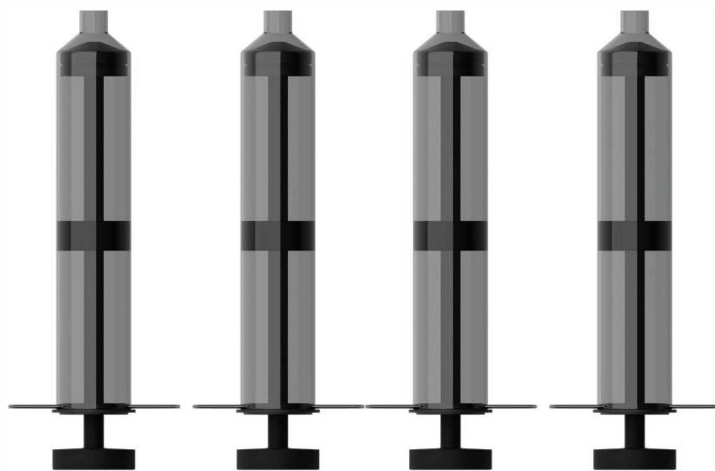


Centrifuge Container



Instructions for Use FDA 510 (K) Labeling

Rev: 4-19-22

Principle of Operation:

Lipocube Centrifuge Container processes adipose tissue which has been removed from a patient to assist the users with cleansing of the adipose tissue before it is re-implanted into the same patient (autologous use) as close to its original form as possible. Lipocube Centrifuge Container is a sterile single use device and is designed to provide the conditions of a closed circuit for cleansing of adipose tissue. Lipocube Centrifuge Containers which are used during centrifugation process (FDA cleared centrifuge machine according to the directions in the manufacturer's labeling) to separate layers of blood, impurities, adipose fat, and oil before being sized through the cubes to cleans and concentrate the adipose tissue. Centrifuge containers can be purchase separately in either 15cc or 20cc sizes. It is important to note that the Centrifuge Container is not intended for harvesting adipose tissue from the patient, nor does the Centrifuge Container contain a centrifuge machine or piston syringe. The Centrifuge Container is intended to be used with existing FDA cleared piston syringes, fat harvesting devices, connectors, stoppers, and FDA cleared centrifuge machines.

Conditions of Use:

Lipocube Centrifuge Container is a sterile single-use medical device intended to be used for cleansing and concentrating adipose tissue within a sterile closed circuit. The adipose tissue after cleansing and concentrating is suitable for being returned to the same patient which alters an original relevant characteristic of the adipose tissue, relating to the tissue's utility for reconstruction, repair, or replacement.

Indications For Use:

The Lipocube Centrifuge Container is disposable and is indicated for autologous fat transfer. The autologous fat transfer is also technically called as autologous fat grafting or reinjection of filtered adipose tissue into the recipient body areas for providing strength, flexibility, cushioning, covering, compressibility, and response to friction and shear. The Lipocube can be used for concentration and transfer of homogenous adipose tissues with legally marketed lipoplasty system when the concentrated and homogenous fat tissue is re-injected into the recipient body areas of the same patient autologously.

This device is intended for autologous fat transfer. The Lipocube is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired.

Neurosurgery / Gastrointestinal Surgery / Urological Surgery / General surgery / Orthopedic Surgery / Gynecological Surgery /Thoracic Surgery / Laparoscopic Surgery / Arthroscopic Surgery / Plastic and reconstructive surgery.

Contraindications:

Centrifuge Container is not intended to be used in intravenous applications.
Centrifuge Container is not indicated for patients suffering from coagulation disorders or receiving anticoagulant therapy.

Sterility:

Centrifuge Container is sterilized using gamma energy.

Storage and Handling:

Store at controlled room temperature 15°C to 25°C.

Warnings:

- **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.
- Single Use Only – Do Not Re-use.
- For Autologous Use Only.
- The harvested fat tissue is only to be used for reimplantation without any additional manipulations. Any manipulations beyond those outlined in this Instruction for Use (IFU) are not recommended.
- Do not re-use Centrifuge Container during the same procedure. Re-use may compromise the sterility and adversely affect performance of the system.
- Do not overfill Centrifuge Container with more than 15 mL or 20mL (depending on model) of total volume of tissue and/or washing solution.
- 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, lung, or circulatory system disease or obesity.
- The volume of blood loss and endogenous body fluid loss 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.
- Wear personal protective equipment whenever handling human tissue, this should include disposable-sterile gowns, masks, hoods, gloves, eyewear, or face shields.

