AROA ECM™

Myriad™

Soft Tissue Bioscaffold

Clinical Evidence

Myriad + NPWT

Myriad™

Clinical Evidence:
Myriad + NPWT

Myriad works synergistically with Negative Pressure Wound Therapy (NPWT) to accelerate tissue regeneration and reduce wound complexity

NPWT aids in the healing process by increasing local blood flow and granulation tissue formation, and removing potentially infectious material.[1] However, it doesn't replace the components of the missing extracellular matrix (ECM).

Rebuilding the ECM is a critical feature of wound healing, involving important interactions between ECM proteins, growth factors and cells.[2]

Myriad works synergistically with NPWT by providing the ECM scaffold, vascular channels and biology known to be important in healing.[3-6]

Day 28

Duration of NPWT therapy with Myriad

Clinical evidence has demonstrated that the duration of NPWT ranges from an median of 3.8-4.0 weeks when Myriad is added to NPWT management of complex volumetric defects, often involving exposed structures.

Myriad Study	Median NPWT duration	Average number of Myriad applications
Cormican, M. T., N. J. Creel, B. A. Bosque, S. G. Dowling, P. P. Rideout and W. M. Vassy (2023). "Ovine Forestomach Matrix in the Surgical Management of Complex Volumetric Soft Tissue Defects: A Retrospective Pilot Case Series." ePlasty 23: e66.	3.8 weeks	1.2
Taarea, R., A. Florence, B. Bendixen and C. A. Castater (2024). "Early Experience with Ovine Forestomach Matrix for the Reconstruction of Abdominal Defects following Emergency Open Abdomen Surgery at a Level 2 Trauma Center." Trauma Cases Rev 10(1): 102.	4.0 weeks	1.7
Bosque, B. A., S. G. Dowling, B. C. H. May, R. Kaufman, I. Zilberman, N. Zolfaghari, H. Que, J. Longobardi, J. Skurka, J. E. Geiger and M. M. Melin (2023). "Ovine Forestomach Matrix in the Surgical Management of Complex Lower-Extremity Soft-Tissue Defects: A Retrospective Multi-Center Case Series." J Am Podiatr Med Assoc 113(3): 22-081.	3.8 weeks	1.0

Myriad™

Myriad + NPWT Protocol

Soft Tissue Defect or Surgical Wound

PRIOR TO MYRIAD PLACEMENT

Prepare the wound bed by cleansing, irrigation and, if necessary, sharp or ultrasonic debridement to ensure the wound is free of debris, necrotic tissue or infected tissue.

FOR MYRIAD MORCELLS™ PLACEMENT*

1. Myriad Morcells may be rehydrated first, either in the tray or poured into the defect and rehydrated with saline
2. Apply Myriad Morcells/Myriad Morcells Fine™ throughout the wound bed, and especially to areas with an irregular surface or depth

If placing Myriad Matrix over Myriad Morcells, refer to the Myriad Matrix Placement instructions

FOR MYRIAD MATRIX™ PLACEMENT*

1. Cut Myriad Matrix according to size of wound
2. Rehydrate Myriad Matrix with sterile saline in a shallow bowl or basin
3. Secure Myriad Matrix in place using standard techniques

OPEN WOUND + PRIMARY DRESSING

Place non-adherent contract dressing over Myriad products to protect from NPWT foam interface

FOR PRIMARY INCISIONAL CLOSURE

For implanting Myriad Matrix, or part of reconstructive tissue flap. Closure as per clinician preference

PLACE NPWT SYSTEM

- Place foam interface over incision or open wound
- Place NPWT drape per standard protocol

PRIMARY INCISIONAL CLOSURE: FIRST 5-7 DAYS

- Keep incisional NPWT system in place
- Myriad does not increase the need for NPWT dressing changes

OPEN WOUND: FIRST 5-7 DAYS

- Keep non-adherent contact layer intact if changing NPWT foam dressing to minimize graft disruption and allow full integration
- Myriad does not increase the need for NPWT dressing changes

DAYS 5-14 DAYS

- Take down NPWT seal and foam
- Gently remove non-adherent contact dressing to evaluate wound
- Rehydrate Myriad
- Keep Myriad graft in place until completely integrated
- Apply new NPWT dressing as needed until depth of wound is flush to adjacent skin

UNTIL WOUND CLOSURE

- Convert to standard-of-care dressing with changes as needed
- Consider outpatient use of Endoform™ or Symphony™ to facilitate closure if not a candidate for skin grafting

