

EmCyte Corporation
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PL-42-70
REV 1

PROGENIKINE
ADIPOSE TRANSFER SYSTEM
PN: PK25
Instruction for Use

INDICATION FOR USE:

The Progenikine Adipose Transfer System is used in medical procedures involving the harvesting and transplanting of autologous tissue. The Progenikine Adipose Transfer System is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The Progenikine Adipose Concentrating 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

WARNINGS:

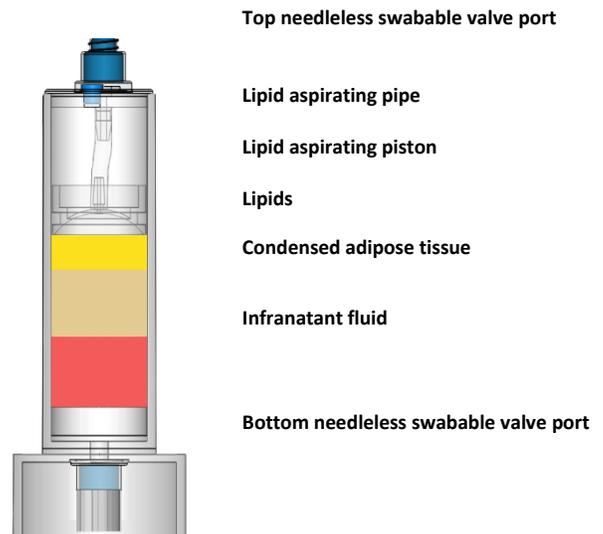
1. Federal law (USA) restricts this device to sale by, or on the order of a physician. The physician is solely responsible for the use of this device.
2. Adipose tissue prepared with this procedure pack is not intended for transfusion.
3. This device will not, in and of itself, produce significant weight 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 loss and endogenous body and 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.

PRECAUTIONS:

1. Refer to the general-purpose centrifuge 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 components of the system.
4. Inspect product prior to use, do not use if tray pack is damaged or opened.
5. Always follow aseptic technique.
6. Aseptic technique, proper skin preparation, and continued protection of the donor site are essential.
7. Dispose of biohazard fluids contaminated disposable following hospital policy and procedures for biological waste, use Universal Precautions.
8. After processing, keep the adipose process disposable vertical. Tilting may mix fluids, affecting process results
9. Do not re-sterilize.
10. Disposable is for single patient use only.
11. Discard all unused components at the end of the procedure.
12. Results may or may not be permanent.
13. Results of this procedure will vary depending on patient age, surgical site, and experience of the surgeon.
14. Re-use may lead to infection or illness/injury/death.
15. This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
16. The amount of fat removed should be limited to that necessary to achieve the desired cosmetic effect.

Progenikine Adipose Process Disposable

QTY	Kit Components
1	18G needle
1	Safety scalpel #11
1	60mL syringe
1	Vaclock syringe
1	Fenestrated drape
1	CSR wrap
1	Progenikine Adipose Processing Disposable
1	Female/female connector
2	12mL syringe
1	30mL syringe
2	Alcohol pads



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. Aseptic technique, proper skin preparation and continued protection of the donor site are essential.

1. Follow institution's protocol for aseptically preparing and draping the donor site.
2. Anesthetize the area of aspiration using a 25g needle.
3. Create skin puncture through skin only with 18g needle (provided).

COLLECTION OF ADIPOSE TISSUE

1. Using a 20mL or 10mL syringe to 2.1mm x 12mm multiport infiltrator cannula (or compatible cannula), fill the syringe with tumescent fluid.
2. Solubilize the adipose at the donor site.
3. Aspirate adipose tissue.
4. Attach a 20mL or 10mL syringe to the harvester cannula (or suitable cannula).
5. Aspirate the adipose tissue from the donor site. (Fig 1)
6. Once syringe is filled remove the cannula from the syringe.
7. Apply sterile cap to the syringe and place in decanting rack with the port side down. (Fig 2 and Fig 3)
8. Repeat steps 4-7 with additional syringes until desired volume is reached.
9. Decant for at least 1 minute and express the infranatant fluid into disposable cups.

