



STERILE EO

DO NOT
RE-USE

STERILIZED USING
ETHYLENE OXIDE

Lipo-Pro LP-120 - Adipose Transfer System

Sterile: Contents sterile unless package is opened, damaged or expired. Do Not Re-sterilize

Indications for Use:

The Lipo-Pro Adipose Transfer System is used in medical procedures involving the harvesting and transplanting of autologous tissue. The Lipo-Pro system is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The Lip-Pro Adipose Transfer System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired: Arthroscopic Surgery, Gastrointestinal Surgery, General surgery, Gynecological Surgery, Laparoscopic Surgery, Neurosurgery, Plastic and Reconstructive Surgery, Thoracic Surgery, and Urological Surgery.

CONTRAINDICATIONS

Use only for autologous adipose aspiration and transfer as determined by a licensed physician. The device is intended to be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of adipose aspiration and transfer. The procedure should be performed on patients that are suitable for such procedure only.

Warnings:

1. Federal law (USA) restricts this device to sale by, or on the order of a physician. The physician is solely responsible for the use of this device.
2. Adipose tissue prepared with this procedure pack is not intended for transfusion.
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 or lung disease, circulatory diseases, or obesity.
5. The volume of blood and endogenous body fluid loss may adversely affect intra- and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely fluid replacement is essential for patient safety.
6. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

CAUTION: This product is for single-use only. It has not been designed to be re-used/re-sterilized. Reprocessing may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use instruments can also cause cross-contamination leading to patient infection. These risks may potentially affect patient safety.

After use, this product may be a potential biohazard. Handle in a manner, which will prevent accidental puncture. Dispose of in accordance with applicable laws and regulations. Carefully place the used needle in a sharps biohazard container after the procedure is completed.

Note: *These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.*

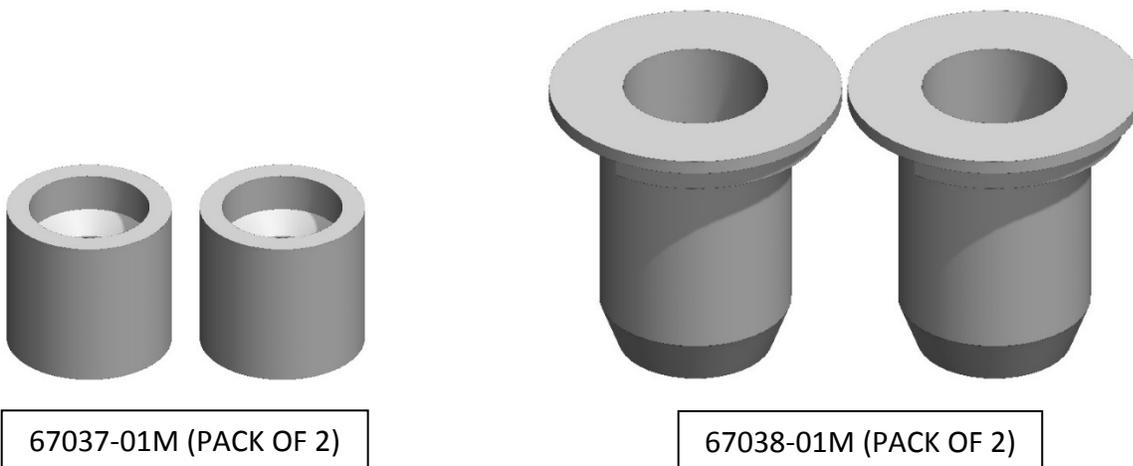
Precautions:

1. Refer to the Operator’s Manual for additional information concerning centrifuge operation and maintenance, warnings, and cautions.
2. Use of this device is limited to qualified physicians trained in suction lipoplasty.
3. Avoid bending, twisting and/or damaging the processing components of the system.
4. Inspect product prior to use; do not use if the package is damaged or opened.
5. Always follow aseptic and/or sterile technique where appropriate.
6. Aseptic technique, proper skin preparation, and continued protection of the donor site are essential.
7. Using Universal Precautions, dispose of biohazardous fluids and contaminated single-use disposables following hospital policy and procedures for biological waste.
8. After processing, keep the adipose process disposable vertical. Tilting may mix fluids, affecting process results.
9. Do not re-sterilize.
10. Disposable is single use only.
11. Re-use of disposable processing components may lead to infection or illness/injury/death.
12. Discard all unused components at the end of the procedure.
13. Results may or may not be permanent.
14. Results of this procedure will vary depending on patient age, surgical site, and experience of the surgeon.
15. Remnants of liquids and oils on the mating surfaces of syringes and cannulas can interfere with a good seal.