Precautions:

- Inspect the Centrifuge Container package for signs of damage prior to using.
- Centrifuge Container is for single use only and must be used immediately after removal from the sterile packaging.
- Discard the entire Centrifuge Container if the packaging is damaged or opened.
- Aseptic techniques must be used to minimize the possibility of contamination of Centrifuge Container.
- Treat all blood and fluids using Universal Precautions (Blood-borne Pathogen Precautions).
- This device is designed to remove blood from tissue and wash tissue to subsequently transfer the tissue back to the patient.
- Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty and tissue transfer.
- Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
- 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.
- Overfilling of Centrifuge Container may result in a biohazard to the operating staff and/or device malfunction.
- Centrifuge Container is intended to be used in combination with luer lock syringes (not included) for operation and final delivery.

- Adipose tissue harvested using cannula larger than 2.1 mm may cause clogging (1.6 mm maximum hole size is recommended).
- Patients younger than 12 should be excluded since fat harvesting process is not recommended for earlier ages due to immature metabolic balance and unproportioned anatomy.
- The markings on the label, both in the operating manual and on the product must be paid attention and the operating principles should be fully understood.
- Centrifuge Container must never be disassembled before and/or after treatment.
- Failure to comply with one or all the terms of use, particularly the indications, may cause serious health problems.
- You should take precautionary measures against body fluids that may spill or splash during or after the device operation. Used equipment should be treated as medical waste.
- The device is not recommended for the patients who have active cancer, who are breastfeeding or undergoing pregnancy, and children under 12 years of age.
- Check the expiration date before use. Do not use products out of expiration date.
- Make sure all components of the device/kit are available.

Adverse Reactions:

- Some common side effects associated with autologous fat transfer procedures are asymmetry, excessive and/or inadequate correction of the treatment area, tissue pellets, bleeding, and scarring.
- Temporary swelling, bruising, tissue pigmentation and redness may occur at the injection area during the treatment process.
- Local infection, allergic reactions and inflammation may be observed.
- Toxic shock is not a possible outcome to be considered since the medical device is autologous use.

Components:

This package contains 4 Centrifuge Containers (either 15cc or 20cc depending on model). Please use 4 FDA cleared 20ml luer lock piston syringes (syringe barrel radius ϕ 9.5mm) to transfer tissue back and forth to the Centrifuge Container.

To harvest tissue, please use an FDA cleared fat harvesting cannula; 200mm long, 3.0mm thick, 2.0mm pore size multi-hole, cannula.




Please use FDA cleared centrifuge and stopper during the concentration process



Opening the Package:

- Tear off the transparent film carefully.
- Open the pack.
- Before removing the materials in the pack, ensure that your sterile gloves, protective equipment, and at least 1000mm x1000mm sterile drape are available.
- During the unpacking, involve an assistant with the same personal protective equipment as yours.
- Place your sterile drape on a previously disinfected area.
- Never place the Centrifuge Container on a sterile drape.
- Materials in the pack are double foliated. When tearing the packs, never place the outer pack on the sterile drape, and dispose of it as the domestic waste.
- Unpack the materials according to the aseptic rules and place them on the sterile drape in order.
- Check the number and type of pack contents you have placed on the sterile drape with the Centrifuge Container content list.

Note: Some of the operating instructions listed below may be performed in parallel, since the above-mentioned auxiliary operation mode will shorten the processing time. Thus, you may target obeying the aseptic rules and reducing the risk of contamination by decreasing the process time.

