

## LipoGrafter® Kit INSTRUCTIONS FOR USE

### READ BEFORE USING

**Caution: Federal (USA) law restricts this product for sale by or on the order of a Physician.**

The LipoGrafter® Kit is a sterile, single use disposable device that is used in harvesting, sedimenting, and transferring autologous fat to the desired anatomy. The components of the LipoGrafter® Kit are as follows:

- KVAC® Syringe
- AT-Valve®
- 4 Collection bags with silicone tubing and luer connectors

#### Component Description

##### **KVAC® Syringe**

The KVAC® Syringe is fabricated from medical grade polycarbonate. The KVAC® Syringe includes a 30-cc syringe, a plunger, and two stainless steel ribbon springs. The 30-cc syringe is secured to the plunger of the KVAC® Syringe that is attached to the two stainless steel springs. The KVAC® Syringe is designed to provide a relatively vacuum pull force over the entire range of the plunger excursion.

##### **AT-Valve®**

The AT-Valve® is fabricated from medical grade polycarbonate that is designed to connect with the KVAC® Syringe, a harvesting cannula, and to a collection bag in the harvesting phase of the autologous fat. In the reinjection phase of the autologous fat, the AT-Valve® is connected to an injection syringe, a grafting cannula and to a collection bag. **Note that a collection bag is used for collection and sedimentation of the harvested fat.**

##### **Collection Bags with Silicone Tubing and Luer Connections**

The autologous fat from the KVAC® Syringe is transferred to a collection bag via silicone tubing with luer connections. The autologous fat then sediments by gravity inside the collection bag.

LipoGrafter is intended to be used in conjunction with a liposuction cannula with a standard luer connection per ISO 80369-7.

##### **Indications for Use**

The LipoGrafter® Kit is indicated to facilitate Autologous Fat Transfer (AFT). AFT is the harvesting, sedimenting and transfer of autologous fat tissue back into the same patient following a medical procedure, such as breast reconstruction resulting from disease or injury.

##### **Contraindications**

Contraindications to autologous fat transfer include the presence of skin infections, open lesions, varicose veins in the area of treatment, any disease processes that adversely affect wound healing, and poor overall health status of the individual.

##### **Warnings**

Do not overtighten. If the cannula gets obstructed while grafting, applying too much force on the injection syringe might prolapse the AT-Valve®. Instead, disconnect the cannula and clean it by flushing it separately. Reuse of this device may pose risks to the patient due to cross-contamination and/or loss of sterility. Dispose of LipoGrafter and all packaging that has been in contact with the patient in accordance with standard procedures for discarding regulated medical waste materials.

The components of the LipoGrafter Kit are supplied sterile and are intended to for single use only.

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 and pregnancy.

##### **Serious Incidents**

Patients may experience temporary pain, bruising and / or soreness at the injection site. In addition, some adverse events associated with autologous fat transfers are bleeding, scarring, fat necrosis infection, allergic reaction, necrosis, cyst formation and inflammation. Like any other surgical procedure, the LipoGrafter System should be used with caution in patients with chronic medical conditions such as diabetes, heart, lung, or circulatory system disease or obesity and patients with active implantable or active body-worn medical devices and with metallic passive medical devices or other metallic objects present on or inside the body. Physicians are advised to consult with patients for medical clearance prior to autologous fat transfer procedures.

All serious incidents shall be promptly reported to MTF Biologics and the competent authorities.

##### **Precautions**

- Only surgeons who have read these Instructions for Use should use the LipoGrafter® Kit.
- The LipoGrafter® Kit is a closed system. Ensure that there are no air bubble leaks in the Silicone tubing or the AT-Valve®.
- Insert a 14-gauge needle in the injection side of the collection bag to vent any purged air during harvesting.  
**Note: The 14-gauge needle should not be used during the reinjection phase.**

##### **Sterilization**

The components of the LipoGrafter® Kit are supplied sterile.

Note: Validation testing performed on the LipoGrafter® Kit demonstrates sterility assurance level (SAL) of 10<sup>-6</sup>.

##### **Clinical Benefits**

LipoGrafter System is a closed system where the lipoaspirate is minimally manipulated for optimal survival of the lipoaspirate. The AT-Valve saves time when reloading the fat from the collection bag to the grafting syringe.

##### **Performance Characteristics**

Controlled suction, closed system, minimal process of grafts, controlled volume re-injection, minimal contamination risk and minimal tissue trauma and graft exposure.

##### **Packaging and Labeling**

The device shall not be used under any of the following circumstances:

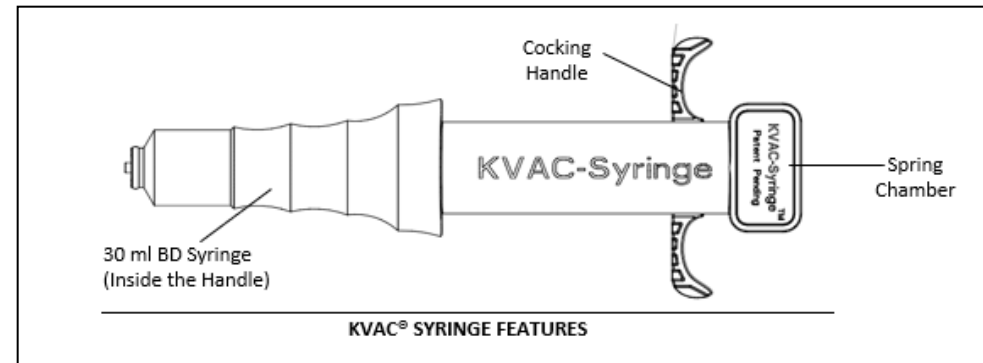
- If the container seal is damaged or has any physical damage
- If the container label is severely damaged, not legible or missing.
- If the expiration date on the container label has passed