Closure

*As per the IFU provided

Myriad™

Clinical Evidence:
Myriad + NPWT

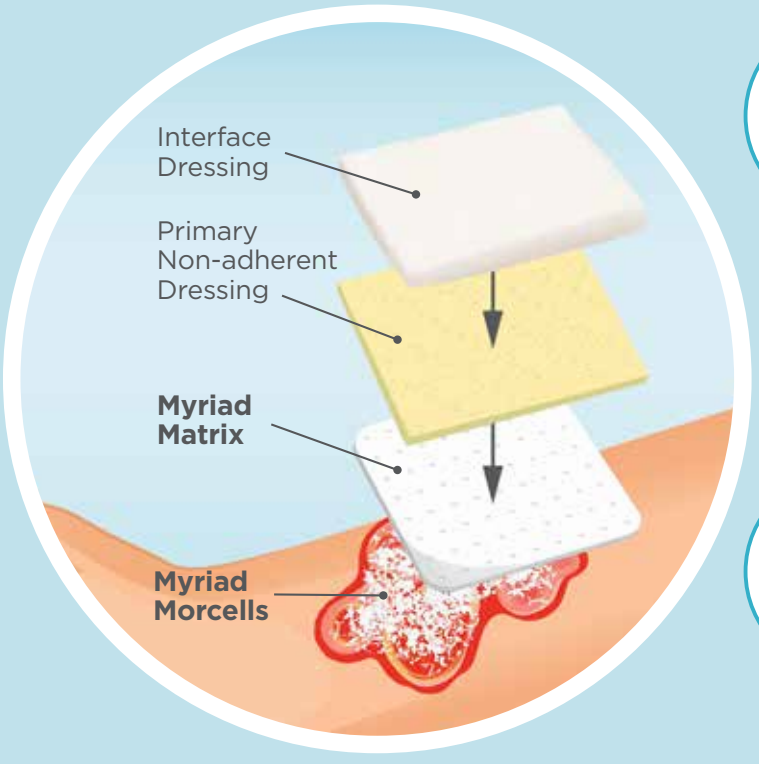
How to use Myriad + NPWT

All Myriad devices are compatible with NPWT. When utilizing NPWT as a secondary dressing, it is important to have a non-adherent dressing placed between the Myriad products and the foam interface dressing.

- The non-adherent dressing can be placed directly over the Myriad products with the option to secure it in place with sutures.
- The NPWT dressing can be changed every 2-3 days according to institutional protocols, or recent studies have shown this can be extended to every 5-7 days.[3,6]
- When implanted under an incisional closure or reconstructive tissue flap, Myriad Matrix is compatible with incisional NPWT.[5]

Dressing Change Guidance

It is important to ensure the Myriad device remains adequately hydrated between dressing changes.



5-7 days for first dressing

The first dressing change is recommended between days 5-7. At the scheduled dressing change, carefully remove the interface and non-adherent dressings to avoid disrupting Myriad in the wound bed.

10-14 days for primary non-adherent dressing

Consider leaving the primary non-adherent dressing in place for the initial 10-14 days to minimize interference as the Myriad device integrates.

Myriad™

Clinical Evidence:
Myriad + NPWT

Cormican, M. T., N. J. Creel, B. A. Bosque, S. G. Dowling, P. P. Rideout and W. M. Vassy (2023). "Ovine Forestomach Matrix in the Surgical Management of Complex Volumetric Soft Tissue Defects: A Retrospective Pilot Case Series." ePlasty 23: e66

Key takeaways - defect characteristics:

A retrospective case series of 10 patients with 13 volumetric soft tissue defects surgically managed in a Level 1 trauma center.

85% had exposed structures

85% of defects had exposed structures and all were CDC grade 2 or higher

7 of 13 defects had staged reconstruction

Staged reconstruction was used in 7 of 13 defects, with the remaining 6 healing via secondary intention

Outcomes

23 days mean overall time

Mean time to 100% granulation was 23 days

0 complications

There were no major complications

6.4 weeks mean time to closure

Mean overall time to closure was 6.4 weeks

Myriad complements NPWT usage

3.8 weeks median duration of NPWT usage

NPWT median duration of usage with Myriad was 3.8 weeks

1.2 median Myriad applications

Median of only 1.2 Myriad applications

5-7 day dressing interval

Dressing change frequency was adapted to every 5-7 days, as opposed to typical frequency of every 2-3 days

"... this may have significant long-term impacts on the health economics of managing these complex defects by reducing the burden and costs associated with postoperative care of these patients ..."

