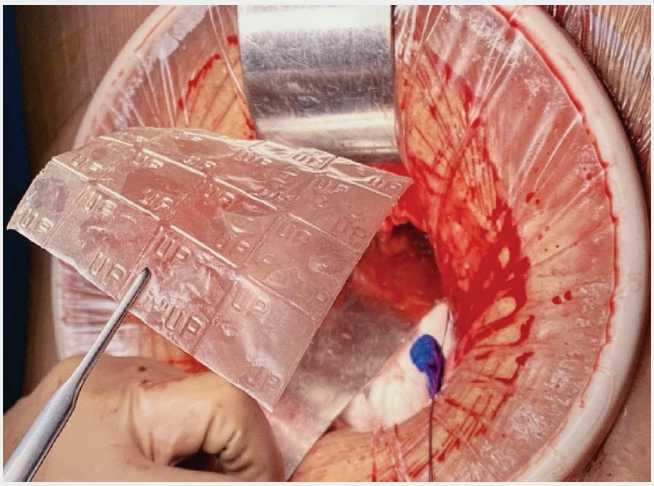
MIMEDX

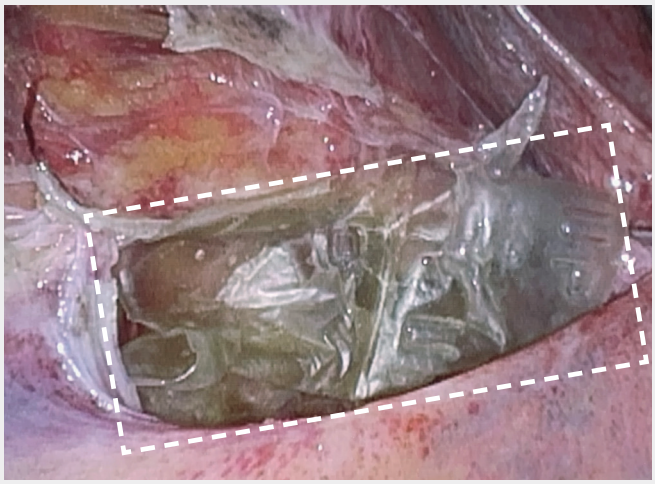
ADVANCED PLACENTAL-BASED ALLOGRAFTS

GYNECOLOGIC SURGERY CASEBOOK

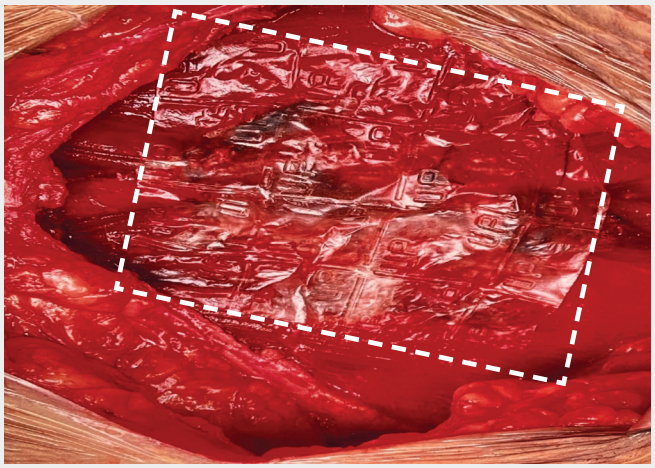
GERRY L. SOTOMAYOR, MD



Abdominal Hysterectomy



Vaginal Cuff on Pelvic Floor Application

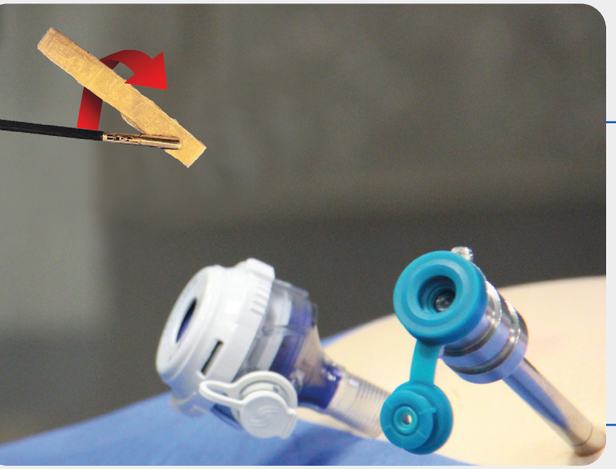


Abdominal Wall Application

US-GS-2200049 v1.0

Tips for Minimally Invasive Surgical (MIS) Procedures

- Cut AMNIOFIX® to desired size, if needed, and prior to introduction into the port
- Minimum 5 mm port
- Irrigate and suction / aspirate the area prior to introducing AMNIOFIX to prevent accidental removal of the graft
- Surgical equipment and surgical site should be dry and clean of debris (pass gauze in and out of trocar)
- AMNIOFIX is introduced through the assistant port with an atraumatic grasper
- Ensure graft is not hydrated / wet prior to introduction



Common Method

1. Grasp the corner of dry graft

2. Wrap the graft around the atraumatic grasper

