

**100021141**  
**(REV. A)****HARVEST® ADIPREP® PROCEDURE PACK**

4/2023

**HARVEST® ADIPREP® PROCEDURE PACK**  
51431 (ADI-25-01), 51432 (ADI-25-02)  
**INSTRUCTIONS FOR USE**  
GLOBUS MEDICAL 100021141  
**RX ONLY****GLOBUS MEDICAL, INC.**  
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1-866-456-2873**WITHIN THE UNITED STATES ONLY****ENGLISH****HARVEST® ADIPREP® PROCEDURE PACK 51431 (ADI-25-01), 51432 (ADI-25-02)**  
**INSTRUCTIONS FOR USE****INDICATIONS**

The AdiPrep® Adipose Transfer System is used in medical procedures involving the harvesting and transferring of autologous tissue. The AdiPrep® system is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The AdiPrep® Adipose Transfer System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired: arthroscopic surgery, gastrointestinal surgery, general surgery, gynecological surgery, laparoscopic surgery, neurosurgery, plastic and reconstructive surgery, thoracic surgery, urological surgery, and orthopedic surgery.

**WARNINGS**

1. Federal law (U.S.) restricts this device to sale by or on the order of a physician. The physician is solely responsible for the use of this device.
2. Adipose tissue prepared with this system is not intended for transfusion.
3. **Do Not Reuse/Not for Reuse:** Globus Medical products bearing the "Single Use Only" symbol are intended for single use only and are not intended to be reused or re-sterilized in any manner. Globus Medical cannot ensure the functionality or sterility of the product if it is reused or re-sterilized.

Reuse of a single-use product could result in:

- Product performance issues due to a loss of product integrity, including but not limited to the following:
  - Fluid leaks
  - Parts that are warped or deformed
  - Plastics that are brittle and discolored
  - Filters that have reduced filtration capabilities
- Exposure to excessive ethylene oxide (EO) residuals
- Viral infections such as hepatitis or human immunodeficiency virus (HIV)
- Bacterial infections
- Cross-contamination

Any of these risks could result in serious injury or death. These risks are shared by product users, donors, patients, and recipients of end products of the device.

4. This device will not, in and of itself, produce significant weight reduction.
5. This device should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart or lung disease, circulatory diseases, or obesity.
6. The volume of blood and endogenous body fluid loss may adversely affect intraoperative and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely fluid replacement is essential for patient safety.
7. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

**CAUTIONS**

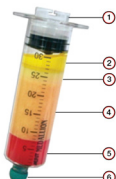
1. Use of this device is limited to qualified physicians who are trained in suction lipoplasty.
2. Do not use if the packaging is open or damaged.
3. Use aseptic technique throughout all procedures to ensure patient safety or product quality.
4. Health professionals responsible for aspirating the adipose tissue should be trained in the practice of medicine and be aware of the inherent risks. Aseptic technique, proper skin preparation, and continued protection of the donor site are essential.
5. All adipose tissue components should be handled as infectious. To minimize the potential for exposure to blood-borne pathogens, observe universal precautions when handling blood and blood components.
6. Disposables that have come in contact with adipose tissue should be considered biohazardous waste and should be handled and disposed of in accordance with applicable regulations and your institution's standard operating procedures (SOPs). Incineration and decontamination by autoclaving are the currently recommended methods for disposing of adipose tissue samples and adipose tissue products.
7. Separated adipose tissue products should be used within four (4) hours of collection.
8. After processing on the SmartPrep® Centrifuge System, make sure the process disposable is properly supported in an upright position. Tilting or tipping it could cause fluids to spill from one chamber into another and affect processing results.
9. The results of this procedure may or may not be permanent and will vary depending on the patient's age, the surgical site, and the experience of the surgeon.
10. This device is designed to contour the body by removing localized deposits of excess fat through small incisions. The amount of fat removed should be limited to that necessary to achieve the desired cosmetic effect.
11. Remnants of liquids and oils on the mating surfaces of syringes and cannulas can interfere with a good seal.
12. To ensure proper device operation, allow the procedure pack or kit to come to room temperature before use.
13. Clean and disinfect the SmartPrep® Centrifuge System after each use and between uses. Please refer to the SmartPrep® Centrifuge System Operator's Manual for cleaning and disinfecting.
14. The AdiPrep® Procedure Packs should only be used with the SmartPrep® Centrifuge System.

