MIMEDX

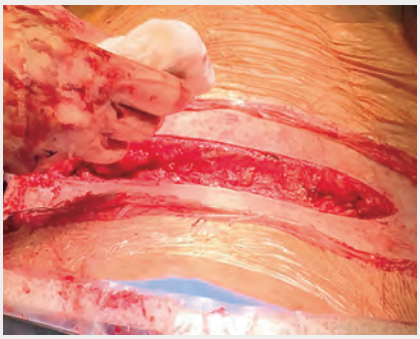
VOLUME 1 | EDITION 1

ADVANCED PLACENTAL-BASED ALLOGRAFTS

INCISION MANAGEMENT IN CHALLENGING PATIENTS CASEBOOK

COMPLEX SURGICAL INCISIONS:

BELOW THE KNEE AMPUTATION (BKA) WITH AMNIOFIX® AFTER DEHISCENCE OF PRIOR AMPUTATION



CAESAREAN SECTION WITH AMNIOFIX

OPEN LAPAROTOMY IN COMORBID PATIENT WITH AMNIOFIX

DEHISCIENCE / REVISIONS:

LOWER EXTREMITY BYPASS DEHISCENCE WITH EPIFIX® AND NPWT

ABDOMINAL WALL DEHISCENCE WITH EPIFIX

KELOID SCAR REVISION WITH EPIFIX

Below the Knee Amputation (BKA) with AMNIOFIX after Dehiscence of Prior Amputation

Shonak B Patel, MD, Christopher J Lecroy, MD | Vascular Surgery | Pensacola, FL

Challenge

Despite advances in vascular surgery, endovascular therapy, and wound management, closure of diseased limbs remains challenging. The primary goal of limb salvage is to restore and maintain ambulation. However, closure challenges can further complicate the clinician's efforts. Challenges to wound closure in this setting include non-compliance, PAD, hygiene, smoking, multiple comorbidities, etc. Reported closure rates for transmetatarsal amputations (TMA) range from 40-70%[1], while reoperation rates range from 8 to 63%, with approximately one-third resulting in a major amputation.[2] Once other more conservative limb salvage options have been exhausted, BKA can still offer the patient a relatively functional limb for use with prosthetic to ambulate.

Clinical History

The patient is a 56-year-old female with a history of severe peripheral artery disease, uncontrolled diabetes, end stage renal disease on dialysis, coronary artery disease with a prior percutaneous coronary intervention, and diabetic foot ulcers that led to a TMA by podiatry. She did not have the appropriate arterial revascularization at the time and the TMA site dehisced due to pressure from walking and the impaired closure from severe comorbidities. The wound worsened with necrosis and infection, to the point where re-approximation of the tissue was no longer possible (Figure 1).

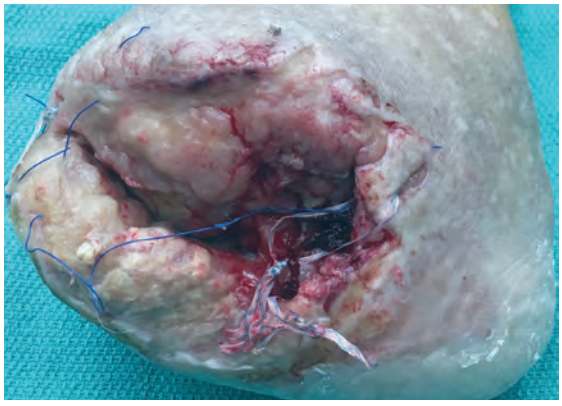


Figure 1: Non-healing dehiscence after TMA

The patient was referred to vascular surgery for her lower limb peripheral arterial disease. Atherectomy and angioplasty were performed to address her superficial femoral artery stenosis and anterior tibial artery stenosis, which successfully improved perfusion to the foot with three vessel run off. The wound would still not heal after one month with multiple debridements and treatments by podiatry. The patient was referred back to vascular surgery and scheduled for a BKA.