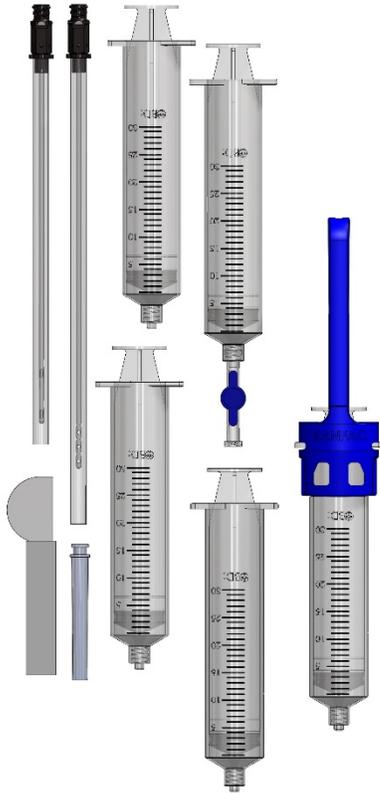
Centrifuge bucket adapters:

If using Eppendorf centrifuge, adapter kit part number 67037-01M, must be purchased separately.

If using Harvest centrifuge, adapter kits part number 67037-01M and 67038-01M, must be purchased separately.



1



Components Pouch 1:

- 1 each infiltrator cannula
- 1 each aspiration cannula
- 5 each 30 mL syringe
- 1 each fem/fem manifold
- 1 each syringe Vacuum Pressure Handle (VPH)
- 1 each scalpel

2



Components Pouch 2:

- 1 each 60cc syringe
- 2 each 30cc syringe
- 2 each Vacuum Pressure Handle (VPH)
- 4 each bottom centrifuge adapter
- 4 each female/female luer adapter
- 4 each non-vented syringe cap
- 4 each male/male luer adapter

Instructions for Use:

Preparation of the Donor Site

Precaution: The health care professional responsible for aspirating the adipose tissue should be trained in the practice of medicine and the inherent risks. Use a combination of sterile and aseptic technique; proper skin preparation and continued protection of the donor site are essential.

Note: Optimal lipo-aspiration technique has been shown to improve collection volumes of adipose tissue. The literature has shown that optimal lipo-aspiration technique includes a pre-tunneling step that helps minimize the volume of unwanted infranatant fluid collected upon adipose tissue harvesting. Please refer to the following publication for more detailed information on optimal lipo-aspiration technique:

Alexander, R., Use of Micro-cannula Closed Syringe System for Safe and Effective Lipo-aspiration and Autologous Fat Grafting, *The American Journal of Cosmetic Surgery*, 2013; 30: 1 – 12.

Note: The centrifuge bucket adapters included as part of the Lipo-Pro Accessory Kit is not shipped in sterile condition.

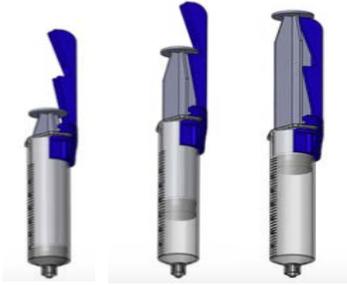
1. Using sterile technique, peel back the Tyvek outer pouch and transfer the tub into the sterile field containing pouch 1, pouch 2 and pouch 3 of the Lipo-Pro Procedure Pack.
2. Follow the institution's protocol for sterile and aseptic preparation and draping of the donor site.
3. Anesthetize the area of aspiration (25g needle NOT provided).

