AmnioFix® SURGICAL

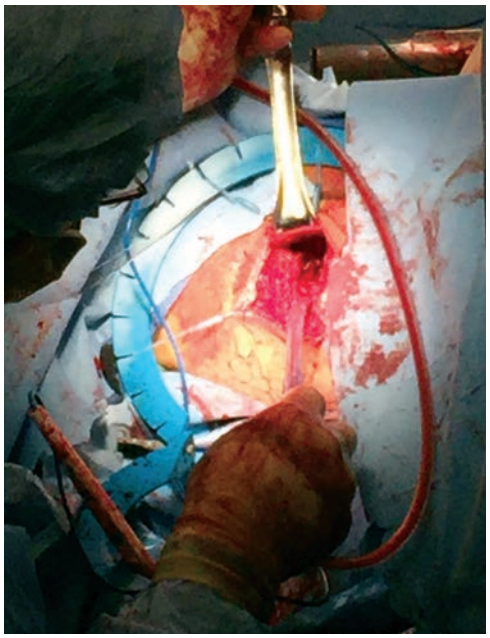
CASE EXAMPLES

Challenges in Colorectal Surgical Procedures

Doctor/Practitioner Information
Dennis E. Choat MD, FACS, FASCRS
Fayetteville, GA

LOWER ANTERIOR RESECTION

ABDOMINOPERINEAL RESECTION



MiMedx

PATIENT CASE EXAMPLE

Anastomotic Wrap with AmnioFix® after Lower Anterior Resection

CHALLENGE: COMORBIDITIES AND UNDERLYING DISEASE CAN IMPAIR HEALING

The healing process is the same throughout the body, and patient comorbidities, compromised surgical sites (e.g., irradiated tissue), or underlying disease may impair the healing process. The most frequent post-operative surgical complications after colorectal resections are surgical site infection (SSI), anastomotic leakage, intraabdominal abscess, ileus, and bleeding. In open colorectal surgery, the incidence of SSI ranges from 2-25%, and the incisional SSI rates in colon and rectal resections were reported as 9.4% and 18.0%, respectively. 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.[1] Additionally, anastomotic leaks can have 3x higher post-operative infection and mortality rates. They are also associated with increased LOS of +7 days and average costs of approximately $73,000.[2]

CLINICAL HISTORY

A 62-year-old male with Lynch Syndrome and a prior subtotal colectomy presents with a recurrent cancer in his sigmoid colon. The patient was scheduled for an open lower anterior resection with rectal preservation. Comorbidities included morbid obesity, sleep apnea, and hypertension.

SURGICAL INTERVENTION

A midline laparotomy was created and dense adhesions were encountered. Significant adhesiolysis was required to due to prior surgery and likely from either the tumor or diverticulitis. Once all adhesions were taken down and the colon was accessible, a 14 cm portion of small bowel, sigmoid, and rectum was resected (Figures 1-3). A circular stapler was used to close the anastomosis (Figure 4).

