Reference Number

Use by

Do not re-use. For single use only

Do not re-sterilize

Store at 59°F to 86°F (15°C to 30°C)

Manufacturer

Bimini Health Tech
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Lot Number

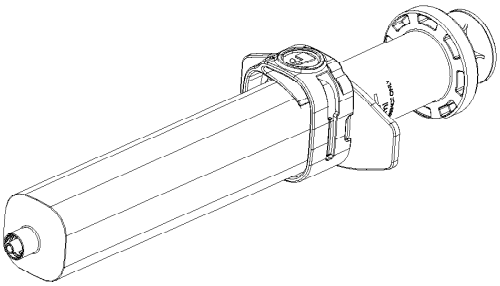
Sterilized using Ethylene Oxide

Do not use if package is damaged

Keep package dry

See Instructions For Use

dermapose



INSTRUCTIONS FOR USE

Dermapose™ Refresh

Microsizing Syringe

600-035-01 Rev D
Effective Date: 03/31/2025

Description

Dermapose™ Refresh is a sterile, single use, microsizing syringe system intended for the harvesting, concentrating, and transferring of autologous fat tissue back to the same patient when the transfer of harvested adipose tissue is desired. It consists of a 50 mL vacuum-lock syringe with a built-in, 800 µm filter for screening the tissue particle size to allow for easier injection through small, 18-21G injectors. For optimum performance, Dermapose Refresh should be used in conjunction with the Dermapose Refresh Stand, which is a reusable, autoclavable component designed to hold the syringe securely during use.

Dermapose Refresh is composed of the following components:

Components	Quantity
Dermapose Refresh	1
30 mL Luer Lock Syringe	2
Luer Lock Cap, Orange	3
Female Luer to Luer Transfer	1
Harvest/infiltration cannula	1

Indications For Use

The Dermapose Refresh is a sterile medical device intended for the closed-loop processing of lipoaspirate tissue in medical procedures involving the harvesting, concentrating and transferring of autologous adipose tissue harvested with a legally marketed lipoplasty system.

The device is intended for use in the following surgical specialties when the transfer of harvested adipose tissue is desired: orthopedic surgery, arthroscopic surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, gynecological surgery, thoracic surgery, laparoscopic surgery, and plastic and reconstructive surgery when aesthetic body contouring is desired.

Only legally marketed accessory items, such as syringes, should be used with the system. If harvested fat is to be transferred, the harvested fat is only to be used without any additional manipulation.

Contraindications

The following are contraindications for use of Dermapose Refresh:

- Intravenous applications.

Sterility

Dermapose Refresh is sterilized with ethylene oxide.

Storage and Handling

- Store at controlled room temperature 59°F to 86°F (15°C to 30°C).

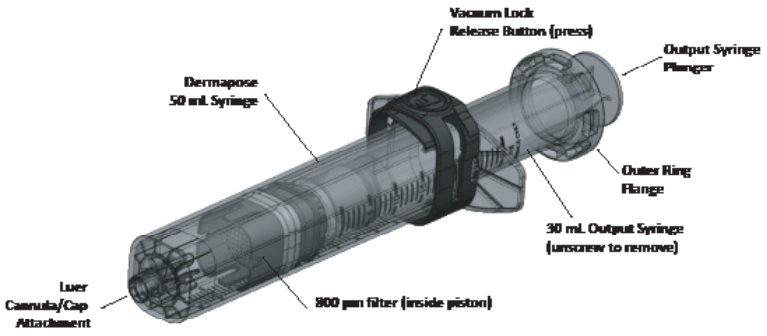
Warnings

- 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 Dermapose Refresh during the same procedure. Re-use may compromise the sterility and adversely affect performance of the system.
- Do not overfill Dermapose Refresh with more than 50 mL 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.

Precautions

- Inspect the Dermapose Refresh package for signs of damage prior to using.
- Dermapose Refresh is for single use only and must be used immediately after removal from the sterile packaging.
- Discard the entire Dermapose Refresh if the packaging is damaged or opened.
- Aseptic techniques must be used to minimize the possibility of contamination of Dermapose Refresh.
- Treat all blood and fluids using Universal Precautions (Blood-borne Pathogen Precautions).
- This device is designed to remove localized deposits of excess fat through small incisions and 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 Dermapose Refresh may result in a biohazard to the operating staff and/or device malfunction.
- Dermapose Refresh is intended to be used in combination with luer lock syringes (not included) for final delivery.
- Adipose tissue harvested using cannula larger than 2.1 mm may cause clogging (1.6 mm maximum hole size is recommended).
- European Reporting Requirements: Any serious incident that has occurred in relation to the device should be reported to Bimini Health Tech and the competent authority of the Member State in which you, as the user and/or patient, are established.

Diagram



Operating Instructions

PREPARATION

1. An anesthetic solution should be compounded and introduced to the patient, per physician direction using aseptic technique.
2. Peel open the tray to reveal sterile contents and remove the sterile Dermapose Syringe.
3. Attach a luer lock cannula to the Dermapose 50 mL Syringe (2.1 mm cannula with 1.6 mm maximum hole size is recommended).
4. Compress the syringe to its minimum volume in preparation of harvest.

HARVESTING

5. Following sterile technique and liposuction best practices, introduce cannula into patient with syringe in compressed position. Pull Output Syringe to create vacuum; Output Syringe will lock in place near the 50 mL mark.
6. Perform syringe vacuum harvest until desired volume is obtained or a maximum of 50 mL of lipoaspirate is obtained. The final output of clean, sized fat tissue will be approximately 25-40% of the lipoaspirate (12-20 mL is a typical output).
7. Cap syringe with supplied orange luer cap and decant syringe with cap down for 5 minutes in the Dermapose Refresh Stand (not included).

WASHING

8. To drain tumescent waste fluid, remove the orange cap and expel the lower fraction of fluid.
9. To wash tissue, introduce 15 mL of Lactated Ringers' solution into the syringe via the included 30 mL syringe and luer-to-luer connecter and agitate contents for 10 seconds.
10. Cap syringe, place in Dermapose Refresh Stand, and decant for 3 minutes.
11. To drain wash waste, remove the cap and expel the lower fraction of fluid.
12. Perform a second wash by repeating steps 9-11.

SIZING

13. After tissue is sufficiently washed and drained, cap syringe and place into the Dermapose Refresh Stand.
14. With the syringe securely sitting tip down in the stand and the cap on, press the Vacuum Lock Release Button and compress the Outer Ring Flange of the 30 mL Output Syringe. This will force Output Syringe Plunger to rise and fill with microsized tissue.

    Note: if the tissue will not flow, be sure you are not blocking the movement of the Output Syringe Plunger. If it still will not flow, it is possible that the screen is clogged. Ensure that the harvest cannula was of appropriate size, per step 3.
15. Remove this 30 mL Output Syringe by unscrewing it from the Dermapose 50 mL Syringe.

DELIVERY

16. Transfer the microsized tissue to small syringes for injection via the clear luer-to-luer transfer adapter (included).

    Note: 1 mL or 3 mL luer lock syringes (not included) are recommended for injection. It is recommended to use a 21G (0.8 mm) or larger injection cannula to limit clogging.
17. After all tissue has been transferred into injection syringes, properly dispose of all components using Universal Precautions for Blood-borne Pathogens

℞ ONLY CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.