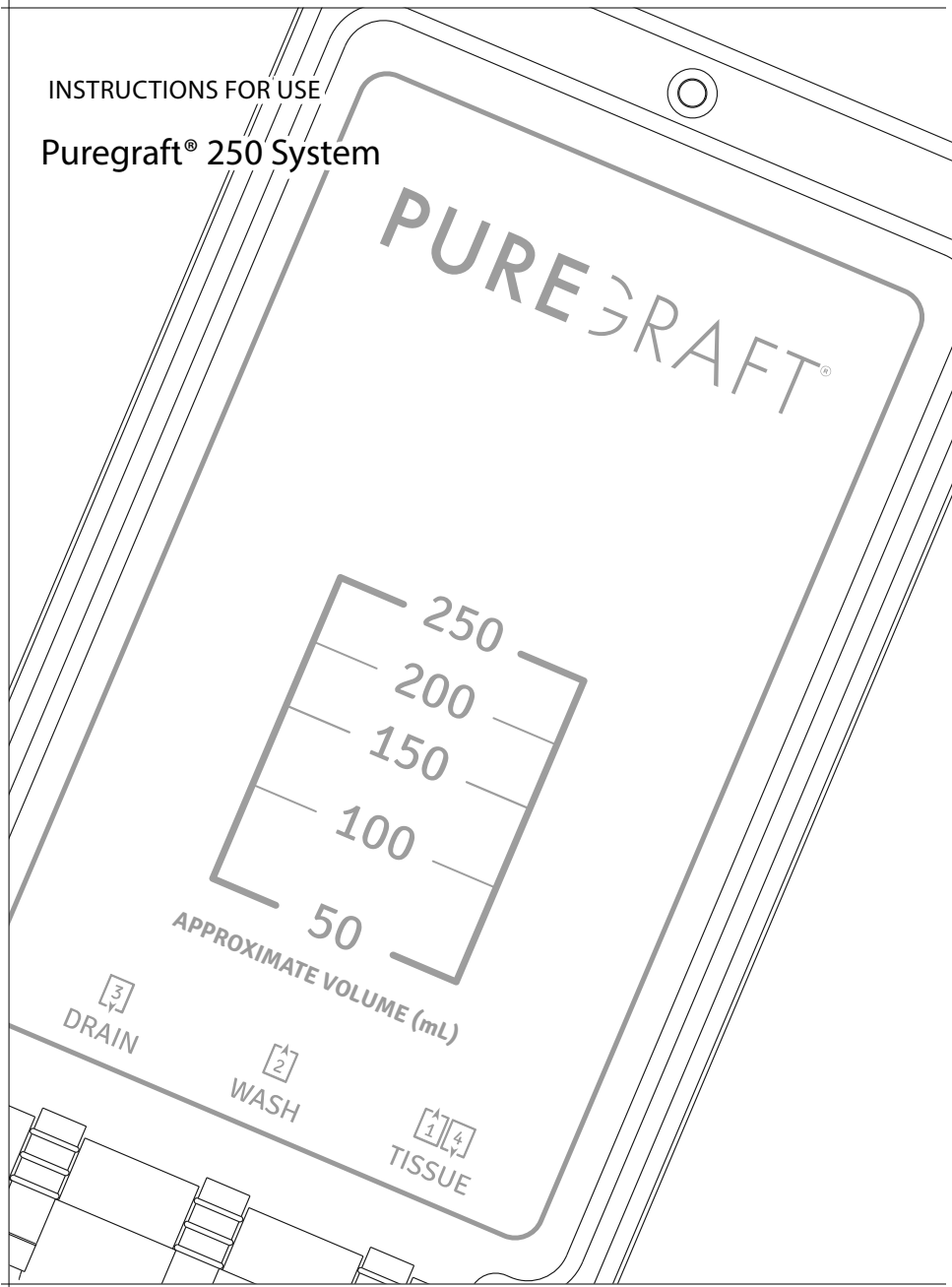


PUREGRAFT

INSTRUCTIONS FOR USE

Puregraft® 250 System



DESCRIPTION

The Puregraft® 250 System is a sterile, single use, closed system intended for the preparation and delivery of autologous fat grafts back to the same patient for cosmetic and reconstructive surgery applications. The Puregraft 250 System is composed of the following components:

COMPONENTS	QUANTITY
Puregraft 250 Bag	1
Puregraft 250 Drain Bag	1
Inlet Tubing Set	1
Tissue Access Port Adapter (TAPA)	8
Luer Lock Syringe Adapter	2

For optimal performance, the Puregraft 250 System should be used in conjunction with the Puregraft Instrument Set. This set is composed of the following reusable, autoclavable components:

COMPONENTS	QUANTITY
Puregraft Easel	1
Puregraft Slider	1

The Puregraft Easel was designed as a stand to hold the Puregraft 250 Bag for optimal fluid flow and the Puregraft Slider facilitates the movement of excess fluids away from the tissue and into the Puregraft 250 Drain Bag while guiding the tissue towards the port labeled "Tissue" for graft extraction. For storage, sterilization, and proper instructions for usage of these products, see the separate Instructions for Use included in the product packaging of the Puregraft 550/IS Instrument Set.

INDICATIONS FOR USE

The Puregraft 250 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

The following are contraindications for use of the Puregraft 250 System:

- Intravenous applications.

