

Progenikine® Concentrating System

Date: September 2023

PN: PK25

Instruction for Use

ATTENTION OPERATING SURGEON

NOTE: DEVICE IS FOR SINGLE USE ONLY. Discard the entire disposable system after one use, using an acceptable disposal method for products potentially contaminated with blood.

DESCRIPTION

1. The Progenikine® Concentrating System is manufactured by EmCyte Corporation. The kit prepares concentrated adipose tissue. The system contains syringes, needles and the concentrating device accessories.

MATERIALS

2. The materials used are syringes, needles, tubing, connectors, and concentrating devices. The materials consist of medical grade polymers, elastomers and stainless steel that are suitable for use in medical devices. All components in this system are packaged, labeled and sterilized as indicated by the manufacturer's labeling. All components in this system are latex-free.

INDICATION FOR USE STATEMENTS

3. The Progenikine® Concentrating System is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The Progenikine® Concentrating System is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The Progenikine® Concentrating 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 and Re-constructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Laparoscopic Surgery, Arthroscopic Surgery.

USER POPULATION

4. The intended user population is medical professionals who are licensed or certified in clinical practice. The operational context of the device requires users to be trained on aseptic technique and understand blood components. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.

DEVICE USE ENVIRONMENT

5. The device is intended to be used in a health care setting such as a surgery room, clinic or outpatient care center.

WARNINGS

6. 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.
7. Adipose tissue prepared with this procedure pack is not intended for transfusion.

8. This device will not, in and of itself, produce significant weight reduction.
9. This device should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart or disease, circulatory diseases, or obesity.
10. The volume of blood loss and endogenous body fluid may adversely affect intra- and/or postoperative hemodynamic stability and patient safety.
11. The capability of providing adequate, timely fluid replacement is essential for patient safety.
12. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

PRECAUTIONS

13. Refer to the general-purpose centrifuge operator's manual for additional information concerning centrifuge operation and maintenance, warnings and cautions.
14. Use of this device is limited to qualified physicians trained in suction lipoplasty.
15. Avoid bending, twisting and/or damaging the components of the system.
16. Inspect product prior to use, do not use if tray pack is damaged or opened.
17. Always follow aseptic technique and use Universal Precautions.
18. Aseptic technique, proper skin preparation, and continued protection of the donor site are essential.
19. Dispose of biohazard fluids contaminated disposable following hospital policy and procedures for biological waste.
20. After processing, keep the adipose process disposable vertical. Tilting may mix fluids, affecting process results.
21. Follow manufacturer instructions when using centrifuge. Use only EmCyte provided general purpose centrifuge. Outcomes using centrifuges from other manufacturers are unknown.
22. Do not use sterile components of this system if package is opened or damaged.
23. Single use device. Do not reuse. Do not attempt to clean or re-sterilize this product.
24. Do not use after expiration date.
25. Results may or may not be permanent.
26. Results of this procedure will vary depending on patient age, surgical site, and experience of the surgeon.
27. This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
28. The amount of fat removed should be limited to that necessary to achieve the desired cosmetic effect.

POSSIBLE RISKS

29. The patient is to be made aware of the general risks associated with whole blood aspiration. These risks include, but are not limited to: hemorrhage, seroma formation, infection, and/or persistent pain at the harvest site.
30. Reuse may be a potential biohazard

POSSIBLE ADVERSE EFFECTS

31. Damage to blood vessels, hematoma, delayed wound healing and/or infection is associated with blood draw, and/or surgical procedure.
32. Temporary or permanent nerve damage that may result in pain or

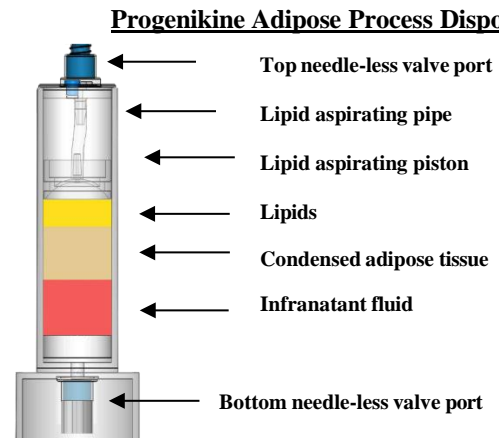
numbness is associated with blood draw, and/or surgical procedure.

