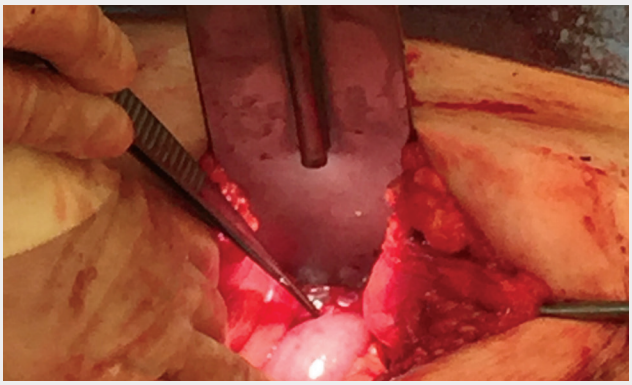
MIMEDX

VOLUME 1 | EDITION 2

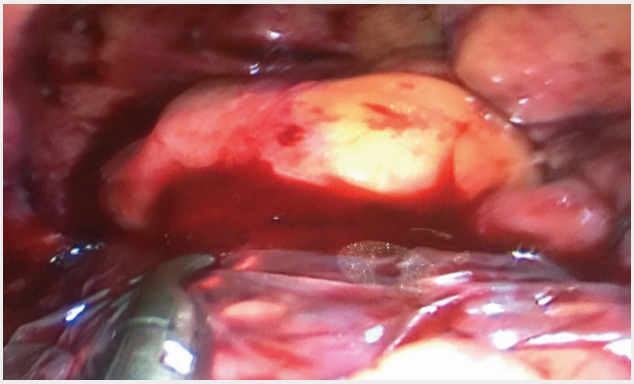
ADVANCED PLACENTAL-BASED ALLOGRAFTS

GENERAL AND COLORECTAL SURGERY CASEBOOK

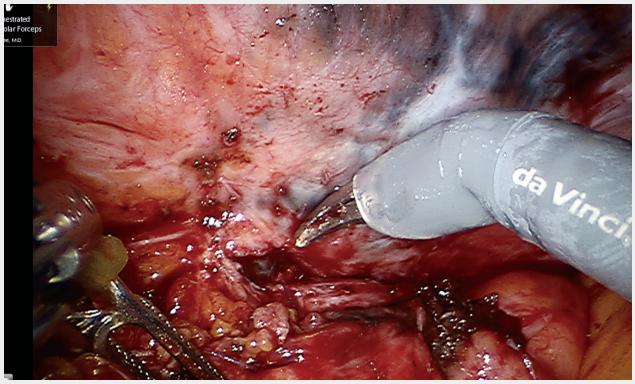
ACUTE ABDOMINAL WALL DEHISCENCE WITH EPIFIX®



LOW ANTERIOR RESECTION WITH AMNIOFIX®



COLOSTOMY REVERSAL WITH AMNIOFIX



COLOVESICAL FISTULA REPAIR WITH AMNIOFIX

SB935.002

Acute Abdominal Wall Dehiscence With EPIFIX

John Ko, MD, PhD, FACS | Plastic Surgery | Elmhurst, NY

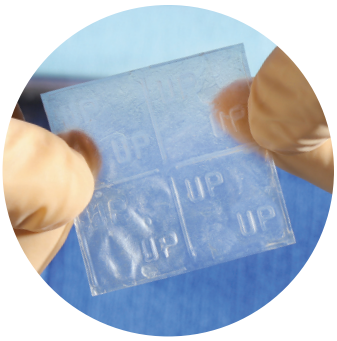
Challenge

A 62-year-old obese male, BMI of 29, type II diabetes, with a history of hypertension, myocardial infarction with stent placements, multiple abdominal surgeries, and over forty years of cigarette smoking, underwent large ventral hernia repair. At one week postop, the patient developed ischemia at the incision line, which led to an incisional dehiscence.