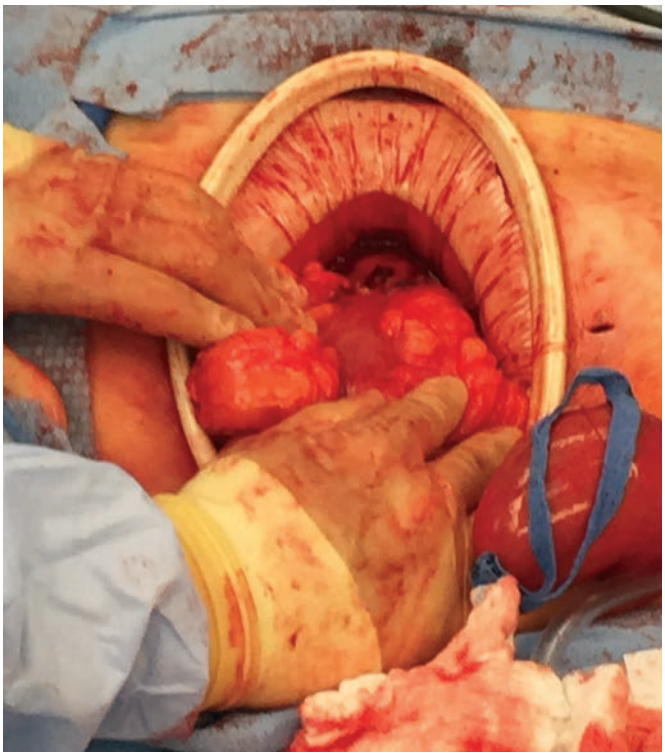


Figure 1
Laparotomy and adhesiolysis

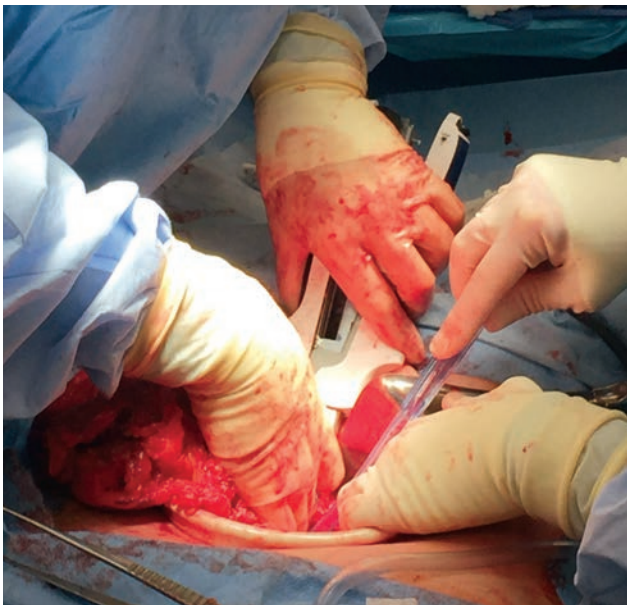


Figure 2
Bowel resection

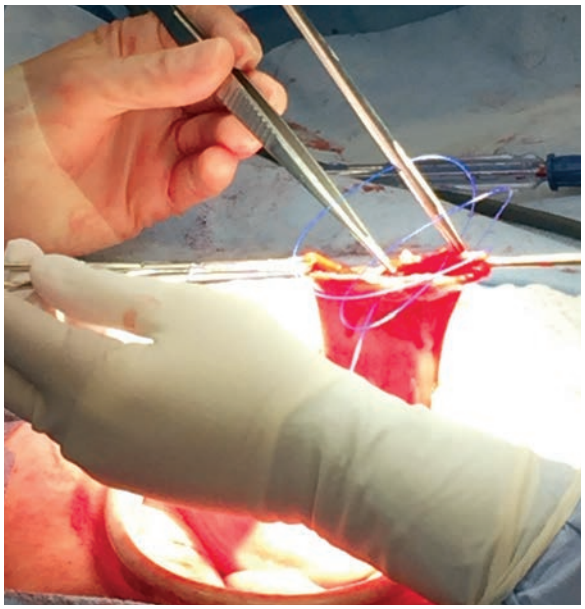


Figure 3
Preparing for anastomosis

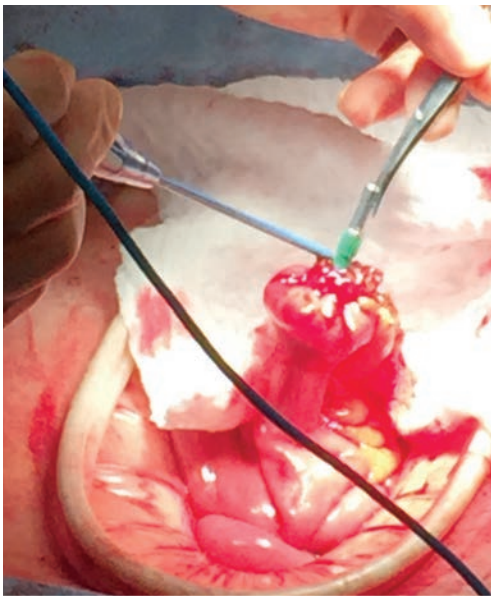
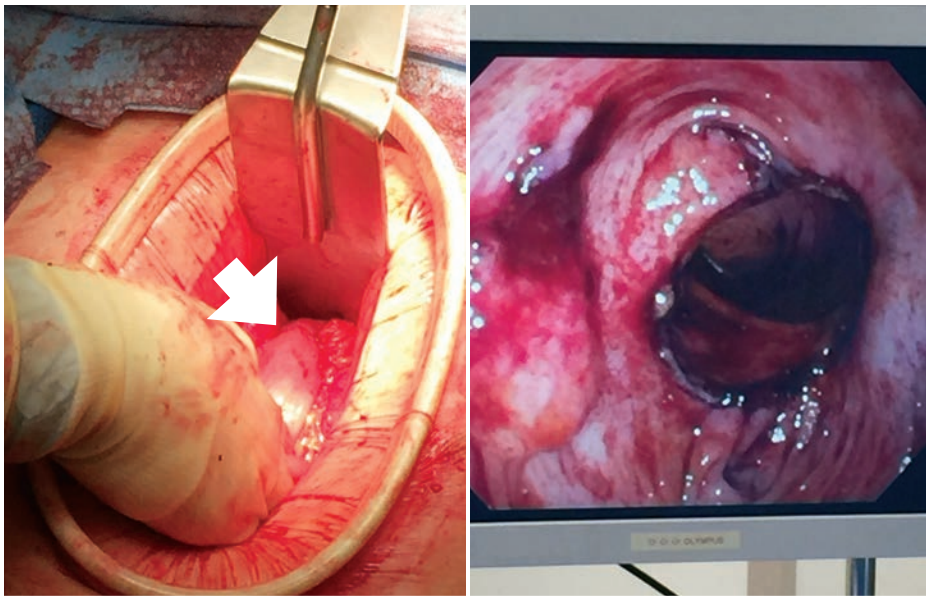