33. Early or late postoperative infection is associated with surgical procedure.
34. Pain associated with site of harvest.

STERILITY

The Progenikine® Concentrating System Concentrating System kits are sterilized by ETO exposure. Do not use any component from an opened or damaged package. Do not resterilize. Discard if kit packaging is damaged or open.

| QTY | Kit Components |
|-----|---|
| 1 | 18G needle |
| 1 | Safety scalpel |
| 1 | 60mL syringe |
| 1 | Fenestrated drape |
| 1 | CSR wrap |
| 1 | Progenikine Adipose Processing Disposable |
| 2 | 12mL syringe |
| 3 | 30mL syringe |
| 2 | Alcohol pads |
| 1 | Adicen emulsifier |
| 2 | Clear caps |
| 1 | Syringe locking device |



PREPARATION STEPS:

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.

Administration of Tumescent Anesthetic Solution

1. Follow institution's protocol for aseptic technique when preparing and draping the donor site.
2. Mark and outline subcutaneous fat tissue harvest site (abdomen or flank).
3. Prepare tumescent local anesthesia solution and transfer into 60mL syringe on sterile field.
4. Locate incision site for infiltrating cannula insertion.
5. Use a 25-gauge needle to create a skin wheel with local anesthetic at the insertion site.
6. Use a scalpel blade or 18-gauge needle. Create a very small opening for the infiltrating cannula to pass through the dermal layer into the subcutaneous adipose layer.
7. Insert blunt infiltrating cannula with the tumescent anesthesia filled syringe into the subcutaneous layer.
8. While withdrawing the infiltrator cannula, slowly inject tumescent anesthetic fluid and disperse evenly throughout subcutaneous tissue.
9. Wait a minimum of 15 minutes following administration of anesthetic fluid before aspiration of the tissue.













COLLECTION OF ADIPOSE TISSUE

1. Attach syringe locking device into the 30mL syringe.
2. Connect the blunt harvester cannula into the 30mL syringe.
3. Insert the cannula into the subcutaneous tissue layer. Pull back the syringe plunger to full extension and lock it to permit vacuum.
4. Advance and move the harvesting cannula in a forward and back motion to collect adipose tissue evenly.
 - a. Create tunnels in the layers of the adipose tissue by continuously changing direction in all areas of collection site.
 - b. Avoid harvest in the same area repeatedly
5. Continue these movements with vacuum applied until desired volume of adipose tissues is extracted.
6. Once syringe is filled with adipose tissue, remove the cannula from the syringe.
7. Apply sterile cap to the syringe. Place the syringe in the decanting rack with the syringe luer port side down. Decant for at least 5 minutes and express the infranatant fluid from the bottom of the syringe.

