



Instructions for Use

TISSU-TRANS® FILTRON® 100cc and 250cc

Sterile Fat Collection and Filtration

3-TT-FILTRON 100 and 250

Product is packaged in clear pouches and are provided sterile. DO NOT re-sterilize. Product part number is provided on pouch label and indicates size.

Shelf Life

Use this product before the expiration date indicated on the label.

Intended Use

The Tissue-Trans® Filtron® is intended to be used with vacuum and/or cleared pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. If the fat is untreated, it may be re-injected via a cleared apparatus.

Tissue-Trans Filtron is used in the aspiration, harvesting, filtering and transferring of autologous tissue.

Tissue-Trans Filtron is intended for use in the following surgical specialties when the aspiration of soft tissue is desired:

- Plastic and Reconstructive Surgery
- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

Indication for Use

The Tissue-Trans Filtron is intended to be used with house vacuum and/or cleared pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. If the fat is untreated, it may be re-injected via a cleared injection apparatus.

STERILE R Sterile Items Included:

- Harvest Canister with Filter and Waste Extraction Port
- Harvest Tubing 6 feet (yellow stripe)
- Transfer Tube 6 inches with Luer Lock tip

Standard Items Also Needed:

- Standard suction tubing (1/4" or 5/16" ID)
- Waste canister
- Suction source (set at approx. 15" Hg. (380mm) or 50% power)
- Cannula
- Luer Lock syringes for transfer and re-injection

Notes before use:

1. The Tissue-Trans FILTRON is sterile and disposable. One patient use.



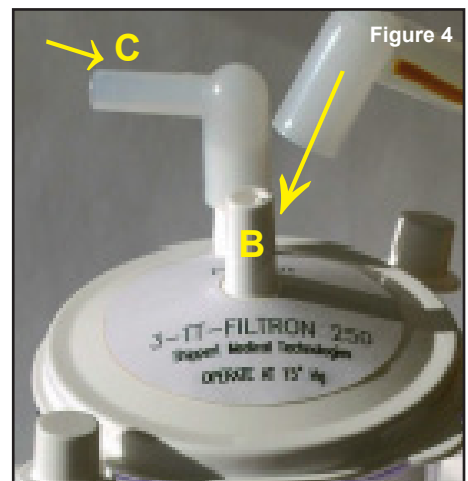
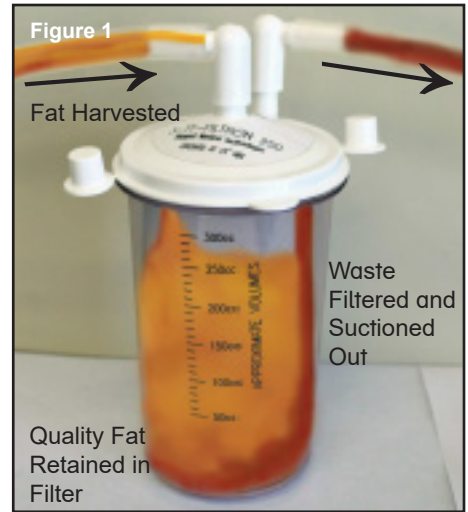
Do Not Re-sterilize or Re-use.

2. Product is ready for use. Do not open canister or lid.
3. Be certain that the tissue is well hydrated - as in superwet tumescent anesthesia.
4. **Must use** a standard waste canister between the FILTRON and suction machine. During harvest, waste is filtered out to waste canister.
5. **Recommended to use** a 3mm Harvest Cannula.
6. **Recommended to use** the medical grade tubing provided to assure non-toxic pathway.
7. Do not use if sterile pouch is torn or punctured.
8. If Filtron does not hold a vacuum, use a new device and call customer service.

Instructions:

1. Remove sterile components and place on sterile surface.
2. **Place FILTRON® upright in sterile field. Must be kept vertical.** **A** See Figure 3.
3. Locate Yellow stripe Harvest Tubing with L connector:
Connect L connector end of tubing to PATIENT Port on the canister lid. **B** See Figure 4.
Connect other end of tubing to cannula.
4. Connect standard suction tubing to the VAC port on the canister lid. **C** See Figure 4.
Connect the other end of tubing to waste canister and suction.
5. Turn on suction. Check all connections.
Adjust vacuum pressure to 15" or 380mm Hg. 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 some 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.

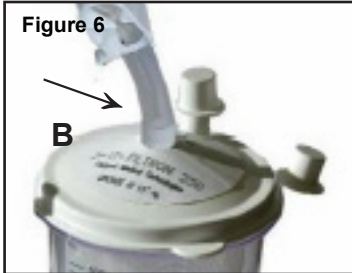




Removal / Transfer

Device remains upright.

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** See figure 5.
3. Attach the Transfer Tube to PATIENT port. **B** See figure 6.
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** See figure 7.

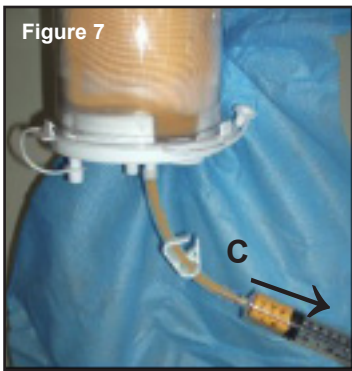


Repeat with additional syringes. If some tissue is left in the unit, remove lid to extract.

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.

Dispose in standard medical biohazard waste receptacle.

Do Not Re-sterilize or Re-use.



Warnings: 1.This device will not, in and of itself, produce 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 remove 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.

Do not reuse or resterilize. Single patient use. Rx only. Federal law restricts this device to sale by or on the order of a physician.

This product is certified as a medical device in the EU exclusively for indications of autologous fat transfer.

	Consult instructions for use
	Quality
REF	Catalog Number
	Use by Date
LOT	Lot Number/Batch Code
STERILE R Sterilized by Gamma Radiation	Sterilized by gamma irradiation
	Do not re-use
	Do not use if package is damaged
	Caution

Not made with natural rubber latex.



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