Figure 4
Proximal bowel around anvil



Figures 5 & 6
Anastomosis complete extraluminal and intraluminal views

Once the anastomosis is complete (Figures 5 & 6), a 2 cm x 12 cm AmnioFix sheet was placed onto the anastomotic suture line and wrapped around the bowel circumferentially. Using AmnioFix in this manner serves to modulate inflammation and reduce risk of compromising the staple line, stimulate angiogenesis (especially in irradiated patients), enhance healing, act as a barrier membrane to reduce scar tissue formation between the anastomotic suture line and surrounding viscera or tissue, and decrease the risk of strictures (Figures 7 & 8).

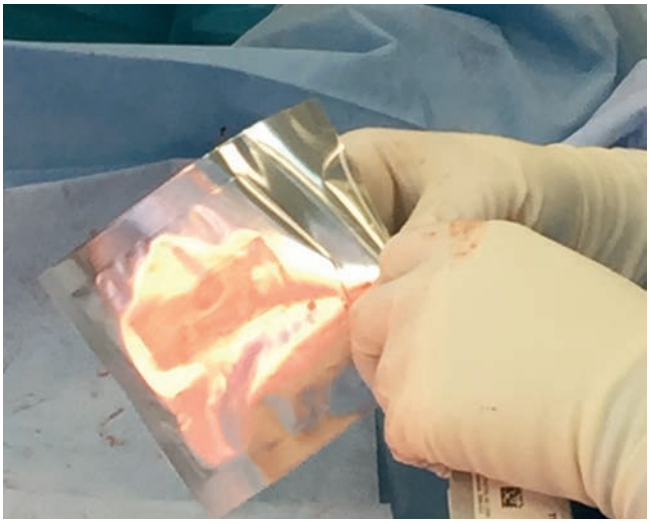


Figure 7
Opening AmnioFix 2 cm x 12 cm

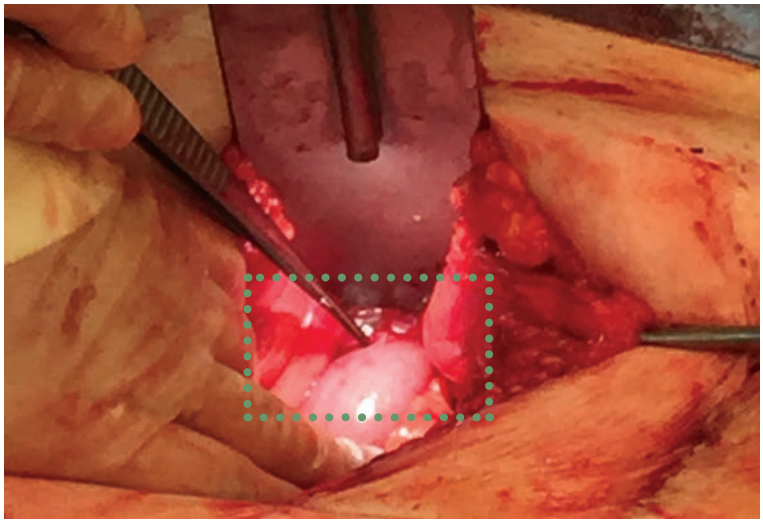


Figure 8
AmnioFix wrapped around the anastomotic suture line

The patient was discharged on post-op day 4 with no complications.

