



XENMATRIX™ AB Surgical Graft

Porcine Dermal Matrix

Coated with Rifampin and Minocycline

Instructions for Use

 Single Use



Read all instructions prior to use

R_x only

 Do not resterilize

STERILE EO



Storage not to Exceed 30°C



Manufacturer:

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BAIRD

DAVOL INC.



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PRODUCT DESCRIPTION

XENMATRIX™ AB Surgical Graft is an acellular, sterile, non-pyrogenic porcine dermal matrix packed dry for use in the reconstruction of soft tissue deficiencies. The device surfaces are coated with the antibacterial agents Rifampin and Minocycline in a bioresorbable L-Tyrosine succinate polymer carrier. The product is designed to have a uniform orange surface and some minor non-uniform color variation on the product surface is normal.

ACTIONS

The device surfaces are coated with a bioresorbable L-Tyrosine succinate polymer which serves as a carrier for the antibacterial agents Rifampin and Minocycline, in equal concentrations of approximately 180 µg/cm². The coating is shaded orange in color from the antimicrobial agents. Absorption of the resorbable polymer carrier is essentially complete in approximately 12 months based on in vitro studies.

In preclinical in vitro and in vivo testing, the antimicrobial agents reduce or inhibit microbial colonization of the device (please see performance data section below). The claim of reduction of bacterial colonization of the device has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

Preclinical effectiveness results cannot be considered predictive of clinical performance.

STORAGE

Store the XENMATRIX™ AB Surgical Graft in a dry environment and protected from direct sunlight. Store at room temperature not to exceed 30°C (86°F). It is for single use only. Do not use if the package is damaged or open.

INDICATIONS

Intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue, including: abdominal plastic and reconstructive surgery; muscle flap reinforcement; hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias. The Rifampin and Minocycline coating has been shown in preclinical in vitro and in vivo testing to reduce or inhibit microbial colonization in the device. The claim of reduction of bacterial colonization of the device has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

CONTRAINDICATIONS

1. XENMATRIX™ AB Surgical Graft should not be used on patients with known sensitivity to porcine products.
2. Do not use in patients with allergy, history of allergy or hypersensitivity to tetracyclines or rifamycins or other components in the device.
3. Do not use in pregnant or nursing women.
4. The contraindications, warnings and precautions regarding the use of the antimicrobial agents Rifampin (a derivative of rifamycinB) and Minocycline (a derivative of tetracycline) apply and should be considered when using this device. See FDA's drug labeling database for Rifampin and Minocycline labeling. For reference the contraindications for Minocycline and Rifampin are as follows:

Contraindications for Oral Capsule (1 mg/kg) of Minocycline:

- This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

Contraindications for both IV (600mg) and Oral Capsule (150mg-300mg) of Rifampin:

- Rifampin is contraindicated in patients with a history of hypersensitivity to Rifampin or any of the components, or to any of the rifamycins.

The use of this product in patients with compromised hepatic function should be carefully considered since Rifampin can cause additional stress to hepatic metabolism. Implantation of this device would not result in detectable systemic concentrations of Rifampin or Minocycline.

Patients implanted with the largest product size (30 cm x 45 cm) are calculated to receive a one time total dose of approximately 327 mg each of Rifampin and Minocycline. This is in contrast to typical systemic treatment doses, which are 600 mg for Rifampin and 200 mg for Minocycline administered multiple times per day, over several days to several months.

5. Not for reconstruction of cardiovascular defects.
6. Not for reconstruction of central nervous system or peripheral nervous system defects.
7. Use of this product in applications other than those indicated has the potential for serious complications.

WARNINGS

1. **This device is not indicated for the treatment of infection. If an infection develops, treat the infection aggressively.**
2. **To minimize recurrences when repairing hernias, the graft should be large enough to provide sufficient overlap beyond the margins of the defect on all sides.**
3. **Prior to use, carefully examine package and product to verify neither is damaged and that all seals are intact. Do not use if the package is damaged or open.**
4. **Postoperative signs of toxicity, as possible evidenced by worsening renal or hepatic function, or an allergic reaction that is unrelated to other therapy is an indication to consider removal of XENMATRIX™ AB Surgical Graft.**
5. **Do not use this product in patients with allergy, history of allergy or hypersensitivity to tetracyclines or rifamycins or other components of the device.**
6. **The safety and performance of XENMATRIX™ AB Surgical Graft in pediatric patients has not been evaluated.**

7.  After use, any unused product and packaging should be treated as a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
8. Do not resterilize. This device has been designed for single use only. Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.

PRECAUTIONS

1. Please read all instructions prior to use.
2. Strict aseptic technique should be followed.
3. The use of this product in patients with compromised hepatic function should be carefully considered since Rifampin can cause additional stress to hepatic metabolism. Rifampin given at systemic therapeutic doses over multiple days, has been shown to produce liver dysfunction. Fatalities associated with jaundice have occurred in patients with liver disease and in patients taking Rifampin with other hepatotoxic agents systemically. Patients with impaired liver function should be given Rifampin systemically only in cases of necessity and then with caution and under strict medical supervision. In these patients, careful monitoring of liver function, especially SGPT/ALT and SGOT/AST should be performed prior to therapy.
4. The risk of anti-anabolic effects (azotemia, hypophosphatemia, and acidosis) can be observed when using tetracyclines post-surgery. In patients with significantly impaired renal function, monitoring of Creatinine and BUN for 24 hours is recommended.
5. Do not alter practice of pre-, peri-, or postoperative administration of local or systemic antibiotics.
6. U. S. federal law restricts this device to sale by or on the order of a physician.
7. Only physicians qualified in the appropriate surgical techniques should use this surgical graft.
8. The surgeon should thoroughly understand the surgical procedure and the performance characteristics of the surgical graft.
9. Place device in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
10. When unable to close skin over the XENMATRIX™ AB Surgical Graft, ensure that the implant remains moist. Avoid drying of the implant through “continued suction devices” as this may negatively impact the performance of the implant.
11. Due to the orange color in the coating, hydration solution and fluid from surgical drains may be tinted orange.

