AROA ECM™

Myriad™

Application Notes

Myriad Matrix™ & Myriad Morcells™

Soft Tissue Bioscaffold

Morcellized Bioscaffold

Unlocking regenerative healing for every*body*

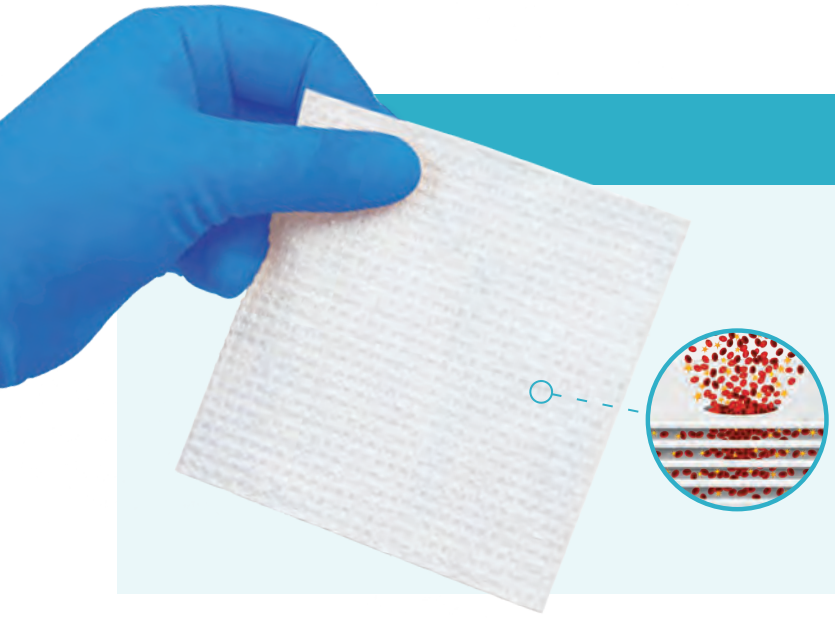
AROA™

Myriad™

Soft Tissue Bioscaffold

Contents

Myriad™ | Portfolio for Soft Tissue Repair



Myriad Matrix™

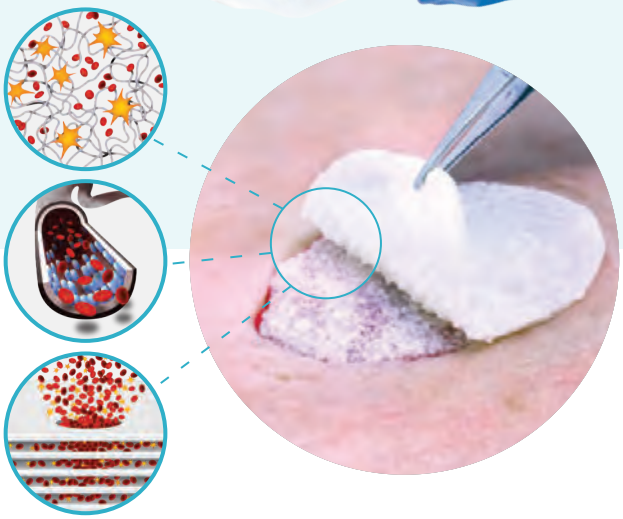
Available as 2-, 3- or 5-layers of non-crosslinked AROA ECM™

For **soft tissue reconstruction, reinforcement** or **complex wounds**

Myriad Morcells™

Morcellized AROA ECM

For **management of acute and chronic wounds,** including closed surgical wounds



Myriad™

Soft Tissue Bioscaffold

General

Always read the **Instructions For Use**. Prescription use only. The following guidelines should not supersede professional or institutional guidelines. These guidelines have been developed based on good surgical technique and the experience of surgeons. The guidelines are intended to be a quick reference to important information on the use of **Myriad Matrix™** and **Myriad Morcells™**. For additional information contact your Sales Representative at **1-877-627-6224**, or **www.aroabio.com**.

Preparation of the Site

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.

If the tissue defect has been irrigated with antiseptic solutions (e.g. hypochlorous acid, sodium hypochlorite, Povidone-iodine, chlorhexidine gluconate) it is recommended to rinse the area with sterile saline prior to application of **Myriad** products. Antiseptic solutions may damage the structure and extracellular matrix (ECM) components found in **Myriad** products.

Ideally the tissue deficit will have healthy and well vascularized tissue to optimize the incorporation of **Myriad** devices. Do not apply **Myriad** devices in the presence of uncontrolled clinical infection.

Wound bed contamination is known to limit the use of certain dermal matrices due to high rates of infection.[1-3] Myriad products have been shown to be relatively resistant to bacterial contamination and may be used in contaminated soft tissue defects without having to wait till a pristine wound bed is achieved.[4-6]

Where exposed bone is present, including calvarium, and denuded of the vascularized periosteum, a burr or drill attachment may be used to expose the vascular diploe. **Myriad** devices can then be applied to the bleeding calvarium or bone.

Product Selection

Consider using **Myriad Morcells** in soft tissue defects with irregular, undermined or tunneled areas.

Myriad Matrix is available in 2-layer, 3-layer and 5-layer configurations. Thicker configurations of **Myriad Matrix** may persist longer in the wound. Consider using;

- 2-Layer and 3-layer configurations in superficial and partial-thickness defects.
- 3-Layer and 5-layer for deep-partial and full thickness defects with, or without, exposed structures.

