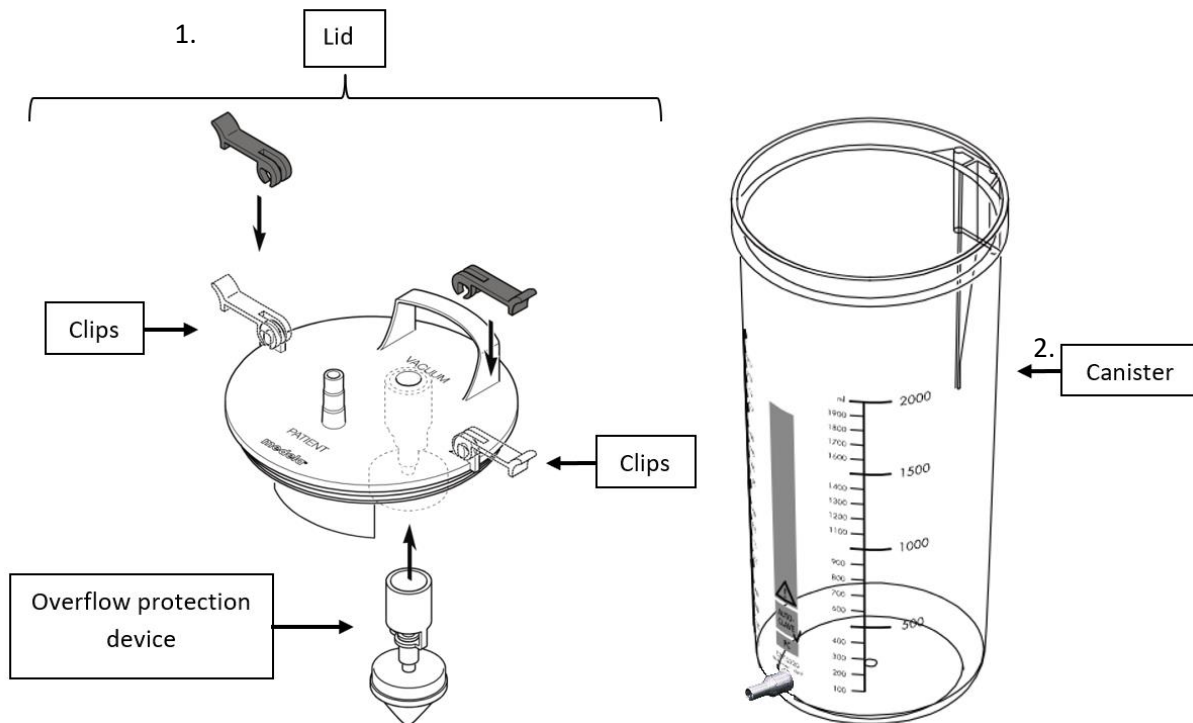


Fat Collection Canister Systems

AYON-SAL-CAN4

Parts included with the canister system:

Item	Part	REF	Description	Type
1	Lid	B89119	3000 CC Canister Lid	Reusable
2	Canister	B89167	3000 CC Canister	Reusable
3	Fill Tube	B89113	Fill tube with pinch clamp and tapered port connector	Reusable
4	Fill Tube	B89107	Fill tube with pinch clamp and luer connector	Reusable
5	Fill Tube	B89109	Fill tube with pinch clamp and Toomey connector	Reusable
6	Canister Stand	B89108	3000 CC Canister Stand	Reusable
7	Vacuum Tubing	B89121	6 ft silicone vacuum tubing with coupling piece	Reusable