Myriad™

Clinical Evidence:
Myriad + NPWT

Open hip defect following motor vehicle accident

36-Year-old, male. Full thickness right hip wound from blunt trauma due to motor vehicle accident. Approximate size; 18 x 13 x 20 cm. Four days after an initial debridement and following a serial sharp debridement, **Myriad Morcells™** 2000 mg were applied and hydrated with blood in situ and then NPWT was applied. At day 5, depth reduction (approx. 2 cm) and budding granulation tissue was noted. Two **Myriad Matrix™** 10 x 20 cm, 5-layer devices were then applied, hydrated with blood in situ, quilted together and secured with staples with continuation of NPWT. By day 15, there was continued formation of robust, vascularized tissue, but the patient declined a STSG. By week 4, there was significant reduction of wound area and volume with no complications. Planned healing was by secondary intention. By week 7, approximately 1 cm of depth remained and by week 13 the wound had fully epithelialized.[3]

Duration of NPWT was 8 weeks.

Initial Defect

Myriad Morcells™ Application

Day 5 - Post debridement

Day 5 - **Myriad Matrix™** Application

Day 8

Week 4

Week 7

Week 21

CC.0168.00

Myriad™

Clinical Evidence:

Application in NSTI of the Thigh

NSTI of the thigh

56-Year-old, trans male. Full thickness wound of the left posterior thigh with exposed hamstrings muscle and tendon. Approximate size: 21 x 10 x 2 cm. Multiple sharp debridements of nonviable tissue were performed and multiple pieces of **Myriad Matrix™** 10 x 20 cm 5-layer were sutured into place. At day 28, 100% vascularized, granular neodermis had formed with no complications. Split thickness skin graft applied at day 35 (not shown) with 100% take of the skin graft and no complications.[3]

Duration of NPWT was 4 weeks.

Initial Defect

Application

Day 8

Day 16

Day 28

Day 56

CC.0156

Myriad™

Clinical Evidence:
Myriad + NPWT

Taarea, R., A. Florence, B. Bendixen and C. A. Castater (2024). "Early Experience with Ovine Forestomach Matrix for the Reconstruction of Abdominal Defects following Emergency Open Abdomen Surgery at a Level 2 Trauma Center." Trauma Cases Rev 10(1): 102.

Key takeaways:

A retrospective observational case series of 3 emergency open abdominal defects

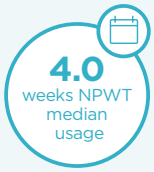
All defects were at or beyond the level of the fascia, clean contaminated (grade 2) and in one case, there was exposed viscera

Outcomes

Average time to full graft integration was 19.3 days

There were no complications

Myriad complements NPWT usage



NPWT median duration of usage with Myriad was 4.0 weeks

NPWT dressings were changed on a weekly basis

"... by using a biological graft to expedite tissue regeneration providers can potentially reduce the number of dressing changes and overall duration of NPWT, thereby reducing financial burden for patients and facilities alike..."

Myriad™

Clinical Evidence:
Myriad + NPWT

Abdominal dehiscence following motor vehicle accident

49-Year-old male. Presented with surgical dehiscence of the fascial layer following multiple damage control laparotomies post a high velocity motor vehicle accident. Other complications included obesity, hypotension, and repaired liver and bladder. After irrigation and debridement, the midline defect measured 31 cm x 7 cm x 4 cm. Myriad Morcells™ 1000 mg was applied and hydrated in situ with sterile saline and blood. NPWT was applied for 2 weeks, with weekly dressing changes. At day 4, **Myriad** was observed to be well adhered and integrating with budding granulation tissue observed. By week 2, **Myriad** was 80% integrated with significant granulation tissue noted. At week 3, there was 90% integration and healthy vascularized tissue was filling in the depth of the wound. At week 6, the wound had fully closed with no complications. Patient ultimately underwent planned hernia repair at 20 weeks and has had no complications or recurrence through 70 weeks post-operatively.[4]

Pre-operative Assessment

Morcells application

Week 2

Week 3

Week 6

CC.0072.01

Myriad™

Clinical Evidence:
Myriad + NPWT

Bosque, B. A., S. G. Dowling, B. C. H. May, R. Kaufman, I. Zilberman, N. Zolfaghari, H. Que, J. Longobardi, J. Skurka, J. E. Geiger and M. M. Melin (2023). "Ovine Forestomach Matrix in the Surgical Management of Complex Lower-Extremity Soft-Tissue Defects: A Retrospective Multi-Center Case Series." J Am Podiatry Med Assoc 113(3): 22-081.