**PROCEDURE PACK COMPONENTS****Caution:** Follow sterile technique whenever you are passing components into the sterile field.**Caution:** Ensure all required components from the table below are present in the applicable procedure pack before you begin the procedure.**Note:** Please follow your healthcare facility's processes and procedures for acquiring components not included in your kit configuration.**Note:** Reinjection devices are not included.**Parts Bag**

51431 (ADI-25-01)	51432 (ADI-25-02)	Component
1	1	25 G Needle
1	1	18 G Needle
4	4	10.2 cm x 10.2 cm (4 in x 4 in) Sterile Sponge
4	4	Alcohol Pad
1	1	Tip Cap Set (10 pack)
3	3	Sterile Cups
1	–	2.1 mm x 12 cm Multiport Infiltration Cannula
1	–	2.1 mm x 10 cm Offset Caraway Cannula
1	1	Patient Label Sheet (6 labels)
1	–	20 mL Johnnie Snap Syringe Lock
1	1	60.9 cm x 91.4 cm (24 in x 36 in) Sterile Drape

**Tray**

51431 (ADI-25-01)	51432 (ADI-25-02)	Component
2	2	20 mL Syringe
2	2	10 mL Syringe
1	1	Green Tip Cap
5	5	Female-Female Luer Lock Connector
1	1	Process Disposable

**ADIPREP® PROCESS DISPOSABLE**

1. Connection point for the plunger handle
2. Lipids and oils
3. Lipid barrier disc
4. Concentrated adipose tissue
5. Infranantant fluid
6. Green tip cap

**PREPARING THE DONOR SITE****Caution:** Health professionals responsible for aspirating the adipose tissue should be trained in the practice of medicine and be aware of the inherent risks. Aseptic technique, proper skin preparation, and continued protection of the donor site are essential.

Optimal lipoaspiration technique has been shown to improve collection volumes of adipose tissue. The literature has shown that optimal lipoaspiration technique includes a pre-tunneling step that helps minimize the volume of unwanted infranantant fluid collected upon adipose tissue harvesting. Please refer to the following publication for more detailed information on optimal lipoaspiration technique: Alexander, R., Use of Microcannula Closed Syringe System for Safe and Effective Lipoaspiration and Autologous Fat Grafting, *The American Journal of Cosmetic Surgery*, 2013; 30: 1–12.

**Note:** The syringe stand included as part of the AdiPrep® Accessory Kit is not shipped in sterile condition. The stand must be autoclaved prior to introducing it into the sterile field..

1. Open all components of this procedure pack in the sterile field.
2. Ensure that the lipid barrier disc in the process disposable slides up and down freely. If the lipid barrier disc does not move freely, do not dispense blood or cellular material into the process disposable. Tap the bottom of the process disposable to dislodge the lipid barrier disc.
3. Follow your institution's standard operating procedure (SOP) for sterile and aseptic preparation and draping of the donor site.
4. Use the 25G needle to anesthetize the area of aspiration.
5. Use the 18G needle to create a puncture through the skin only.

**COLLECTING THE ADIPOSE TISSUE**

1. Attach a 20 mL or a 10mL syringe to the multiport infiltration cannula.
2. Fill the syringe with tumescent fluid.
3. Insert the multiport infiltration cannula through the skin puncture site, and solubilize the adipose tissue at the donor site.
4. Attach a 20mL or a 10mL syringe to the offset caraway cannula or another suitable cannula.
5. Aspirate the adipose tissue from the donor site, as shown in Figure 1.

**Figure 1: Aspirating the adipose tissue**

6. After the syringe is filled, carefully remove it from the offset caraway cannula.

- Place a tip cap on the syringe.
- Place the syringe with tip cap facing downward into a decant rack, as shown in Figure 2.



**Figure 2: Syringe in a decant rack**

- Repeat steps 4 through 8 using additional syringes until the desired volume of adipose tissue is collected.
- Allow all adipose tissue samples to sit for at least 1 minute, so that the infranatant fluid settles to the bottom of the syringe.
- Express the infranatant fluid out of the syringe and into the disposable cups.

#### OPTIONAL RINSE

If the adipose tissue contains excessive red blood cells, an optional rinse can be performed. Performing the rinse may reduce the final cell concentrations in the sample of concentrated adipose tissue. Complete the following steps to perform the optional rinse.

- Add sterile saline to an empty syringe.
- Use the female-female luer lock connector to connect the saline-filled syringe to the syringe that contains the adipose tissue.
- Transfer the saline into the syringe that contains the adipose tissue.
- Disconnect the syringe that contains the adipose tissue and place a tip cap on it.
- Mix the saline and the adipose tissue together using a back-and-forth rocking motion.
- Place the syringe with tip cap facing downward in a decant rack, and allow the rinsed adipose tissue to sit for at least 1 minute.
- Express the infranatant fluid out of the syringe and into the disposable cups.
- If necessary, repeat steps 1 through 7.

#### PREPARING THE PROCESS DISPOSABLE

- Ensure that the process disposable plunger is completely depressed and flush with the lipid barrier disc at the bottom of the syringe.
- Use the female-female luer lock connector to transfer the adipose tissue from the offset caraway cannula to the process disposable, as shown in Figure 3.