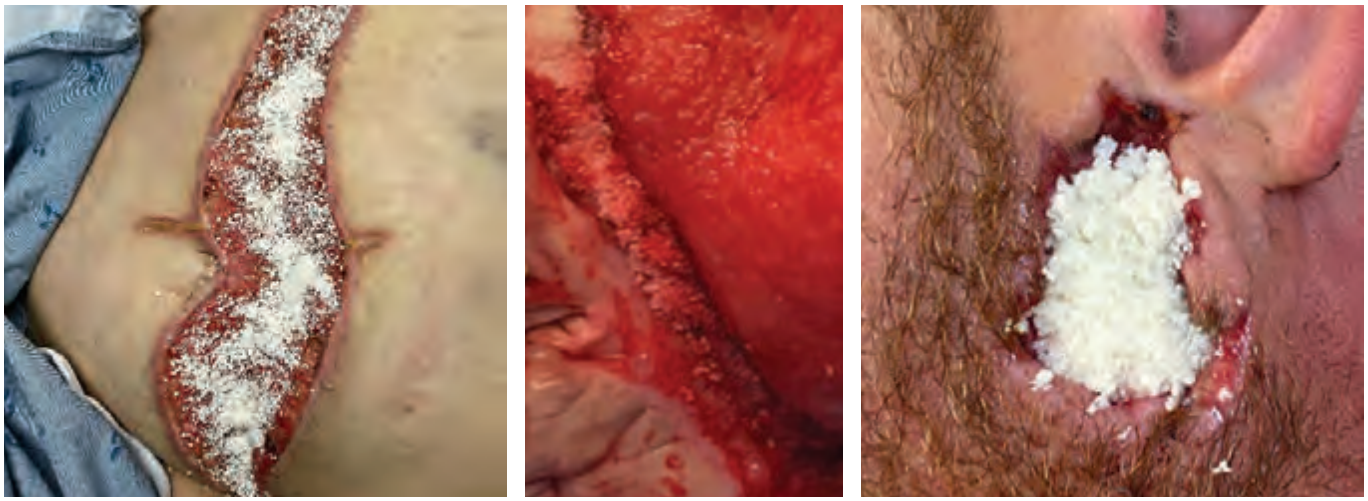
Myriad Morcells and **Myriad Matrix** may be used in combination.
Consider using both **Myriad** devices in instances of significant volumetric tissue loss.

Preparing Myriad Morcells

1) **Myriad Morcells** are supplied in a sterile tray. **Myriad Morcells** may be poured directly from the tray into the soft tissue deficit, then rehydrate in the soft tissue defect. Alternately, **Myriad Morcells** can be rehydrated with sterile saline and then transferred to the defect.

2) Apply **Myriad Morcells** throughout the wound bed, and especially to areas with an irregular surface or depth to achieve a more planar surface (Figure 1).

Figure 1. Representative images showing application of **Myriad Morcells**.



3) **Myriad Morcells** may be packed into tunneled or undermined areas of the wound.

Consider using **Myriad Matrix** to bolster the **Myriad Morcells** to the soft tissue deficit (Figure 4).

Preparing Myriad Matrix

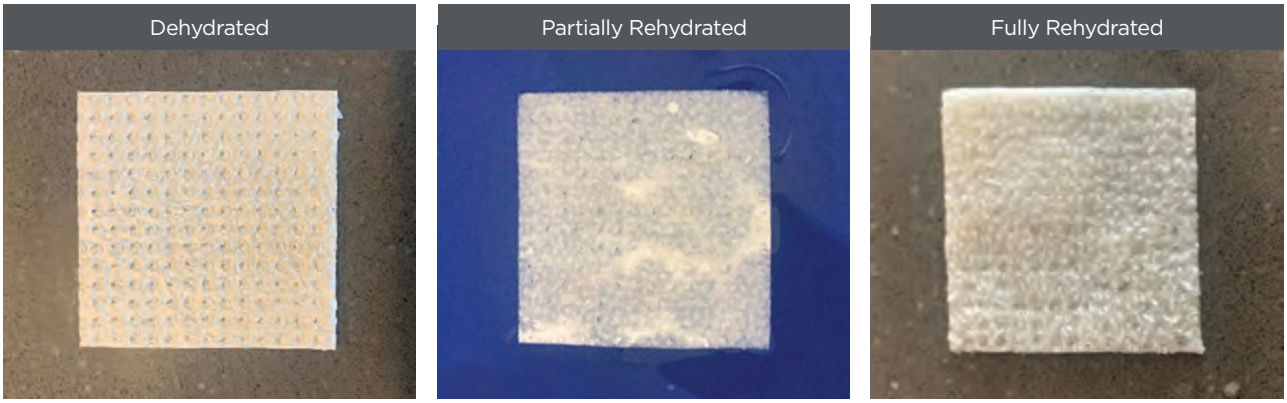
Prior to and during rehydration of the device it is important to limit excessive handling to preserve the engineered multi-layer structure of the device.

1) Once removed from the packaging using aseptic technique, place the **Myriad Matrix** device in a shallow sterile bowl or basin, ensuring that the container is larger than the device, so the device can lie flat during rehydration.

2) Add sufficient sterile saline to cover the device and rehydrate.

As the device rehydrates you may notice a change in the appearance of the device, from white to opaque (Figure 2).

Figure 2

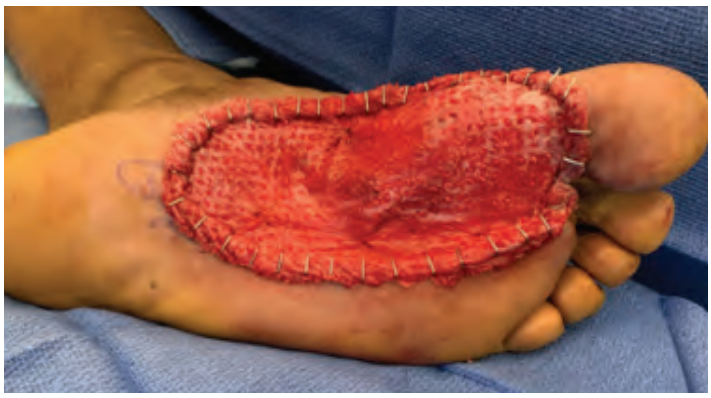


Do not rehydrate **Myriad** devices in antiseptic solutions (e.g. hypochlorous acid, sodium hypochlorite, Povidone-iodine, chlorhexidine gluconate) as these chemical disinfectants may damage the structure or ECM components.