Studies have shown a direct correlation between the number of comorbidities and clinical outcomes. A significant rise in complications, length of stay, and mortality rates is associated with the rise in number of patient comorbidities.[1-3]

Surgical Intervention

The patient was managed with serial debridement and wet-to-dry dressings for two months, then placed on negative pressure wound therapy (NPWT) for four weeks at home. After one month of NPWT, the wound had only decreased by 30%. NPWT was discontinued, and EPIFIX was applied every other week, instead of weekly, due to the travel distance for the patient. EPIFIX is a dehydrated human amnion/chorion membrane allograft. The product provides a semi-permeable barrier that supports the healing cascade and protects the wound bed to aid in the development of granulation tissue in acute and chronic closures. It provides a biocompatible human extracellular matrix and retains 300+ regulatory proteins.[4-6]



EPIFIX

Follow-Up

Upon examination at his two month EPIFIX follow-up visit, the wound was fully closed and re-epithelialized. The patient returned for a routine one-year visit and has remained fully closed and asymptomatic.

Following debridement

Four weeks of NPWT, only 30% size reduction, first EPIFIX 4 cm x 4 cm applied

Week 2: Two 2 cm x 3 cm EPIFIX applied

Week 4: One 2 cm x 3 cm EPIFIX applied

Week 8: Wound closed and stable

Low Anterior Resection With AMNIOFIX

Dennis E. Choat MD, FACS, FASCRS | Colon and Rectal Surgery | Fayetteville, GA

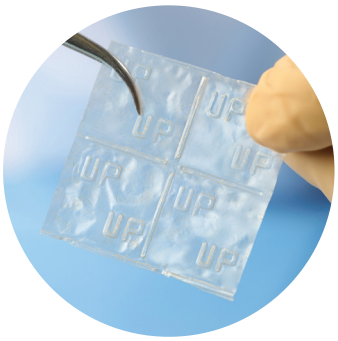
Challenge

A 62-year-old male with Lynch Syndrome and a prior subtotal colectomy presents with recurrent cancer in sigmoid colon. Comorbidities included morbid obesity, sleep apnea, and hypertension.

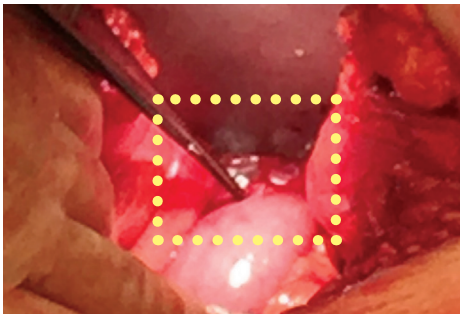
Anastomotic leakage is the most serious complication specific to intestinal surgery and ranges from 2.9% to as high as 15.3%. At least one-third of the mortality after colorectal surgery is attributed to leaks.[7] Additionally, anastomotic leaks can have 3x higher postoperative infection and mortality rates.[8]

Surgical Intervention

Significant adhesiolysis was required due to prior surgery and likely from either the tumor or diverticulitis. A 14 cm portion of small bowel, sigmoid, and rectum was resected. The anastomosis was completed using a circular stapler, and a 2 cm x 12 cm AMNIOFIX sheet was placed onto the anastomotic suture line and wrapped around the bowel circumferentially. AMNIOFIX is a dehydrated human amnion/chorion membrane allograft. AMNIOFIX sheets provide a semi-permeable protective barrier that supports the healing cascade. AMNIOFIX provides a human biocompatible extracellular matrix (ECM) and retains 300+ regulatory proteins.[4-6] **NOTE: In the Retrospective, Multi-center Study highlighted below, results showed that use of AMNIOFIX around colonic anastomosis reduced leakage by 74.25%.**



AMNIOFIX



2 cm x 12 cm AMNIOFIX wrapped around the anastomosis

Follow-Up

The patient was seen postop day 14 with normal bowel control and no wound infections or other complications.

PRESENTED at The American College of Surgeons Clinical Congress 2017, San Diego, CA

Dehydrated Human Amnion/Chorion Membrane in Colorectal Anastomoses: A Retrospective Multi-Center Study

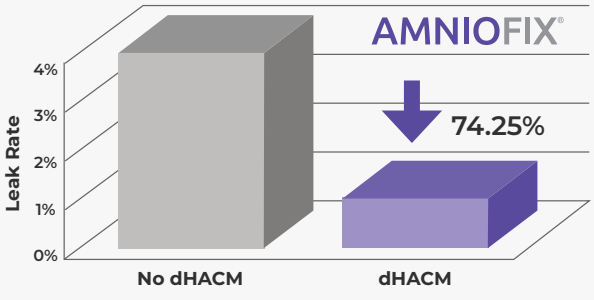
F. Raymond Ortega, MD, FACS; Dennis Choat, MD, FACS, FASCRS; Emery Minnard, MD; Jeffrey Cohen, MD

