



**STERILE EO**

DO NOT  
RE-USE

STERILIZED USING  
ETHYLENE OXIDE

### **Lipo-Pro LP-30 - 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 Lipo-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.

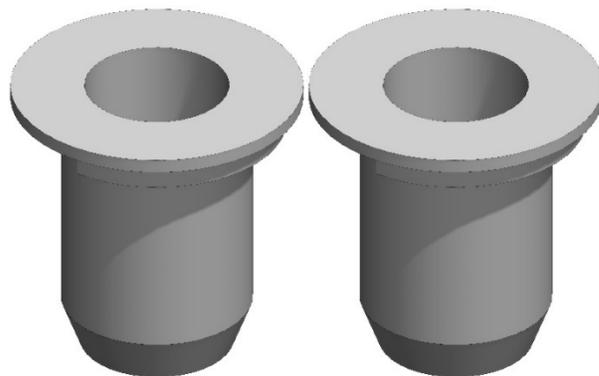
**Note:** *These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.*

**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.

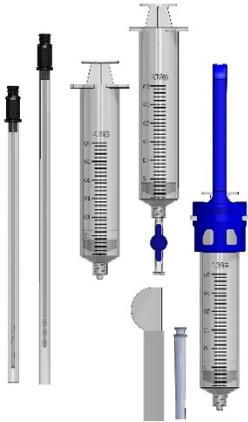
**Centrifuge bucket adapter:**

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



67038-01M (PACK OF 2)

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**Components Pouch 1:**

- 1 each infiltrator cannula
- 1 each aspiration cannula
- 3 each 30 mL syringe
- 1 each female/female luer manifold
- 1 each syringe Vacuum Pressure Handle (VPH)
- 1 each scalpel
- 1 each 18GA Needle

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**Components Pouch 2:**

- 2 each top transfer container
- 2 each vented cap
- 2 each bottom centrifuge adapter
- 2 each non-vented syringe cap
- 2 each female/female luer



### Components Pouch 3:

- 2 each bottom transfer container
- 1 each 30 mL syringe
- 1 each syringe Vacuum Pressure Handle (VPH)
- 1 each female/female luer

### 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.**

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 the Pouch (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 to the 30 mL syringe and then the syringe to the aspiration 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.



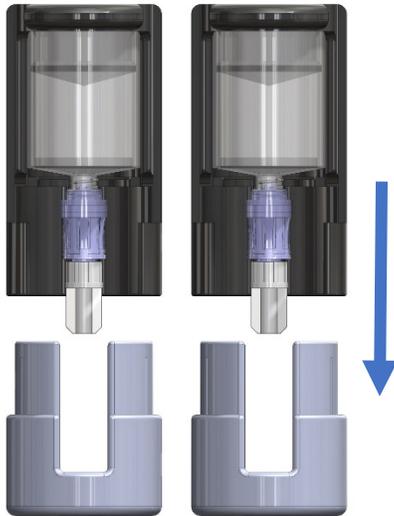
8. Once the syringe is filled, carefully remove the aspiration cannula from the syringe and remove the VPH from the syringe.
9. Repeat steps 3-8 until approximately 30 mL of aspirated tissue is reached.
10. Attach the aspiration syringe to one end of the female/female luer manifold and on the other end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

#### **Open the Pouch (Pouch 2) Containing Top and Bottom Transfer Containers**

11. Transfer the adipose sample back and forth between the two 30 mL syringes at least 10 times to ensure homogenization of the sample.
12. Remove the vented cap from the swabable luer from each of the two top containers.
13. Load equal amounts of aspirate (up to 15 mL per container) into each of the two top containers.
14. Remove the non-vented syringe cap and secure it to the swabable luer adapter.



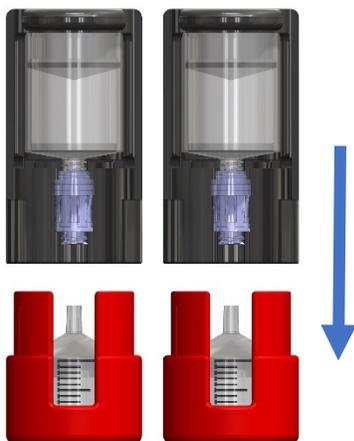
15. Assemble the top transfer container into the bottom centrifuge adapter by pushing the two together until a positive stop is felt.



16. Place the assembled top container and bottom adapter and “pouch 3” into the tub and pass off of the sterile field. *All components from pouch 1 should stay on the field. Use dispensing cups for any excess fluid as desired*

#### **Concentration of Adipose Tissue:**

1. Weigh both the assembled top container and bottom adapter to make sure they are within 2 grams of each other.
2. Place both centrifuge assemblies opposite each other (180 degrees) with the top container on top and bottom adapter on the bottom into in the centrifuge 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 pouch number 3 keeping the components in the blue tub
5. Open the lid on the centrifuge.
6. Remove the Lipo-Pro Process Disposables from the centrifuge.



7. Using sterile technique, remove the non-vented luer and attach a 30 mL syringe to the upper container and remove the liquid infranatant until the yellow fat graft is flush with the bottom of the container.
8. Assemble the two upper containers into the two empty lower containers from pouch 3 by pushing the two together until a positive stop is felt.
9. Place both centrifuge assemblies opposite each other (180 degrees) with the upper container on top and lower container on the bottom into in the centrifuge bucket. Place the two bottom assemblies with luer caps securely attached opposite each other (180 degrees) if a four-place bucket rotor system is available. Otherwise, the two different assemblies will need to be centrifuged sequentially.
10. 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.
11. Remove the two top and bottom centrifuge assemblies; Inspect the contents of the top and bottom containers and transfer any desired component using the plunger from the bottom container to the top container and then pull apart the top and bottom containers
12. Using sterile technique, transfer the remaining contents of the bottom container to a 5 mL syringe. If the graft is too viscous to transfer, use the 30 mL syringe and vacuum assist handle to create greater suction to transfer the graft.
13. A user within the sterile field attaches a Female/Female luer connector to a suitable treatment syringe and the syringe containing the adipose tissue is transferred into the field.
14. The adipose concentrate is now ready for use.
15. *Use dispensing cups for any excess fluid as desired*

**Not Made With Natural Rubber Latex**

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(US ONLY)



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