



Lipo-Pro EXP - 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.

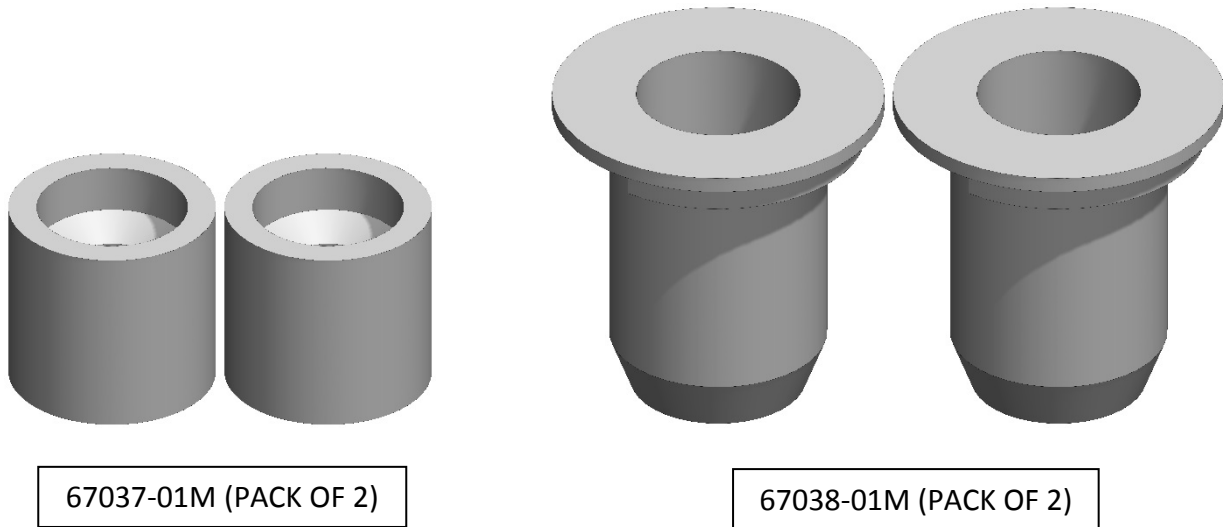
CAUTION: This product is for single-use only. It has not been designed to be re-used/re-sterilized. Reprocessing may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use instruments can also cause 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.*

Centrifuge bucket adapters:

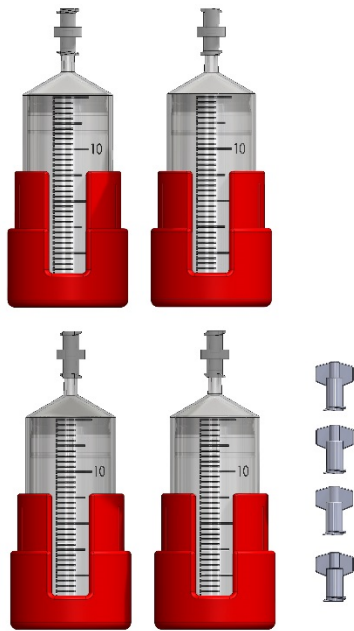
If using Eppendorf centrifuge, adapter kit part number 67037-01M, must be purchased separately.

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



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.



Components:

- 4 each centrifuge containers
- 4 each non-vented syringe cap
- 4 each female / female 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.

1. Using sterile technique, peel back the Tyvek outer pouch containing the Lipo-Pro EXP Procedure Pack.
2. Load equal amounts of adipose aspirate into each of the four centrifuge containers repeating until the containers are full or the desired amount of aspirate has been loaded in equal aliquots to each container
3. Remove the female/female luer adapter from the container and install the non-vented luer cap onto the container.

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 up into in the centrifuge adapter and bucket.

3. Close the lid on centrifuge device. For a programmable centrifuge, (i.e. Eppendorf), set the time for 8 minutes and the RPM to 3,200; for Harvest, stop the centrifuge 10 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 an extraction syringe to the container using a female/female luer adapter and transfer the separated fat as desired. Note: the least dense fraction of the fat graft will be at the top of the syringe and the densest fraction of the fat graft will be at the bottom of the syringe. To select a graft of a different density, change the extraction syringe during the extraction process.
7. Secure the non-vented syringe cap onto the container.
8. Using the syringe containing the fraction of fat graft desired transfer the fat graft; a user within the sterile field attaches a female/female luer adapter to a suitable treatment syringe and the syringe containing the adipose tissue is transferred into the field
9. The adipose concentrate is now ready for use.
10. *Use dispensing cups for any excess fluid as desired*



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U.S. and Foreign Patents Pending