Ranfac®

LIPO-PRO™

High Density Fat Grafting

LP-30 SYSTEM OVERVIEW

Abbreviated Instructions. For Complete Instructions Refer to IFU and/or Your Lipo-Pro™ Representative.

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LIPO-PRO™
Indication 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:

Neurosurgery, gastrointestinal surgery, urological surgery, plastic & reconstructive surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, arthroscopic surgery

510(K) Number: K150156

The LIPO-PRO™ Fat Transfer System was designed by Endocellutions, LLC and developed in collaboration with Ranfac Corp.

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LIPO-PRO™

The proprietary LIPO-PRO™ adipose processing system, allows a clinician to create a minimally manipulated graft consisting of clean, **High-Density** fat that can be transferred immediately to a small gauge needle for application…

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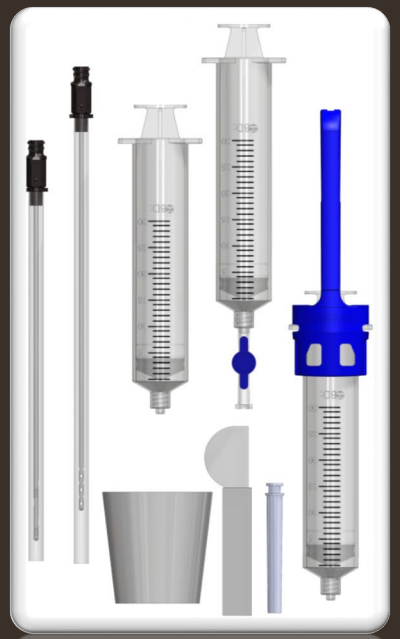
LIPO-PRO™ LP-30
Sterile Tray Components

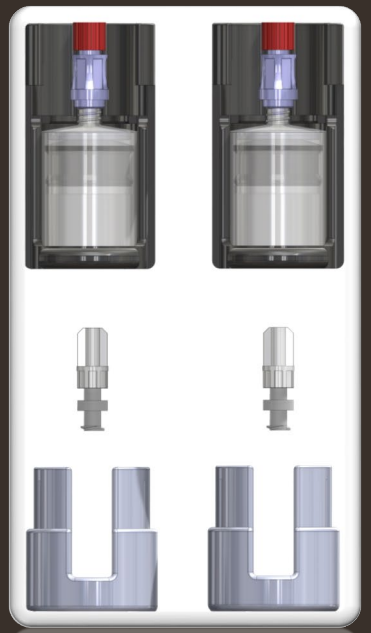
The Lipo-Pro™ Procedure Tray Includes 3 Individually Packaged, Sterile Pouches

- Pouch 1: Tools for Tissue Access, Injection, and Aspiration
- Pouch 2: First Spin Components
- Pouch 3: Second Spin & Transfer

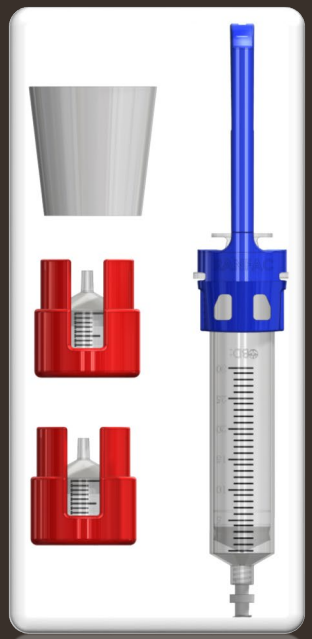
Pouch 1



Pouch 2



Pouch 3



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Pouch 1: Lipoaspirate preparation

Access

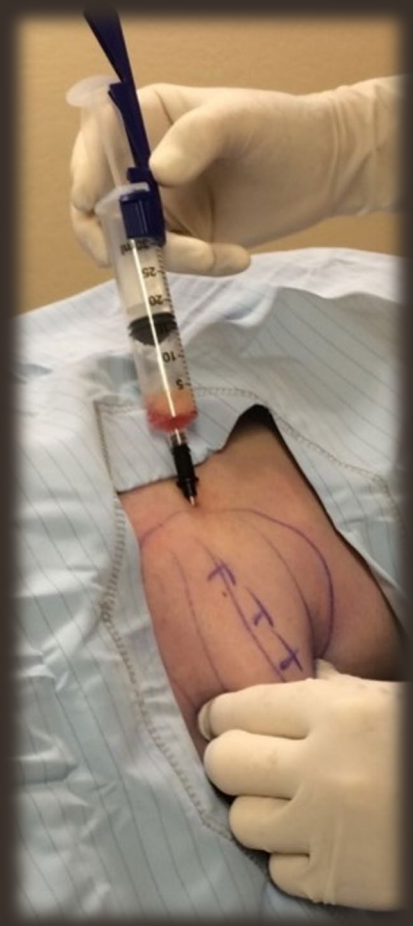
- Create skin puncture through the skin.