3. Introduce through the trocar

Case 1: Total Abdominal Hysterectomy With Bilateral Salpingectomy

Gerry L. Sotomayor, MD

Clinical History

44-year-old married female with a history of pelvic pain, menorrhagia, MRI revealed fibroid uterus (15 weeks). She also has a history of chronic anemia. Patient is status post 3 Cesarean sections and PPS (postpartum sterilization).

Challenge

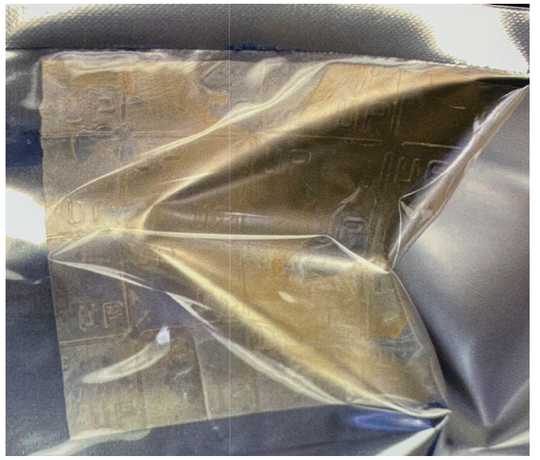
Patient contains a 15 weeks size uterus with fibroids and adhesions. Obesity (BMI > 35), chronic anemia, and poorly controlled diabetes.

Surgical Intervention

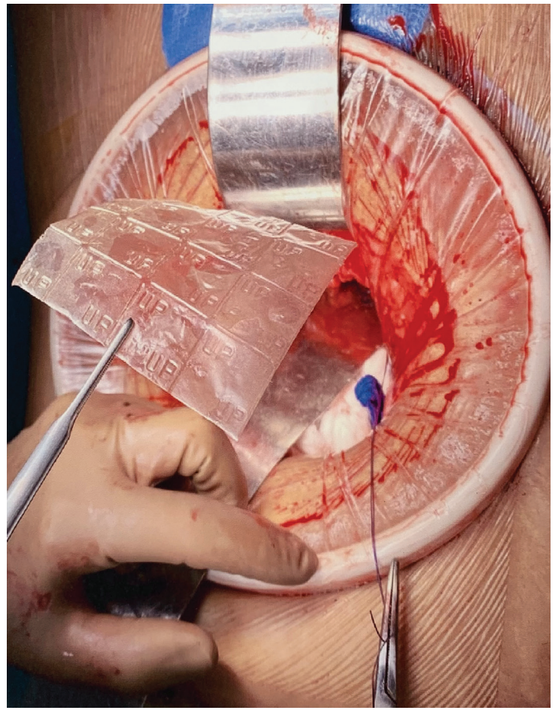
A Total Abdominal Hysterectomy with bilateral salpingectomy was performed on the patient. An extensive adhesion formation was encountered. Cell saver was used during the procedure without need for a transfusion. The vaginal vault was covered with AMNIOFIX 7 cm x 7 cm, as well as the anterior abdominal wall. She also had the On-Q system for pain management.

