



AdiPrep™ Adipose Transfer System

Instructions for Use



ADI-25-01 / ADI-25-02

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Indications for Use:

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

Warnings:

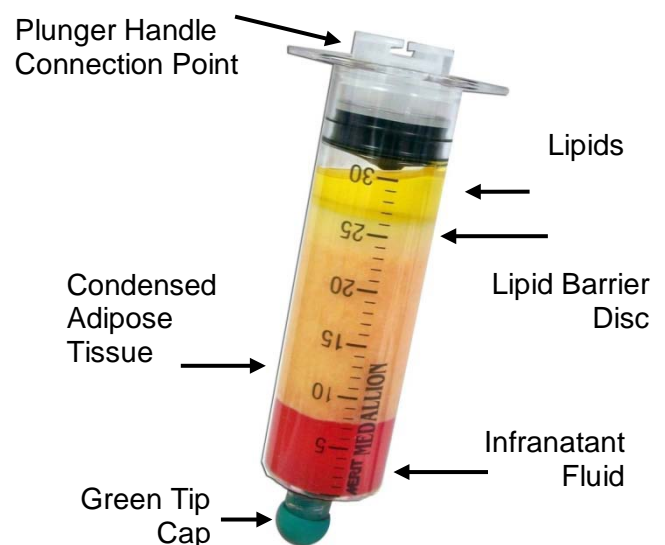
1. Federal law (USA) restricts this device to sale by, or on the order of a physician. The physician is solely responsible for the use of this device.
2. Adipose tissue prepared with this procedure pack is not intended for transfusion.
3. This device will not, in and of itself, produce significant weight 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 SmartPreP2 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 resterilize.
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.

Quantity		Procedure Pack Components
01	02	Parts Bag
1	1	25G Needle
1	1	18G Needle
4	4	4" x 4" Sterile Sponge
4	4	Isopropyl Alcohol Pad
1	1	Tip Cap Set (10 pack)
3	3	Sterile Cups
1	-	2.1x12 Multiport Infiltrator Cannula
1	-	2.1x10 Offset Carraway Cannula
6	6	Patient Labels
1	-	Johnny Snap, 20 mL
1	1	24" x 36" Sterile Drape
		Tray
2	2	20 mL Syringe
2	2	10 mL Syringe
1	1	Tip Cap (green)
5	5	Fem/Fem Connector
1	1	Harvest Adipose Processing Disposable
Note: Reinjection devices not included		

Harvest Adipose Process Disposable



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 (25g needle provided).
3. Create skin puncture through skin only with 18g needle (provided).

Collection of Adipose Tissue

1. Using a 20 mL (or 10 mL) syringe to 2.1mm x12mm multiport infiltrator cannula (or compatible cannula) and fill syringe with tumescent fluid.
2. Solubilize the adipose at the donor site.
3. Aspirate Adipose Tissue.
4. Attach a 20 mL (or 10 mL) syringe attach a 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. Place tip cap on syringe. (Fig 2)
8. Place capped syringe with tip cap facing down place into decant rack. (Fig 3)
9. Repeat steps 4-8 with additional syringe until desired volume is reached.
10. 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

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

Processing Adipose Tissue

1. Transfer adipose tissue (recommended volume of 25 mL, minimum volume 15 mL) into adipose processing disposable with fem/fem connector. (Fig 4)
2. With plunger handle extended to the 30 mL mark on the syringe, slide the plunger handle laterally, removing handle from disposable (handle will be reattached in step 8)
3. Place green tip cap on to syringe.
4. Ensure adipose centrifuge adapter and green balance weight are installed in trunnions (refer to SMP2 operator's manual for further instructions). (Fig 5)
5. Place the adipose process disposable into the adapter with green tip cap pointing down and close the lid. (Fig 8)



Figure 1



Figure 2



Figure 3



Figure 4

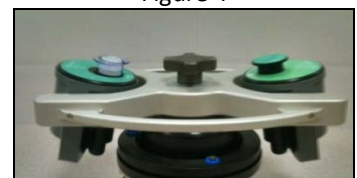


Figure 5

6. Close lid on machine, the AMBER “LID OPEN” light must be off.
 - a) For SMP2 with serial number 0101 – 5999 (Fig 6) press GREEN “START” button to start the process.
 - b) For SMP2 with serial number 6000 and above (Fig 7) press BLUE “PRP” button to start the process.
 - c) The approximate centrifuge run time is 4 minutes at 1000/g.
 - d) Once the display shows 10 on the control panel Press RED “Stop” Button. (Fig 9)
7. Remove the adipose process disposable from centrifuge. (Fig 10)
8. Re-attached the handle and remove green tip cap. (Fig 11)
9. Express the infranatant fluid from the adipose process disposable into disposable cup until the concentrate adipose tissue is reached (**do not express concentrated adipose tissue out of syringe**).
10. Transfer condensed adipose tissue to transfer syringe(s) leaving “oil” behind in the adipose process disposable. (Fig 12)
11. Adipose concentrate is now ready for use.

Fig 6 - SMP2 Control Panel – S/N 0101-5999

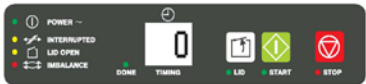


Fig 7 - SMP2 Control Panel – S/N 6000>



Figure 8

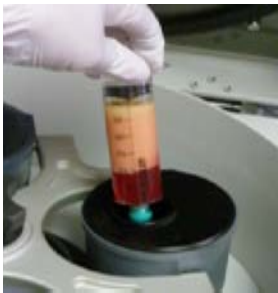


Figure 10



Figure 11



Figure 12



Figure 9

Figure 9 – Step 13

Figure 10 - Step 14

Figure 11 – Step 16

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