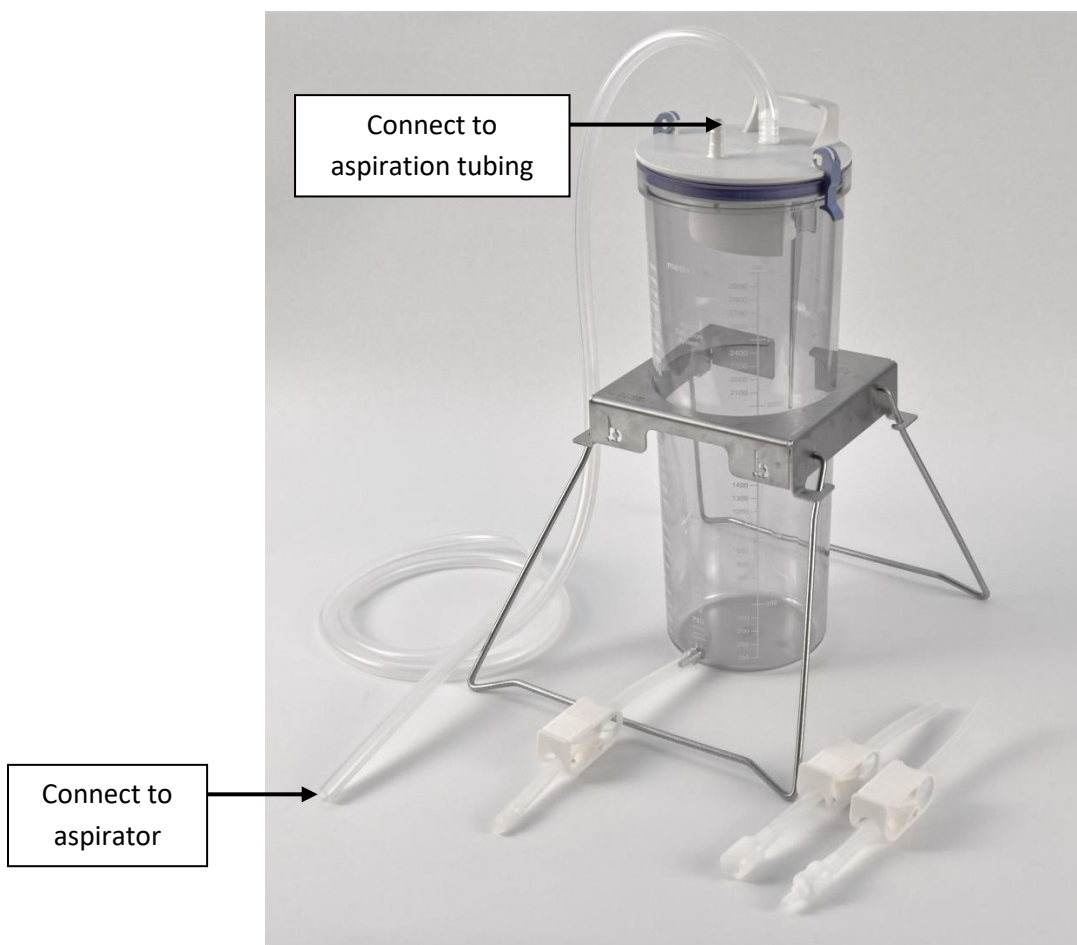
KITS:

All kits include

- (1) canister
- (1) lid
- (3) fill tubes
- (1) stand
- (1) vacuum tubing

Setup Instructions

1. All parts must be sterilized prior to use
2. Using sterile technique, place canister lid onto canister and secure with both clips
3. Place canister with lid into canister stand. Stainless steel canister port should be on the same side as the **b**'s in the stand.
4. Connect 6ft silicone vacuum tubing to "vacuum" port on canister lid using the white plastic coupling piece
5. Connect open end of 6ft silicone vacuum tubing to approved aspirator.
6. Connect fill tubing of choice to stainless steel port at bottom of canister and close the pinch clamp
7. Connect approved aspiration tubing to "patient" port on canister



MANUAL CLEANING AND STERILIZATION INSTRUCTIONS

CAUTION: Sterilizers vary in design and performance parameters. Verify that the cycle parameters of the sterilizer meet the parameters outlined in the sterilization instructions contained in this IFU.

CAUTION: Use only neutral pH enzymatic cleaning solution. Do not use cleaning solutions with chlorine or chloride as the active ingredient is corrosive to stainless steel and aluminum.

1. At point of use

- a. Remove all tubing and the lid from the canister. Remove the canister from the canister stand. Disassemble the stand and lid.
- b. Remove excess soil and contaminants with a damp lint-free wipe.

2. Processing

- a. The devices must be cleaned within 30 minutes of end-of-use to minimize the potential for organic material to dry on the devices.
- b. Prior to cleaning, always check the container, lid, overflow protection and silicone tubes for cracks, brittle and flawed spots. If any defects are seen, discard the component(s) via biohazard waste and replace with new component.

3. Cleaning Solution

Use a neutral pH enzymatic solution, (such as STERIS® Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner). Use directed concentration per manufacturer instructions.