Follow-Up

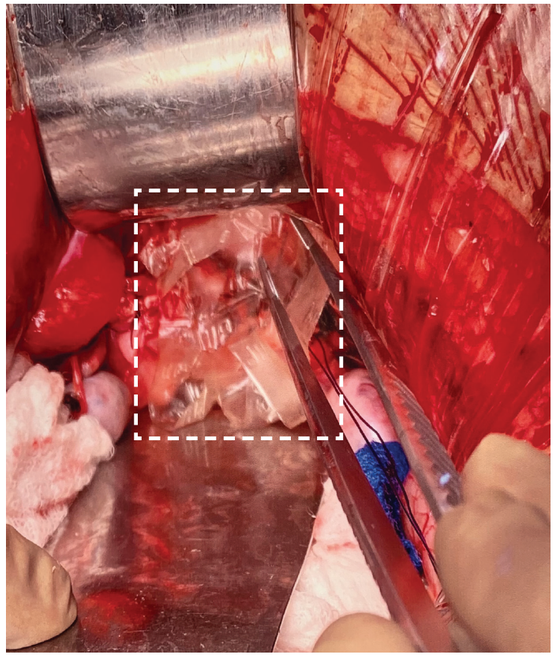
Minimal pain experienced by the patient post-operatively. No infection or hernia encountered. A follow-up with visit at 7 days and 40 days revealed excellent recovery with ability to return to work sooner than expected.



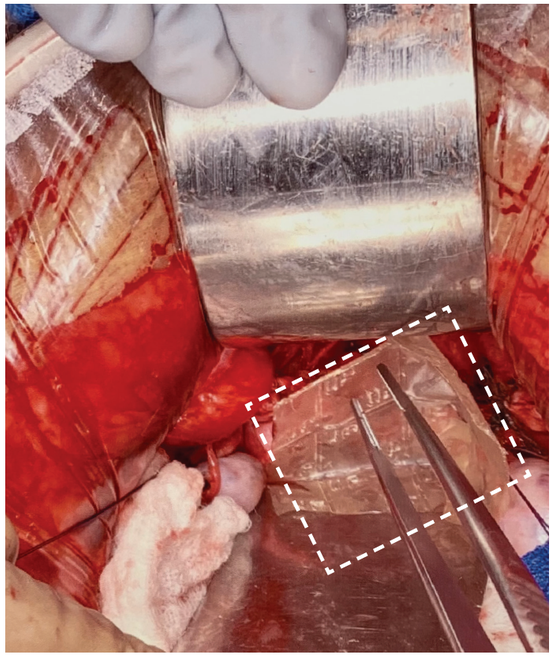
AMNIOFIX 7 cm x 7 cm graft



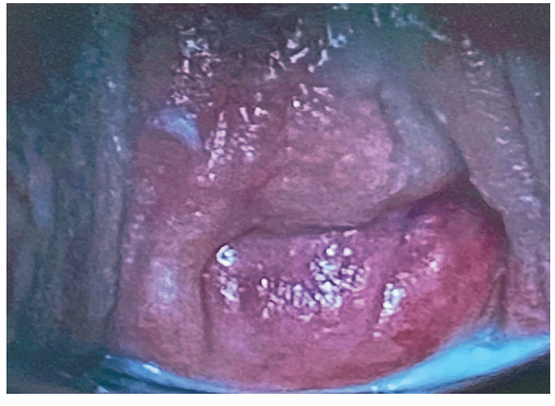
Placement of AMNIOFIX 7 cm x 7 cm graft on vaginal vault



Placement of AMNIOFIX 7 cm x 7 cm graft on vaginal vault



Placement of AMNIOFIX 7 cm x 7 cm graft on anterior abdominal wall



Vaginal cuff 6 weeks after application

Case 2: Laparoscopic Assisted Vaginal Hysterectomy With Bilateral Salpingo Oophorectomy and Lysis of Adhesions

Gerry L. Sotomayor, MD

Clinical History

60-year-old married female has a history of post-menopausal bleeding for 6 months. Patient has a negative PAP and EMB (endometrial biopsy). A 6 cm uterine polyp was identified. The patient had lost 3g HgB (hemoglobin) since the onset of bleeding.