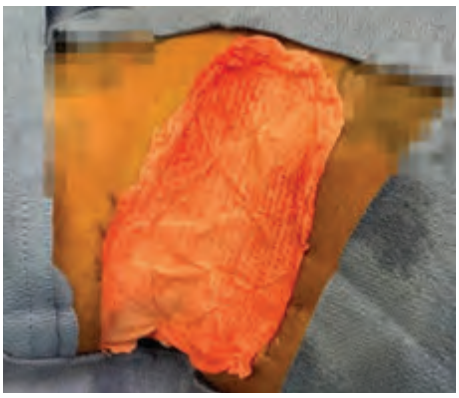
Always use asceptic technique e.g. avoid placing the device on linting surfaces (e.g. surgical drapes, back table drapes) as lint fibers may contaminate the device and have been known to increase rates of infection.[7, 8]

3) Trim the **Myriad** device to fit, if necessary, providing an allowance for overlap. Position the device to achieve maximum contact between the device and prepared wound surface. It is recommended to suture, or staple the device in place, avoiding excess tension (Figure 3). Fixing the device in place helps to ensure intimate contact with the underlying wound bed and reduces movement of the device during the healing process. Also, consider bolster staples or sutures to the central part of the device to further ensure intimate and sustained contact to the underlying tissue.

Figure 3. Examples of **Myriad Matrix** surgical fixation.



Stapled to the wound perimeter of the foot plantar.



Sutured to wound perimeter on axilla. Tacked down with interrupted absorbable sutures in central portion.

Multiple devices may be sutured together.

Dressing Selection

Myriad products may be used with a range of primary and secondary dressings.

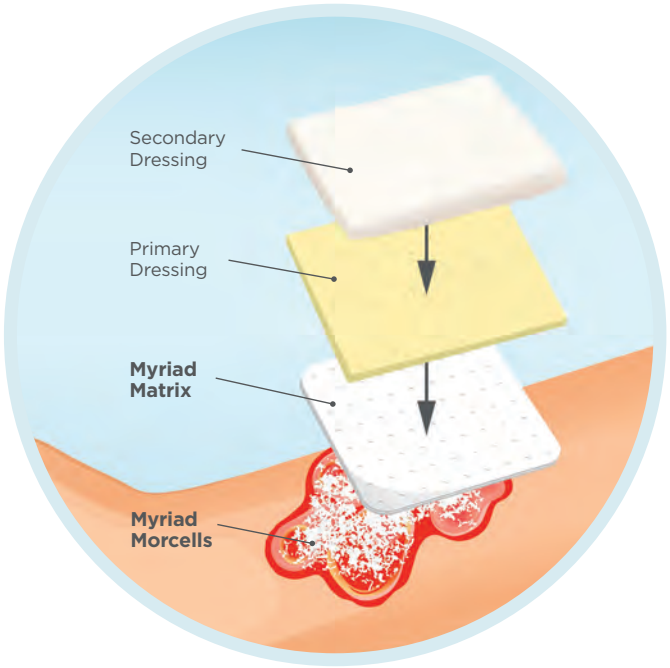


Figure 4.
Use of **Myriad** products with primary and secondary dressings.

Primary Dressing

It is recommended to use a non-adherent petrolatum or silicon-based dressing (e.g. Xeroform®, Adaptic™ or Mepitel®) (Figure 4) placed directly in contact with **Myriad** productsto surrounding tissue to prevent loss and limit movement.

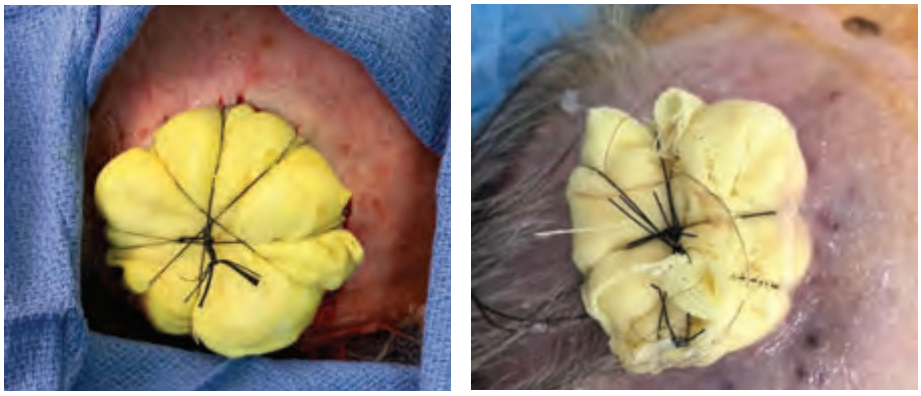
Secondary Dressing

Secondary dressings, including foams, abdominal gauze (ABD) pads, NPWT or bolster dressings can be used in conjunction with **Myriad** products dependent on the level of exudate, patient factors, wound site and institutional protocols.

Bolster Dressing

Repair of full thickness wounds, for example following tumor resections (Figure 5), may benefit from the use of a secondary bolster dressing (e.g. cotton wool, gauze) to ensure intimate contact between **Myriad** products and the underlying tissues.

Figure 5. Use of a bolster dressing to ensure approximation of **Myriad** to the underlying tissue defect.



NPWT

Myriad products are compatible with standard NPWT devices. 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. It is recommended that the foam interface be changed no sooner than 3-5 days to allow for adequate integration of the graft, but this is at the clinician's discretion. When implanted under an incisional closure or reconstructive tissue flap, **Myriad Matrix** is compatible with incisional NPWT.

Dressing Changes

Dressing change frequency is determined by several factors, including;

- Which **Myriad** product was utilized (i.e. **Matrix** or **Morcells**), and the amount of **Myriad** product applied
- The size and depth of the soft tissue defect
- The amount of exudate
- Institutional and clinical guidelines

The use of **Myriad** products should not increase the frequency of dressing changes.

Dressing Change Guidance

It is important to ensure the **Myriad** device remains adequately hydrated between dressing changes. The first dressing change is recommended between days 5-7.

At the scheduled dressing change, carefully remove the secondary and primary dressings to avoid disrupting **Myriad** in the wound bed.

