

Symbol Reference Key

	Consult instructions for use
	Quantity
	Catalog Number
	Use by Date
	Lot Number/Batch Code
	Sterilized by gamma irradiation
	Do not re-use
	Do not use if package is damaged
	Caution
	Manufactured By

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



AN INNOVIA MEDICAL COMPANY

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Instructions for Use

SUMMIT MEDICAL
TISSU-TRANS® MEGA 1500cc

Sterile Fat Collection and Decantation
3-TT-MEGA 1500

Product is packaged in clear pouches and are provided sterile.
DO NOT re-sterilize.

45896 | RevC | AUG2021

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 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.



Shelf Life

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

Intended Use

This product is intended for use in the aspiration, harvesting and transferring of analogous tissue. This product is to be used with cleared medical grade pumps, tubing and cannulas for the collection of aspirated fat.

Indication for Use

This product is indicated for the collection of aspirated fat for aesthetic body contouring.

Sterile Items Included

- Harvest Canister with 1500cc bag
- Harvest Tubing 6 feet (medical grade)
- Transfer Tube 6 inches with Luer Lock Tip (medical grade)

Standard Items Also Needed

- Tail canister stand with universal bracket
- Sterile mayo-stand drape (or equivalent) to cover canister stand
- Suction tubing (1/4" or 5/16" ID)
- Waste canister system
- Suction source set at approx. 15" Hg (380mm) or 50% full power
- Harvest Cannula
- Re-injection Cannula
- Luer Lock syringes for transfer and re-injection

Notes before use

1. The Tissu-Trans® Mega 1500 is sterile and disposable. One patient use.
 Do Not Re-sterilize or Re-use.
 The device could cause infection or the inert properties of the device could change if re-sterilized or re-used.

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 device 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 device does not hold a vacuum, use a new device and call customer service.

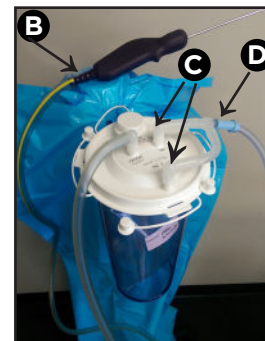
Instructions

1. Remove sterile components from pouch and place on sterile surface. Remove and discard protective packaging.
2. Drape canister stand with sterile Mayo stand cover (or equivalent). **A**
3. Attach "Y" tubing to VAC ports 1 & 2 (long length of "Y" tubing to VAC port 1 and short length of "Y" tubing to VAC port 2 on canister lid) and check connections (**C**). Secure MEGA 1500 to canister stand by inserting clear bracket on canister into universal slots on stand - being careful to maintain sterility. **A**
4. Harvest tubing is supplied coiled. Remove tape and connect "L" connector end to PATIENT port. Connect loose end to Liposuction handle/cannula. (3mm cannula recommended for best harvest and to prevent clogging). **B**
5. Connect standard suction tubing to the "Y" connector (VAC) on unit. Connect other end of tubing to standard waste canister and suction machine. (**D**)
6. Turn on suction. Adjust to 15" or 380mm Hg.
7. **1500cc bag MUST inflate BEFORE beginning harvest. E**
 May cover holes on cannula to create vacuum and help with inflation.
8. Harvest up to 1500cc of fat. If overfilled, contents will move to waste canister.
9. Turn off suction. Disconnect tubes from MEGA lid, maintaining sterility.
10. On MEGA lid, cap VAC1 and VAC2 Ports with attached caps. (**E**)
11. Attach the Transfer Tube to PATIENT port. Close the white pinch clamp on the Transfer Tube. (**G**)
12. When all ports are securely capped, carefully invert the MEGA 1500.
13. Reattach inverted canister to the canister stand using the same bracket. (**H**)
 Let unit set undisturbed for 15-20 minutes.
14. Contents will decant forming a visible line between waste and fat.
15. Open pinch clamp on Transfer Tube and drain waste into basin to discard. (**I**)
16. Attach Luer Lock syringe to Transfer Tube and draw out fat as required. (**J**)
17. When removing fat, air pressure must be equilibrated inside harvest bag. May need to inject air back into bag after each syringe removal of fat.
18. Dispose in standard medical biohazard waste receptacle.



The MEGA is placed inline between the cannula and standard waste canister.

1. MEGA



Bag Must Inflate