Challenge

Patient was identified with anemia, adenomyosis, adhesions (pelvic), and a large cervical polyp (6 cm x 2 cm) that was not resectable in an office setting.

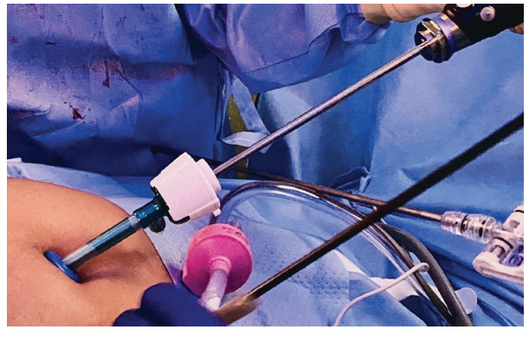
Surgical Intervention

A LAVH with BSO and LOA was performed. Previous tubal ligation and infection created extensive adhesions.
The polyp had necrosed partially prior to surgery. AMNIOFIX 7 cm x 7 cm sheet was applied to the cuff prior to closure.

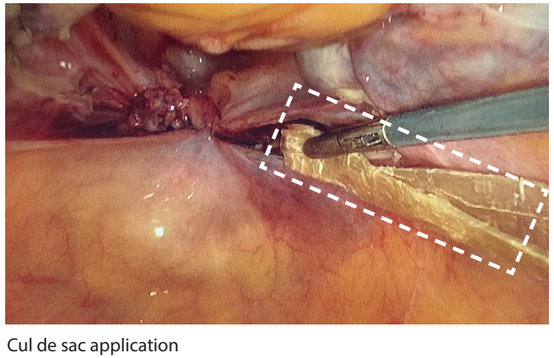
Follow-Up

Patient underwent a 24 hour hospitalization with no pain, bleeding, or infection. The vaginal cuff was observed at 2 and 6 weeks intervals with proper resolution and granulation tissue noticed.