Figure 2: AMNIOFIX

Surgical Intervention

A standard BKA was performed. Based on the patient's history of an inability to close wounds in the setting of adequate perfusion, AMNIOFIX was used. AMNIOFIX is a dehydrated human amnion/chorion membrane allograft (Figure 2). AMNIOFIX sheets provide a semi-permeable protective barrier that supports the healing cascade. It also protects the wound bed to aid in the development of granulation tissue in chronic and acute closures. AMNIOFIX provides a human biocompatible extracellular matrix and retains 300+ regulatory proteins.[3-5]

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A 6 cm by 16 cm AMNIOFIX allograft was cut into several pieces and placed into the surgical site. One portion of the allograft was placed on the muscular bed, where the AMNIOFIX allograft would be positioned between muscle and bone after the subcutaneous tissue was closed (Figure 3). The other portions were placed in the subcutaneous space before dermal closure to support closure in this high risk suture line (Figures 4-6).

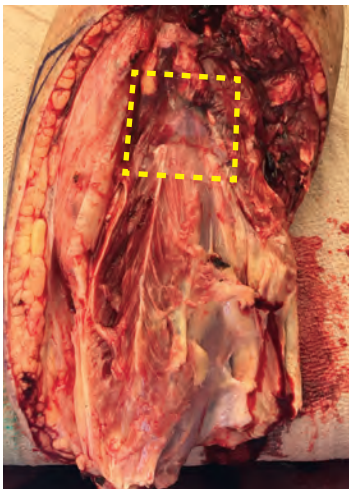


Figure 3: AMNIOFIX placed on muscular bed

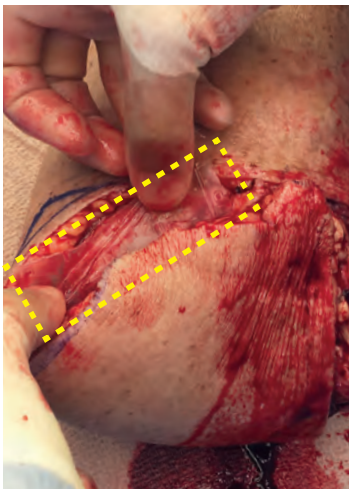


Figure 4: AMNIOFIX in subcutaneous tissue before closure

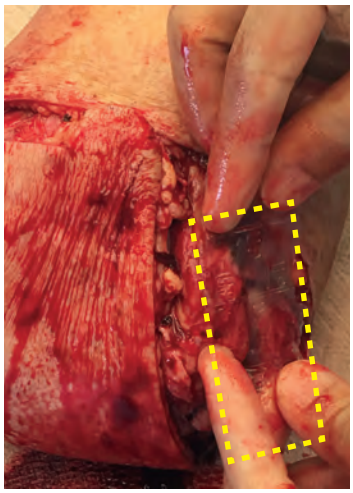


Figure 5: AMNIOFIX in subcutaneous tissue before closure

Figure 6: Flap closure

Follow-Up

The patient fell onto her stump in the hospital five days post-operatively. Despite the fall and resultant mild dehiscence, there was no swelling and the stump remained intact (Figure 7). This type of injury could have resulted in amputation failure. After thirty days, the BKA incision was fully closed. The patient was again seen eleven weeks post-op and the amputation remained stable (Figure 8).

Figure 7: S/P fall onto stump on Day 5

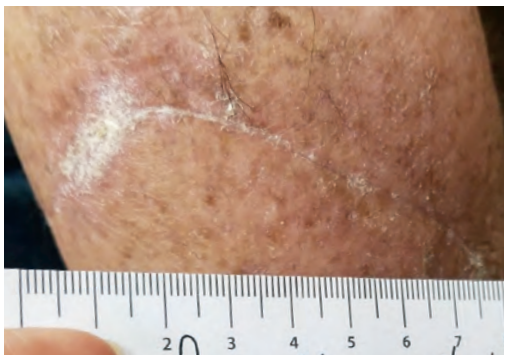


Figure 8: Wound fully closed

Conclusion

High-risk patients, even in the setting of the adequate perfusion, can encounter postoperative wound complications. In this case, despite the early signs of dehiscence, the amputation wound site closed in a very challenging patient with a history of non-healing.

Caesarean Section with AMNIOFIX

Angela F. Falany, MD | Obstetrics & Gynecology | Canton, GA

Challenge

Adhesions were expected after two prior full-term C-section deliveries, and there were concerns for postoperative wound complications due to the patient's obesity and large pannus.

Clinical History

31-year-old G4, P2012 with a BMI of 46 scheduled for her 3rd full-term C-section and bilateral salpingectomy.