Consider leaving the primary dressing in place for the initial 10-14 days to minimize interference with incorporation of the **Myriad** devices.

If portions of **Myriad** adhere to the primary dressing, add saline to hydrate and loosen the adherent material.

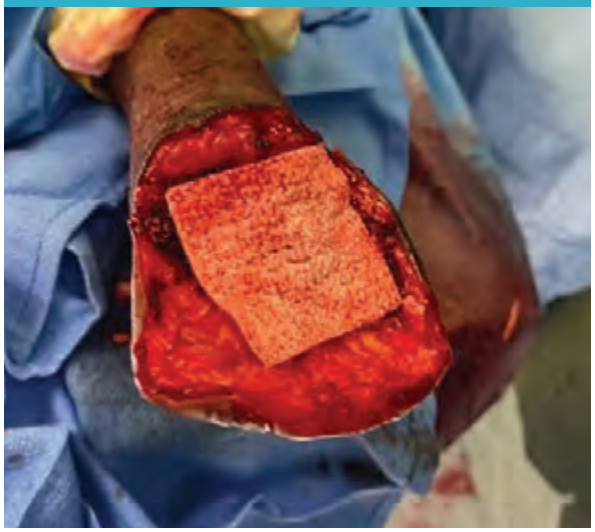
Moisture retention: A moist wound environment is important for wound healing and soft tissue repair. Always ensure **Myriad** products are fully rehydrated prior to use in either implant or dermal repair procedures. Where moisture retention is a potential concern, consider using a moistened alginate-based dressing placed over the non-adherent dressing. Additionally, a hydrogel may be added to the surface of the **Myriad** product, or on top of the primary dressing.

What to Expect on Placement of the Device

Myriad Matrix and **Myriad Morcells** absorb blood and blood components once placed in contact with the tissue defect. Absorption of blood and blood components will be visible on placement of the device (Figure 6).

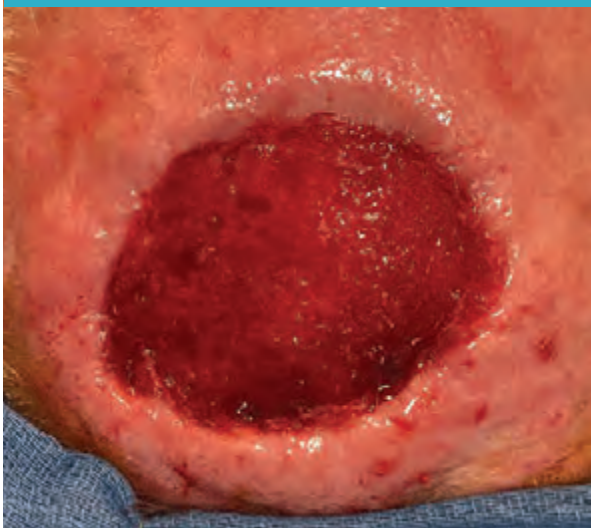
Figure 6. Appearance of **Myriad** products on application to the soft tissue defect.

Myriad Matrix



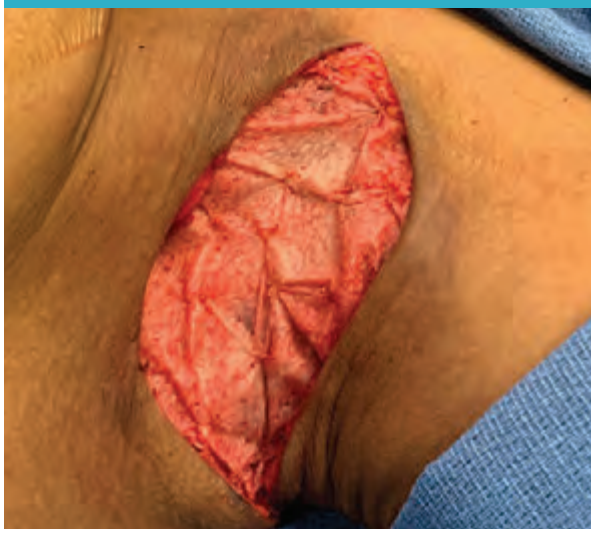
Trans metatarsal amputation.

Myriad Matrix



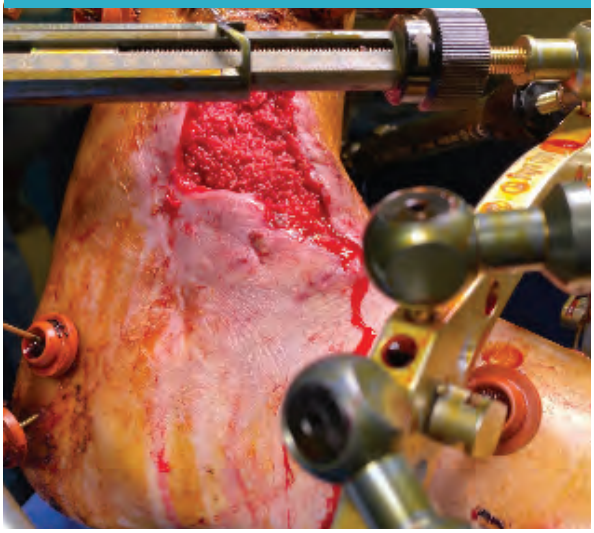
Scalp tumor resection.

Myriad Matrix



Axilla resection.

Myriad Morcells



Dorsal foot reconstruction.

Device Appearance and Integration in a Soft Tissue Defect

Myriad products incorporate into the wound bed over time as the devices provide a scaffold for new tissue formation.

The rate of incorporation is dependent on several factors such as the form and thickness of the **Myriad** device used, patient factors and site of the tissue deficit. Typically, buds of granulation tissue will be visible by 7-14 days as the device begins to integrate into the newly formed tissue (Figure 7).

Allow time for the device to incorporate. Tissue repair takes time, especially in instances of full thickness injuries, or significant volumetric tissue loss. Patience is required during the early stage of healing (<14 days) as the patient's cells populate the **Myriad** scaffold and begin the tissue repair process.

