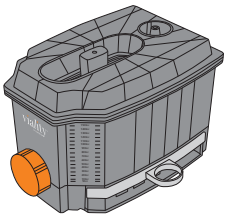


lipoaspirate wash system

INSTRUCTIONS FOR USE

viability™
by sientra.

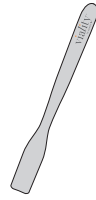
contents



Viality™ Lipoaspirate Wash System



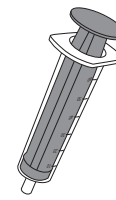
2 Packets of AuraClens™ Concentrating Wash



Mixing Spatula



PET Storage Bottle 1000 mL



Covidien™ Monoject™ 60 mL Syringe Toomey Type

COMPONENTS NOT PROVIDED:
Liposuction Machine,
Liposuction Cannula,
1L Sterile Saline,
Waste Canister,
High Vacuum Tubing



prep

MIX AURACLENS SOLUTION

Add the contents of one AuraClens™ packet and 1 liter of sterile, room-temperature, 0.9% normal saline to 1L sterile bottle to prepare the AuraClens™ solution. Mix until fully dissolved.



1L Sterile Saline



step 1

HARVEST FAT

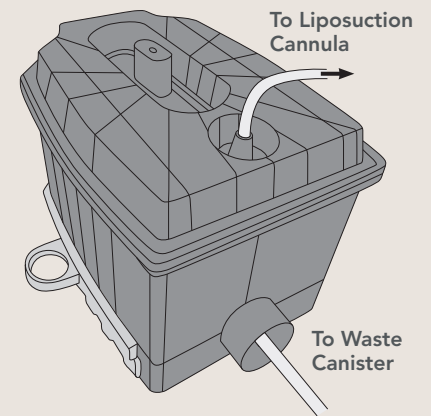
Connect liposuction machine to waste canister. Connect waste canister to vacuum port. Connect liposuction cannula to harvest port on top of the device and harvest up to 1,050 mL of lipoaspirate.

NOTE: do not remove or tamper with drawer until harvesting and cleaning of fat are completed (Step 3). Ensure that lid, top access port and front cap are all fit snugly to ensure vacuum seal.

WARNING: This device will not, in and of itself, produce significant weight reduction.

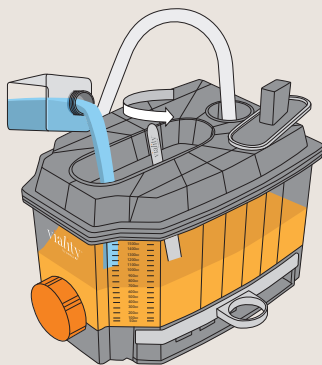
PRECAUTION: This device is designed to contour the body by removing localized deposits of excess fat through small incisions.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.



step 2

WASH FAT



2A Turn off vacuum. Open top access cap and slowly pour AuraClens™ solution into the collection chamber in a 1:1 ratio with harvested fat, while gently mixing with spatula.

2 MIN

2B Let sit for 2 minutes.

OPTIONAL: Continue gentle mixing with spatula during this step.

30 SEC

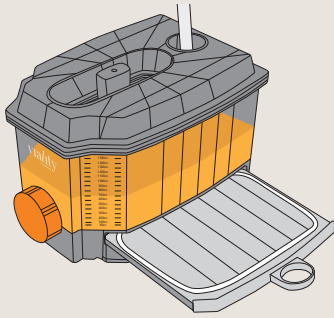
2C Turn on vacuum to remove fluid. Maintain vacuum for 30 seconds to maximize amount of fluid removed.

NOTE: Turn vacuum off when this step is completed.

3

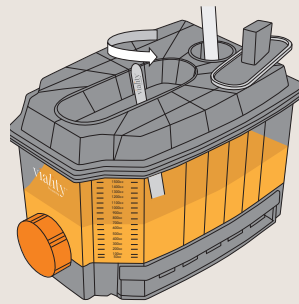
step 3

CONCENTRATE FAT & LOAD SYRINGES



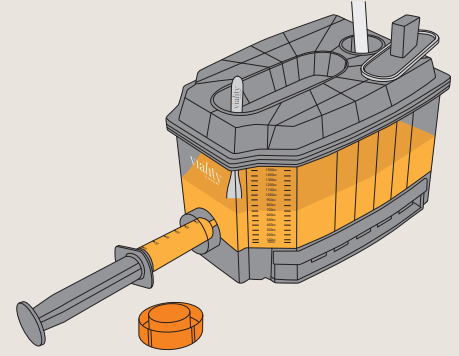
3A Remove the drawer by pulling the handle straight out to allow foam layer to absorb remaining fluid.

NOTE: a gentle side-to-side motion may help to ease removal of the drawer.



3B Gently mix adipose tissue with spatula for 3 minutes to maximize the amount of fluid removed.

3 MIN



3C Remove orange front cap to insert 60cc toomey tip syringe into collection port and load syringe.

NOTE: Spatula can be used to assist in loading of syringes.

Indications for Use

The Viality™ Lipoaspirate Wash System is to be used to filter and wash aspirated, harvested 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 to be used without any additional manipulation.

The Viality™ system may be used in processing harvested adipose tissue obtained in surgical specialties, including plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery. The Viality™ system is not intended to process autologous adipose tissue other than for aesthetic body contouring uses.

Safety Information

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. The device is also contraindicated for intravenous applications.

WARNINGS

The Viality™ Lipoaspirate Wash System is a sterile, disposable unit for single patient use. The Viality™ system must be used during the same surgical procedure in which autologous adipose tissue is collected and reinjected into the same patient. This device should not be reused in the same patient in a subsequent surgical procedure, or for more than one patient, as such use may result in infection and/or transmission of communicable diseases. Do not use the device if sterile packaging is damaged.

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, or if pregnant. 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.

This device will not, in and of itself, produce significant weight reduction.

PRECAUTIONS

Use of the Viality™ Lipoaspirate Wash System is limited to those physicians who, by means of formal professional training, have attained proficiency in suction lipoplasty and tissue transfer. 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.

This device is designed to contour the body by removing localized deposits of excess fat through small incisions.

ADVERSE EFFECTS

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. Potential adverse effects of using the Viality™ Lipoaspirate Wash System include fat necrosis, cyst formation, infection, chronic foreign body response, allergic reaction, and inflammation.

Symbology



= Manufacturer (name and address)



= Use-by-date



= Batch Code



= Catalog Number



= Sterilized using irradiation



= Do not resterilize



= Do not use if package is damaged/if the product sterile barrier system or its packaging is compromised and consult instructions for use



= Double barrier system



= Do not reuse



= Consult instructions for use or consult electronic instructions for use



= Caution



= Non-pyrogenic



= Medical Device



= Unique device identifier

Rx Only

= Prescription only

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Phone: 805-562-3500