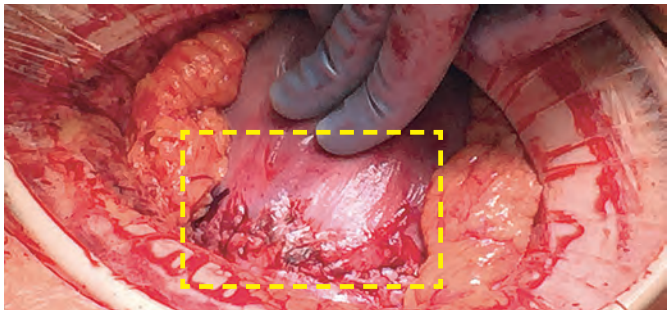
Surgical Intervention

Dense adhesions were present while gaining access to the uterus and well as between the bladder and the uterus. Adhesiolysis left a defect in the uterus and bilateral salpingectomy was performed. AMNIOFIX was placed on each tubal excision site and the uterus defect closure. (NOTE: Normally, this surgeon would have preferred to place AMNIOFIX on the entire uterine suture line, especially if a future C-section was expected.)

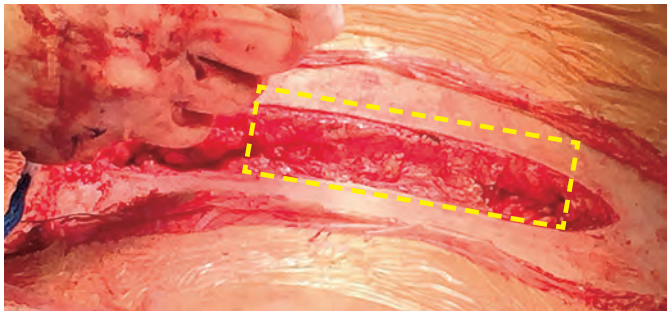
After fascial closure, a 2 cm x 12 cm AMNIOFIX graft was also placed in the incision site and then, the skin was closed.

Follow-Up

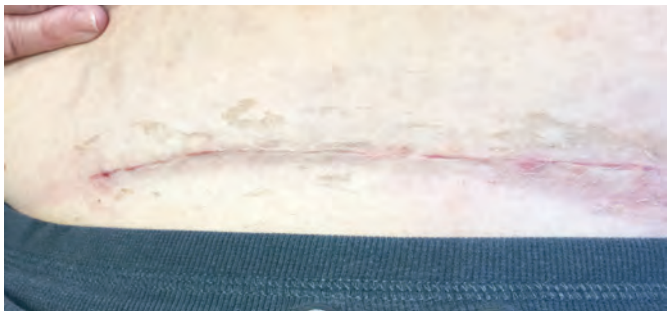
At 10 day follow-up, the incision was fully closed without signs of infection. This was impressive considering the large pannus fully covering the incision site. The patient also indicated that she had a faster recovery compared to her prior deliveries.



AMNIOFIX placed on uterus defect closure



AMNIOFIX placed in subcutaneous space after fascial closure



Incision 10 days postop

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Open Laparotomy in Comorbid Patient with AMNIOFIX

Angela F. Falany, MD | Obstetrics & Gynecology | Canton, GA

Challenge

Patient at high risk of post-operative wound complications due to heavy smoking and malnutrition.

Clinical History

A 48-year-old female presented in the ER for a pelvic mass. She stated that her abdominal pain had progressively worsened over the past six months to the point that she is unable to eat due to the pain. Upon examination, the patient was noted to have a 22 cm abdominal mass and weighed only 85 pounds due to lack of eating. Significant social history included heavy smoking at 2 ½ packs a day. The patient had not been seen previously due to lack of medical insurance.

Surgical Intervention

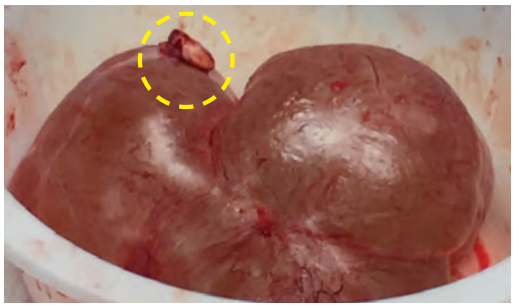
The patient underwent an open laparotomy to remove the large mass, which was the right ovary. The left ovary was also removed and attention was placed towards the midline closure. Due to the heavy smoking and malnutrition, the patient had an increased risk of surgical site complications such as dehiscence, skin separation, and infection. After fascial closure, AMNIOFIX was placed into the laparotomy incision closure.