Early Timepoints (<14 days)

Figure 7. **Myriad** products at early (<14 days) timepoints.

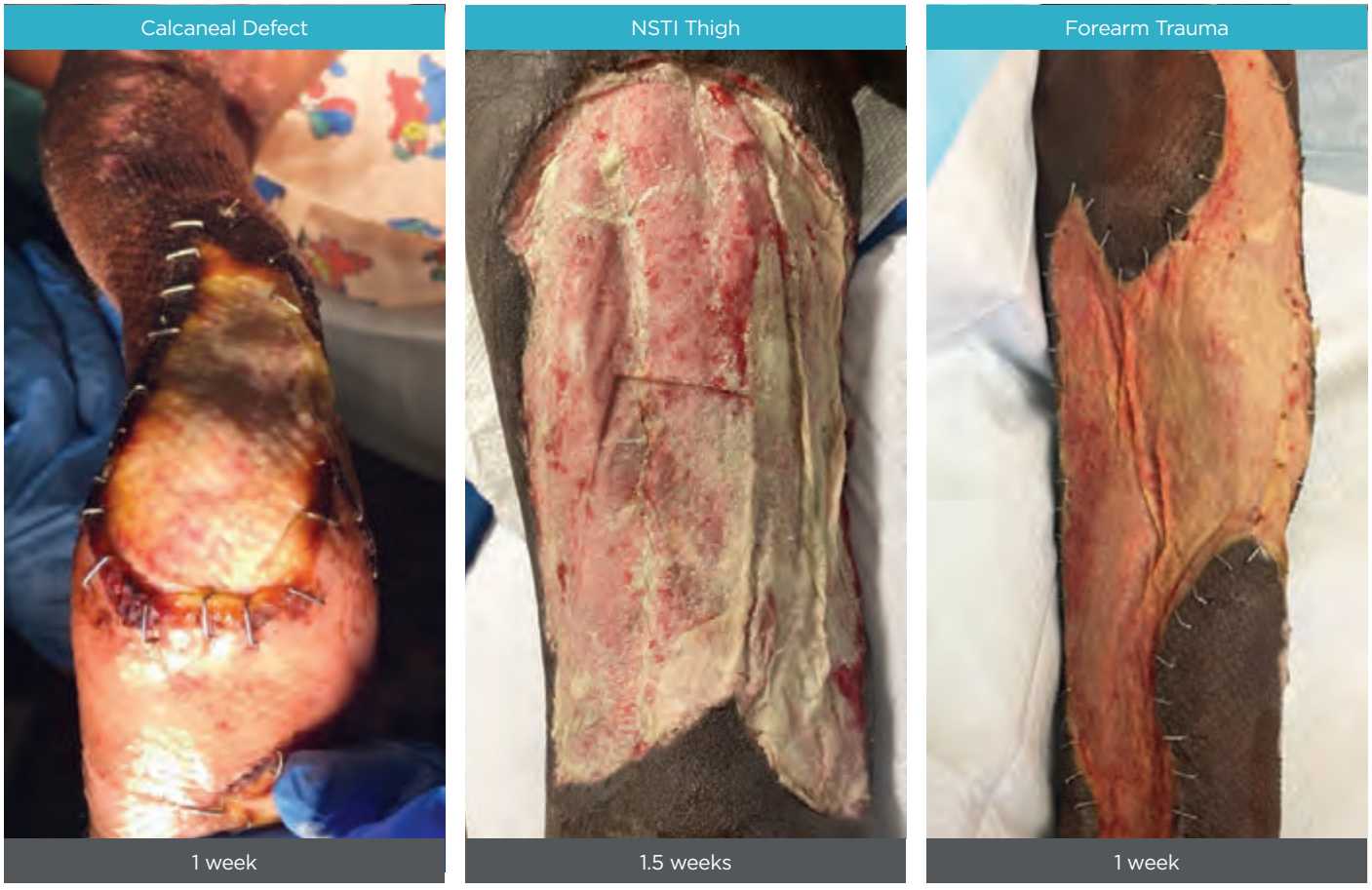
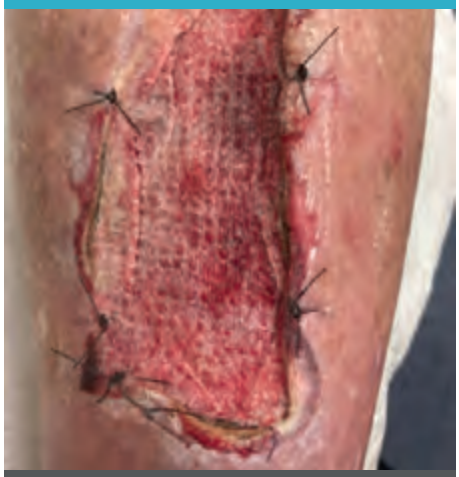


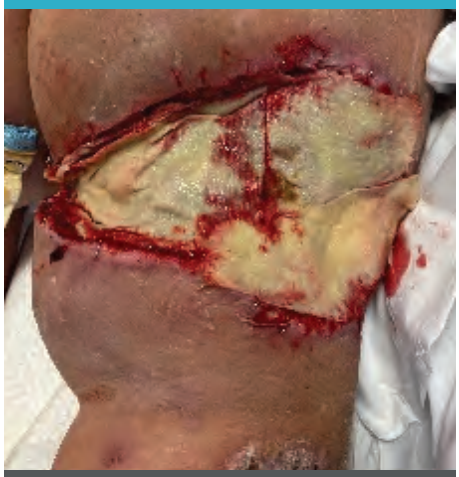
Figure 7 (Continued from previous page). **Myriad** products at early (<14 days) timepoints.

