

REVOLVE ENVI™
Advanced Adipose System 600

Instructions For Use

DEVICE DESCRIPTION

REVOLVE ENVI™ 600 Advanced Adipose System (REVOLVE ENVI™ 600 System) is a single use, sterile, disposable canister intended for harvesting, filtering and transferring of autologous adipose tissue. The system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted in the same patient during the same surgical procedure, the harvested fat is only to be used without any additional manipulation.

INDICATIONS FOR USE

REVOLVE ENVI™ 600 System is used for aspiration, harvesting, filtering, and transferring of autologous adipose tissue for aesthetic body contouring. The system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

REVOLVE ENVI™ 600 System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired: plastic and reconstructive surgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

CONTRAINDICATIONS

Contraindications to autologous fat transfer include the presence of any disease processes that adversely affect wound healing, and poor overall health status of the individual.

WARNINGS

1. REVOLVE ENVI™ 600 System must be used within a single surgical procedure. Reuse of REVOLVE ENVI™ 600 System in the same patient in a subsequent surgical procedure, or for more than one patient, may result in infection and/or transmission of communicable diseases.
2. Do not use the product if sterile packaging is damaged.
3. This device will not, in and of itself, produce significant weight reduction.
4. 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.
5. 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.

PRECAUTIONS

1. This device is designed to process localized deposits of excess fat harvested through small incisions and subsequently transfer the tissue back to the patient.
2. 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 and tissue transfer.
3. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
4. Results of this procedure may or may not be permanent.
5. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.
6. Inverting the device may cause the device to malfunction.

ADVERSE EFFECTS

Some common adverse effects associated with use of the REVOLVE ENVI™ 600 System and/or autologous fat transfer procedures are asymmetry, over- and/or under-correction of the treatment site, tissue lumps, bleeding, scarring, fat necrosis, cyst formation, chronic foreign body response, allergic reaction, and infection and inflammation of various levels. If an unanticipated event occurs, alteration of surgical plan may be necessary at the surgeon's discretion.

USER PROVIDED COMPONENTS

Ensure the following user-provided components are available for use with the REVOLVE ENVI™ 600 System.

Liposuction Tubing and Cannula



Lactated Ringer's (LR) Solution



Waste Canister(s)



Catheter Tip Syringe



Toomey Syringe



Luer Lock Syringe



REVOLVE ENVI™ 600 SYSTEM COMPONENTS

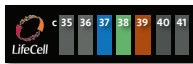
Vacuum Tubing Set



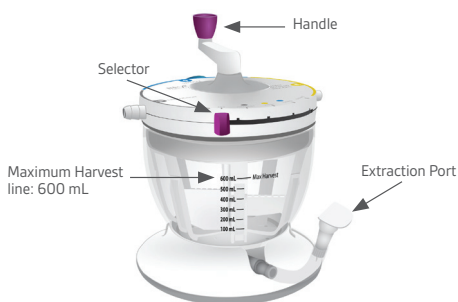
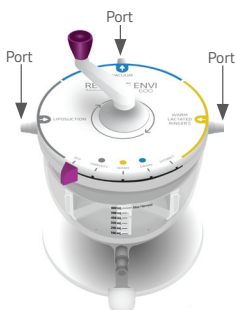
Lactated Ringer's (LR) Tubing Set



Temperature Strip



Syringe Adapter



PREPARATION AND DEVICE SET-UP

1. Verify the expiration date prior to using the device.
2. Utilize aseptic technique when unpacking the device and components.
3. Place the device on a flat, stable surface.
4. The Lactated Ringer's Solution should be warmed to a target temperature of 37-39°C (98.6-102.2°F) when ready to wash. See "Guidelines for Tissue Temperature Management".
5. Inspect the device and ensure that the Extraction Port Cap is closed.
6. Connect user provided Liposuction Tubing to LIPOSUCTION port (Fig. 1).
7. Connect the VACUUM port to waste canister using Vacuum tubing with blue connector (Fig. 1).
8. Connect Lactated Ringer's tubing with yellow connector to WARM LACTATED RINGER'S port (Fig. 1). The bag spike end of the tubing can remain in the sterile field until ready for Wash step.



Figure 1

HARVEST

1. Press down and move the Selector on the device to the HARVEST position (Fig. 2).
2. Apply sufficient vacuum for harvesting per standard liposuction practice.
3. Suction the adipose tissue into the REVOLVE ENVI™ 600 System using an appropriate user-provided liposuction cannula. Refer to volume markings on the device for minimum and maximum harvest volume (Fig. 3).

Note: Underfilling or overfilling may cause the device to malfunction.

Note: Prolonged occlusion of the liposuction tubing may cause bubbling of the lipospirate.

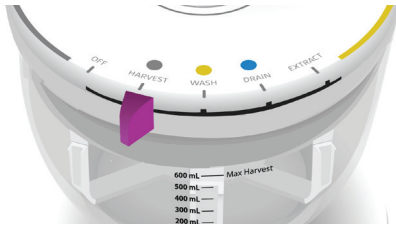


Figure 2

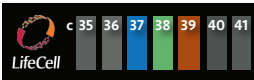


Figure 3

WASH

1. Wash solution must be warmed before being introduced into the device. Apply Temperature Strip to bag to confirm Lactated Ringer's Solution has been warmed to the target temperature.

Temperature Strip



Temperature Strips provide a visual indication of the Lactated Ringer's Solution temperature after it has been warmed to between 37-39°C (98.6-102.2°F). Remove liner from self-adhesive backing and ensure that the application surface of the Lactated Ringer's Solution is clean and dry before applying.

