1000021381
(REV. A)

HARVEST® GRAFT DELIVERY PACK

3/2023

GLOBUS MEDICAL, INC.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
USA
Customer Service:
Phone 1-866-GLOBUS1 (OR)
1-866-456-2871
Fax 1-866-GLOBUS3 (OR)
1-866-456-2873

HARVEST® GRAFT DELIVERY PACK
51449 (GDP-10)
INSTRUCTIONS FOR USE
GLOBUS MEDICAL 1000021381
RX ONLY

WITHIN THE UNITED STATES ONLY

ENGLISH **HARVEST® GRAFT DELIVERY PACK INSTRUCTIONS FOR USE**

INDICATIONS

The Harvest® Graft Delivery System is indicated for the delivery of allograft, autograft, or synthetic bone graft materials to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with intravenous fluids, blood, plasma, platelet-rich plasma, bone marrow, or other specific blood component(s) as deemed necessary by the clinical use requirements.

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. This device is only intended for use on a single patient during a single procedure, and it should not be used for multiple patients.
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.

CAUTIONS

1. Do not use if the packaging is open or damaged.
2. Use aseptic technique throughout all procedures to ensure patient safety or product quality.
3. All blood and blood 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.
4. Disposables that have come in contact with bone marrow 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 bone marrow samples and bone marrow products.
5. To ensure proper device operation, allow the procedure pack or kit to come to room temperature before use.

GRAFT HYDRATION KIT COMPONENTS

51449 (GDP-10)	Component
2	Graft Syringe/Piston Assembly
1	Mixing Nozzle
1	Petri Dish
1	Push Rod Assembly
1	1 mL Syringe
–	3 mL Syringe
2	10 mL Syringe
1	Clip, 10:1
–	Clip, 10:3
3	Female-Female Luer Lock Connector

LOADING THE GRAFT MATERIALS

1. Remove the plunger from the graft syringe and fill the syringe with the desired amount of graft material, as shown in Figure 1.
2. Replace the plunger. If necessary, the plunger can be used to compress the graft material, as shown in Figure 1.
3. Attach the two-sided female-female luer lock connector to the graft syringe.

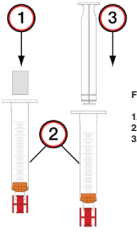

Figure 1: Loading the graft materials

1. Loading the graft material
2. Graft syringe/piston assembly
3. Compressing the graft material with the plunger

PREPARING THE LIQUID APPLICATOR

1. Fill either the 1 mL syringe or the 3 mL syringe with activator solution.
2. Fill the 10 mL syringe with the concentrated autologous biologic of the surgeon's choice.
3. Attach the filled 1 mL syringe or 3 mL syringe and the filled 10 mL syringe to the white Y-connector.
4. Attach the grey plunger clip to the syringe plungers.

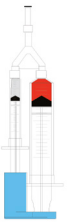

Figure 2: The liquid applicator after preparation

INJECTING FLUIDS INTO THE GRAFT SYRINGE

1. Attach the white Y-connector to the female-female luer lock connector that is already attached to the graft syringe.
2. Inject the contents of the assembled liquid applicator into the graft syringe, as shown in Figure 3, until the graft material is completely hydrated

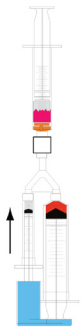

Figure 3: Injecting the contents of the liquid applicator into the graft syringe

3. Remove the graft syringe and let it sit for 1 to 2 minutes.
4. If needed, repeat steps 1 through 3 with the other graft syringe.

REMOVING THE GRAFT MATERIAL FROM THE GRAFT SYRINGE

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Caution: Disposables that have come in contact with bone marrow 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 bone marrow samples and bone marrow products.

1. Withdraw the plunger from the graft syringe.
2. Insert the push rod through the luer tip of the graft syringe, see 1 in Figure 4.
3. Depress the push rod to expel the contents from the graft syringe and into the petri dish, see 2 in Figure 4.

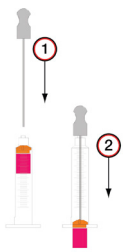

Figure 4: Removing the graft material from the graft syringe

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			
REF	CATALOGUE NUMBER	STERILE R EO A	COMPONENTS STERILIZED USING MULTIPLE METHODS
LOT	LOT NUMBER		CONSULT INSTRUCTIONS FOR USE
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
2 STERILE	DO NOT RESTERILIZE		TEMPERATURE RANGE
1	PRODUCT QUANTITY		DO NOT USE IF PACKAGE IS DAMAGED
Rx ONLY	PRESCRIPTION ONLY		