Inject

- Attach a 10 mL (or 60 mL) syringe to the multiport infiltrator cannula (or suitable cannula).
- Fill the syringe with tumescent fluid and solubilize the adipose tissue at donor site.

Aspirate

- Aspirate the adipose tissue from the donor site by engaging the vacuum pressure handle with the aspirating syringe to maintain negative pressure. Aspirate 30 mL of Adipose



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Pouch 1: Homogenization

Prior to filling the centrifuge syringes, ensure proper homogenization by connecting the syringe filled with lipoaspirate to supplied 30cc syringe attached with 1-way stopcock and pushing back and forth at least 10 times.

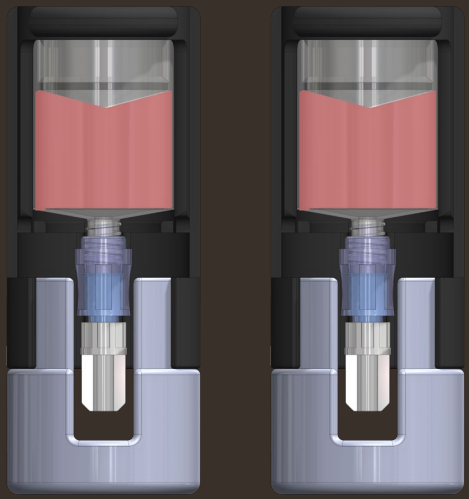
Pouch 2: Centrifugation

Filling Centrifuge Containers

- Remove red vented cap from the swabable luer from each of the top two containers.
- Load equal amounts of aspirate into each of the top two containers.
- Remove fem/fem luer adaptor from non-vented male luer cap. Attach winged luer cap to bottom of syringes.
- Assemble the upper container with empty, grey bottom clip by pushing the two together until a positive stop is felt.
- Pass off sterile field with Pouch 3 Components
  (All components from Pouch 1 should stay on the field)

Loading 1 of 2 Top Containers

Loaded 1st Spin Containers Attached to Bottom Clip



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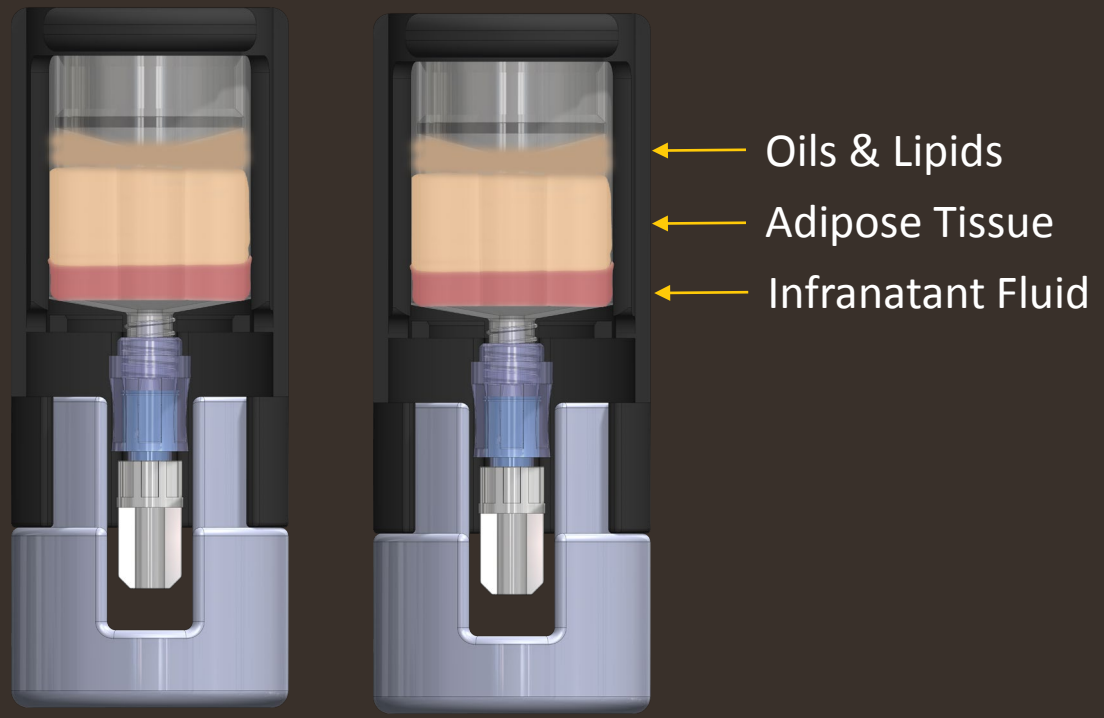
1st Spin* – 2 Minutes, 2,500 RPM

Place both centrifuge assemblies opposite each other with the upper container on top and lower container on the bottom into in the centrifuge bucket.

