

THE Red Head

US Patent 8,366,694 and 8,100,874

Non-Sterile, Single Use Canister System

Instructions For Use

INTENDED USE: For use in aspirating subcutaneous fatty tissue including autologous fat collection.

PRECAUTIONS:

- This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
- 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.
- Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
- Results of this procedure may or may not be permanent.
- The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

WARNINGS:

- **SINGLE USE ONLY**
- This device **must be** sterilized before use.
- Proper setup of the device is critical for safe operation. **NEVER** exceed 18inHg or 450mmHg.
- **DO NOT** fill the canister past the **2500 ml STOP** mark.
- Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- This device will not, in and of itself, produce significant weight reduction.
- 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.
- 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.

TERMS:

Note: Use to point out easiest means of carrying out the techniques.

Warning: Used to indicate that the safety of patients and hospital personnel could be involved.

Precaution: Use to point out special procedures or precautions that must be complied with to avoid damage.

Contents:

Non-Sterile Components: Red Head Canister, Fat Evacuation Tube, Manifold, Sterilization Pouch

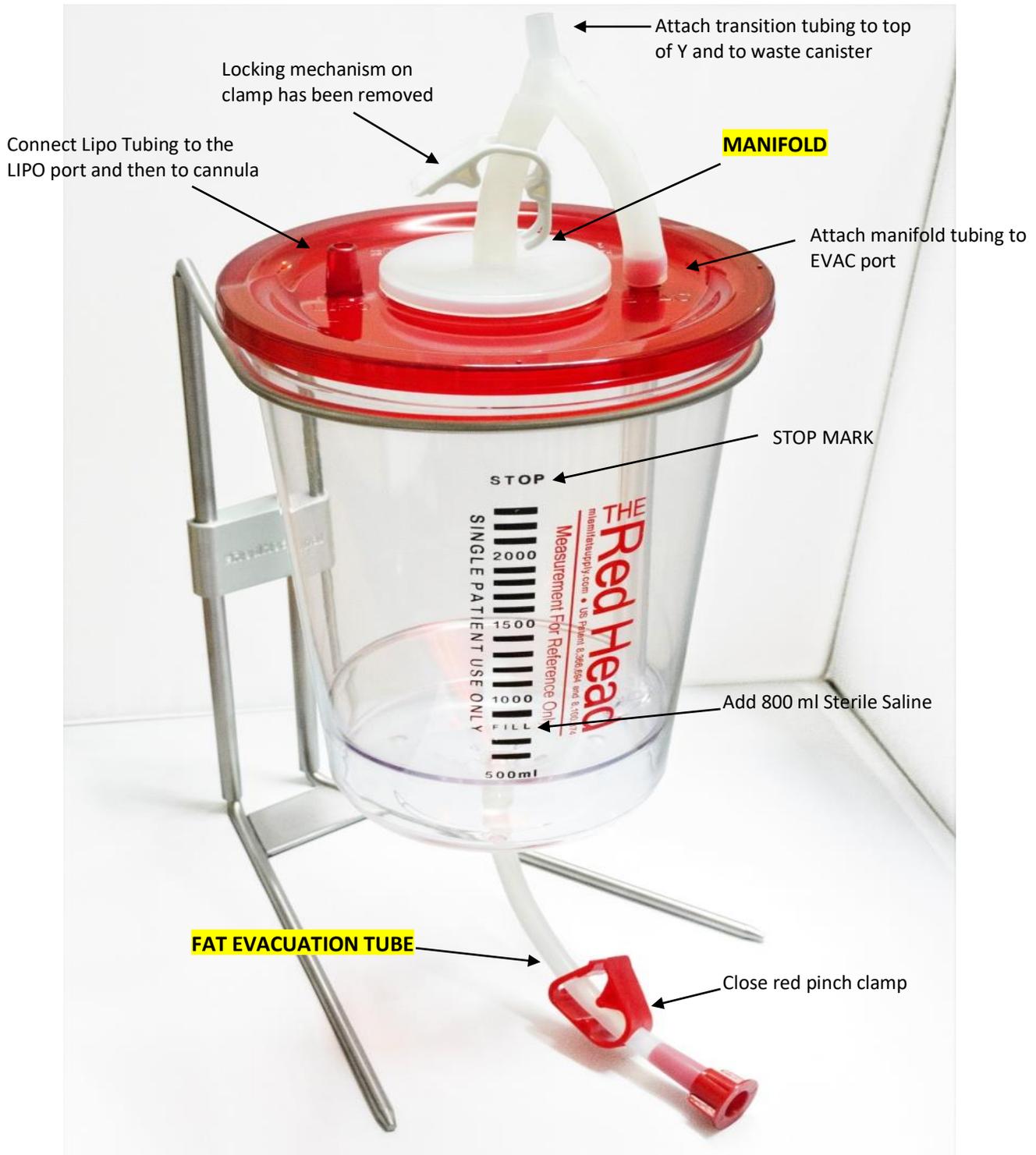
Sterile Components: 60cc Monoject Toomey Syringe, 6' x 9/32" Argyle Connecting Tubing

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 or humidity extremes.



SETTING UP THE RED HEAD: The following instructions should be followed as written to ensure proper cleaning and sterilization of the device. Unless otherwise noted, please perform steps in the order specified.