##### **Directions for Use**

###### **OPERATING THE KVAC® SYRINGE**

The KVAC® Syringe is a spring-loaded, manually operated vacuum device. A 30 ml BD syringe is embedded inside the device. A vacuum along the entire excursion of the plunger is created inside the syringe by the pull of embedded force springs. The springs assembled inside the “Spring Chamber” are attached to the “Cocking Handles” and are not accessible. In the relaxed position, the springs are wound and the plunger is at its outermost position. There is no force, no movement and no vacuum in the relaxed position. The “Handle” is designed as an ergonomic holding feature for the user. The luer tip of the syringe is accessible for connection to instruments. This device is intended for use by qualified healthcare professionals in an appropriate medical facility in adequate clinical settings..

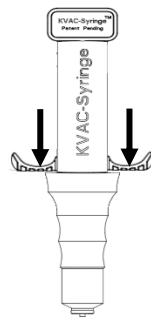
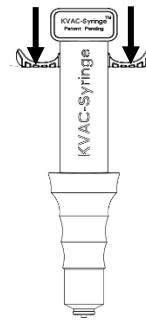
##### **HARVESTING PHASE OF THE KVAC-SYRINGE**



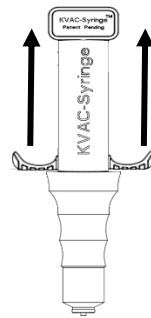
**COCKING THE KVAC® SYRINGE**

To operate the KVAC® Syringe, the user pushes the “Cocking Handles” toward the “Handle”. The user holds the handle with one hand while pushing the cocking handles with the cupped thumb and index fingers of other hand. This is the cocked position. The plunger is all the way in and the springs are unwound. The syringe is empty and is ready to accept the inflow of aspirate. In the absence of inflow (fluid or air) into the syringe, this position is maintained.

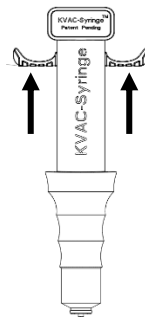
**Please note that both cocking handles are designed to be pushed simultaneously by the index and thumb of the cupped hand. Forceful pushing on only one of the two handles creates an imbalance that might break the spring connection.**



When the cocking handles are let loose, the unwinding of the springs pull the plunger. This pulling action creates the needed vacuum inside the syringe. Once the aspiration begins, the springs pull the plunger with a c force to maintain the desired vacuum inside the syringe.



KVAC® Syringe with plunger down and spring-loaded mechanism is ready to aspirate the autologous fat



KVAC® Syringe with plunger all the way up and springs completely unloaded, the autologous fat aspirates inside the syringe

Competent Authority  
Dutch Health and You Care Inspectorate (IGJ)  
2518, 6410 DA Heerlen, The Netherlands  
Email: meldpunt@igj.nl

**EC REP**  
**EMERGO EUROPE**  
Westervoortsedijk, 60 6827 AT, Arnhem,  
The Netherlands

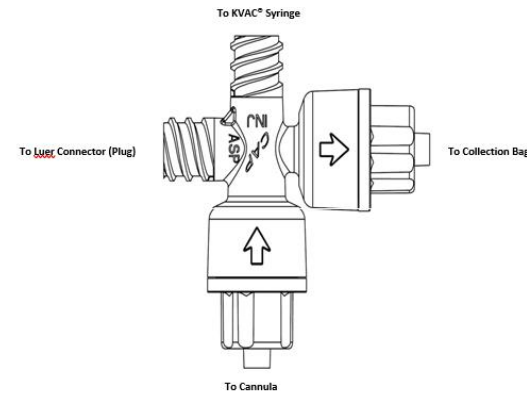
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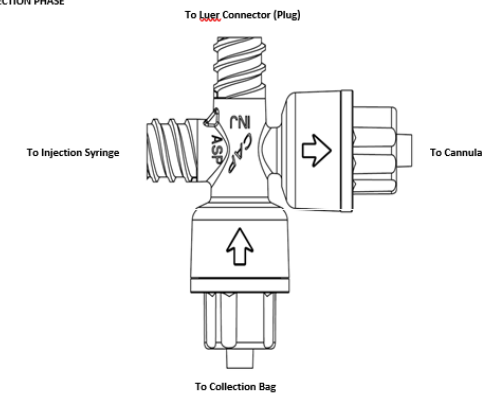
**AT-VALVE® CONNECTIONS**

The AT-Valve® is a multi-purpose valve. The valve body houses two one-way duckbill silicone valves. The flow directions are marked by arrows on the valve body. The AT-Valve® can be used in “Harvesting” or “Reinjection” phases. In either phase, only three ports are actively used. The remaining port has to be plugged with the included male luer connector


**HARVESTING PHASE**





**REINJECTION PHASE**





**Symbols Used on Labeling**


- 


Manufacturer
- 


Keep dry
- 


UDI Unique Device Identifier
- 


Do not re-sterilize
- 


Keep away from sunlight
- 


Single *sterile* barrier system
- 


Do not reuse
- 


REF Catalog number
- 


Single *sterile* barrier system with protective packaging inside
- 


Consult Instructions for Use
- 

STERILE EO Sterilized using Ethylene Oxide
- 

LOT Lot number
- 

Do not use if package is damaged
- 

Expiration date
- 

Rx ONLY Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
- 

MD Medical Device



125 May Street, Edison NJ 08837 USA  
Outside of the United States +1.732.661.0202