FOLLOW UP

The patient was seen post-op day 14 with normal bowel control, no wound infections, no erectile dysfunction, and had already discontinued pain medication.

CONCLUSION

In my experience using AmnioFix in over 100 various colorectal procedures, I have anecdotally observed a decrease in complications such as anastomotic leaks (2 of 100), infection, and erectile dysfunction. Similar observations were made in this case where no post-op complications were noted.

I also had the opportunity to go back for a second look on two patients for complications unrelated to the AmnioFix and observed the graft was still partially visible at 5 days, and there was minimal swelling in the area of the graft placement with no visible adhesions. Significant swelling was expected and adhesions are common, so these observations were promising.

REFERENCES

1. Kirchhoff P, Clavien PA, Hahnloser D. Complications in colorectal surgery: risk factors and preventive strategies. Patient Saf Surg. 2010 Mar 25;4(1):5.
2. 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 Jun;18(6):1176-85.

PATIENT CASE EXAMPLE

AmnioFix® used in Abdominoperineal Resection

CHALLENGE: RISK OF IATROGENIC INJURY LEADING TO POST-OP SEXUAL DYSFUNCTION AND INCREASED RISK OF WOUND COMPLICATIONS DUE TO CROHN'S DISEASE

Two common problems associated with rectal cancer treatment are recurrence and pelvic nerve damage. Despite improved oncologic outcomes with advances in technique, sexual dysfunction remains a common problem after colorectal cancer treatment. Several publications, where modern surgical techniques were employed, cite both erectile and ejaculatory dysfunction rates as high as 45% post-op.[1] These rates were shown to be higher in abdominoperineal resection (APR) than anterior resection.[2]

In addition, patients with comorbidities have an increased risk of post-op complications, and APR patients specifically may encounter complications such as wound infection, dehiscence, delayed healing, and persistent perineal sinus. These complications can result in significant morbidity leading to increased length of stay, hospital readmission, home nursing, and other additional medical costs.[3] A very wide range of perineal wound complication rates have been reported. One study of 160 patients showed an overall complication rate of 41%, however patients that underwent pre-operative radiation therapy had a 2-fold increase over those without radiation therapy (47% vs. 23%).[4]

CLINICAL HISTORY

The patient is a 64-year-old male who had two prior surgeries related to his Crohn's disease, including ileostomy. The patient was lost to follow up and presented with mucoid rectal discharge. Biopsy confirmed tumor in the distal portion of remaining rectal stump. The patient did not receive radiation therapy due to personal preference to proceed directly to surgery. The patient was scheduled for an abdominoperineal resection to address the tumor and remaining rectal stump.

SURGICAL INTERVENTION

Dense adhesions were encountered during laparotomy from the two prior surgeries, including small bowel adhesions to the suture line of the rectal stump. After extensive adhesiolysis, the rectal stump was mobilized and resected. The specimen included rectum, anus, and skin (Figures 1-3).