Leg Hematoma Defect



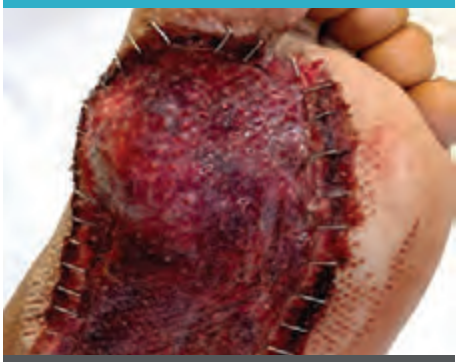
1 week

Arm Trauma



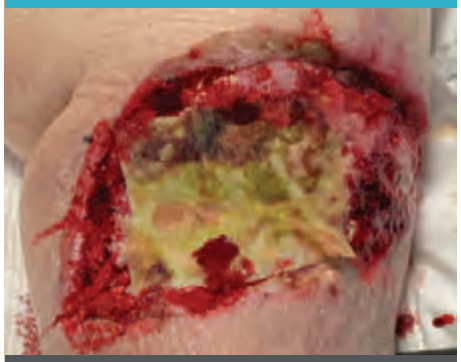
1 week

Fibromatosis Resection



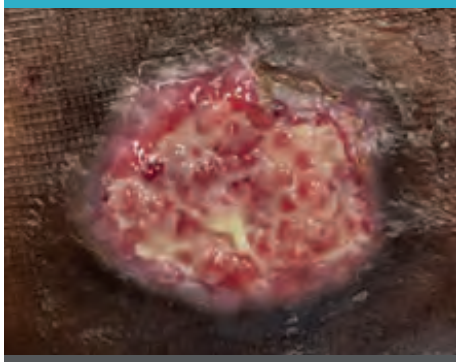
4 days

Leg Trauma



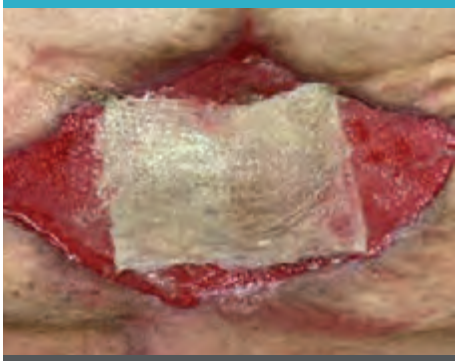
1 week

Leg Ulcer



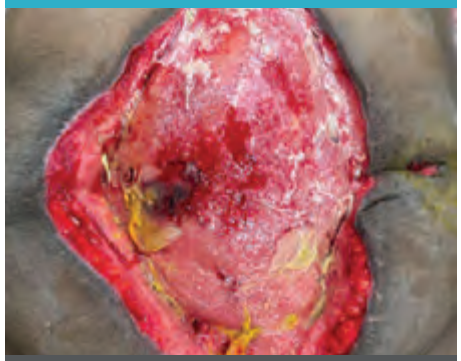
1 week

Abdominal Dehiscence



1 week

Abdominal Gunshot Wound



1 week

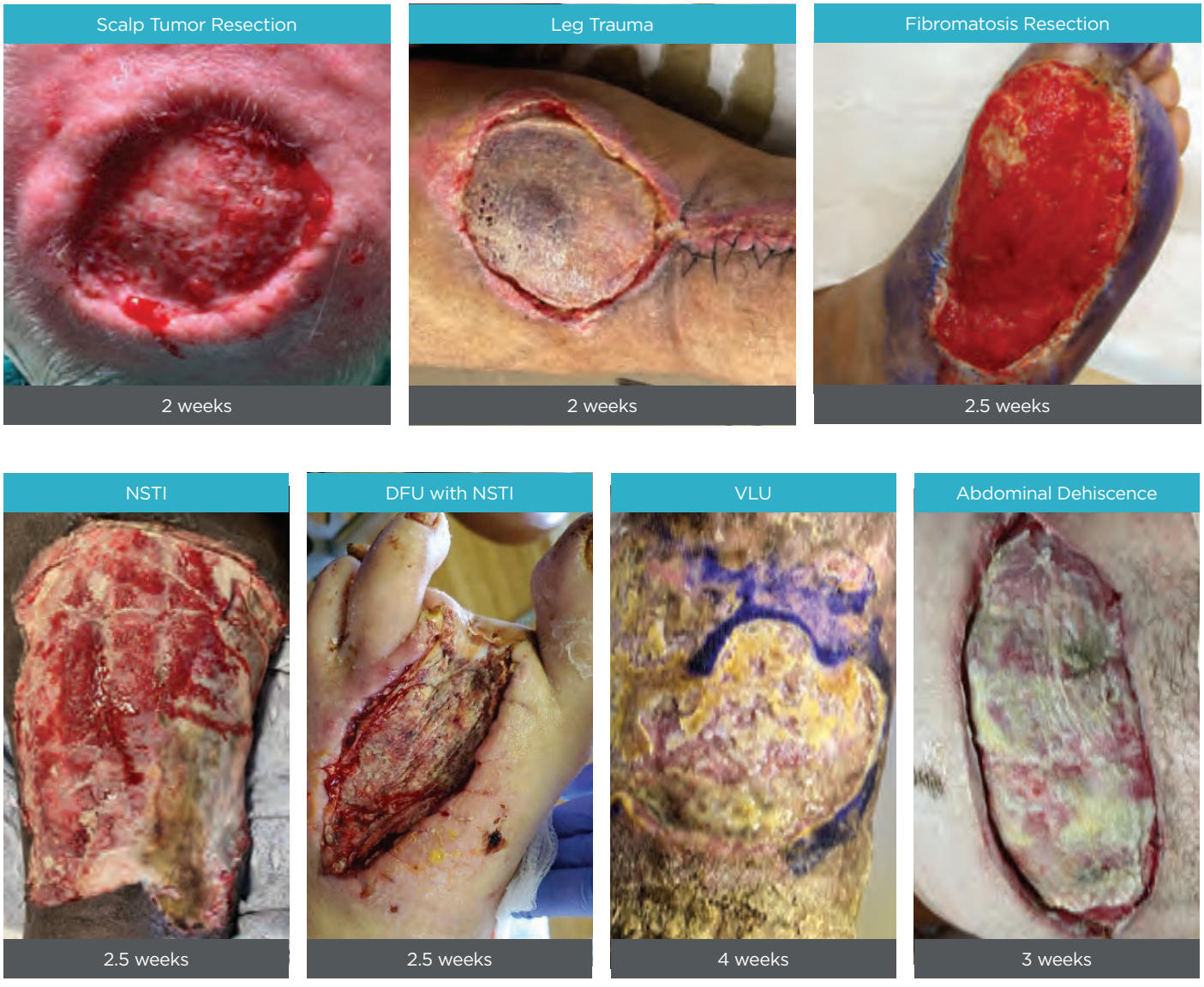
Later Timepoints (>14 days)

Over time the extent of newly formed tissue will increase as **Myriad** products become fully incorporated into the newly formed tissue (Figure 8).