3 Sites, N= 2,390 colonic anastomosis

- 2,000 were the base-line cohort without AMNIOFIX
- 390 had AMNIOFIX applied to the anastomosis

	No dHACM	AMNIOFIX®
Anastomotic Leaks	80 of 2,000	4 of 390
Anastomotic Leak Rate	4.0%	1.03%

Anastomotic Leak Rate with and without dHACM



SB935.002

Colostomy Reversal With AMNIOFIX

Francis S. Lee MD, FACS, Quan Le, Christina W. Lee | General Surgery | Irvine, CA

Challenge

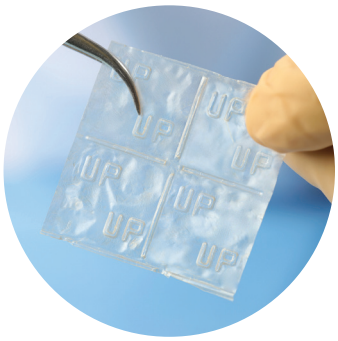
A 68-year-old male underwent an emergency Hartmann's procedure with a rectosigmoidectomy and end colostomy with a rectal pouch, due to a perforation of the sigmoid colon from acute diverticulitis.

Though wound healing in elderly people is not necessarily impaired, age related changes are evident. Comorbidities, which are associated with impaired healing, are more prevalent in older patient populations and can delay healing by 20-60%.[9]

Anastomotic leakage is the most common and much feared intraoperative complication in colostomy reversal.[10,11] One study showed the anastomotic leakage rate at as high as 3.8%.[12] In addition to anastomotic leakage, other common postoperative complications include wound infection, incisional hernia, ileus, and enteric fistula formation.[10,11]

Surgical Intervention

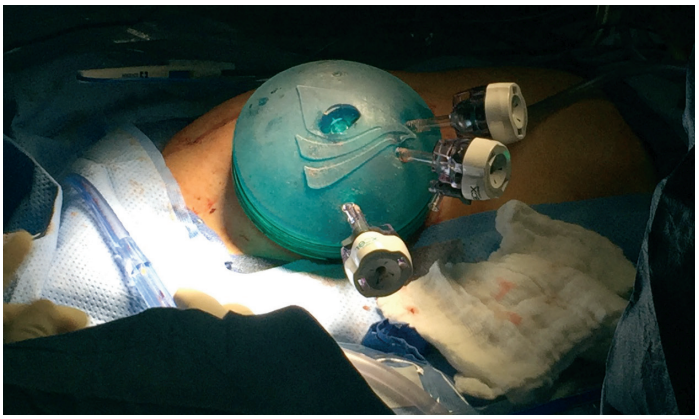
Five months later, when the patient's overall condition improved, a colostomy reversal using a single-port laparoscopic technique with AMNIOFIX was performed. A 2 cm x 6 cm AMNIOFIX graft was placed laparoscopically on the colorectal anastomotic, stapled site and stitched into place with absorbable sutures. AMNIOFIX is a dehydrated human amnion/chorion membrane allograft. The product provides a semi-permeable barrier that supports the healing cascade. It provides a biocompatible human extracellular matrix and retains 300+ regulatory proteins.[4-6]



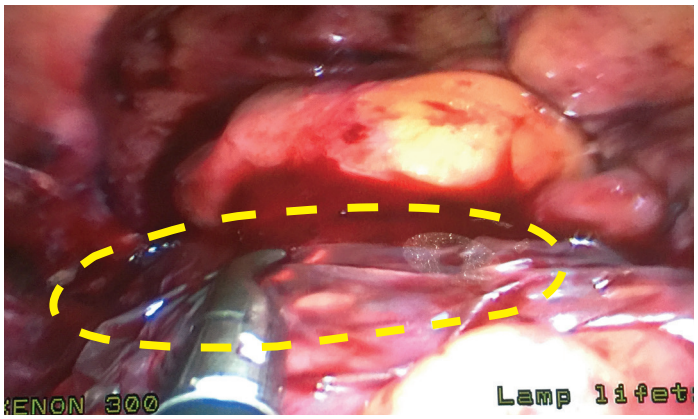
AMNIOFIX

Follow-Up

The patient was seen two weeks after the surgery with no postoperative complications. The patient was having normal bowel movements daily.