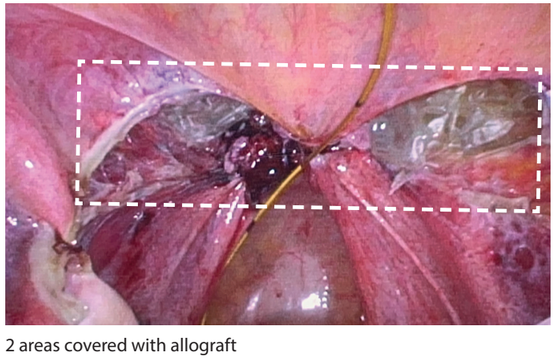
Rolled graft in atraumatic grasper



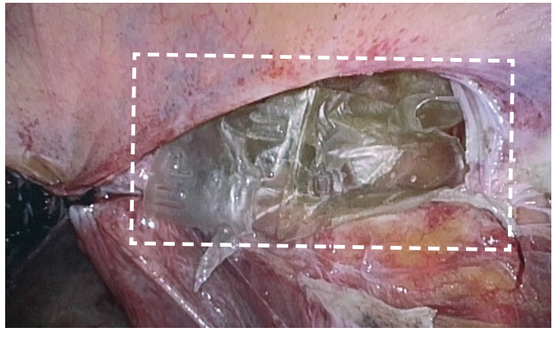
Graft pushed through 5 mm port



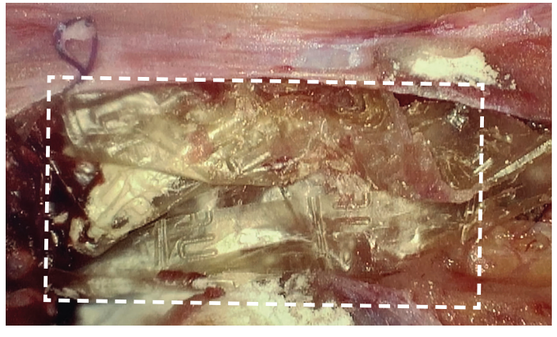
Cul de sac application

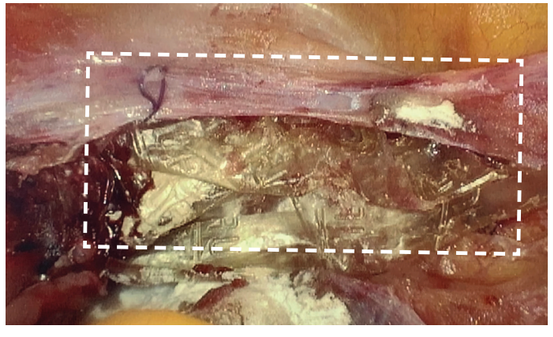


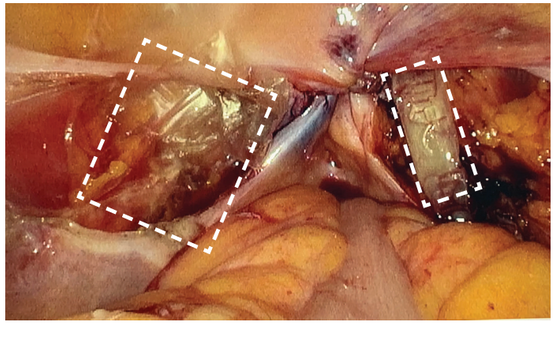
2 areas covered with allograft



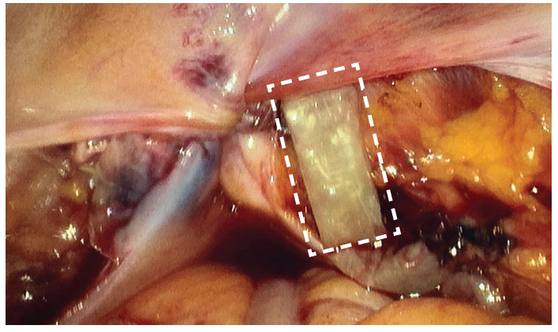
Close-up view of allograft

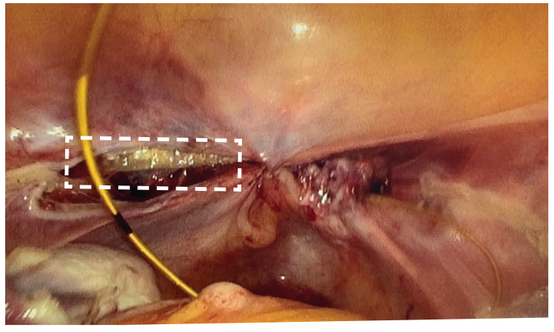


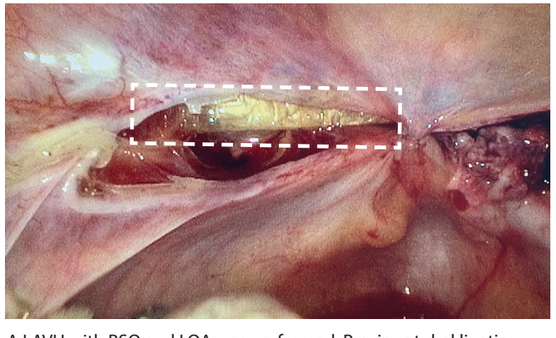




A LAVH with BSO and LOA was performed. Previous tubal ligation and infection created extensive adhesions. The polyp had necrosed partially prior to surgery. AMNIOFIX 7 cm x 7 cm sheet applied to the cuff prior to closure.







