MIROMESH™ is a non-crosslinked acellular surgical mesh that is derived from the highly vascularized porcine liver.
Because only Miromatrix® Medical can decellularize the whole liver, the resulting biologic mesh, made from full thickness sections of the liver, has unique characteristics. 

MIROMESH is easy to handle, provides an open collagen network, and is supplied terminally sterilized 10^6 SAL (Sterility Assurance Levels) in a pre-hydrated state. MIROMESH has been validated for viral inactivation.

The native vasculature of the liver down to the capillary beds is preserved within MIROMESH as demonstrated through the perfusion of a red dye through an open vessel into a MIROMESH that has been clamped around the edges.

PRECLINICAL STUDIES SUGGEST CELLULAR IN-GROWTH AND REVASCULARIZATION

30 days post-implant in a rat model, robust cellular ingrowth and neovascularization (arrows) deep into MIROMESH are demonstrated.2

30 days post-implant in a rabbit model, robust vascular overgrowth is demonstrated on MIROMESH.4

30 days post-implant in a rabbit model, histological evidence indicates fibroblasts migrating deep into MIROMESH via the native vascular network and aligning within the matrix.3
Miromatrix is engaged in the development of fully biological human organs for transplant. This work has progressed at a rapid pace and is applicable to liver, kidney, lung, pancreas, heart, bone and a variety of other tissues and organ components (for example, heart valves). The positive conclusion of our efforts will mean an end to the organ transplant waiting list and such incredible things as the elimination of much of dialysis and a cure for liver failure. We intend to revolutionize patient care and to truly make a difference.

**BIOLOGIC MESH MANUFACTURING BY WHOLE LIVER PERFUSION DECELLULARIZATION**

Perfusion decellularization rapidly removes cellular material while maintaining the native architecture, vasculature and tissue structure.

**PERFUSION DECELLULARIZATION OF MAJOR ORGANS**

**LUNG**

The successful perfusion decellularization, recellularization, and transplantation of a rat lung in a rat model to demonstrate oxygen transport

**LIVER**

The successful revascularization and transplantation of a re-endothelialized perfusion decellularized whole liver into a pig model followed by an angiogram after 1 hour to demonstrate the lack of thrombosis

**KIDNEY**

Following 1 hour of native blood flow through the revascularized liver, radiopaque dye was infused to demonstrate the lack of thrombosis and maintenance of the capillary beds

**MIROMATRIX MEDICAL INC.**

The future is now

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CAUTION
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. This product is intended for use by trained medical professionals.

DEVICE DESCRIPTION
Miromatrix Biologic Mesh is a noncrosslinked acellular surgical mesh that is derived from the highly vascularized porcine liver and is processed and stored in a phosphate buffered aqueous solution. Miromatrix Biologic Mesh is packaged in an inner sterile pouch and outer non-sterile pouch.

INTENDED USE
The Miromatrix Biologic Mesh is intended to be implanted to reinforce soft tissue.

CONTRAINDICATIONS
This device is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

WARNINGS
Do not resterilize.
This product is for single use only; discard all open and unused portions of the device.
Do not use if the package is opened or damaged
Do not use if seal is broken or compromised.
After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

PRECAUTIONS
Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
Soak the device for a minimum of 2 minutes using a sterile basin and room temperature sterile saline or room temperature sterile lactated Ringer’s solution to cover the mesh.
Place device in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
Miromatrix Biologic Mesh should be hydrated and moist when the package is opened. If Miromatrix Biologic Mesh is dry, do not use.

STORAGE
Miromatrix Biologic Mesh is a sterile medical device that should be stored in a clean, dry location at room temperature, in its original packaging. Avoid prolonged exposure to elevated temperatures.
Expiration date of the product is indicated as year (4 digits) and month (2 digits). The product expires after the last day of the month indicated.
Do not use the product if the heat indicator has been activated.

STERILIZATION
This product has been sterilized with electron beam irradiation.

REFERENCES
1. A vessel on the open edge of MIROMESH was cannulated and a red dye was injected into the graft to demonstrate the presence of the native liver vasculature, including the capillaries, within MIROMESH.
2. Study information on file at Miromatrix Medical Inc.
3. Study information on file at Miromatrix Medical Inc.
4. Study information on file at Miromatrix Medical Inc.
6. Study performed at Miromatrix Medical Inc. and The Mayo Clinic.