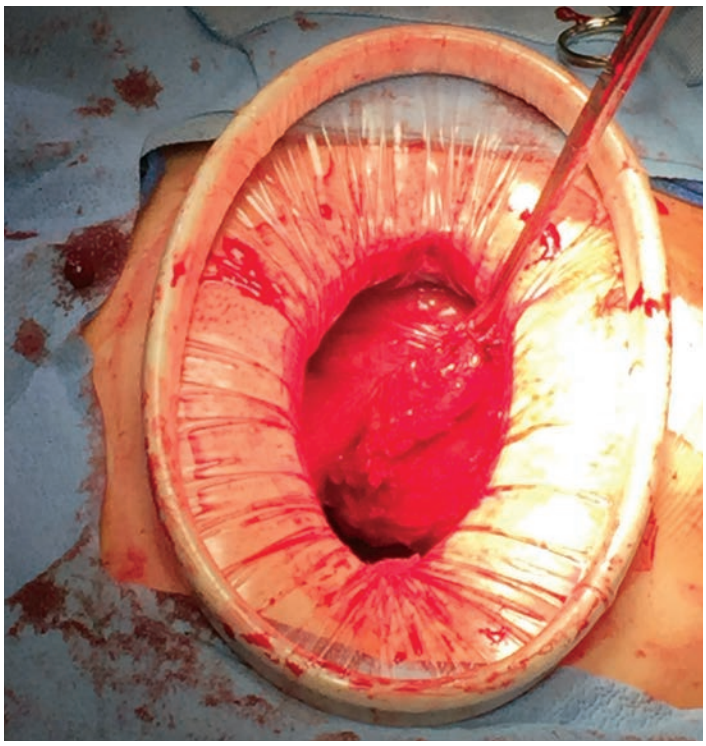


Figure 1
Laparotomy and isolation of rectal stump

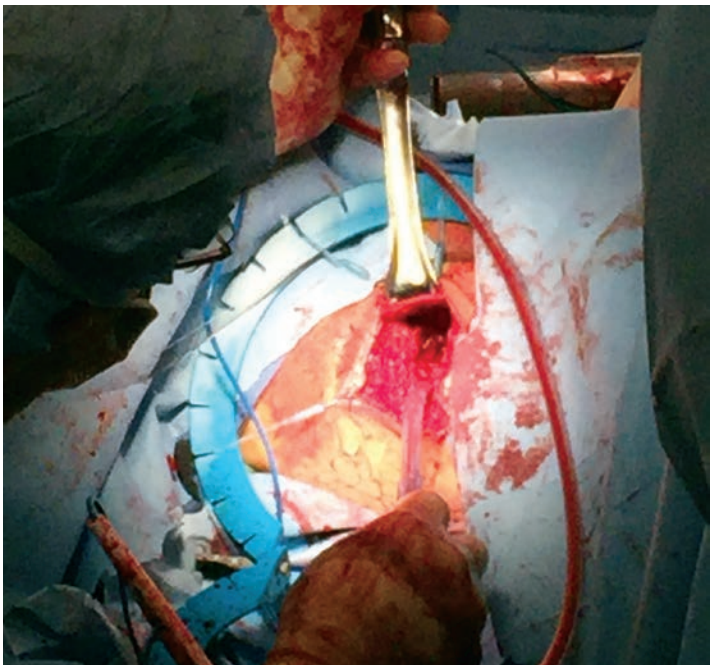


Figure 2
Perineal resection

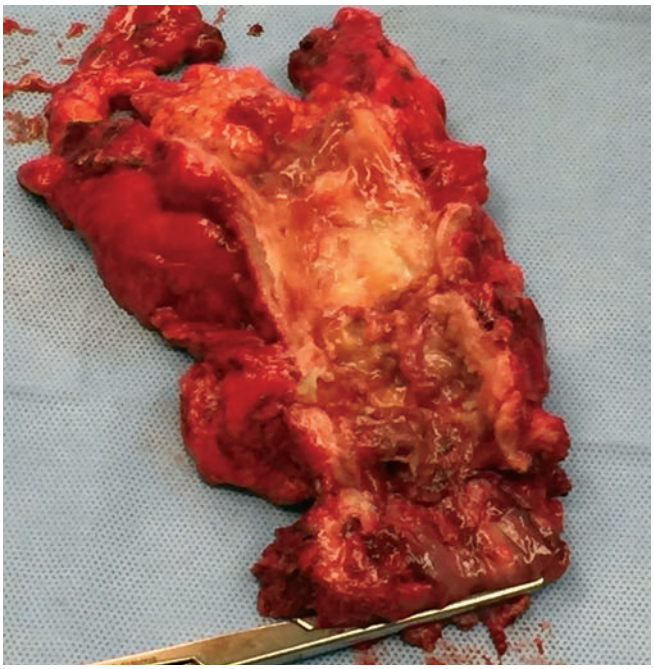


Figure 3
Rectal stump and anus with tumor

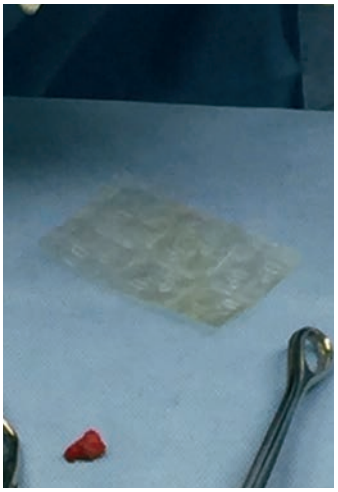
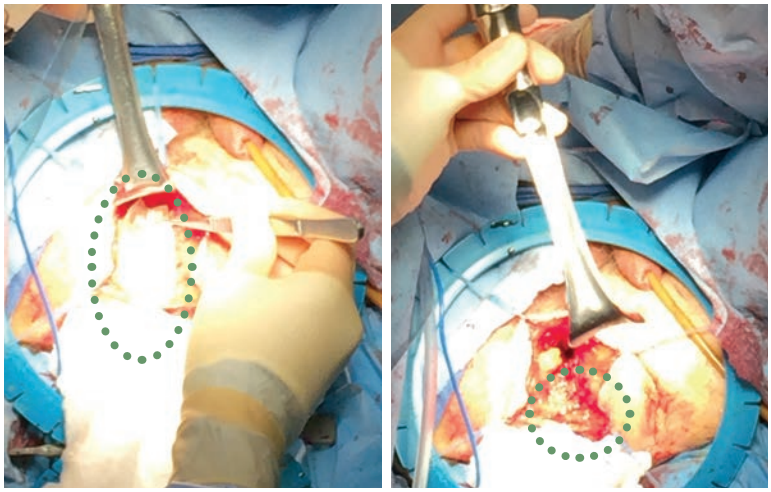


