Biomet Biologics
P.O. Box 587
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Warsaw, Indiana 46581 USA

01-50-1469
Date: 2010-08

Vortech™ Adipose Transfer System (VATS)

ATTENTION OPERATING SURGEON

NOTE: FOR SINGLE USE ONLY. Discard all disposable components of the system after one use, using an acceptable disposal method for products potentially contaminated with blood.

DESCRIPTION

The Vortech™ Adipose Transfer System contains a Fat Concentrator that is used to remove excess fluid from adipose tissue by centrifugation utilizing the Vortech™ base unit. The Fat Concentrator is used for concentrating the patient's own fatty tissue harvested with a legally marketed lipoplasty system for autologous fat transfer procedures. The device is filled with adipose tissue and then processed on a base unit. The 4 ½ minute-centrifugation process removes excess fluid from fatty tissue. After removal of surplus fluid is completed, adipose tissue is available for use as deemed necessary by the clinical requirements.

MATERIALS

The materials used in the Fat Concentrator, syringes, and accessories consist of medical grade polymers, elastomers, and stainless steel suitable for use in medical devices. All components are packaged, labeled and sterilized as indicated by the manufacturer's labeling. All components in this kit are latex-free.

INDICATIONS

The Vortech™ Adipose Transfer System is used in medical procedures involving the harvesting and transferring of autologous tissue. The Vortech™ Adipose Transfer System is used for concentrating fat harvested with a legally marketed lipoplasty system. The Vortech™ Adipose Transfer System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired.

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

CONTRAINDICATIONS

DO NOT reinject adipose tissue intravascularly.

1. Do not connect to a patient's vascular system of circulating blood volume.

WARNINGS

1. This device will not, in and of itself, produce significant weight reduction.
2. 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.
3. 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 replacement is essential for patient safety.
4. Single use device. Do not reuse.
5. Do not use components of this system if package is opened or damaged.
6. Use only the Vortech™ base unit with Fat Concentrator.
7. Follow Vortech™ Operator's Manual, 01-50-1433, when using the base unit.
8. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
9. Use of this device requires the harvesting of potentially clinically significant amount of fat tissue from the patient.

PRECAUTIONS

1. This device is designed to remove localized deposits of excess fat through small incisions and subsequently transfer the tissue back to the patient.
2. 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.
3. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
4. Results of this procedure may or may not be permanent.
5. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.
6. The patient is to be made aware of the general risks associated with treatment and possible adverse effects.
7. The impact of the fatty tissue loss on the health status of the patient should be considered.
8. To minimize clogging of adipose tissue, use a 4 mm or smaller cannula when loading the harvested fat into the Fat Concentrator.

POSSIBLE ADVERSE EFFECTS

1. Early or late postoperative infection.

STERILITY

The Vortech™ Adipose Transfer System is sterilized by exposure to a minimum dose of 25 kGy gamma radiation. All other components supplied in this system are sterilized by their respective suppliers. Single Use Only. Do not resterilize. Do not use any component from an opened or damaged package or past the expiration date.

INSTRUCTIONS FOR USE

NOTE: Use standard aseptic technique throughout the following procedures.

1. Fill (3) 60 ml syringes with harvested adipose tissue.
2. Remove the red cap from the port on the top of the fat concentrator. Carefully attach and load the first syringe containing the adipose tissue. Repeat for the two remaining syringes. Remove luer extension (which allows concentrator to cycle freely).
3. Press the green button on the base to begin the cycle. The device will cycle for approximately 4 ½ minutes. However, the green button can be pressed a second time to stop the cycle.
4. Attach the desired syringe to the extraction port and withdraw the product.

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

Comments regarding the use of this device can be directed to Attn: Regulator Affairs, Biomet, Inc., P.O. Box 587. Warsaw, IN 46581 USA, Fax: 574-371-3968.

Authorized Representative: Biomet U.K., Ltd.
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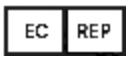
Symbol Legend	
	Manufacturer
	Date of Manufacture
	Do Not Reuse
	Caution
	Sterilized using Ethylene Oxide
	Sterilized using Irradiation
	Sterile
	Sterilized using Aseptic Processing Techniques
	Sterilized using Steam or Dry Heat
	Use By
	WEEE Device
	Catalogue Number
	Batch Code
	Flammable
	Authorized Representative in the European Community