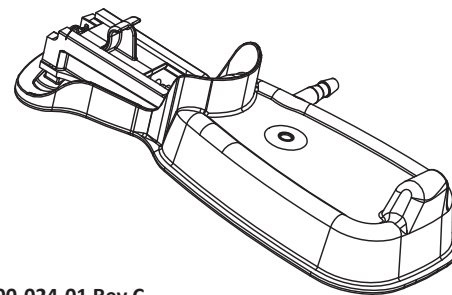


dermapose
Access



INSTRUCTIONS FOR USE

**Dermapose™
Access**
Fat Harvest System

600-024-01 Rev C
Effective Date: 2022-Nov-15

Description

Dermapose™ Access is a sterile, single use, system intended to assist the harvesting of autologous fat grafts from a patient for aesthetic body contouring. It creates a guided incision for cannula introduction at a controlled depth (10 mm) under the skin for the purpose of small volume adipose tissue harvest. Dermapose Access is composed of the following components:

Components	Quantity
Dermapose Access System	1
Harvest/infiltration cannula	1

Indications For Use

The Dermapose Access fat harvest system is intended for use in aesthetic body contouring.

Contraindications

The following are contraindications for use of Dermapose Access:

- Intravenous applications.

Sterility

Dermapose Access 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.
- 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 or lung diseases, circulatory diseases, 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.

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

REF

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

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LOT

Lot Number

STERILE EO

Sterilized using Ethylene Oxide



Do not use if package is damaged



Keep package dry



See Instructions For Use

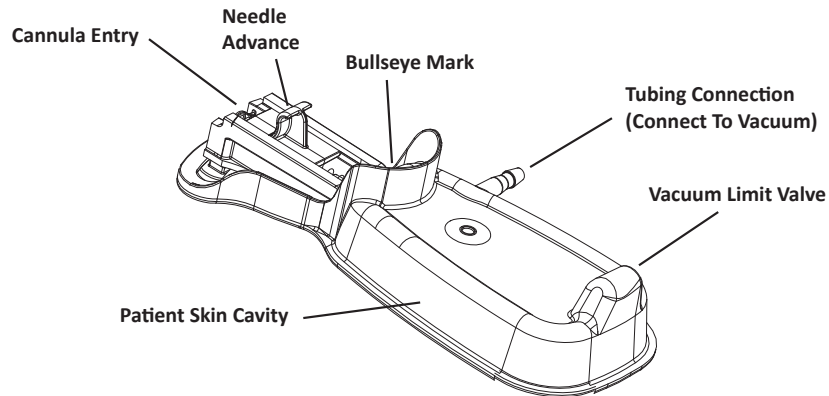
Precautions

- Inspect the Dermapose Access package for signs of damage prior to using.
- Discard Dermapose Access if the packaging is damaged or opened.
- Dermapose Access contains a sharp needle. Use caution when handling.
- Dermapose Access is for single use only and must be used immediately after removal from the sterile packaging.
- Aseptic techniques must be used to minimize the possibility of contamination of Dermapose Access.
- Treat all blood and fluids using Universal Precautions (Blood-borne Pathogen Precautions).
- Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education, have demonstrated proficiency in suction lipoplasty.
- Physicians must use reasonable judgment in deciding when and where to use the product. This should include an assessment of sufficient adipose tissue for harvesting.
- This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
- Procedure results will vary depending upon patient age, surgical sites, and experience of the physician.
- Results of this procedure may or may not be permanent.
- Tissue removed should be limited to that necessary to achieve a desired cosmetic effect.
- Dermapose Access is intended to be used in combination with luer lock syringes (not included) for syringe vacuum aspiration (Dermapose Refresh is recommended).
- Do not use a cannula other than what is provided.
- **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.

Vacuum Pump Requirements

A vacuum pump capable of at least 18 inHg (60 kPa) of vacuum is required in order to lift the patient's skin into the guide cavity (it is not being used for liposuction). The pump should have a standard barb fitting of approximately ¼". It is not necessary to have a collection canister (as fluid should not enter the tubing) but it is recommended in case of leakage. To protect the pump from possible fluid ingress Dermapose Access includes a protective filter.

Diagram



Additional Supplies

The following supplies are commercially available and are not included with Dermapose Access:

- Topical anesthetic (optional).
- Sterile gauze and surgical tape (or equivalent).
- Local injectable anesthetic solution per prescribing physician.
- Sterile anesthetic introduction system (such as a syringe or syringe repeater system).
- Sterile patient marker, sterile drape, sterile gloves, disposal equipment, luer syringes.

Operating Instructions

PREPARATION

1. Prepare the treatment area using sterile, aseptic technique.
2. Mark the intended location of the Dermapose Access on the patient with a 1" circle around the intended incision location. If desired, apply a topical or local anesthetic to this location to minimize pain.
3. Peel open the tray to reveal sterile contents and place onto sterile field.
4. Uncoil tubing to ensure it is free of folds and creases. If folds and creases are present, pinch tubing perpendicular to the area and roll it for relief.
5. Connect the tubing to the vacuum pump, pinch or block tubing, turn on pump and set vacuum to 18 inHg (60 kPa). Turn off pump.
6. An anesthetic/tumescent solution should be compounded and prepared in a syringe (25 mL per site is recommended), per physician direction at the location to be harvested. **To minimize contour irregularities, it is recommended to harvest only as much tissue as required and from inconspicuous locations such as the inner thigh or love handle.** It is recommended that tissue is harvested symmetrically from the patient.
7. Attach supplied cannula to tumescent solution syringe and purge air from syringe.

TUMESCENT INTRODUCTION

8. Align the needle entry location (Bullseye Mark) within the marked circle on the patient and turn on pump. Check that skin is taut into Patient Skin Cavity.
Note: Dermapose Access is equipped with Vacuum Limit Valve to limit vacuum to approximately 18 inHg (60 kPa). When activated, the valve may make a vibrating sound as it controls the vacuum.
9. Introduce the cannula/tumescent syringe into the Cannula Entry hole and slide in approximately 2" (50 mm) until it hits the silicone membrane seal. Confirm that the pump is on and skin is taut. **Vacuum must remain on until tissue harvest is complete.**
10. Slowly but firmly slide Needle Advance forward to penetrate the silicone membrane and patient skin. Confirm that needle has penetrated skin, follow through with the cannula. Release the spring-loaded Needle Advance to safely retract the needle, leaving the cannula in place.
11. Infuse target area with tumescent solution using range of motion provided by device articulation.
12. Remove cannula, leave vacuum pump on, and allow anesthetic to take effect per physician direction.

TISSUE HARVEST

13. Attach the supplied 2.1 mm x 150 mm cannula to a luer lock syringe (Dermapose Refresh is recommended).
14. Following sterile technique and liposuction best practices, introduce cannula into patient through Cannula Entry hole with syringe in compressed position and pull syringe open to create vacuum.
15. Perform syringe harvest until desired volume is obtained or a maximum of 50 mL of lipoaspirate is obtained. Remove cannula and turn off vacuum pump (or disconnect tubing) when harvest is complete.

TISSUE WASHING

16. For optimum fat transfer results, use a commercially available, closed-system, sterile filtration device (such as Dermapose Refresh or Puregraft 50) to reduce the amount of tumescent solution, broken adipocytes, blood and lipids.

DELIVERY

17. After tissue is sufficiently washed and drained, transfer tissue to 1 mL or 3 mL syringes and attach preferred injection cannulas (not included).
18. After tissue has been transferred to injection cannulas, properly dispose of all components according to your facility's sharps disposal procedure and Universal Precautions for Bloodborne Pathogens.