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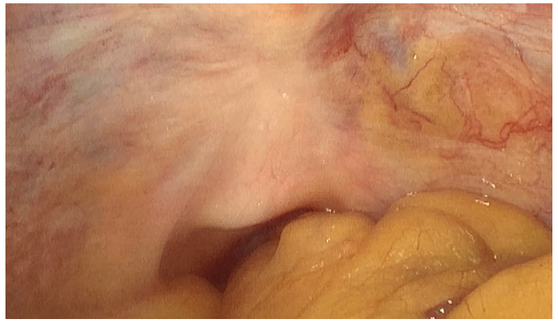


Postop view at 4 month interval

Case 3: Laser Ablation Cone

Gerry L. Sotomayor, MD

Clinical History

31-year-old single female with a history of abnormal PAP smear. Coloscopic evaluation revealed the presence of CIN II, HGSIL. There is also bacterial vaginosis and candida infection. The patient desires future pregnancies.

Challenge

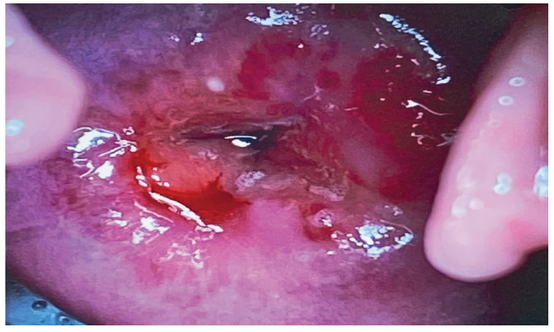
Patient experienced recurrent cervicitis/vaginitis. Very friable tissue and extensive cervical area involving cervical intraepithelial neoplasia. She would like to preserve her cervical canal functions. Her predilection for surgery is with laser due to the rapid healing and less tissue trauma.

Surgical Intervention

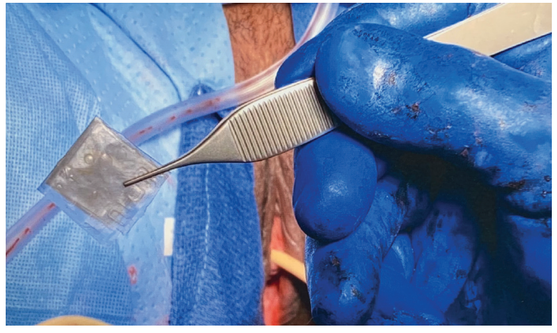
CO_2 laser ablation cone done to a depth of 7 mm in affected areas plus a 7 mm safety margin beyond the treated area. All the char was removed and a 4 cm x 4 cm AMNIOFIX folded allograft was inserted in the endocervical canal. Another 2 cm x 2 cm AMNIOFIX allograft was applied to the ectocervical tissue at the conclusion of the surgery.

Follow-Up

A six week follow-up examination showed a significant amount of granulation tissue present in over 60% of the treated areas. Long term follow-up PAP smears have proven an excellent repair, both in the endo and ectocervical tissue layers.



Pre-surgery



4 cm x 4 cm AMNIOFIX allograft folded

6 week follow-up

Case 4: Marsupialization of Recurrent Bartholin Cyst

Gerry L. Sotomayor, MD

Clinical History

31-year-old married female has a history of recurrent left Bartholin cysts. Previously incised and drained causing chronic dyspareunia (painful intercourse) and scarring.

Challenge

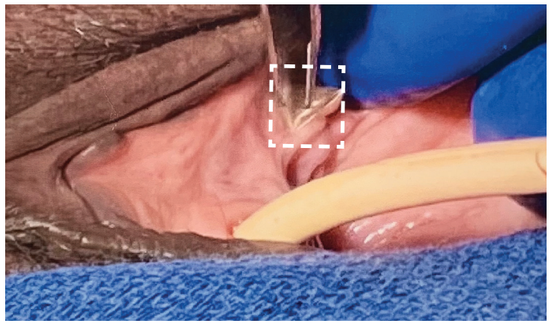
Worse scar tissue formation, poor healing, and reappearance of new Bartholin cysts. Dyspareunia is possibility in the future.

