

USER MANUAL: REVOLVE™ System

Guidelines for Tissue Temperature Management:

1. Use ONLY pre-warmed solutions for washing/filtering, warmed to temperature range of 37°C -39°C (98.6-102.2°F), per IFU. Cooler fluids cause the adipose to thicken and congeal. If room temperature fluids are used to wash, or the adipose is allowed to cool for more than a few minutes, the congealed adipose may clog the mesh filter. Utilizing solutions at temperatures below or above 37-39°C may lead to sub-optimal procedure outcomes.
2. Solutions can be pre-warmed in a fluid warmer or a warming chamber.
Alternately, a one liter bag can be pre-warmed in a microwave –
 - approximately 90 seconds using an 800 watt microwave;
 - approximately 72 seconds using a 1000 watt microwave;
 - approximately 60 seconds using a 1200 watt microwave;
 - approximately 48 seconds using a 1500 watt microwave.
 - Surgeons should confirm their own institutions' policies on use of microwaving prior to proceeding with these guidelines.
 - They should also assure that any microwaved Lactated Ringer's solution is in the 37°C -39°C (98.6-102.2°F) range prior to inserting it in REVOLVE™ System.
 - Once warmed, keep the solutions in a warmer to maintain 37°C -39°C (98.6-102.2°F) range until filling canister. Ensure appropriate temperature prior to use.

3. Begin the washing phase IMMEDIATELY after completion of the harvest phase. Do not let the tissue cool in the canister.

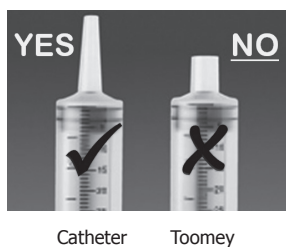
Guidelines for Tissue Harvest:

1. Harvest at least 100 ml of adipose within the mesh filter. The maximum harvest is 350 ml of adipose within the mesh; do not overfill the canister, or the mesh filter may clog.
2. Harvest 20% - 30% more adipose than the desired or targeted amount. The washing phase reduces the volume of the adipose as harvested by washing out oils, interstitial fluids, trapped fluid pockets, and captures and retains collagen and stringy tissue.

Guidelines for Tissue Transfer:

1. Immediately extract the washed adipose into catheter tip syringes after washing is complete. If fat is thick or difficult to extract using catheter tip syringes, add a small amount of warm fluid to the tissue, stir, and then extract.
2. Use catheter tip syringes for tissue transfer from the device; Toomey syringes will not work.

Catheter tip syringes are legally, commercially available from all major syringe manufacturers. Common sizes are 30/35 ml, 50/60 ml, and 100/120 ml.



Device Description: REVOLVE™ 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, the harvested fat is only to be used without any additional manipulation.

Indications for Use: REVOLVE™ 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™ 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™ System must be used within the same surgical procedure. Reuse of REVOLVE™ 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 remove localized deposits of excess fat through small incision 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. Filling the device with adipose tissue over the maximum fill volume line can lead to occlusion of the mesh resulting in mesh tear.

Adverse Effects:

1. Some common adverse effects associated with autologous fat transfer are asymmetry, over- and/or under-correction of the treatment site, tissue lumps, bleeding, and scarring.
2. Potential adverse effects associated with REVOLVE™ System include fat necrosis, cyst formation, infection, chronic foreign body response, allergic reaction and inflammation.

The expiration date provided on product labels are 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.

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