Single-port laparoscopic approach



2 cm x 6 cm AMNIOFIX placed on anastomosis

Colovesical Fistula Repair With AMNIOFIX

Francis S. Lee, MD, FACS, Shahn Thaliffdeen, Alexander T. Phan, Christina W. Lee | General Surgery | Irvine, CA

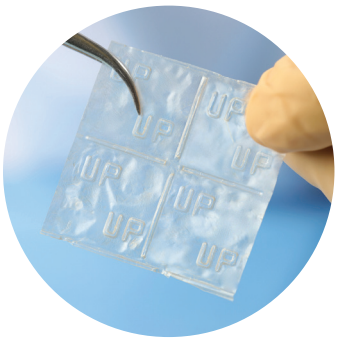
Challenge

A 71-year-old male presented with diverticulitis of the distal colon. Significant medical history included diabetes mellitus, nephrolithiasis with bilateral nephrostomy tubes, and kidney failure with ongoing hemodialysis. After responding to conservative therapy, the patient began passing gas though his urethra. A CT scan identified a small fistula between the patient's colon and bladder.

In this case, the treatment of the patient's colovesical fistula was further complicated by advanced age, several comorbidities, and significant medical history. An elderly patient with these comorbidities is at higher risk of postop complications from extensive surgery; therefore, it was decided to avoid a sigmoidectomy.

Surgical Intervention

With the use of a robotic surgery approach and AMNIOFIX, the patient was able to undergo a less invasive and lower risk procedure. This approach allowed for a simple fistula resection and primary repairs on both sides of the fistula tract. 2 cm x 3 cm AMNIOFIX sheets were placed on both bladder and colon primary repair sites.



AMNIOFIX

AMNIOFIX is a dehydrated human amnion/chorion membrane allograft. AMNIOFIX sheets provide a semi-permeable protective barrier that supports the healing cascade. AMNIOFIX provides a human biocompatible extracellular matrix (ECM) and retains 300+ regulatory proteins.[4-6]

A loop ileostomy diversion was placed for eight weeks to further minimize risk of fistula recurrence. After eight weeks, the patient returned for an ileostomy reversal. A 4 cm x 6 cm AMNIOFIX sheet was placed on the loop ileostomy repair site and stitched into place with an absorbable suture. Prior to stoma site closure, a laparoscope was inserted at the ostomy site to observe the previous fistula repair site. There were no adhesions observed where the AMNIOFIX was placed, and the bladder was smooth and shiny in appearance. The stoma site was then closed, and the patient was discharged two days later without complications.

Follow-Up

The patient's follow-up was two weeks after the ileostomy takedown. He had normal bowel movements and no complications.

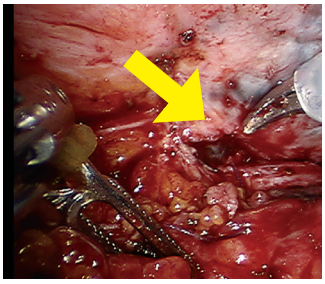
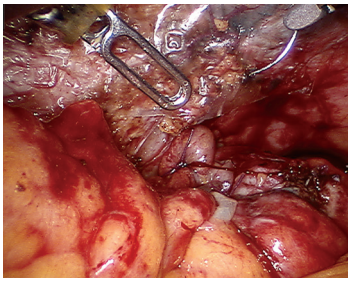
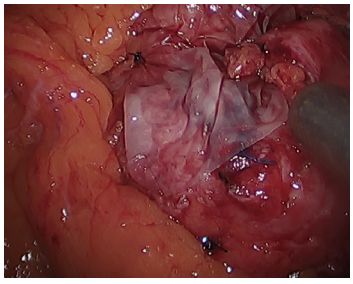