PROCESSING STEPS

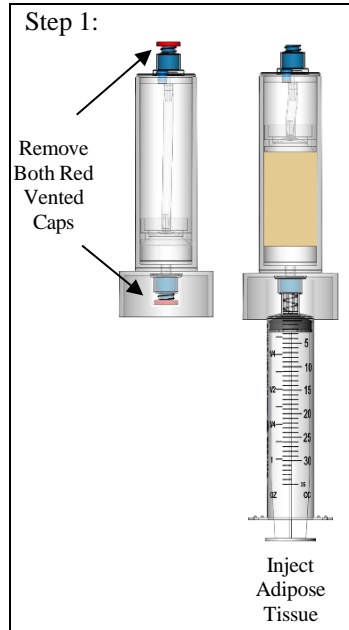
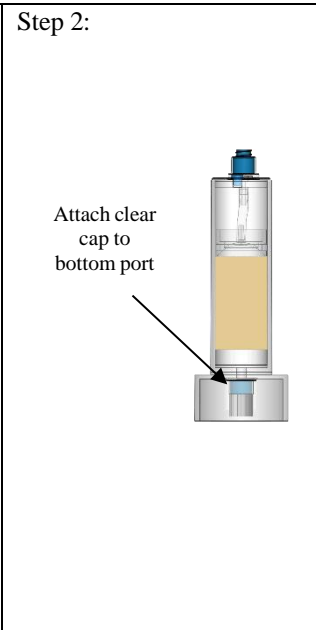
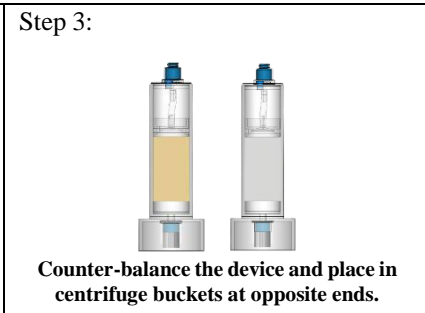
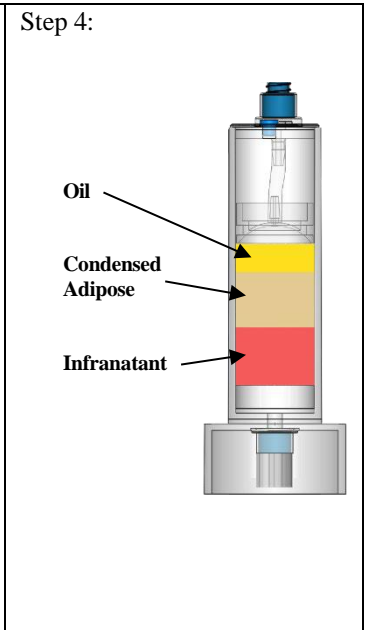
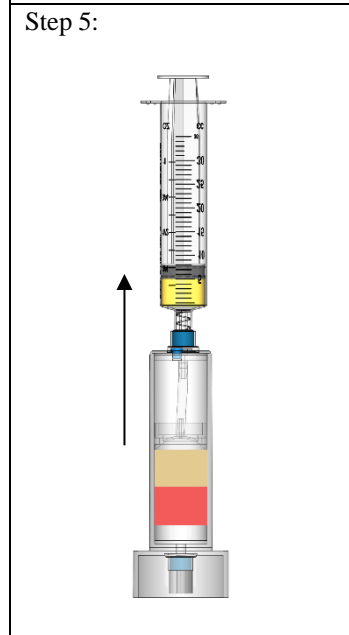
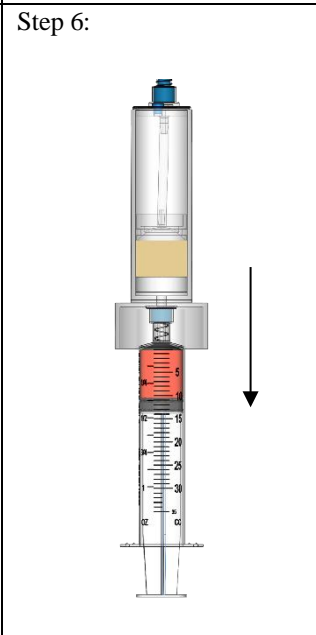
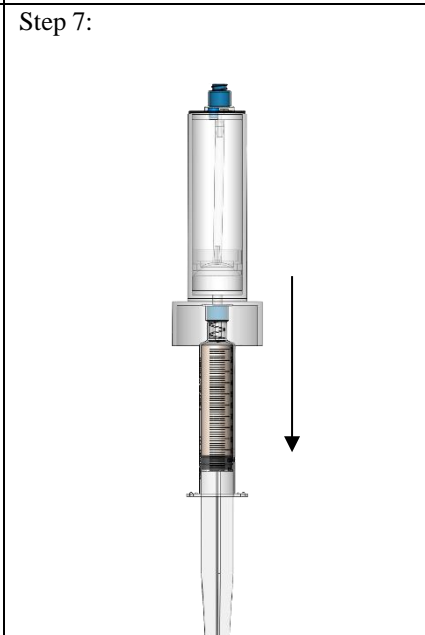
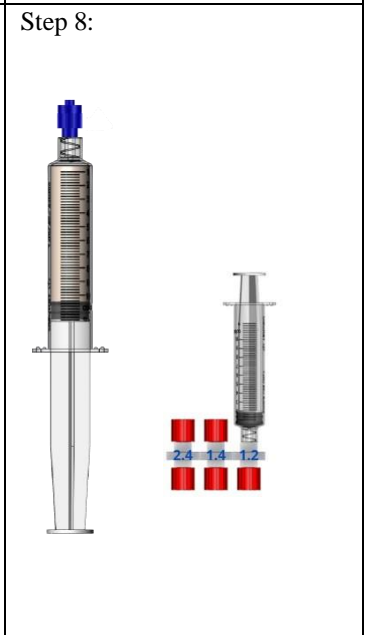
1. Remove both red vented caps from the processing device. Inject adipose tissue through the bottom port.
2. Attach clear non-vented cap onto the bottom port.
3. Counterbalance the device and place centrifuge buckets at opposite ends.
 - a. Sapphire Series Centrifuge: PROGENIKINE
 - b. Platinum Series Centrifuge: PROGENIKINE
 - c. Executive Series Centrifuge: 4 minutes 2500 RPM
4. After centrifugation, the adipose will be separated into oil (top), condensed adipose (middle), and infranatant fluid (bottom).
5. Attach the 30mL syringe onto the top port and aspirate the oil.
6. Remove the clear cap from the bottom port, attach the 30 mL syringe and aspirate the infranatant fluid.
7. Attach 12 mL syringe to the bottom port and aspirate adipose tissue.
8. Adipose concentrate is now ready to use. If needed, emulsify using Adicen.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