Surgical Intervention

Patient underwent LAVH Marsupialization with copious irrigation and proper cyst wall approximation to muscosa was performed. A 2 cm x 2 cm AMNIOFIX folded allograft was placed in the cavity and the edges of the incision were loosely sutured to keep the allograft in place.

Follow-Up

Excellent recovery was observed at two and six week interval postoperative visits. No scarring or infection encountered. Dyspareunia resolved per patient.



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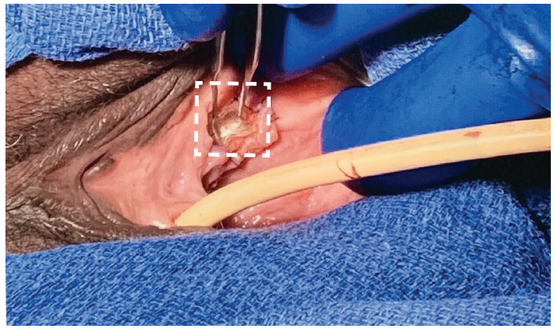
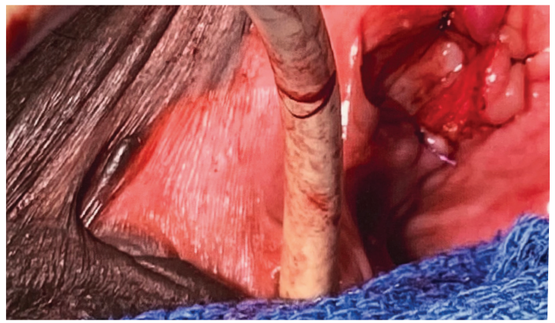
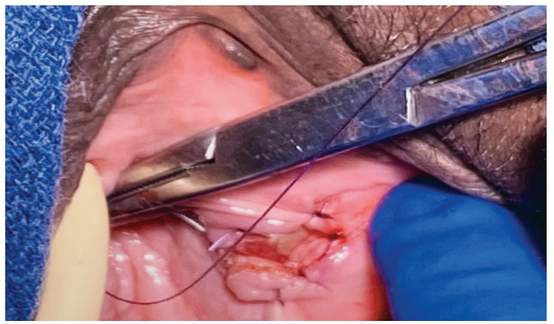
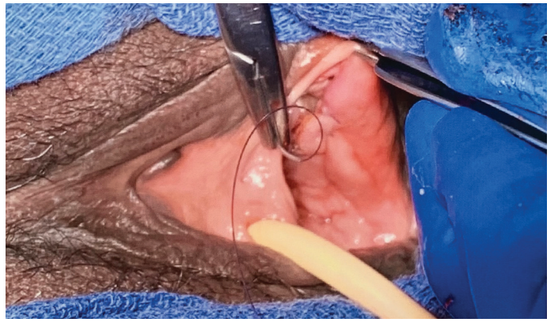






The edges of the incision were loosely sutured to keep the allograft in place



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Case 5: Rectus Abdominis Diastasis at Laparotomy

Gerry L. Sotomayor, MD

Clinical History

45-year-old married female with a diastasis recti admitted for TAH (total abdominal hysterectomy) and BSO (bilateral salpingo oophorectomy). Her current employment requires constant use of abdominal muscles. Patient has been suffering a burning type pain in the abdominal area.

Challenge

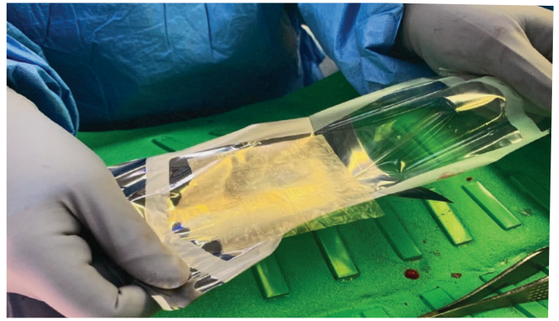
Recurrent hernia formation is possible. Chronic pain may not be resolved due to type of work.

