Shelf Life

.l9d6l. Use this product before the expiration date indicated on the

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

Indication for Use

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

STERILE Sterile Items Included

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

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- Tall canister stand with universal bracket
- canister stand Sterile mayo-stand drape (or equivalent) to cover
- Suction tubing (¼" or ₅¼" ID)
- Waste canister system
- bower • Suction source set at approx. 15" Hg (380mm) or 50% full
- Harvest Cannula
- Re-injection Cannula
- Luer Lock syringes for transfer and re-injection

IFU-45896 | RevD | SEP2022

Sterilized by gamma STERILE R irradiation 2 Do not re-use Do not use if package $\langle \! \langle \! \rangle \! \rangle$ is damaged Caution Manufactured By F: 1-888-229-1941 | +1 651-789-3979 www.summitmedicalusa.com

AN INNOVIA MEDICAL COMPANY d C d Summit Medical LLC 815 Vikings Parkway, Suite 100 St. Paul, MN 55121 | USA P: 1-888-229-2875 | +1 651-789-3939

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.

Sterile Fat Collection and Decantation 3-TT-MEGA 1500 Product is packaged in clear pouches and are provided sterile.

DO NOT re-sterilize.

SUMMIT MEDICAL TISSU-TRANS® MEGA 1500cc





significant weight reduction. 1. This device will not, in and of itself, produce senin'sW

- in patients with chronic medical conditions. 2. This device should be used with extreme caution
- body fluid loss may adversely affect intra and/or 3. The volume of blood loss and endogenous

postoperative hemodynamic stability.

Precautions

- small incisions. removing localized deposits of excess fat through J. This device is designed to contour the body by
- lipoplasty. who have attained proficiency in suction 2. Use of this device is limited to those physicians
- patient age, surgical site, and experience of the 3. Results of this procedure will vary depending on

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- permanent. 4. Results of this procedure may or may not be
- that necessary to achieve a desired cosmetic effect. 5. The amount of fat removed should be limited to





Symbol Reference Key

for use

Quantity

53

REF

LOT

Consult instructions

Catalog Number

Lot Number/Batch

Use by Date

Code

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 lit) 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.
- ▲ Do not exceed 20" or 508mm 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.

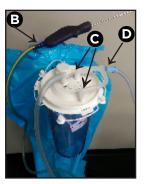


The MEGA is placed inline between the cannula and standard waste canister.

1. MEGA









Bag Must Inflate