| | | |
|---|---|--|
|  Do not use if package is damaged |  Single use only | |
|  STERILEEO |  Rx Only Prescription Use | |
|  Consult instruction for use |  Attention, read instruction for use | |
|  Do not re-sterilize |  Store in a cool place |  Store in a dry place |
|  MD Medical Device |  Non-Pyrogenic | |
|  EmCyte Corporation 4331 Veronica S. Shoemaker Blvd. Fort Myers, FL 33916 Phone: 239-481-7725 | | |

PROCESSING OF ADIPOSE TISSUE

NOTE: Swab needle-less 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 Adipose Tissue through bottom port</p> <p>Remove both red caps and inject 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>Sapphire Series Centrifuge Set to: PROGENIKINE</p> <p>Platinum Series Centrifuge Set to: PROGENIKINE</p> <p>Executive Series Centrifuge Set to: 4 minutes / 2500 RPM</p> | <p>Step 4:</p>  <p>Oil</p> <p>Condensed Adipose</p> <p>Infranantant</p> <p>After centrifugation, the adipose will be separated into infranantant fluid, condensed adipose and oil</p> |
| <p>Step 5:</p>  <p>Attach the 30mL syringe onto the top port and aspirate the oil</p> | <p>Step 6:</p>  <p>Remove the clear cap from the bottom port, attach the 30mL syringe and aspirate the infranantant fluid</p> | <p>Step 7:</p>  <p>Attach 12mL syringe onto the bottom and aspirate adipose tissue.</p> | <p>Step 8:</p>  <p>Adipose concentrate is now ready for use. If needed, emulsify using Adicen</p> |