Operation of the Centrifuge Container


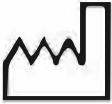





<p>1. Transfer the harvested adipose tissue to the assembled Lipocube Centrifuge Container with the help of FDA cleared connector.</p>	
<p>2. Pull the plunger of processed fat fill syringe till the end where the gasket meets the flange. Before process, screw the FDA cleared combi stopper to the tip of the syringe.</p>	
<p>3. Remove the modular plungers by unscrewing from the tip points and make the syringe ready for centrifugation.</p> <p>4. Switch on and adjust the centrifuge machine according to the manufacturer's supplied user instructions.</p> <p>5. Place the Lipocube Centrifuge Container into the sample holder facing the flange downside of the holder (the combi stopper will face up). In case of missing fat volume, use the same amount of phantom on the opposite arm of the sample holder to balance the placed sample. Close the centrifuge lid and adjust the speed to 1800G for 3 minutes.</p>	







<p>6. Open the lid of centrifuge after the process is completed. Observe the adipose tissue in three different phases where the targeted material precipitates in the middle. Remove the Lipocube Centrifuge Container from the centrifuge carefully (without shaking or turning upside down). Keep the flange down and attach the plunger body. Keep in mind that from then on, you should always keep the Lipocube Centrifuge Container tip up and vertical.</p>	
<p>7. Attach the FDA cleared connector to the tip of the Lipocube centrifuge container and attach an empty 20ml lock FDA cleared syringe to the opposite end of the connector. 8. Push the content of the centrifuged Lipocube Centrifuge Container towards the empty syringe until middle layer and take the middle layer in new syringe which will be processed by Lipocube cubes.</p>	






Packaging Configuration:

Differences	Lipocube Centrifuge Container
Packaging Content	4 Centrifuge Containers (15CC/20CC)

Symbol Glossary:

Symbol	Standard Reference	Symbol Title	Explanatory Text
	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)	Manufacturer	Indicates the medical device manufacturer
	ISO 15223- 1:2016 Reference no. 5.1.3. (ISO 7000-2497)	Date of manufacture	Indicates the date when the medical device was manufactured
	ISO 15223- 1:2016 Reference no. 5.1.4. (ISO 7000-2607)	Use by date	Indicates the date after which the medical device is not to be used iso_15223 Use-by date iso_grs_7000_2607 Use by date
	ISO 15223- 1:2016 Reference no. 5.1.5. (ISO 7000-2492)	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223- 1:2016 Reference no. 5.1.6. (ISO 7000-2493)	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified ISO 15223 Catalogue number ISO 7000 Catalog number
	ISO 15223-1:2016 Reference no. 5.2.4. (ISO 7000-2502)	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	ISO 15223-1:2016 Reference no. 5.2.6.(ISO 7000-2608)	Do not resterilize	Indicates a medical device that is not to be resterilized

Symbol	Standard Reference	Symbol Title	Explanatory Text
	ISO 15223- 1:2016 Reference no. 5.3.1. (ISO 7000-0621)	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	ISO 15223- 1:2016 Reference no. 5.3.2. (ISO 7000-0624)	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	ISO 15223- 1:2016 and ISO 15223-1:2020(E) DRAFT Reference no. 5.3.4. (ISO 7000-0626)	Keep dry Keep away from rain	Indicates a medical device that needs protection from moisture ISO 15223 Keep dry ISO 7000 Keep away from rain
	ISO 15223- 1:2016 Reference no. 5.3.7. (ISO 7000-0632)	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	ISO 15223- 1:2016 Reference no. 5.2.8. (ISO 7000-2606)	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	ISO 15223-1:2016E Reference no. 5.4.2. (ISO 7000-1051)	Do not re-use	Indicates a medical device that is intended for one single use only NOTE: Synonyms for “Do not reuse” are “single use” and “use only once”.

Symbol	Standard Reference	Symbol Title	Explanatory Text
	ISO 15223-1:2016 and ISO 15223-1:2020 Reference no. 5.4.3. (ISO 7000-1641) Reference no. 5.4.3. (ISO 7000-1641)	Consult instructions for use Operator's manual; operating instructions	Indicates the need for the user to consult the instructions for use iso_15223 Consult instructions for use iso_grs_7000_1641 Operator's manual; operating instructions
	ISO 15223- 1:2016 Reference no. 5.4.4. (ISO 7000-0434A)	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences
R_x Only	N/A	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	DIRECTIVE 2012/19/ EU (WEEE)	Collect separately	Separate collection for waste. Do not dispose of in municipal waste. The symbol indicates separate collection is required.
	NA	Fat Flow Route	These dots show the fat flow route through the device
	NA	Counterclock wise Positioning	This shows the counterclockwise direction

Manufacturer:

StemC Biotechnology Inc
Merkez Mah. Baglar Cad. No:14
B IC Kapı No:27 Kagithane/ Istanbul 34330 TR