

TISSU-TRANS® FILTRON 100cc and 250cc Sterile Fat Graft Collection and Filter Unit

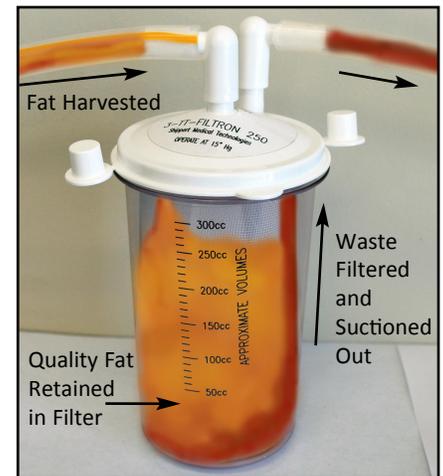
FILTRON in use

Sterile Items Included:

- ◆ Harvest Canister with Filter and Waste Extraction Port
- ◆ Harvest Tubing 6 feet with attached L connector (medical grade, yellow stripe)
- ◆ Transfer Tube 6 inches with Luer Lock tip (medical grade)

Standard Items Also Needed:

- ◆ Standard Suction tubing (1/4" or 5/16" ID)
- ◆ Waste canister
- ◆ Suction source (set at approx. 15" Hg. (37.5cm) or 50% power)
- ◆ 3mm Harvest Cannula *see recommended
- ◆ Re-injection Cannula *see recommended
- ◆ Luer Lock syringes for transfer and re-injection



ISO 10993 compliant
FDA cleared
patent pending

Notes before use:

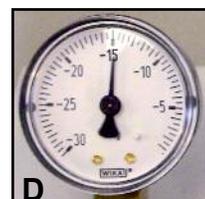
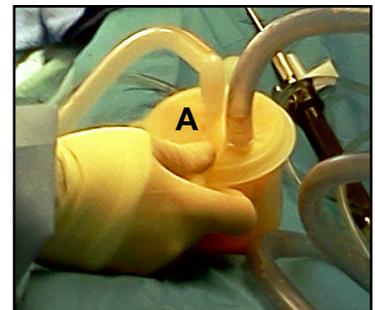
1. **Must use** a 3mm Harvest Cannula *see recommended
2. Be certain that the tissue is well hydrated- as in superwet tumescent anesthesia.
3. **Must use** a standard waste canister between the FILTRON® and suction machine.
During harvest, waste is filtered out to waste canister.
4. The Tissu-Trans® FILTRON is sterile and disposable.
One patient use.
5. Product is ready for use. **Do not open canister or lid.**
6. **Must use** the medical grade tubing provided to assure non-toxic pathway.

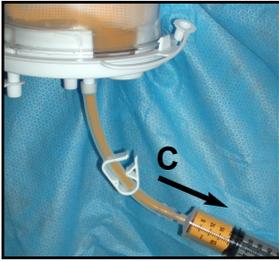


Instructions:

1. Remove sterile components and place on sterile surface.
2. **Place FILTRON upright in sterile field. Must be kept vertical. A**
Nurse to keep finger or thumb on unit to keep upright.
3. Locate Yellow stripe Harvest Tubing with L connector:
*Connect L to PATIENT Port on the canister lid. **B**
*Connect other end to liposuction cannula.
4. Connect standard suction tubing to the VAC port on the canister lid. **C**
Connect the other end to waste canister and suction.
5. Turn on suction. Check all connections.
Adjust vacuum pressure to 15" Hg, 1/2 atmosphere, or 50% power. D
System may be tested with sterile saline to ensure proper flow.
6. Harvest desired volume of fat. Quality fat will remain in filter and waste will be suctioned out to waste canister. Fat remaining in filter will be ready for reinjection.

Filtered fat may still have 3-5% liquid, which is necessary to ensure proper flow during transfer. After fat is transferred to syringes, it may be decanted further and excess liquid expelled.





REMOVAL/TRANSFER System is inverted.

1. Turn off suction. Disconnect tubes from FILTRON lid, maintaining sterility.
2. Remove one white cap that is attached to side of FILTRON lid. Use to close VAC port. **A**
3. Attach the Transfer Tube to PATIENT port. **B**
Close the white pinch clamp on the Transfer Tube. **All ports are now closed.**
4. Carefully invert the FILTRON upside down.
5. Attach Luer Lock syringe to Transfer Tube. Open pinch clamp and draw out fat to be reinjected. **C** Repeat with additional syringes.
6. When desired volume has been transferred, discard entire system.
7. Attach re-injection cannula. Fat is ready to be re-injected to recipient site.

Fat Graft Instrument and Cannula Guide

Recommended equipment for autologous fat transfer/fat grafting by procedure.

PROCEDURE Re-injection Site	HARVEST Instruments		RE-INJECTION Instruments	
	<i>Tissu-Trans® Model</i>	<i>Harvest Cannula with Biplane Handle</i>	<i>Re-injection Syringe</i>	<i>Re-injection Cannula</i>
EYELIDS/LIPS up to 250cc	3-TT-FILTRON 250	3-H-SB-24H-3x30 24hole, 3mm x 30cm	3-S-LL1 1cc Luer Lock Syringes	3-C-1H2-18x8 1hole, 18gauge x 8cm
FACE/BODY	3-TT-FILTRON 500 face	3-H-SB-24H-3x30 24hole, 3mm x 30cm	3-S-LL5 5cc Luer Lock Syringes	3-C-1H2-16x8 1hole, 16gauge x 8cm
	3-TT-FILTRON 1000 body	3-H-SB-4H-3x30 4hole, 3mm x 30cm	3-S-LL10 10cc Luer Lock Syringes	3-C-1H2-14x8 1 hole, 14gauge x 8cm
BODY Breast/Buttocks up to 2000cc	3-TT-FILTRON 2000	3-H-SB-4H-3x30 or 3-H-SB-24H-3x30	3-S-LL60 60cc Luer Lock Syringes	3-CTT-1H2-3x15 1hole, 3mm x 15cm
BODY Breast/Buttocks up to 1500cc	3-TT-MEGA 1500 Decantation Method	3-H-SB-4H-3x30 or 3-H-SB-24H-3x30	3-S-LL60 60cc Luer Lock Syringes	3-CTT-1H2-3x15 1hole, 3mm x 15cm

*Using the recommended cannulas with the Tissu-Trans® FILTRON units will reduce plugging and complications, and deliver the most favorable lipocyte harvest.



24H small fat parcels

4H large fat parcels



1H2

Following directed by FDA. Warnings: 1.This device will not, in and of itself, product significant weight reduction. 2. This device should be used with extreme caution in patients with chronic medical conditions. 3.The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability. Precautions: 1.This device is designed to contour the body by removing localized deposits of excess fat through small incisions. 2.Use of this device is limited to those physicians who have attained proficiency in suction lipoplasty. 3.Results of this procedure will vary depending on patient age, surgical site, and experience of the physician. 4.Results of this procedure may or may not be permanent. 5.The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect. 6.All reusable components must be sterilized and all disposable components replaced for each patient. This product is intended for use with cleared medical grade pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. Fat may be re-injected via a cleared injection apparatus. This product is used in aspiration, harvesting and transferring of autologous tissue. Intended for use in specialties where the aspiration of soft tissue is desired. Do not reuse or resteri-ize. Single patient use. Rx only. Pyrogen free. Federal law restricts this device to sale by or on the order of a physician.