STEP	INSTRUCTIONS			
VISUAL INSPECTION	1. Open box and visually inspect contents. If the box or contents show signs of damage or wear do not use.			
STAND AND CLAMP	2. Wash and sterilize stand and clamp (sold separately) according to stand instructions. 3. Place clean and sterilized stand onto sterile field. Caution: Make sure stand is clamped securely to table using the provided clamp.			
CLEANING	4. Open non-sterile protective bag containing Red Head canister, manifold and fat evacuation tube. NOTE: NEVER remove large red lid on canister. 5. Remove the contents from the protective plastic bag. 6. Thoroughly clean the outside of the canister with an alcohol wipe. 7. Wipe the manifold and fat evacuation tube with an alcohol wipe. 8. Allow the components to dry thoroughly before packaging for sterilization.			
STERILIZATION	9. Place into sterilization pouch and seal. Do not place the manifold and fat evacuation tube inside the canister. Place alongside the canister inside the pouch. Sterilize according to instructions. <ul style="list-style-type: none"> a. Prevacuum Steam Sterilization: 4 minutes Full Cycle at 132°C (270°F), 30 minutes minimum dry time. b. Gravity Displacement Steam Sterilization: 30 minutes Full Cycle @ 121°C (250°F), 20 minutes minimum dry time. 10. PLEASE CAREFULLY REVIEW THE FOLLOWING STERILIZER INSTRUCTIONS: <table border="1" data-bbox="407 1203 1492 1444" style="margin-left: 20px;"> <tr> <td style="text-align: center;">1. STERILIZE ONLY WITH COMPATIBLE DEVICES WITH SIMILAR DIMENSIONS OR CHARACTERISTICS.</td> </tr> <tr> <td style="text-align: center;">2. DO NOT ALLOW THE RED HEAD TO TOUCH ANYTHING METAL OR THE SIDES OF THE AUTOCLAVE</td> </tr> <tr> <td style="text-align: center;">3. DO NOT PLACE ANYTHING NEXT TO OR ON TOP OF THE RED HEAD TO AVOID DAMAGING THE CANISTER OR LID.</td> </tr> </table> 11. After steam sterilization open the sterile pouch and place Red Head canister and all components into the sterile field.	1. STERILIZE ONLY WITH COMPATIBLE DEVICES WITH SIMILAR DIMENSIONS OR CHARACTERISTICS.	2. DO NOT ALLOW THE RED HEAD TO TOUCH ANYTHING METAL OR THE SIDES OF THE AUTOCLAVE	3. DO NOT PLACE ANYTHING NEXT TO OR ON TOP OF THE RED HEAD TO AVOID DAMAGING THE CANISTER OR LID.
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ASSEMBLY	12. Attach fat evacuation tube securely to bottom of Red Head and place Red Head into stand. CLOSE RED PINCH CLAMP on the fat evacuation tube. 13. Pour 800 ml of injectable, sterile saline or lactated Ringers solution through large opening. Do not use sterile water as this will damage fat cells. 14. Secure center cap onto lid and attach tubing to the EVAC port. NOTE: THE WHITE PINCH CLAMP DOES NOT HAVE A LOCKING TAB AND MUST BE HELD MANUALLY 15. Connect the provided Suction Tubing to the Y connector on the lid manifold. Connect the other end to the waste canister. 16. Connect Lipo Tubing to the LIPO port on the top of the lid. Connect the other end of the tubing to the cannula.			



Questions? Please call our office 352-557-6979
 For visual instructions please view the in-service video on the Red Head page at
www.miamifatsupply.com

Harvest Instructions

1. Turn on aspirator, crimp liposuction tubing and set vacuum level to 18 inHg or 450mmHg.
2. Begin harvesting. **DO NOT FILL CANISTER PAST 2500 ML MARK. This is indicated on the canister as STOP.**
3. Allow fat to separate from fluids before attempting to evacuate the fluids.
4. **LOWER FLUID LEVEL:** Remove cannula from patient and CLOSE white pinch clamp on the center cap of the lid. The clamp will not lock. Manually hold clamp closed. You will observe the fluid transferring to the waste canister through the evacuation tubing. **After draining fluid always make sure tubing is open and not restricted in any way.**
5. To stop fluid evacuation release the white pinch clamp. **If you are going to harvest more fat, do not reduce fluids below the 800 ml mark – RELEASE** white pinch clamp on lid and continue to harvest. NOTE: The white pinch clamp **MUST** remain open during harvesting.
6. **Final Fluid Evacuation:** Allow enough time (5 – 10 minutes) to get clear separation between fat and fluids. Turn on the vacuum, and close the white pinch clamp on the center cap of the lid. When the fat reaches the funnel you will observe an air break in the lower chamber. As soon as all the fluid is evacuated from the lower chamber, stop the evacuation by turning off the vacuum and opening the pinch clamp on the center cap of the

Fat Extraction

1. Make sure the vacuum is OFF and the lipo port is OPEN by removing the lipo tubing. Leave this port open. If this port is closed you will have difficulty extracting the fat because of the vacuum lock.
2. Connect Toomey syringe to fat evacuation tube, turn and push to attach. Do not over tighten. (Provided in sterile kit)
3. Open the red pinch clamp on the fat evacuation tube and draw out the small amount of fluid that remains in the tube. Close the pinch clamp and discard fluid.
4. Reattach the Toomey syringe, draw out the fat, close the pinch clamp, remove syringe. Continue process until desired amount of fat is collected. (Note: Remember to close the pinch clamp before removing the syringe.)
5. To harvest more tissue reload the Red Head with 800 cc's of sterile saline and repeat.