Note: If adipose tissue contains excessive red cells perform optional rinse.

OPTIONAL RINSE:

1. Add saline to syringe(s) with adipose tissue, place tip cap onto syringe and stand (luer down) for 1 minute.
2. Express infranatant fluid out of syringe.
3. If necessary, repeat steps 1 & 2



Figure 1



Figure 2



Figure 3

STERILE EO

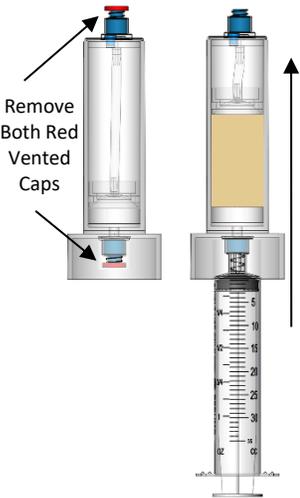
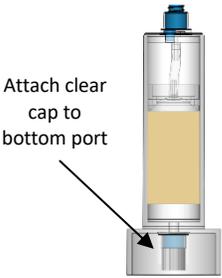
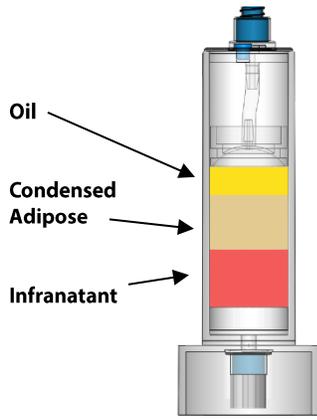
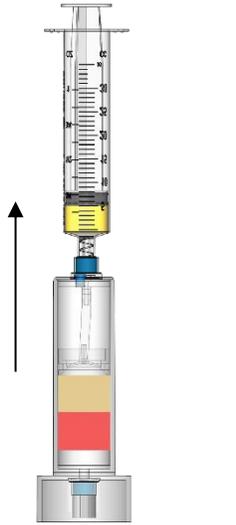
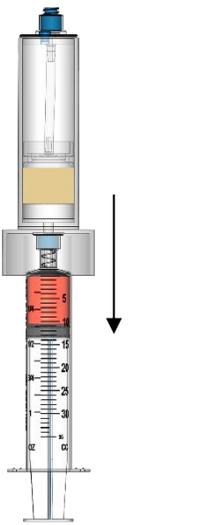
Single
Use Only



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PROCESSING OF ADIPOSE TISSUE

NOTE: Swab needless swabable valve ports with sterile alcohol before and after accessing with a sterile syringe.

<p>Step 1:</p>  <p>Remove Both Red Vented Caps</p> <p>Inject 25mL Adipose through bottom port</p> <p>Remove both red caps and inject 25mL of adipose tissue through the bottom port.</p>	<p>Step 2:</p>  <p>Attach clear cap to bottom port</p> <p>Attach the non-vented CLEAR CAP onto the bottom port</p>	<p>Step 3:</p>  <p>Counter balance the device and place in centrifuge buckets at opposite ends.</p> <p>PLATINUM SERIES CENTRIFUGE Platinum Series Centrifuge Process at "PROGENIKINE" setting</p> <p>EXECUTIVE SERIES CENTRIFUGE Executive Series Centrifuge Process at 4 minutes 2500 RPM</p>	<p>Step 4:</p>  <p>Oil</p> <p>Condensed Adipose</p> <p>Infranant</p> <p>After centrifugation, the adipose will be separated into infranant fluid, condensed adipose and oil</p>
<p>Step 5:</p>  <p>Attach the syringe to the top port and aspirate the lipid oil</p>	<p>Step 6:</p>  <p>Remove the clear cap from the bottom port, attach the syringe and aspirate the infranant fluid</p>	<p>Step 7:</p>  <p>Transfer the condensed adipose tissue to the transfer syringe</p>	<p>Step 8:</p>  <p>Adipose concentrate is now ready for use</p>