGE TO QUALIFY FOR A CREDIT.