AMNIOFIX is a dehydrated human amnion/chorion membrane allograft for acute and chronic closures in sheet and fenestrated configurations. 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.[3-5]

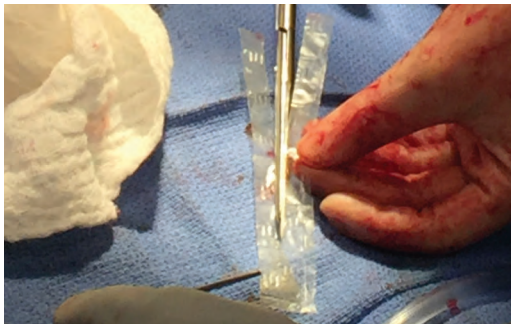
The patient was discharged without complications.

Follow-Up

The patient was seen multiple times within the first few weeks and the incision looked good and was fully closed.

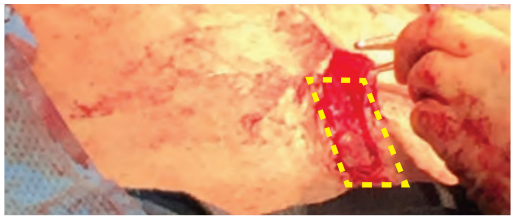


Left ovary (A) laid on top of right ovary (entire mass) to show scale



2 cm x 12 cm AMNIOFIX cut lengthwise

After fascial closure, the two pieces 1 cm x 12 cm AMNIOFIX placed into entire incision line and damp towel was used to maneuver grafts into position



Skin closed over AMNIOFIX

NOTE - Once AMNIOFIX is in its desired position, take care not to press damp cloth too hard, as the graft can stick to the cloth and move out of position. Clinicians commonly poke small holes in the graft. AMNIOFIX FENESTRATED sheets are also available.

Lower Extremity Bypass Dehiscence with EPIFIX and NPWT

Shonak B Patel, MD, Christopher J Lecroy, MD | Vascular Surgery | Pensacola, FL

Challenge

Data suggests that wound complications following lower extremity bypass surgery are observed in >11% of cases. Notably, wound complications are one of the most common reasons for hospital readmission within 30 days.[6] Wound dehiscence in lower extremity bypass patients commonly occurs secondary to an underlying seroma, hematoma, or tissue flap created during saphenous vein harvest. These wounds can be challenging to close as they often extend along the entire limb. Furthermore, closing these wounds in an expedited fashion helps preserve graft integrity and patency, thus avoiding potential graft infection and or occlusion.

Clinical History

A 78-year-old male presented with a right first toe necrosis and underwent endovascular therapy for known superficial femoral artery (SFA) occlusion. The patient had multiple comorbidities including diabetes, hypertension, hyperlipidemia, peripheral arterial disease, and prior smoking. The initial revascularization was successful, but on follow-up, duplex surveillance showed recurrent occlusion. He subsequently underwent a right femoral to above the knee popliteal bypass with a greater saphenous vein graft. Intraoperatively, a drain was placed along the harvest site. The drain was removed on post-op day four. At that time, the incision was intact with no fluid collection observed. Unlike our current practice when treating high-risk patients, no AMNIOFIX allografts were placed in the surgical site at the time of the bypass procedure.

During his post-operative hospitalization, his venous bypass was found to be occluded secondary to outflow disease. The patient underwent endovascular therapy with successful revascularization of his native right SFA. A stent graft was placed and good two-vessel runoff to his right foot was noted.

