



OptiMesh®

Spineology Inc.
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CAUTION: United States Federal law restricts this device to sale by or on the order of a physician.

DESCRIPTION

OptiMesh® is a sterile mesh graft containment device knitted from polyester yarn made of polyethylene terephthalate (PET) thread. OptiMesh is offered in a range of shapes and sizes. Each mesh is supplied on a disposable holder for ease of handling and placement. OptiMesh is packaged into double Tyvek/Mylar film pouches, placed in a carton, and then terminally sterilized by gamma radiation.

The OptiMesh PET material is not bioresorbable.

OptiMesh is designed to maintain the relative position of bone graft materials, thereby limiting the migration of the graft materials into unintended areas.

Spineology Inc. expressly warrants that these devices are fabricated from the foregoing material specifications. No other warranties, expressed or implied, are made.

INTENDED USE / INDICATIONS

OptiMesh is intended to maintain the relative position of bone graft material (such as autograft or allograft) within a vertebral body defect (e.g. tumor) that does not impact the stability of the vertebral body and does not include the vertebral endplates.

The safety and effectiveness of this device used for fusion of the interbody space has not been established.

CONTRAINDICATIONS

- Do not use this device in patients with instability (e.g. resected or collapsed vertebral bodies or fracture of the anterior column). This device does not provide structural support.
- Infection, systemic or local, to the surgical site is a contraindication for placement of any surgical implant.
- Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery.
- Any patient unable or unwilling to adhere to physician's postoperative instructions.
- Circulatory problems, such as thrombophlebitis, lymphedema, uncorrectable coagulopathy, or vascular deficiency at the implant site are contraindications for bone grafting.

PRECAUTIONS

- Spineology's OptiMesh instruments are to be used as directed for proper filling of the mesh.
- The surgeon should be familiar with the use of OptiMesh instruments prior to surgery.
- OptiMesh is provided sterile. Product packaging should be inspected for continuity and the components should be handled appropriately to ensure sterility.
- Resterilization of OptiMesh is not recommended under any circumstances.
- OptiMesh should never be reused.
- OptiMesh is not intended to be trimmed or cut.

CLEANING AND DECONTAMINATION

Cleaning Instructions

Cleaning and decontamination of previously used instruments is required before subsequent introduction into the sterile field.

- Following use, disassemble devices as instructed for cleaning.
- Preventing drying prior to cleaning will facilitate cleaning.
- Soak in enzymatic detergent (mixed per manufacturer's recommendations) for one (1) minute or longer.
- Use a soft brush for manual cleaning and a soft bottle brush to clean the tube devices. Pay special attention to inner diameters and crevices during cleaning.
- Ultrasonic cleaning is acceptable, per established hospital methods.
- Rinse thoroughly under running water for one (1) minute or longer.

Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments which exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned and resterilized immediately after use.

STERILIZATION

All instruments must be sterilized by the hospital before use and following any cleaning and decontamination procedures. Instrument trays are provided for storing and sterilizing the instruments. Sterilization can be performed on wrapped trays with the following cycle parameters:

Sterilization Method:	Steam
Sterilizer Type/Cycle:	Prevacuum
Temperature:	132 degrees C Minimum 270 degrees F Minimum
Exposure Time:	4 Minutes Minimum

Deviations from the recommended methods of cleaning and decontamination are not advised. It is the sole responsibility of the user to qualify such deviations.

A surgical technique manual will be available, including information regarding instrument use, size selection and filling of the device.

FURTHER INFORMATION OR PRODUCT COMPLAINTS:

Contact Spineology at:



Spineology Inc.

7200 Hudson Blvd. N., Suite 205
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Phone: 1.651.256.8500
Fax: 1.651.256.8505

DEVICE RETRIEVAL

Contact Spineology to discuss Revision / Retrieval.

E.U. AUTHORIZED REPRESENTATIVE

Quality First International
Bexhill-on-Sea, United Kingdom



SYMBOL DEFINITIONS



Quality First International: E.U. Authorized Representative



Refer to package insert included with implants for indications for use.



Method of Sterilization: Irradiation



Expiration Date



Lot Code (for traceability)



Single Use Only



Catalog Number