Surgical Intervention

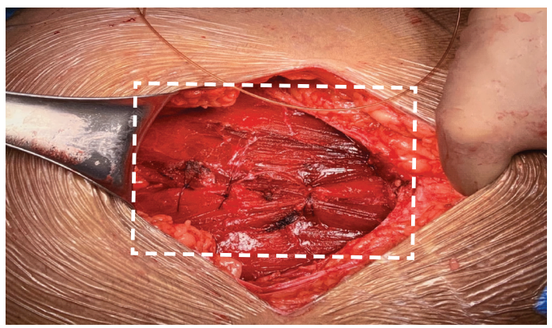
A Pfananstiel incision was done and a severe rectus abdominis diastasis encountered. The TAH and BSO was carried in the usual fashion with application of AMNIOFIX at the vaginal cuff. The abdominal wall repair was done with interrupted stitches and two 7 cm x 7 cm AMNIOFIX allografts were placed over the surgical site. On-Q pain management system was used.

Follow-Up

The two and six week interval postoperative visits revealed a rapid recovery with minimal scarring encountered. The incision closed very well.



Two 7 cm x 7 cm AMNIOFIX allografts were placed over the surgical site



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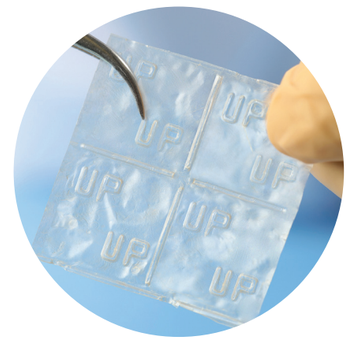
MIMEDX® Advanced Treatments

AMNIOFIX®



What Is AMNIOFIX?

AMNIOFIX is a dehydrated human amnion/chorion membrane allograft. The product is available in sheet configurations in a variety of sizes to reduce wastage.

Protective Barrier

- Provides a protective barrier that supports the healing cascade
- Protects the wound bed to aid in the development of granulation tissue

Retains Regulatory Proteins

- 300+ regulatory proteins[1-3]

Product Advantages

- Patented PURION® processing
- Terminally sterilized for additional level of safety
- Easy to apply
- Shelf-stable*
- 5-year shelf life
- Compatible with negative pressure wound therapy (NPWT) and hyperbaric oxygen therapy (HBOT)

Clinical Uses Examples

- Comorbid patients with complex defects or delayed healing
- Hysterectomy
- Endometriosis
- Myomectomy
- Cesarean Section

Product Details

AMNIOFIX is processed using PURION, a unique patented method for placental-based allografts that is in accordance with the American Association of Tissue Banks (AATB) standards. The product is derived from donated C-sections of live births in the US. The product undergoes active preservation of the extracellular matrix (ECM), regulatory proteins, and removal of blood contaminants via a proprietary cleansing process. For an additional level of safety, the product is terminally sterilized.

**See Instructions for Use*

To find out more about MIMEDX products:

Please Call: 866.477.4219 Email: customerservice@mimedx.com

REFERENCES 1. Koob TJ, Lim JJ, Massee M, Zabek N, Denozière G. Properties of dehydrated human amnion/chorion composite grafts: Implications for wound repair and soft tissue regeneration. J Biomed Mater Res B Appl Biomater. 2014;102(6):1353-1362. **2.** Lei J, Priddy LB, Lim JJ, Massee M, Koob TJ. Identification of Extracellular Matrix Components and Biological Factors in Micronized Dehydrated Human Amnion/Chorion Membrane. Adv Wound Care (New Rochelle). 2017;6(2):43-53. **3.** MIMEDX Internal Report. MM-RD-00086, Proteome Characterization of Purion Processed Dehydrated Human Amnion Chorion Membrane (dHACM) and Purion Plus Processed Dehydrated Human Umbilical Cord (dHUC) Allografts.

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