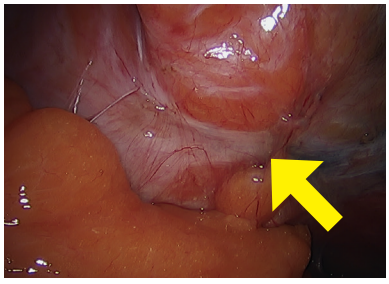
Image of fistula



2 cm x 3 cm AMNIOFIX placed on bladder repair



4 cm x 6 cm AMNIOFIX placed on Ileostomy reversal at 8 weeks

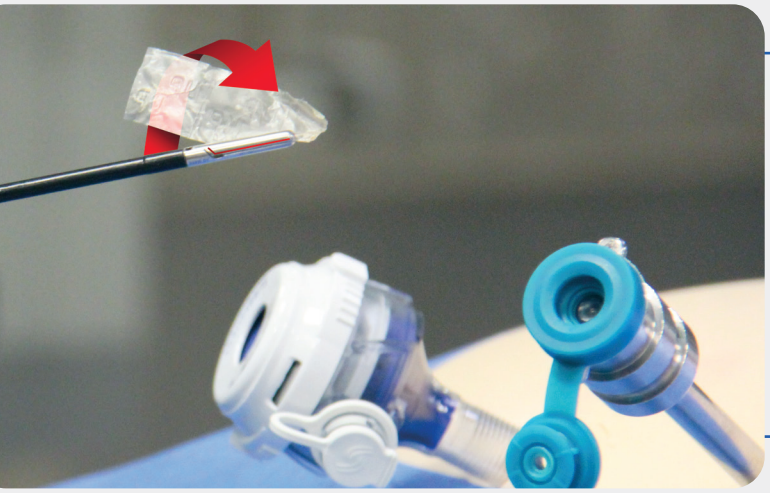


2nd look at 8 weeks – repaired fistula with no adhesions observed

SB935.002

Tips for Minimally Invasive Surgical (MIS) Procedures

- AMNIOFIX sheet configuration is the most common choice for MIS procedures
- Cut AMNIOFIX to desired size if needed, prior to introduction into the port
- Minimum 8 mm port
- Irrigate and suction / aspirate the area prior to introducing AMNIOFIX to prevent accidentally suctioning out 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

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REFERENCES: **1.** Thombs BD, Singh VA, Halonen J, Diallo A, Milner SM. The effects of preexisting medical comorbidities on mortality and length of hospital stay in acute burn injury: evidence from a national sample of 31,338 adult patients. *Ann Surg.* 2007;245(4):629-634. **2.** Myles PS, Iacono GA, Hunt JO, et al. Risk of respiratory complications and wound infection in patients undergoing ambulatory surgery: smokers versus nonsmokers. *Anesthesiology.* 2002;97(4):842-847. **3.** Dunne JR, Malone DL, Tracy JK, Napolitano LM. Abdominal wall hernias: risk factors for infection and resource utilization. *J Surg Res.* 2003;111(1):78-84. **4.** 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. **5.** 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. **6.** MM-RD-00086, Proteome Characterization of PURION Processed Dehydrated Human Amnion Chorion Membrane (dHACM) and PURION PLUS Processed Dehydrated Human Umbilical Cord (dHUC) Allografts. **7.** Kirchhoff P, Clavien PA, Hahnloser D. Complications in colorectal surgery: risk factors and preventive strategies. *Patient Saf Surg.* 2010;4(1):5. **8.** Hammond J, Lim S, Wan Y, Gao X, Patkar A. The burden of gastrointestinal anastomotic leaks: an evaluation of clinical and economic outcomes. *J Gastrointest Surg.* 2014;18(6):1176-1185. **9.** Sgonc R, Gruber J. Age-related aspects of cutaneous wound healing: a mini-review. *Gerontology.* 2013;59(2):159-164. **10.** Khan S, Alvi R, Awan Z, Haroon N. Morbidity of colostomy reversal. *J Pak Med Assoc.* 2016;66(9):1081-1083. **11.** Pittman DM, Smith LE. Complications of colostomy closure. *Dis Colon Rectum.* 1985;28(11):836-843. **12.** Kaiser AM, Israelit S, Klaristenfeld D, et al. Morbidity of ostomy takedown. *J Gastrointest Surg.* 2008;12(3):437-441.

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