Two weeks later the patient came to the office for staple removal. The incisions had closed, but he had a small seroma at the right medial thigh incision site, which dehisced the next day (Figure 1). The wound was treated initially with wet to dry dressings for four weeks, but did not significantly reduce in size. At this point due to the slow closure progression advanced wound therapy was warranted. The physician felt that the patient met the medical necessity criteria for advanced wound therapy and EPIFIX was investigated as an option for in-office treatments. All prior standard of care (SOC) treatments and wound progression were fully documented, an insurance authorization request was submitted, and EPIFIX was approved for treatments.^ EPIFIX is a dehydrated human amnion/chorion membrane allograft (Figure 2). EPIFIX sheets provide a semi-permeable protective barrier that supports the healing cascade and protects the wound bed to aid in the development of granulation tissue in acute and chronic closures. EPIFIX provides a biocompatible human extracellular matrix and retains 300+ regulatory proteins.[3-5]

Figure 1: Dehiscence and seroma at the right medial thigh incision site

Figure 2: EPIFIX

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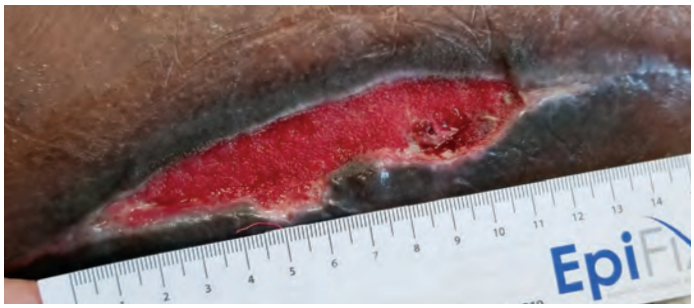

Figure 3: S/P four weeks of SOC dressings, prior to EPIFIX application

Figure 4: Week 2, S/P two EPIFIX + NPWT treatments

A small area was debrided around a thrombosed vein, which was excised. A 4 cm x 4.5 cm EPIFIX Mesh allograft was cut into two pieces, placed to fit onto the wound, and dressed with a non-adherent dressing and negative pressure wound therapy (NPWT). The NPWT dressing was left in place for five days in order to leave the EPIFIX undisturbed, and the process was repeated again the following week (Figure 3,4). Weekly applications of EPIFIX covered with non-adherent and conventional dressings were done in the office setting thereafter. The wound was closed after six weeks of EPIFIX application (Figures 5,6).

Figure 5: Week 4, S/P four EPIFIX treatments

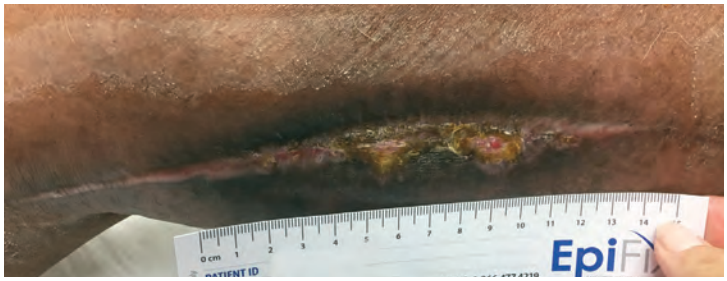

Figure 6: Week 6, S/P six EPIFIX treatments

Figure 7: Week 10, wound fully closed and stable

Follow-Up

The patient returned for another follow-up four weeks later and the wound remained fully closed and stable (Figure 7). Lastly, the original complication with the right first toe nearly resolved with only a small scab and an amputation being avoided.

Conclusion

Saphenous vein harvest site breakdown is common among patients with peripheral arterial disease and patients with morbid obesity. In this case, weekly EPIFIX applications during in-office visits supported wound closure that was not seen with SOC.

^**NOTE-** Insurance reimbursement varies by payer, geography, and patient-specific factors. Your local Account Executive or Field Reimbursement Manager can help explain the Insurance Verification Process, as well as resources available to customers.

Acute Abdominal Wall Dehiscence with EPIFIX

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

Challenge

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.[7,8]

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.[3-5]

EPIFIX

Follow-Up

Upon examination at his two month EPIFIX follow-up visit, the wound was fully closed and re-epithelialized.

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

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Keloid Scar Revision with EPIFIX

Sanders R. Callaway, MD | Dermatology | Augusta, GA

Clinical History

Patient presented with keloid scar (Figure 1) after Caesarean section procedure.

Treatment

One third of the keloid scar was treated with EPIFIX in revision surgery to evaluate its outcome prior to treating the remainder of the scar (Figure 2). EPIFIX was placed within the incision site before suturing.

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Follow-Up

The scar was greatly reduced in height and in color (Figure 3). Subsequent revision surgery treated the remainder of the keloid scar with EPIFIX.