Collection of Adipose Tissue

Open Pouch 1 Containing Components for Aspirating Fat

1. Create skin puncture through the skin only using scalpel and / or 18 gauge needle provided.
2. Attach a 30 mL (or 60 mL) syringe to the multiport infiltrator cannula (or suitable cannula).
3. Fill the syringe with tumescent fluid.
4. Insert the infiltrator cannula through the skin puncture site, and solubilize the adipose tissue at the donor site.
5. Attach the VPH handle to the 30 mL syringe and then the syringe to the harvester cannula.
6. Insert the aspiration cannula through the same skin puncture site used for the infiltrator cannula

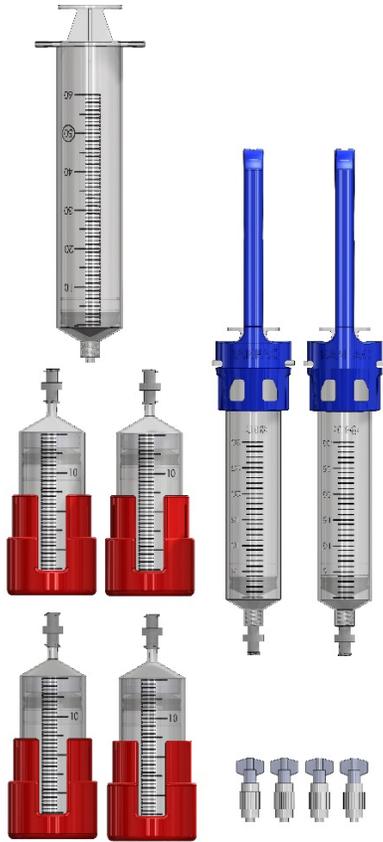
7. Aspirate the adipose tissue from the donor site by engaging the VPH with the aspirating syringe to maintain negative pressure. To engage the VPH pull back the plunger to the first or second locking position (shown below) to achieve the desired negative pressure.



8. Once the syringe is filled, carefully remove the aspiration cannula from the syringe and remove the VPH from the syringe.
9. Repeat steps 3-8 until approximately 30 mL of aspirated tissue is reached
10. Attach the aspiration syringe to one end of the female/female luer manifold and on the other end attach an empty 30 mL syringe.

Open the Pouch (Pouch 2) Containing Transfer Containers

11. Transfer back and forth the adipose sample between the two 30 mL syringes at least 10 times to ensure homogenization of the sample
12. Load equal amounts of aspirate into each of the two containers repeating until containers are full or the desired amount of aspirate has been obtained
13. Remove the non-vented syringe cap and secure it to the luer adapter



Concentration of Adipose Tissue:

1. Weigh each container that are placed 180 degrees opposite each other in the centrifuge to make sure they are within 2 grams of each other.
2. Place each of the equal weight centrifuge assemblies opposite each other (180 degrees) with the non vented luer face down into in the centrifuge adapter and bucket.
3. Close lid on centrifuge device. For a programmable centrifuge, (i.e. Eppendorf), set the time for 2 minutes and the RPM to 2,000; for Harvest, stop the centrifuge 2 minutes into the standard 14 minute cycle
4. Open the lid on the centrifuge.
5. Remove the Lipo-Pro Process Disposables from the centrifuge.
6. Using sterile technique, remove the non-vented luer and attach a 60 mL syringe to the upper container and remove the liquid infranatant until the yellow fat graft is flush with the bottom of the container.
7. Secure the non vented syringe cap onto the container
8. Place centrifuge assemblies opposite each other (180 degrees) with the non-vented luer cap facing up.
9. Close lid on centrifuge device. For a programmable centrifuge, (i.e. Eppendorf), set the time for 2 minutes and the RPM to 2,000; for Harvest, stop the centrifuge 2 minutes into the standard 14 minute cycle.

10. Remove the containers.
11. Using sterile technique and a 30 mL syringe, remove oil and any excess fat and the transfer the remaining contents to be used clinically into a 20 mL syringe.
12. A user within the sterile field attaches a Fem/Fem connector to a suitable treatment syringe and the 20 mL Lipo-pro syringe and the adipose tissue is transferred into the field
13. The adipose concentrate is now ready for use.
14. *Use dispensing cups for any excess fluid as desired*



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U.S. and Foreign Patents Pending