

PUREGRAFT SYNC

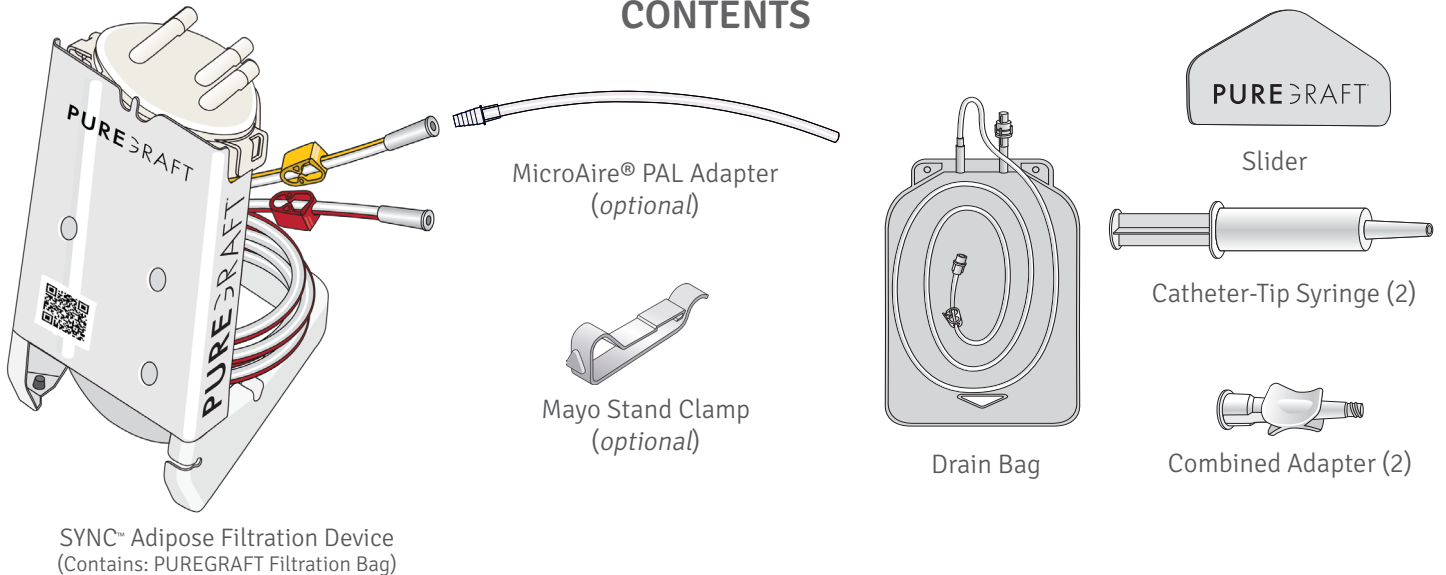
ADIPOSE FILTRATION SYSTEM



BIMINI
HEALTHTECH

INSTRUCTIONS FOR USE

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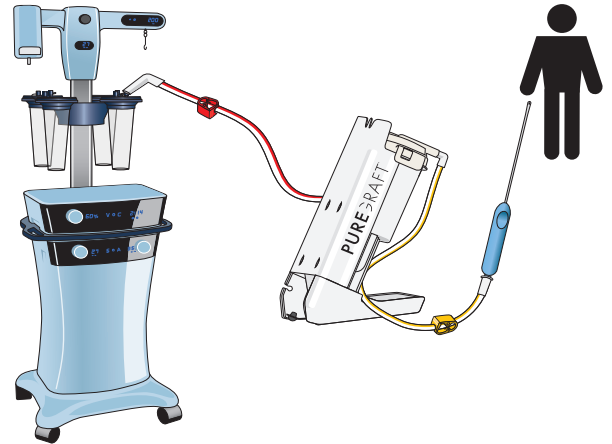
NOT PROVIDED: 510(k) cleared Lipoplasty Device with Waste Canister | Irrigation Tubing | 1L Lactated Ringer's (LR) Solution | Luer Syringes

1

HARVEST

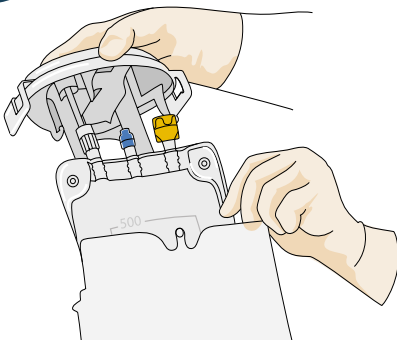
- 1A: Connect **red tube** (6ft) to waste canister of a 510(k) cleared Lipoplasty Device.
- 1B: Connect **yellow tube** (12ft) to liposuction cannula.
- 1C: Harvest **100-500mL** of tissue into PUREGRAFT SYNC.

NOTE: During liposuction, waste fluid will be automatically evacuated to waste canister.

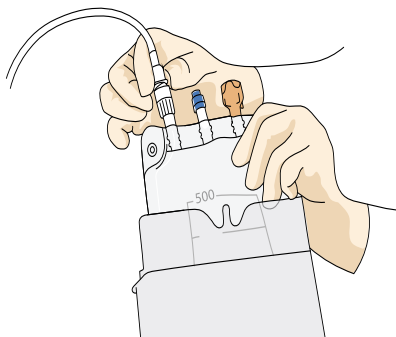


2

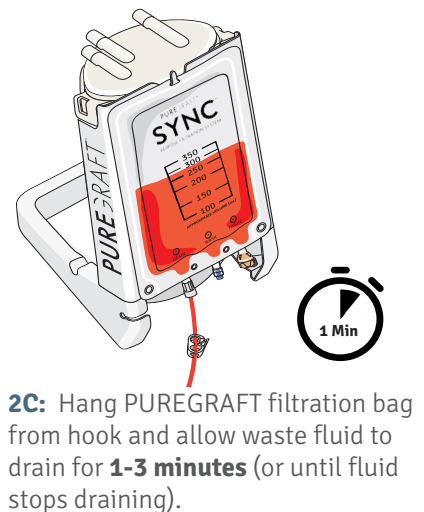
REMOVE BAG



2A: Turn off vacuum. Open and completely remove lid to expose **PUREGRAFT filtration bag**.