Figure 1: Preoperative presentation

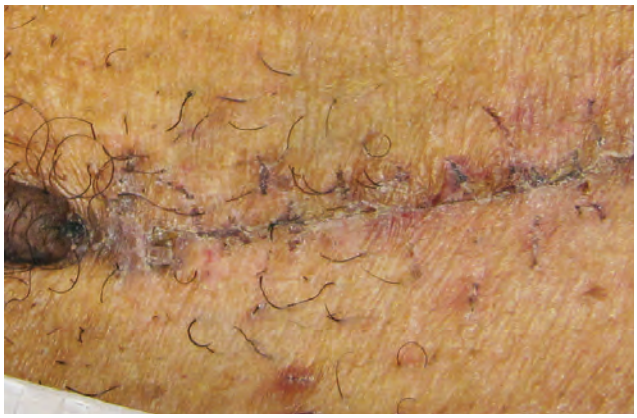

Figure 2: Post-scar revision using EPIFIX on 1/3 portion of original scar

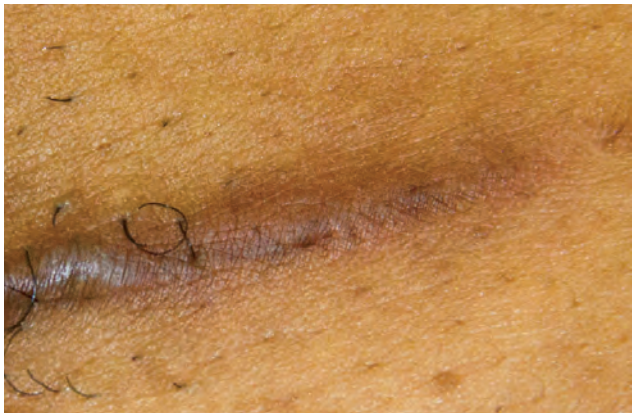

Figure 3: Scar after EPIFIX treatment

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OFFICE or CLINIC ⟷ **OPERATING ROOM**

EPIFIX® / EPIFIX® MESH / AMNIOFIX® / AMNIOFIX® FENESTRATED

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- Acute and chronic wounds
- Provides a barrier membrane
- MESH and FENESTRATED configurations allow for the transfer of exudate

SHEET

MESH

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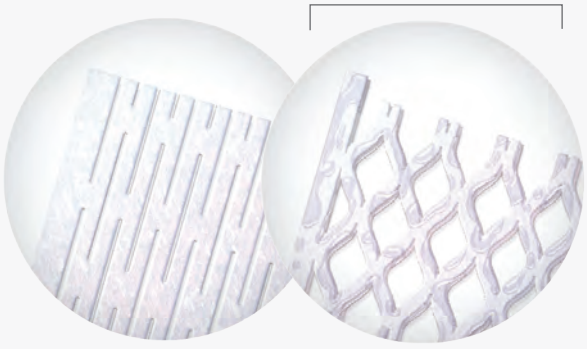
Dehydrated umbilical cord allograft with ECM and 250+ regulatory proteins.[5,9]

- Smaller, deeper wounds or surgical sites
- When graft fixation is desired
- Provides a barrier membrane
- 2 cm x 3 cm expands to 12 cm^2 (EPICORD EXPANDABLE)[10]

SHEET

EXPANDS



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REFERENCES 1. Ammendola, et al. Int Wound J. 2007;14(1):9-15. **2.** Thorud, et al. J Foot Ankle Surg. 2016;55(5):1007-1012. **3.** Koob, et al. J Biomed Mater Res B Appl Biomater. 2014;102(6):1353-62. **4.** Lei, et al. Adv Wound Care. 2017;6(2):43-53. **5.** MM-RD-00086, Proteome Characterization of PURION Processed Dehydrated Human Amnion Chorion Membrane (dHACM) and PURION Plus Processed Dehydrated Human Umbilical Cord (dHUC) Allografts. **6.** Zhang, et al. J Vasc Surg. 2014; 59(5):1331–39. **7.** Thombs, et al. Ann Surg. 2007;245(4):629-34. **8.** Dunne, et al. J Surg Res. 2003;111(1):78-84. **9.** Bullard, et al. J Biomed Mater Res B Appl Biomater. 2019;107(4):1035-1046. **10.** See MIMEDX Product Instructions for Use for further details.

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