4. Cleaning: Manual

- a. Inspect all devices for the presence of any soil or debris.
- b. Rinse all devices thoroughly with utility water.
- c. Wash canister, lid, and stand with nylon or nonabrasive cleaning brush until all visible debris or oil is removed.
- d. Use wire nylon brush to clean inner lumen (hole) of stainless-steel canister port and fill tube(s).
- e. Brushes and wire brushes should fit snugly but still be able to be moved around easily within the area to be cleaned.
- f. Flush fill tube(s) and 6ft silicone suction tube and coupling piece with utility water.
- g. Rinse all devices thoroughly in utility water.
- h. It is important to remove any detergent residue before wrapping.
- i. Check the items for visible debris and oil; repeat previous cleaning steps until no visible signs of debris or oil are present.
- j. Once clean, place items within only legally marketed sterilization packaging. (such as Halyard® Health, *Quick-Check*® H400, 36"x36"; Cardinal Health Paper Sterilization Pouch, 92152, 12"x15"; HuFriedy 8"x16") This includes wraps used for autoclaving medical devices and equipment.

5. Sterilization

- a. All reusable products should be individually packaged or wrapped using legally marketed sterilization wraps. (such as Halyard® Health, *Quick-Check*® H400, 36"x36"; Cardinal Health Paper Sterilization Pouch, 92152, 12"x15"; HuFriedy 8"x16")
- b. Do not stack metal products with plastic products within the autoclave.
- c. Avoid having any plastic or silicone components touching any metal directly.
- d. Prior to autoclaving, always check the suction canister, lid, overflow protection, fill tubing, and 6 ft silicone suction tube and coupling piece for cracks, brittle and flawed spots. Check stainless steel port on canister for burrs. If any defects are seen, discard the component(s) via biohazard waste and replace with new component(s).
- e. All reusable products should be individually packaged or wrapped using legally marketed / FDA approved sterilization wraps.

Steam pre-vacuum sterilization parameters:

Temperature: 132° C / 270° F

Exposure Time: 4 minutes

Dry Time: minimum 15 to 30 minutes

Temperature: 134°C/273

Exposure Time: 5 minutes

Dry Time: minimum 15 to 30 minutes

9. Storage

Sterile, packaged multi-use instruments should be stored in a dry, dust-free location with appropriate environmental controls.

NOTE: *If there is concern that the functionality of the device may be compromised, please contact Black & Black Surgical.*

Inspection Criteria

Before and after use each component should be evaluated for defects or flaws which hinder performance.

Follow the appropriate steps listed for each component below.

Any damaged components should always be discarded via medical or biohazard waste methods according to your facility.

Inspection Criteria (contd)

1. Canister lids and overflow protection component – Importance is to maintain negative pressure within canister.

- The lid should have a snug fit and be able to clamp without any resistance
- After cleaning and prior to use (post sterilization) examine to make sure the lid is working appropriately.
- Best way to test for air leakage is to close off all ports to see if suction is maintained
- If suction cannot be maintained due to lid defect, dispose of and replace with new one
- The canister lids can be used until no longer performing as intended.

2. Canister – Importance is to collect lipoaspirate and maintain negative pressure

- The canister should be able to hold negative pressure and not leak any fluid during a procedure
- After cleaning and prior to use (post sterilization) examine to make sure the canister is working appropriately.
- Most common defects are cracks or flaws around bottom of canister
- Best way to test negative pressure is to close off all ports (collection tube port and bottom luer port) to see if suction is maintained
- Make sure luer ends are aligned appropriately and screwed on tight.
- Best way to test for fluid leakage is while cleaning to see if any fluid leaks from the canister
- If suction cannot be maintained or there is leakage detected at any time dispose of and replace with new one
- The canister can be used until no longer performing as intended.

3. Extraction Tube – Importance is to maintain suction and allow transfer of lipoaspirate

- The extraction tube should be able to hold negative pressure and not leak any fluid during a procedure
- After cleaning and prior to use (post sterilization) examine to make sure the extraction tube is working appropriately.
- Though very rare, common defects are cracks or flaws around the silicone portion of the extraction tube
- Best way to test negative pressure is to close off middle clamp and apply the luer end cap to see if suction is maintained
- Make sure both luer ends are aligned appropriately and screwed on tight as this can lead to air loss
- Best way to test for fluid leakage is while cleaning to see if any fluid leaks from the metal or silicone portion of the assembly
- Again, make sure both luer ends are aligned appropriately and screwed on tight as this can lead to fluid loss
- If suction cannot be maintained or there is leakage detected at any time dispose of and replace with new one
- The extraction tube can be used until no longer performing as intended.



Black & Black Surgical, Inc.
5175 South Royal Atlanta Dr.
Tucker, GA 30084 USA
Phone: 770-414-4880 Fax: 770-414-4879



Apyx Medical
5115 Ulmerton Rd.
Clearwater, FL 33760 USA
Phone: (800) 537-2790