**Figure 3: Transferring the adipose tissue**

- If the process disposable is completely filled with adipose tissue, proceed to step 5.
- If the process disposable is not completely filled with adipose tissue, fill an empty syringe with sterile saline and connect it to the process disposable using the female-female luer lock connector. Inject the sterile saline into the process disposable until it is completely filled.
 

**Note:** The process disposable is completely filled when the plunger handle is extended to the top of the process disposable and cannot move any further. The plunger handle must be fully extended prior to removing it from the process disposable and attaching the green tip cap.
- Slide the plunger handle laterally to remove it from the process disposable.
- Place the green tip cap on the process disposable and transfer it out of the sterile field for processing on the SmartPrep® Centrifuge System.

#### PROCESSING THE ADIPOSE TISSUE IN THE SMARTPREP® CENTRIFUGE SYSTEM

The AdiPrep® Accessory Kit that contains the two AdiPrep® adapters is required to operate the SmartPrep® Centrifuge System with the AdiPrep® process disposable.

- Install the two adapters into the rotor buckets with the white dots facing the center of the rotor, as shown in Figure 4.



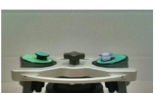
**Figure 4: White dots facing the center of the rotor**

- Ensure that each adapter is properly seated, as shown in Figure 5.



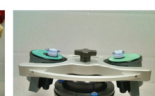
**Figure 5: Adapter seated correctly (1) and adapter seated incorrectly (2)**

- Complete one of the following steps to load the system properly and avoid an imbalance:
  - Load an AdiPrep® process disposable into one of the adapters, and load the AdiPrep® balance weight into the other adapter, as shown in Figure 6.



**Figure 6: Loading one AdiPrep® process disposable**

- Load AdiPrep® process disposables of equal volume into each adapter, as shown in Figure 7.



**Figure 7: Loading two AdiPrep® process disposables**

- Close the lid and verify that the LID OPEN indicator is not illuminated.
- Complete the following steps if you are using the SmartPrep®2 Centrifuge System:
  - Press the PRP button.
 

The window below the TIMING indicator displays the remaining time of the processing cycle.
  - When the display indicates 10 minutes remaining (approximately 4 minutes have passed), press the STOP button.
  - When the rotor has stopped, press the LID button to open the lid, and remove the process disposables.
- Complete the following steps if you are using the SmartPrep®3 Centrifuge System:
  - Press the AdiPrep® button.
  - When the processing cycle is complete and the rotor has stopped, press the LID button to open the lid, and remove the process disposables.

#### TRANSFERRING THE CONCENTRATED ADIPOSE TISSUE

- Reattach the plunger handle to the process disposable and remove the green tip cap, as shown in Figure 8.



**Figure 8: Removing the green tip cap**

- Express the infranatant fluid from the process disposable into disposable cups until the concentrated adipose tissue reaches the tip. Do not express the concentrated adipose tissue out of the process disposable.
- For proper sterile transfer, a user in the sterile field attaches a female-female luer lock connector to a suitable syringe that will be used for treatment.
- A user outside the sterile field attaches the process disposable to the female-female luer lock connector.
- The user inside the sterile field draws the concentrated adipose tissue into the treatment syringe, as shown in Figure 9. The layer of lipids and oils will remain in the process disposable outside the sterile field.



**Figure 9: Drawing the concentrated adipose tissue into the treatment syringe**

- The user outside the sterile field removes the process disposable from the female-female luer lock connector. The concentrated adipose tissue is in the sterile field and ready for use.

#### STORAGE CONDITIONS

Long-term Storage Range:

0°C to 25°C (32°F to 77°F)

Permitted Excursions:

-29°C to 0°C (-20°F to 32°F) for up to 72 hours

25°C to 50°C (77°F to 122°F) for up to 6 weeks

#### LATEX AND PYROGEN STATEMENTS

This product is not made with natural rubber latex. The fluid pathways are non-pyrogenic.

#### RETURN OF USED PRODUCT

If for any reason this product must be returned to Globus Medical, a returned authorization (an RA number) is required from Globus Medical prior to shipping.

IT IS THE RESPONSIBILITY OF THE HEALTH CARE INSTITUTION TO ADEQUATELY PREPARE AND IDENTIFY THE PRODUCT FOR RETURN SHIPMENT.

Please contact your local representative for information regarding returned goods and product complaints.

SYMBOL TRANSLATION			
	CATALOGUE NUMBER		COMPONENTS STERILIZED USING MULTIPLE METHODS
	LOT NUMBER		CONSULT INSTRUCTIONS FOR USE
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	DO NOT RESTERILIZE		TEMPERATURE RANGE
	PRODUCT QUANTITY		DO NOT USE IF PACKAGE IS DAMAGED
	PRESCRIPTION ONLY		