STERILITY

- The Puregraft 250 System is sterilized with gamma irradiation

STORAGE AND HANDLING












- Use only if sterilization indicator is red.
- Store at controlled room temperature 15°C to 30°C (59°F to 86°F)

WARNINGS

- Single Use Only – Do Not Re-use.
- For Autologous Use Only.
- The harvested fat is only to be used for reimplantation without any additional manipulations. Any manipulations beyond those outlined in the Instructions For Use are not recommended.
- Do not attempt to re-use the Puregraft 250 System during the same procedure. Re-use may compromise the sterility and adversely affect performance of the system.
- This device will not, in and of itself, produce significant weight reduction.
- This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes, heart or lung diseases, circulatory diseases, or obesity.
- The volume of blood loss and endogenous body fluid may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely fluid replacement is essential for patient safety.
- Do not overfill the Puregraft 250 Bag with more than 400 mL of total volume of tissue and/or washing solution.

PRECAUTIONS

- Inspect the Puregraft 250 System package for signs of damage prior to using.
- The Puregraft 250 System is for single use only and must be used immediately after removal from the sterile packaging.
- Discard the entire Puregraft 250 System if the packaging is damaged, opened or the sterilization indicator is invalid.
- Aseptic techniques must be used to minimize the possibility of contamination of the Puregraft 250 System.
- Treat all blood and fluids using Universal Precautions (Blood-borne Pathogen Precautions).
- This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
- Use of this device is limited to those physicians who, by means of residency training or sanctioned continuing medical education, have demonstrated proficiency in suction lipoplasty.
- Results of this procedure will vary depending upon patient age, surgical sites, and experience of the surgeon
- 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.
- The Puregraft 250 System is recommended to be used in combination with a Toomey style syringe and the supplied TAPA for tissue transfer into and out of the system.
- The Puregraft 250 System is intended to receive adipose tissue harvested with a 3mm diameter Mercedes-Tip Cannula.
- Overinflating or overfilling of the Puregraft 250 Bag may result in a biohazard to the operating staff and/or device malfunction

-  Catalog Number, Reference Number
-  Lot number
-  Use by
-  Sterilized Using Irradiation. Sterile Fluid Path
-  Do not re-use. For single use only
-  Do not use if package is damaged
-  Do not re-sterilize
-  Keep package dry
-  Store at 50°F to 86°F (15°C to 30°C)
-  See Instructions For Use
-  Manufacturer

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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OPERATING INSTRUCTIONS

PREPARATIONS:

1. Place sterile Puregraft Easel and Slider in an upright operating position.
2. Open Tyvek pouches containing the Puregraft 250 System, and hang the Puregraft 250 Bag on the Easel. Place the Puregraft 250 Drain Bag well below the level of the Puregraft 250 Bag, and ensure that the pinch clamp is positioned near the Puregraft 250 Bag and in the open position.
- 3 **Note:** Lactated Ringer's can be added to the port labeled "Inlet" by using the Inlet Tubing Set contained in the Puregraft 250 System, or directly into the port labeled "Inlet" using a Luer Lock syringe. Lactated Ringer's can also be added via port labeled "Tissue" using TAPA and Toomey style syringe. If using the Inlet Tubing Set, connect the male Luer end to the port labeled "Inlet" on the Puregraft 250 Bag, and hand off the tubing so that the Lactated Ringers bag can be spiked. Close the pinch clamp to prevent Lactated Ringer's from entering the Puregraft 250 Bag at this time. If using a syringe, pour Lactated Ringer's into a sterile bowl on the sterile field.

TISSUE COLLECTION AND ADDITION:

4. Aseptically collect adipose tissue into a Toomey style syringe and attach a TAPA to each filled syringe.

Note: If alternate means of adipose tissue harvest are used, tissue should be aseptically transferred to the Puregraft 250 Bag using Toomey syringes or other tubing and connectors.
5. Attach the tissue-filled syringe to the Puregraft 250 Bag by placing the male portion of the TAPA into the port labeled "Tissue" and pushing the syringe plunger to empty the syringe contents into the bag.

Note: Minor fluid seepage can occur during introduction and removal of tissue through the port labeled "Tissue".
6. Introduce 30-50% more tissue than the total desired graft volume, for a total volume between 50-250mL of tissue into the Puregraft 250 Bag by repeating step 5 above. Ensure excess fluid is draining into the Puregraft 250 Drain Bag.

GRAFT WASHING AND PROCESSING:

7. Close the pinch clamp on the Puregraft 250 Drain Bag. If using the Inlet Tubing Set, open the pinch clamp to the bag of Lactated Ringer's. If using the Syringe Method, draw Lactated Ringer's from sterile bowl into syringe and connect to the port labeled "Inlet" on the Puregraft 250 Bag. Reference the table below for recommended Lactated Ringer's volume to be added. be added.

TISSUE VOLUME (mL)	WASH VOLUME (mL)
50	50
100	100
150	150
200	150
250	150

Table 1.

8. Agitate the tissue-filled Puregraft 250 Bag manually for approximately 15 seconds ensuring that all corners of the bag are accessed.
9. Open pinch clamp on Puregraft 250 Drain Bag and allow fluid to drain from the Puregraft 250 Bag into the Puregraft 250 Drain Bag for approximately 3 minutes, then close pinch clamp.
10. Repeat Steps 7 & 8 to repeat tissue wash, and open pinch clamp on Puregraft 250 Drain Bag to drain excess rinse fluid for 1-5 minutes depending on preferred graft hydration level.
11. Use Puregraft Slider to guide tissue towards port labeled "Tissue". Close the pinch clamp to the Puregraft 250 Drain Bag.

GRAFT REMOVAL:

12. Aseptically attach a TAPA to an empty sterile Toomey syringe.
13. Attach the sterile syringe to the Puregraft 250 Bag by placing the male portion of the TAPA into the port labeled "Tissue".
14. Remove tissue from the Puregraft 250 Bag by slowly pulling the syringe plunger until syringe is filled. Use the Puregraft Slider as needed to extract the maximum amount of tissue from the Puregraft 250 Bag.
15. Once tissue is removed from the bag, properly dispose of all disposable components using Universal Precautions for Blood-borne Pathogens.