Figure 4
4 cm x 6 cm AmnioFix graft



Figures 5 & 6
AmnioFix is placed onto the sacrum and perineal floor

Prior to closure of the perineal defect, a 4 cm x 6 cm AmnioFix sheet was placed flat onto the sacrum and perineal floor (Figures 4-6). The goal for this patient was to use AmnioFix as a barrier membrane to protect the nerve plexus around the sacrum to decrease the risk of impotence and retrograde ejaculation, and to enhance healing of the nerves and raw tissue in the area of the resection. AmnioFix has clinically demonstrated a similar decrease in time of return to continence and potency in nerve-sparing robot assisted radical prostatectomy procedures when the graft is placed onto the neurovascular bundles.[5] Additionally, there is Level 1 evidence of enhanced healing in chronic wounds, as well as many clinical case examples of enhanced healing across various complex surgical patients and procedures, including more than 100 of my own cases using AmnioFix as an anastomotic wrap after colectomy.

Figure 7
Incision is closed over AmnioFix

After AmnioFix placement on the sacrum, the patient's perineal defect and midline incision were then closed using a 2 layered closure technique with absorbable suture (Figure 7).

The patient was discharged on post-op day 4 with no complications.

FOLLOW UP

The patient was seen in clinic post-op day 14 with no erectile dysfunction or skin separation. The patient also discontinued pain medication, which is typically needed for 4-6 weeks following APR.

CONCLUSION

AmnioFix is a versatile tool in colorectal procedures, which may enhance healing at both the sites of potentially damaged nerves and perineal wound. In my experience using AmnioFix in over 100 various colorectal procedures, I have anecdotally observed a decrease in post-op complications and pain.

REFERENCES

1. Nagpal K, Bennett N. Colorectal surgery and its impact on male sexual function. Curr Urol Rep. 2013 Aug;14(4):279-84.
2. Santangelo ML, Romano G, Sassaroli C. Sexual function after resection for rectal cancer. Am J Surg. 1987 Nov;154(5):502-4
3. Wiatrek RL, Thomas JS, Papaconstantinou HT. Perineal wound complications after abdominoperineal resection. Clin Colon Rectal Surg. 2008 Feb;21(1):76-85.
4. Bullard KM, Trudel JL, Baxter NN, Rothenberger DA. Primary perineal wound closure after preoperative radiotherapy and abdominoperineal resection has high incidence of wound failure. Dis Colon Rectum. 2005 Mar;48(3):438-43
5. Patel VR, et al. Dehydrated Human Amniotic Membrane Allograft Nerve Wrap Around the Prostatic Neurovascular Bundle Accelerates Early Return to Continence and Potency Following Robot-assisted Radical Prostatectomy (RALP): Propensity Score-matched Analysis. Eur Urol. 2015 Jun;67(6): 977-80.

To find out more about MiMedx® products or to start an evaluation:

Please Call: 866.477.4219 **Email:** customerservice@mimedx.com **Reimbursement Hotline:** 855.882.8480

Since 2006, as the **premier leader** in regenerative medicine, **MiMedx** has been dedicated to advancing healing through innovative biomaterial products and bioimplants. To date, over **25** clinical and scientific papers have been **published** in peer-reviewed journals on our PURION® Processed amniotic membrane allografts. The company's **proprietary PURION Process** and its multi-layer grafts are covered by over **20 issued patents**, with more than 80 patents pending. PURION Processed allografts are **clinically effective** and more than **600,000 allografts** have been distributed to date with **no adverse reactions** attributed to our products.†

† As of April 1, 2016

1775 West Oak Commons Court NE
Marietta, GA 30062

www.mimedx.com AL123.001