Close lid on centrifuge device. For a programmable centrifuge, (i.e. Ependorf), set the time for 2 minutes and the RPM to 2,500.

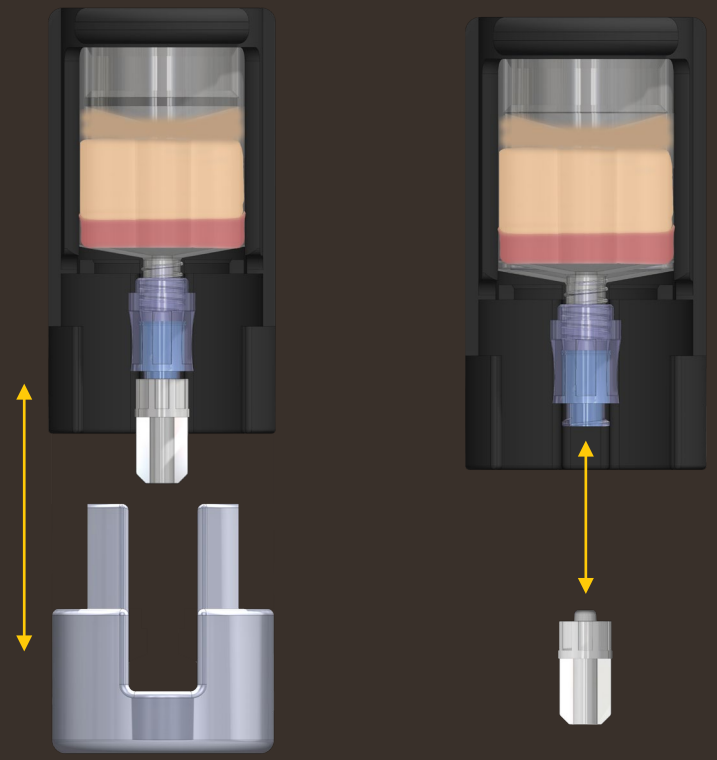
Containers Post Centrifuge



*Actual processing time may differ depending on centrifuge.

2nd Spin Prep – Removing Infranatant

Detach Grey Bottom Clip, and carefully remove Non-Vented Male Luer Cap, leaving the Swabable Connector in place.



Connect supplied 30 cc luer lock syringe to container and remove infranatant.

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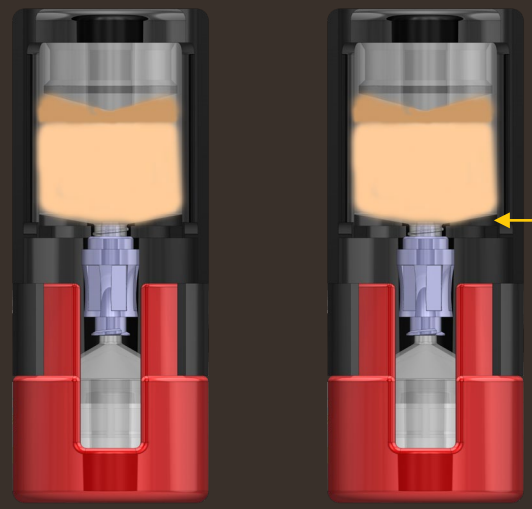
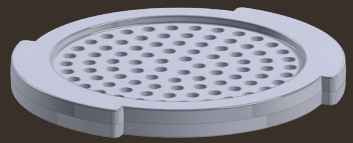
2nd Spin Prep

Assemble the two upper containers into the two empty, red lower containers from pouch 3 by pushing the two together until a positive stop is felt.