As **Myriad** incorporates into a soft tissue defect, it can be observed as a caramel or cream-colored residue. **This is normal and residual Myriad should not be removed.** An odor may be observed at the dressing change.

Residual Myriad

Figure 8. **Myriad** products at later (+14 days) timepoints



The presence of residual **Myriad** and/or an odor do not necessarily signify an infection in isolation of the established clinical signs and symptoms of infection.

It is important to leave residual **Myriad** in place for the following reasons:

- As a mimic of tissue ECM, **Myriad** helps facilitate various cellular processes that occur during healing.[9, 10] Like tissue ECM, **Myriad** devices may also undergo degradation by tissue proteases.
- If **Myriad** is degraded by tissue proteases, a caramel or cream-colored residue may form that has a similar appearance and odor to slough. This is expected as both slough and residual **Myriad** comprise enzymatically digested ECM fragments.
- An important difference is that residual **Myriad** contains ECM components that aid healing and modulate inflammation.[11, 12]
- Residual **Myriad** will continue to facilitate building new tissue as it incorporates and is remodeled into the wound bed.
- The rate of incorporation will vary between wounds. It is important to leave residual **Myriad** in place unless a complication is suspected.

Myriad persists in the wound bed to help facilitate growth of vascular, organized and functional tissue.

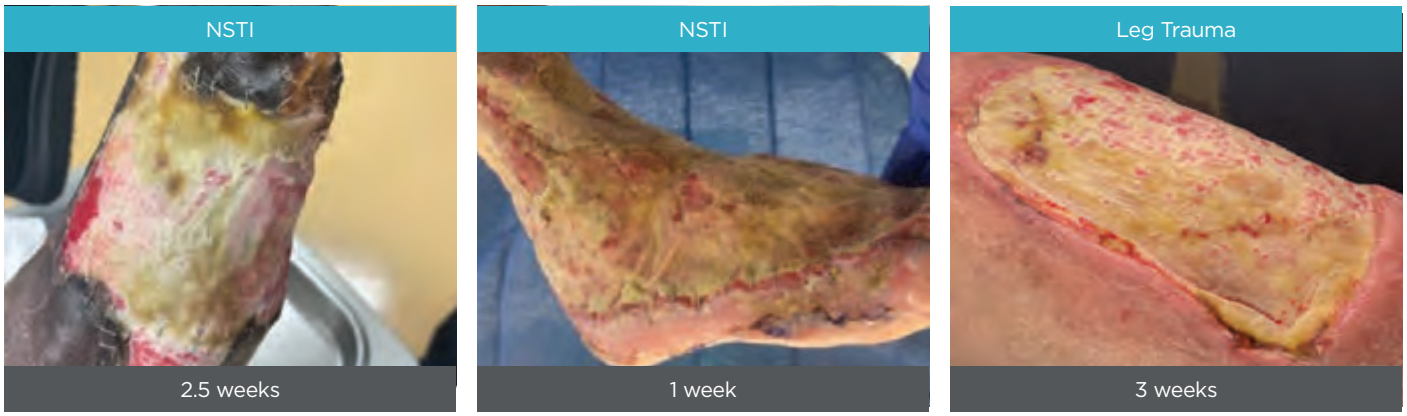
- Contains >150 ECM proteins known to be important in healing.[11]
- Residual vascular channels that aid in the establishment of new vasculature.[13]
- Facilitates functional tissue by providing the natural structure of an ECM bioscaffold.[10]

Repeat applications of **Myriad** products are generally not required. However, large volumetric defects with significant depth may benefit from additional **Myriad** applications to ensure adequate tissue infill.

Moist Wound Environment

It is important to keep **Myriad** products hydrated to ensure optimized healing. If the **Myriad** device appears dry or hardened with a yellow/brown color (Figure 9), rehydrate with saline or hydrogel. A hydrogel may be applied over the primary dressing every 2-3 days. If the device appears adequately hydrated, consider extending the dressing change to 5-7 days.

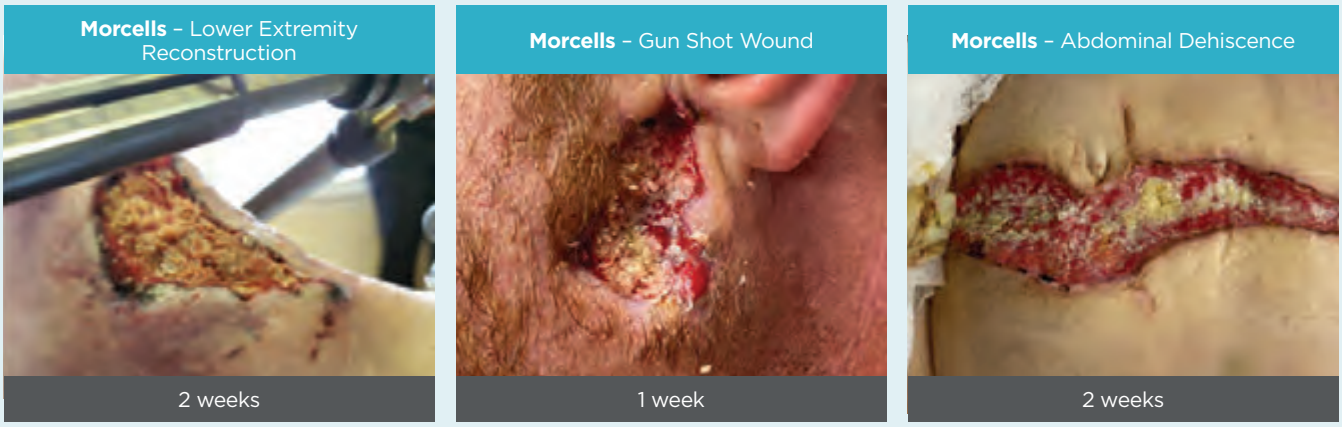
Figure 9. Examples that need hydrating.



