**1000021383**
**(REV. A)**

# HARVEST® SMARTJET® DUAL LIQUID APPLICATOR KIT
# SMARTJET® SPRAY APPLICATOR KIT

3/2023


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**HARVEST® SMARTJET® DUAL LIQUID APPLICATOR KIT**
**51452 (LK/2), 51453 (LK/4)**
**SMARTJET® SPRAY APPLICATOR KIT**
**51451 (SK/S)**
**INSTRUCTIONS FOR USE**
**GLOBUS MEDICAL 1000021383**
**RX ONLY**

**WITHIN THE UNITED STATES ONLY**

**ENGLISH**

## HARVEST® SMARTJET® DUAL LIQUID APPLICATOR KIT
## SMARTJET® SPRAY APPLICATOR KIT
## INSTRUCTIONS FOR USE

### INDICATIONS

***SmartJet® Dual Liquid Applicator Kit***

The SmartJet® Bone Liquid Applicator is designed to facilitate pre-mixing of allograft, autograft, or synthetic bone graft materials for application to an orthopedic surgical site, with I.V. fluids, autologous blood, plasma, platelet-rich plasma, or other specific blood components as deemed necessary by the clinical use requirements.

***SmartJet® Spray Applicator Kit***

The SmartJet Grafting Liquid Applicator is intended for the application of fluids, as deemed necessary, by the surgeon's determination of the clinical use requirements, to facilitate the preparation of soft tissue autograft material prior to the application of the graft material to a repair site.

### 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:

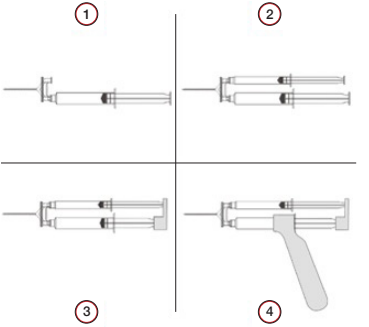
- Product performance issues due to a loss of product integrity, including but not limited to the following:
  - Fluid leaks
  - Parts that are warped or deformed
  - Plastics that are brittle and discolored
  - Filters that have reduced filtration capabilities
- Exposure to excessive ethylene oxide (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. The applicator can be used on multiple sites on a single patient during a single procedure, but it is necessary to wipe the applicator tip after application to each site to prevent clotting in the applicator.
3. Use aseptic technique throughout all procedures to ensure patient safety or product quality.
4. 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.
5. 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.
6. To ensure proper device operation, allow the procedure pack or kit to come to room temperature before use.

**ASSEMBLY INSTRUCTIONS**




**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 | | |