

Notice: SINGLE USE DEVICE ONLY

IMPORTANT – US Federal Law restricts the sale and use of this device by or on the order of a physician.

Device Description:

The intelliFat™ Disposable Adipose Tissue Harvesting and Transfer and intelliFat™ SVT Kits are sterile single-use, disposable suction lipoplasty systems that are intended for closed-loop processing of lipoaspirate tissue in various medical procedures involving harvesting and transferring autologous adipose tissue. These kits contain stand-alone components that are assembled by the physician user. Primary components include: cannulae, filters, resizer, luer adapters, and syringe caps. The intelliFat™ Kits accommodate minimal handling of adipose tissue. These devices may be used in combination with FDA-cleared device such as syringes.

CAUTION: The adipose tissue harvested from intelliFat™ SVT are not to be used in a non-homologous manner as instructed by the FDA in 21 CFR 1271.

Indications for Use:

The intelliFat™ Disposable Adipose Tissue Harvesting and Transfer or SVT Kit is a medical device intended for the closed-loop processing of lipoaspirate tissue in medical procedures involving the harvesting, concentrating, and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system. The device is intended for use in the following surgical specialties when the transfer of harvested adipose tissue is desired: orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and reconstructive surgery when aesthetic body contouring is desired. Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be transferred, the harvested fat is only to be used without any additional manipulation.

CAUTION: Collection, processing and transfer of the patient's tissue should occur under aseptic/sterile conditions. The disposable intelliFat™ SVT syringe and kit must be properly discarded following standard biohazard guidelines after each use. Sealed sterile packages containing the intelliFat™ SVT kit must be inspected before opening. If seal is broken, contents may not be sterile.

CAUTION: The adipose tissue should be used within 4 hours of collection.

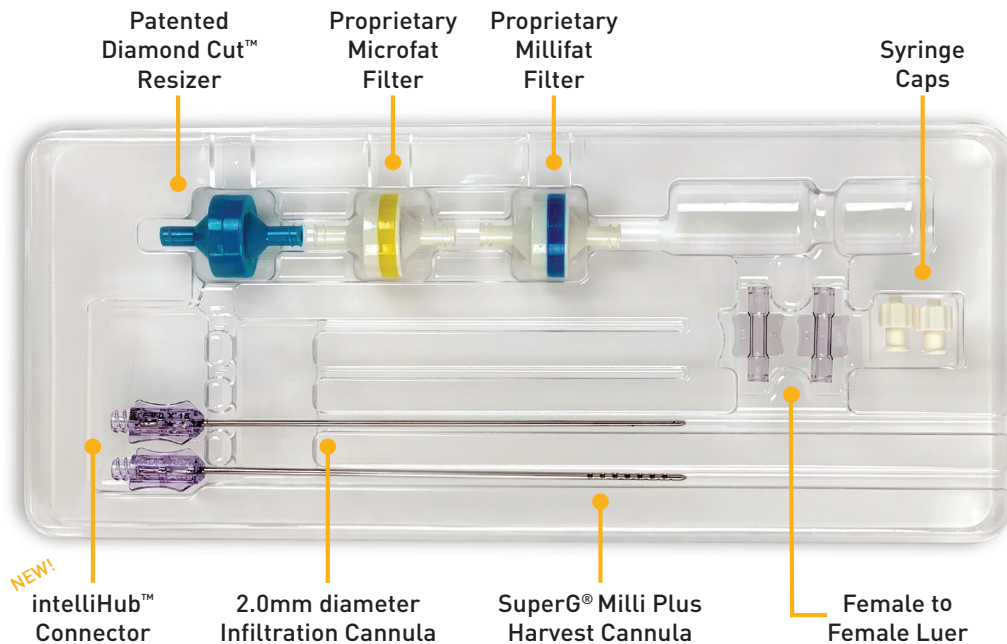
Warnings

- a. This device will not, in and of itself, produce significant weight reduction.
- b. 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.
- c. 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

- d. This device is designed to remove localized deposits of excess fat through small incisions and subsequently transfer the tissue back to the patient.
- e. 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.
- f. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
- g. Results of this procedure may or may not be permanent.
- h. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

Components:



Instructions:

1. Tumescence Infiltration: Infiltrate a volume of tumescent solution equal to the volume of adipose tissue needed for the procedure using the **2.0mm diameter Infiltration Cannula**. For example, if 10cc of SVT is needed for the procedure, infiltrate 10cc of tumescent solution (20cc total will be aspirated, prior to processing).

2. Aspiration: Attach the **2.5 mm SuperG® Milli Plus Cannula** to the **intelliFat™ VacLok®** syringe (or an alternative vacuum source such as the **AcquiCell™** system). With the cannula fully inserted, pull back and lock the syringe at the 10mL mark by rotating the plunger into a locking position to apply a vacuum of approx. 0.4 ATM (12inHg). Harvest the adipose tissue, keeping the cannula parallel to the surface of the skin within the fascial plane. Periodically adjust the locking position as needed to maintain vacuum. Aspirate until the total desired volume has been collected.

3. Processing: Gravity decant the lipoaspirate for **10 minutes** in the 30cc VacLok® syringe used to collect the lipoaspirate. Attach the **Millifat filter** (blue-banded, white-colored filter) to the lipoaspirate-containing VacLok® syringe via the luer connector. Press on the syringe until resistance increase to a point where reasonable back-pressure is felt, to remove tumescent solution from the lipoaspirate.

4. Washing [Optional]: Add a volume of normal saline equivalent to the volume of adipose tissue remaining in the syringe to a sterile syringe of similar size (does not have to be VacLok®). Connect the syringes via a luer transfer connector. Thoroughly mix the contents of both syringes by alternatively pressing on the plungers of the syringes on each side. Allow the SVT to gravity decant and remove excess saline solution once more using the **Millifat filter** as described above.

5. Resizing: Transfer the adipose tissue to a **10cc syringe**. Attach the blue-colored **Diamond Cut™** resizer to the syringe via the luer connector and attach an empty 10cc sterile syringe to the other end. Pass the adipose tissue back-and-forth through the resizer 10-20 times until the tissue is homogenous. **[Optional]:** For a “dryer” SVT product, use the **Microfat filter** (yellow-banded, white-colored filter) to remove excess liquid from the resized SVT. The final product is now ready for injection back into the patient. It is recommended that the adipose tissue is transferred to a 1-3cc syringe, or a controlled injection device, to enable optimal control over the amount of adipose tissue injected.

For instructional video, visit intellifat.com/intellifat-SVT or contact us below for more information.