Myriad Morcells may Persist in the Wound Bed

Powdered ECM or collagen products are typically re-applied every 3-7 days as they are rapidly absorbed into the tissue bed. Depending on levels of inflammation and concentrations of associated tissue proteases, **Myriad Morcells** may persist for up to 14 days (Figure 10). **Morcells** that are still visible in the wound bed at the dressing change may be left in place so that the ECM components can continue to aid healing.

Figure 10. Appearance of **Morcells** in the wound bed.



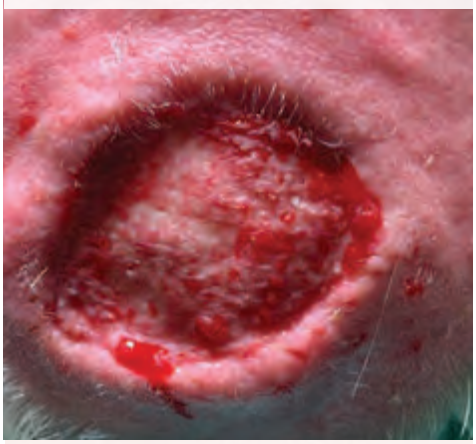
Debridement During the Course of Myriad Healing

During the course of healing and during dressing changes, the surface of the **Myriad** devices may be gently debrided to remove any non-adherent ECM material. However, care should be taken to not remove any adherent portions of the **Myriad** products that have yet to incorporate. These areas are easily identified by the white-cream appearance of the **Myriad** products (Figure 11). Well vascularized granulation tissue is often noted if non-adherent portions of the product are debrided from the surface.

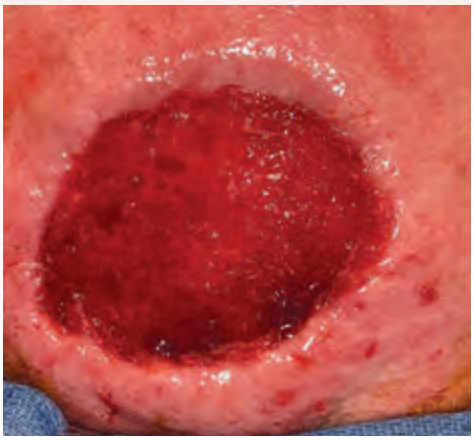
Figure 11. Debridement during the course of **Myriad** healing.

Scalp Tumor Resection

Pre Debridement



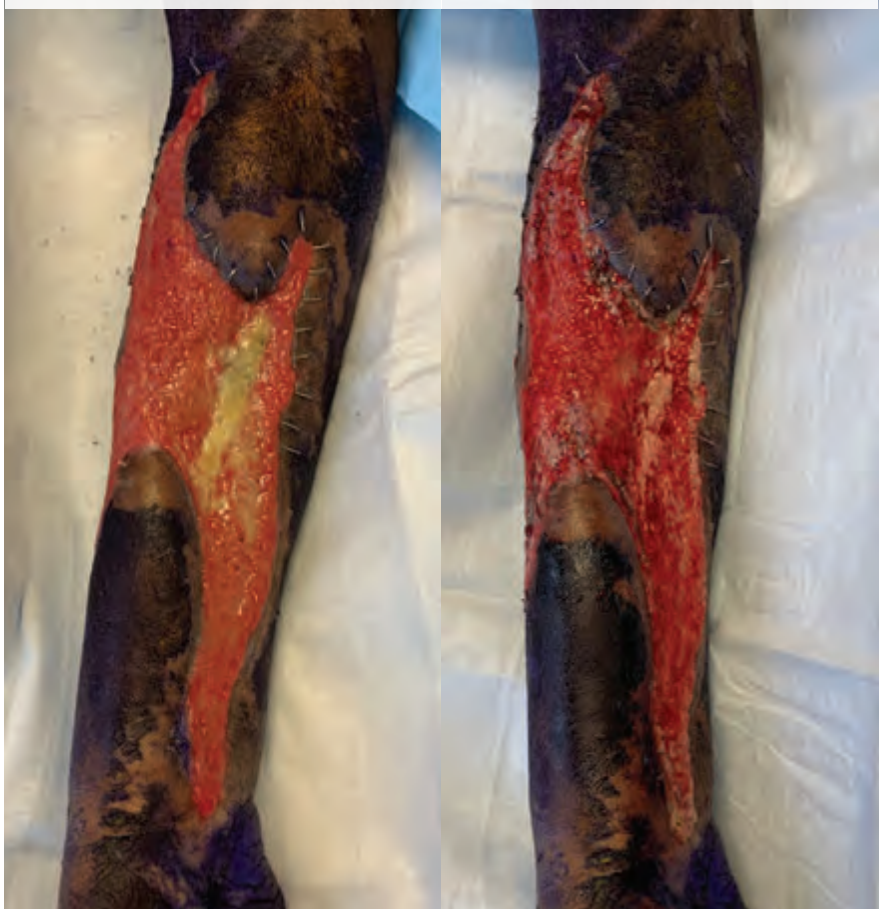
Post Debridement



Arm Trauma

Pre Debridement

Post Debridement



Definitive Closure

Once a robust bed of well vascularized granulation tissue has been established in the wound bed, definitive closure may be achieved either via a split thickness skin graft, or closure via secondary intention. Definitive closure is at the surgeon's discretion taking into account patient factors and institutional guidelines. If the dermal defect is to be closed via secondary intention, consider **Endoform™** products to facilitate epithelialization.

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RX Only.

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