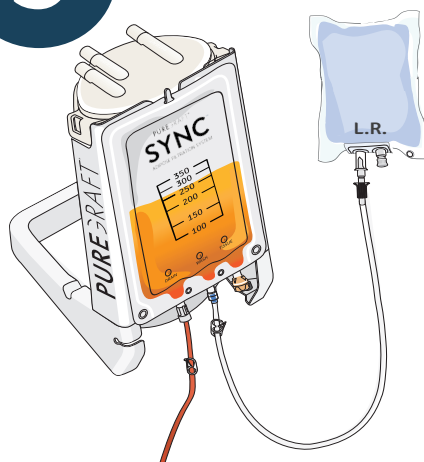
2B: Connect drain bag tube to DRAIN port. Drop **drain bag** to floor.



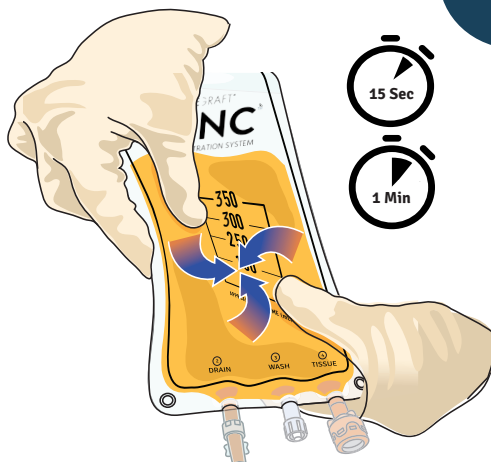
2C: Hang PUREGRAFT filtration bag from hook and allow waste fluid to drain for **1-3 minutes** (or until fluid stops draining).

3

WASH



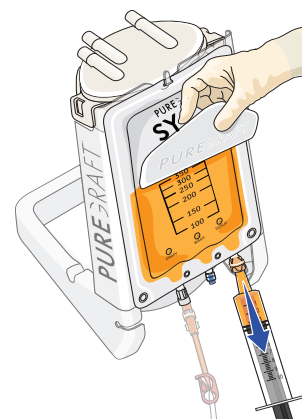
3A: Close DRAIN clamp. Connect irrigation tubing to WASH port and add 200mL Lactated Ringer's (LR) solution.



3B: Gently mix fat for **15 sec.** Open DRAIN clamp for **1-3 min** (or until fluid stops draining).
3C: Repeat 3A-3B for a second wash.

4

REMOVE



Insert **Catheter-Tip syringe** into TISSUE port; use **Slider** to direct tissue into syringe. Use **Combined Adapter** to transfer purified fat to luer syringes for injection.

INDICATIONS FOR USE

The PUREGRAFT SYNC™ Adipose Filtration System is indicated for use in the harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient for aesthetic body contouring.

CONTRAINDICATIONS

Contraindications to autologous fat transfer include the presence of any disease processes that adversely affect wound healing, and poor overall health status of the individual. The device is also contraindicated for intravenous applications.

WARNINGS

The PUREGRAFT SYNC™ Adipose Filtration System is a sterile, disposable unit for single patient use. The SYNC system must be used during the same surgical procedure in which autologous adipose tissue is collected and reinjected into the same patient. This device should not be reused in the same patient in a subsequent surgical procedure, or for more than one patient, as such use may result in infection and/or transmission of communicable diseases. Do not use the device if sterile packaging is damaged.

This device should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart, lung, or circulatory system disease, or obesity, or if pregnant. The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety. This device will not, in and of itself, produce significant weight reduction.

This system should be used with a legally marketed vacuum or aspirator apparatus as a source of suction. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

PRECAUTIONS

Use of PUREGRAFT SYNC™ Adipose Filtration System is limited to those physicians who, by means of formal professional training, have attained proficiency in suction lipoplasty and tissue transfer. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician. Results of this procedure may or may not be permanent. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect. This device is designed to contour the body by removing localized deposits of excess fat through small incisions.

ADVERSE EFFECTS

Some common adverse effects associated with autologous fat transfer are asymmetry, over- and/or under-correction of the treatment site, tissue lumps, bleeding, and scarring. Potential adverse effects of using the PUREGRAFT SYNC™ Adipose Filtration System include fat necrosis, cyst formation, infection, chronic foreign body response, allergic reaction, and inflammation.

SYMBOLS USED

	See Instructions For Use		Lot Number		Sterilized Using Irradiation
	Do Not Reuse		Do Not Use If Damaged		Manufacturer
	Catalog Number		Use By Date		Keep Dry
Rx ONLY	Prescription Only		Country and Date of Manufacture		
	Sterile Barrier with Protective Packaging Inside		Do Not Resterilize		



Bimini Health Tech
 8400 Bellevue Drive, Suite 125
 Plano, TX 75024 USA

Tel: +1 858 348 8050
Fax: +1 858 217 5134
www.puregraft.com