Key takeaways:

N=50
Patients

A retrospective case series of 50 patients **with complex lower extremity defects**

Outcomes

26
days to full graft integration

Mean time to graft integration was 26.0 days

13.7
weeks to heal

Overall mean time to heal = 13.7 weeks

1.0
application per case

Median product applications per case = 1.0

3.8
weeks of usage

NPWT median duration of usage with Myriad was 3.8 weeks

Myriad™

Clinical Evidence:
Myriad + NPWT

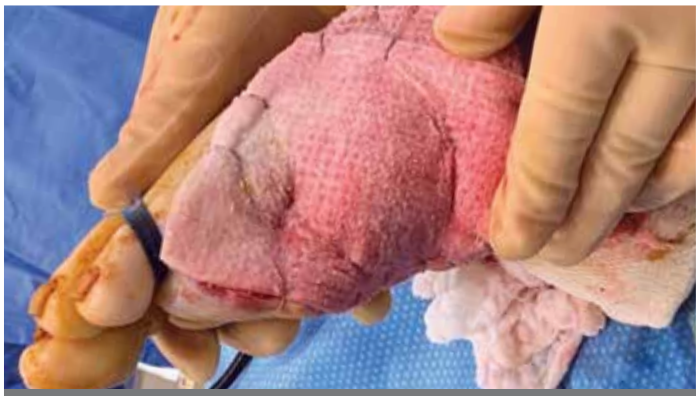
Necrotizing soft tissue infection of the foot

28-Year-old, male with insulin-dependent diabetes presented with a necrotizing soft tissue infection and sepsis of the foot. In a staged procedure, debridement of non-viable soft tissue and bone was performed resulting in a volumetric defect with exposed tendon and bone. At the second stage, **Myriad Matrix™** 10 x 10 cm, 5-layer was applied directly to the wound bed and stapled into place followed by NPWT. At week 1, **Myriad** was well integrated revealing 100% viable granulation tissue and full coverage of bone and tendon. A STSG was placed. At week 3 there was 90% graft take. By week 8 the STSG had fully integrated with a pliable scar. The foot was functional and the patient was able to wear shoes and return to work. There was no recurrence at 6 month follow-up.[5]

Duration of NPWT was 3 weeks.

Initial defect

Resection



Myriad Matrix™ application

Week 1

Week 3 (2 weeks post STSG)

Week 8

CC.0030

References:

1. Norman G, Goh EL, Dumville JC, Shi C, Liu Z, Chiverton L, Stankiewicz M, Reid A. Negative pressure wound therapy for surgical wounds healing by primary closure. Cochrane Database Syst Rev. 2020 Jun 15;6(6):CD009261. doi: 10.1002/14651858.CD009261.pub6. Update in: Cochrane Database Syst Rev. 2022 Apr 26;4:CD009261.
2. Schultz GS, Wysocki A. Interactions between extracellular matrix and growth factors in wound healing. Wound Repair Regen. 2009 Mar-Apr;17(2):153-62.
3. Cormican, M. T., N. J. Creel, B. A. Bosque, S. G. Dowling, P. P. Rideout and W. M. Vassy (2023). "Ovine Forestomach Matrix in the Surgical Management of Complex Volumetric Soft Tissue Defects: A Retrospective Pilot Case Series." ePlasty 23: e66.
4. Taarea, R., A. Florence, B. Bendixen and C. A. Castater (2024). "Early Experience with Ovine Forestomach Matrix for the Reconstruction of Abdominal Defects following Emergency Open Abdomen Surgery at a Level 2 Trauma Center." Trauma Cases Rev 10(1): 102.
5. Bosque, B. A., S. G. Dowling, B. C. H. May, R. Kaufman, I. Zilberman, N. Zolfaghari, H. Que, J. Longobardi, J. Skurka, J. E. Geiger and M. M. Melin (2023). "Ovine Forestomach Matrix in the Surgical Management of Complex Lower-Extremity Soft-Tissue Defects: A Retrospective Multi-Center Case Series." J Am Podiatr Med Assoc 113(3): 22-081.
6. Chaffin, A. E., S. G. Dowling, M. S. Kosyk and B. A. Bosque (2021). "Surgical reconstruction of pilonidal sinus disease with concomitant extracellular matrix graft placement: a case series." J Wound Care 30(Sup7): S28-S34.

For product questions, sampling needs, or detailed questions concerning our products, please contact us:

For the US: **P** 1-877627-6224 | **E** customerservice@aroa.com

For all other countries: call your local representative or email globalsales@aroa.com

AROA™

www.aroa.com

MKT.2142.00 | © April 2024