Do not apply the Temperature Strip before warming the solution.

The temperature will only display if the Lactated Ringer's Solution is between 35-41°C.

2. Confirm that the pinch clamp on the Lactated Ringer's tubing is closed. Uncap bag spike and connect warm Lactated Ringer's Solution bag to LR tubing.
3. Prior to washing, elevate warm Lactated Ringer's Solution bag relative to the device to achieve optimum wash fill rate.
4. Press down and move the Selector on the device to the WASH position (Fig. 4).
5. Add warm Lactated Ringer's Solution to the device by opening and regulating the flow with the pinch clamp (Fig. 5). Continue adding warm Lactated Ringer's Solution and rotating the handle clockwise until the amount of warm LR Solution delivered approximately equals the amount of harvested fat (Fig. 6).

Note: The device has built in LR overflow prevention.

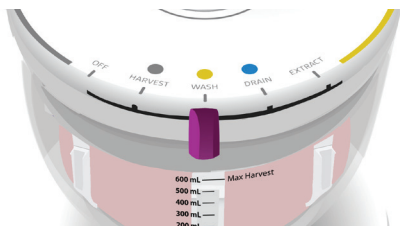


Figure 4



Figure 5



Figure 6

DRAIN

1. Press down and move the Selector on the device to the DRAIN position (Fig. 7) to drain the waste fluid from the canister (Fig. 8).

Note: Ensure suction is on.

2. Wash and Drain steps should be performed at least three times until the desired color and consistency of the graft have been achieved.
3. After the final wash, maintain suction for at least 90 seconds to remove waste fluids from the canister or until the desired consistency of the graft has been achieved.

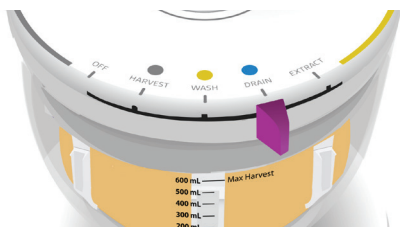


Figure 7



Figure 8

EXTRACTION

1. Press down and move the Selector on the device to the EXTRACT position (Fig. 9).
2. Elevate the Extraction Port. Open the Extraction Port Cap and securely insert the tip of a Catheter Tip/Toomey syringe (Fig. 10).
3. Extract the adipose tissue with the syringe. Repeat with additional syringes as needed. If a syringe becomes clogged during extraction, push plunger toward canister to release clog and then continue to extract.
4. Transfer adipose tissue to Luer Lock syringes via included Syringe Adapter. Do not overtighten Luer connections.

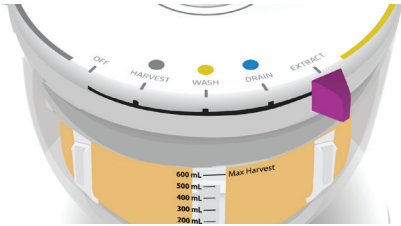


Figure 9



Figure 10

GUIDELINES FOR TISSUE TEMPERATURE MANAGEMENT

1. Use only LR pre-warmed to temperature range of 37-39°C (98.6-102.2°F). Use of room temperature LR or allowing tissue to cool in the device may cause the adipose to thicken and congeal and may clog the mesh filter.
2. Utilizing solutions at temperatures below or above 37-39°C may lead to sub-optimal procedure outcomes.

GUIDELINES FOR TISSUE HARVEST

1. Harvest at least 100 mL of adipose tissue into the device.
2. The maximum harvest volume is 600 mL of adipose tissue; do not overfill the mesh basket or the device may malfunction.

GUIDELINES FOR WASHING, FILTERING, AND CONCENTRATING

1. Do not invert the device at any time as this may cause it to malfunction.
2. At least 2L of Lactated Ringer's Solution are needed to process the maximum amount of adipose tissue (600 mL).
3. Ensure adequate Waste Canister(s) capacity for anticipated volumes of harvesting and washing prior to procedure.

GUIDELINES FOR TISSUE EXTRACTION

1. Catheter Tip, Toomey and Luer Lock syringes are commercially available.
2. Immediately extract the washed adipose into Toomey/Catheter Tip syringes after washing is complete. If the graft is difficult to extract due to the viscosity, select WASH, add a small amount of warm LR to the canister and rotate the handle to gently swirl the contents of the basket.
3. Rotate the handle one-quarter turn clockwise to help move basket contents toward the Extraction Port.
4. Close the Extraction Port Cap between syringe exchanges.

SYMBOLS WITH DEFINITIONS



CONTENTS



STERILIZED
USING
IRRADIATION



DO NOT USE IF
PACKAGE IS DAMAGED



ATTENTION,
SEE
INSTRUCTIONS
FOR USE



MANUFACTURED
BY



FOR SINGLE USE



USE BY DATE



DO NOT
RESTERILIZE

Rx ONLY

CAUTION: FEDERAL
(USA) LAW RESTRICTS
THIS DEVICE TO SALE
BY OR ON THE ORDER
OF A PHYSICIAN



CATALOG
NUMBER



LOT NUMBER



NON-PYROGENIC

The expiration date provided on product labels is in the following format: 4 digit year, 2 digit month, and 2 digit day (YYYY-MM-DD).

This product, including its packaging and components, is not made with natural rubber latex.

For product complaints and potential adverse events, please contact your local Sales Representative, local distributor or Customer Support.



Manufactured by
LifeCell Corporation
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