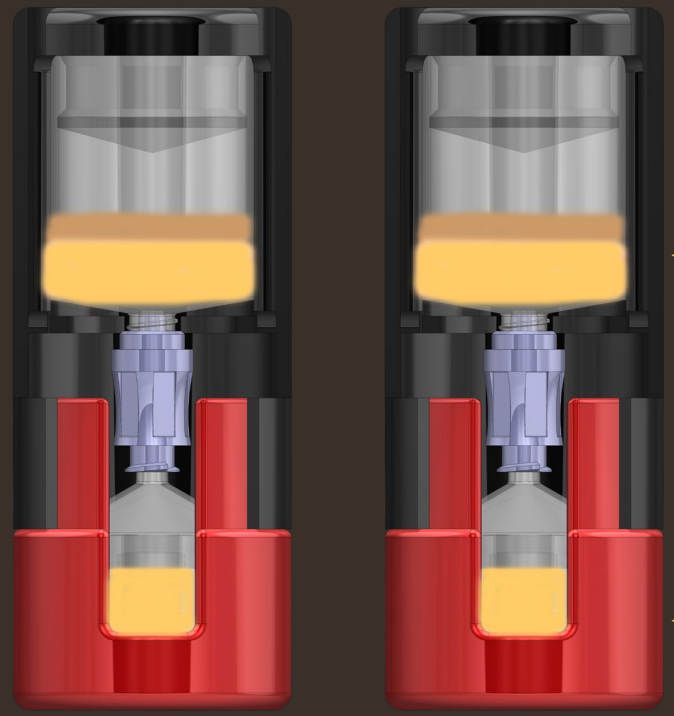


Internal screen will filter fat during centrifugation; ensuring unwanted chunks remain in the upper syringe to be discarded and micronizes the desirable high density fat.

This eliminates the need to micronize fat after processing.

2nd Spin – 3 Minutes, 2,500 RPM

Centrifugal Forces Separate High and Low Density Fat



Oil, Lipids & Low Density Fat

Filtered High Density Fat

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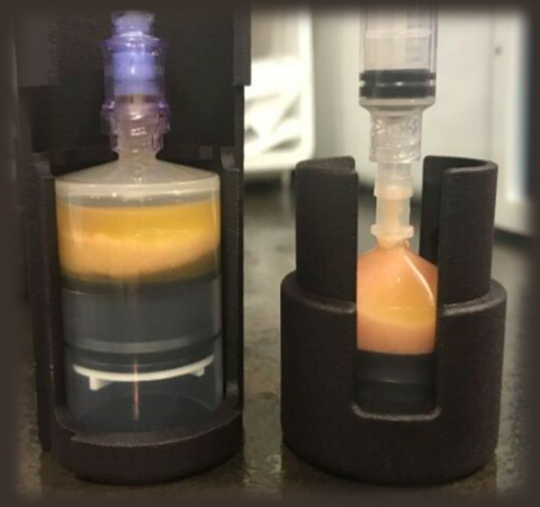
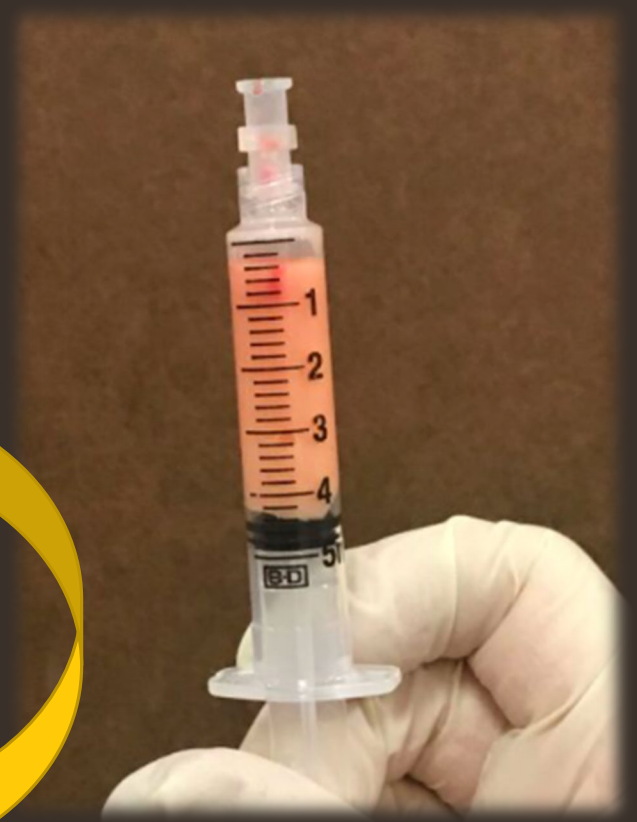
Obtaining the LIPO-PRO™ Fat Graft

Separate by pulling containers apart and transfer high density fat to syringe.



Waste / Oil / Fat that did not penetrate filter

High Density, clean fat!



(Fat Graft prior to transfer to Injection syringe)

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LIPO-PRO™ Injection

LIPO-PRO™ High Density Fat

Graft injected through a **22 gauge** needle without further filtration or emulsification after centrifugation.

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LIPO-PRO™

In Conclusion:

The LIPO-PRO™ fat transfer system by Ranfac allows clinicians to obtain a **high density** fat graft through a proprietary and gentle process with minimal manipulation.

"Greater percentages of highest density fractions of lipoaspirate persist over time compared with lowest density fractions. A vasculogenic mechanism appears to contribute significantly, as highest density fractions contain more progenitor cells and increased concentrations of several vasculogenic mediators than lowest density fractions."

Allen RJ Jr, "Grading lipoaspirate: is there an optimal density for fat grafting?" Plast Reconstr Surg. 2013 Jan;131(1):38-45.