ADVERSE REACTIONS

Potential complications with the use of any prosthesis may include, but are not limited to, allergic reaction or hypersensitivity to device materials or antimicrobial coating, seroma, infection, inflammation, adhesion, fistula formation, erosion, hematoma, and recurrence of tissue defect.

INSTRUCTIONS FOR USE

Use sterile gloves and/or atraumatic instruments to open package.

Preparation

XENMATRIX™ AB Surgical Graft requires hydration. Some larger graft sizes are supplied with hydration trays. If the graft is not supplied with a hydration tray, use a sterile medical basin large enough to fully submerge the graft in hydration fluid. Place the entire graft in room temperature sterile saline or sterile water for at least 5 minutes prior to implantation. The safety and effectiveness of hydrating the graft in combination with solutions other than sterile saline or sterile water have not been tested.

 **Warning:** Do not hydrate the graft for more than 20 minutes. The antimicrobial surface coating has been optimized for hydration times less than 20 minutes. Hydrating for longer than 20 minutes may impact the function of the antimicrobial coating of the implant.

Sizing

Using the proper graft size is essential. The surgical graft should be large enough to provide sufficient overlap beyond the margins of the defect on all sides. Using a XENMATRIX™ AB Surgical Graft that is too small for the defect can cause excessive tension on the suture line.

Deployment

XENMATRIX™ AB Surgical Graft may inhibit deployment through trocars during laparoscopic repairs. If the XENMATRIX™ AB Surgical Graft cannot be easily deployed down the trocar, remove the trocar and insert the implant through the incision. Reinsert trocar.

Fixation

Appropriate fixation is essential to ensure secure graft contact with well vascularized tissue. XENMATRIX™ AB Surgical Graft should be fixated with suture under minimal or no tension. Careful attention to fixation placement and spacing will help prevent excessive tension or gap formation between the graft and fascial tissue.

PERFORMANCE DATA

The safety and performance of the XENMATRIX™ AB Surgical Graft was evaluated in the following assessments:

Biocompatibility testing

Biocompatibility testing in accordance to the current ISO 10993 series was conducted on the finished device and the results indicate that the device is biocompatible per these standards.

Bench testing

Bench testing was conducted comparing the XENMATRIX™ AB device with currently marketed surgical mesh. The testing included the following:

1. Physical Characteristics:
 - a. Device Thickness
 - b. Device (Flexural) Stiffness
2. Functional Characteristics:
 - a. Burst Strength
 - b. Suture Pullout Strength
 - c. Tear Resistance

Results demonstrate that the physical and functional characteristics of XENMATRIX™ AB Surgical Mesh are comparable to those of currently marketed surgical mesh devices.

In vivo strength determinations

The device was implanted in a 28 day, porcine evaluation model and tested for strength characteristics in comparison to currently marketed surgical mesh. This study assessed the following characteristics of the implanted mesh at Time zero (T₀) and Day 28 (D₂₈):

1. Mechanical Testing
 - a. Tensile Strength Testing
 - b. Tissue Ingrowth Testing
 - c. Device Burst Testing
2. Percent Area Contracture
3. Peritoneal Tissue Attachments
4. Histology

Results demonstrate that the in vivo performance of XENMATRIX™ AB Surgical Mesh is comparable to those of currently marketed surgical mesh devices.

Drug Content and Impurities of the Antimicrobial Agents Rifampin and Minocycline

Analytical and in vitro testing was also performed on the device and included speed to kill, kinetic drug release (KDR), drug content and impurity, and polymer degradation testing. The test results demonstrated comparable performance to currently marketed surgical mesh devices with respect to these parameters.

Animal Testing

An in vivo porcine implantation study was performed to investigate the device's mechanical strength and the host inflammatory response to the device over a 28 day duration. At 28 days, the XENMATRIX™ AB surgical mesh had greater tissue-ingrowth/T-Peel Force values than the control surgical mesh. The mechanical strength values (i.e., Ultimate Load/Burst Force, Peak Tensile Strength) of the graft alone were lower than the control surgical mesh.

In addition, two in vivo dorsal implant rabbit infection model studies were performed. Devices were inoculated with bacteria at implantation, and at 7 days, post-implantation, bacterial colonization quantifications were conducted. At that time point the antimicrobial coating on the XENMATRIX™ AB was observed to prevent bacterial colonization of the device in comparison to a control surgical mesh.

The relevance of these studies to human clinical performance outcomes has not been demonstrated.

The correlation of these studies has not been demonstrated to be predictive of positive human clinical outcomes.

Human clinical data

None.

The claim of reduction of colonization has not been established with human clinical data, nor has a clinical impact associated with this claim been demonstrated.

PATIENT RECORD LABEL

A patient record label that identifies the type, size, and lot number of the implant is attached to every package. The label should be incorporated into the patient's permanent medical record to clearly identify the device that was implanted. If you experience a product failure, please contact Davol, Inc. at 1-800-556-6275 for instructions on returning the product.

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	Contents		Upper Limit of Storage Temperature
	Do not use if package is damaged.	Rx only	U. S. federal law restricts this device to sale by or on the order of a physician.