

### Membranes for wound healing:

The products we use are amnion containing no chorion. (Reactions to chorion include allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue, breathing problems, nausea, and vomiting)

- rich in proteins, growth factors and cytokines which, when applied to a wound to bring down inflammation, breaks up fibrous scar tissue, jumpstarts angiogenesis (blood flow) and signals the body's own progenitor (stem) cells to repair, replace and regenerate soft tissue.
- contains a significant number of cytokines and essential growth factors
- reduces pain when applied to a wound
- increases and enhances the wound healing process
- has antibacterial properties
- is non-immunogenic (will not be seen as foreign material)
- provides a biological barrier
- provides a matrix for migration and proliferation of cells
- reduces inflammation
- reduces scar tissue formation
- terminally sterilized to create an acellular product and ensure patient safety

### Definitions

- Necrosis – dead tissue, doesn't come back to life (black tissue)
- Bioburden – gelatinized fluid that needs to come out to allow healing
- Inflammation – Redness and pain (can have inflammation without infection)
- Edema – swelling or water retention
- Pressure offloading – devices utilized
- Granulation – red velvety tissue that skin grows on. Fertilizer that grows the grass. Need granulation for healing
- Epithelization – skin growing on the granulation tissue (yellow tissue)
- Chronic wound – not progressing through normal healing process –

generally speaking if the wound is not healing after a month it is considered a chronic wound

- Debridement – removal of non-viable tissue

### Normal Wound Healing Stages

1. Hemostasis – close by clotting
2. Inflammation – natural part of wound healing – but need to progress past this phase. Is typically the phase that a wound can get stalled in rendering it chronic.
3. Proliferative – all of the fibroblasts come in to start making a structure – wound starts to contract and fills in
4. Remodeling – granulation and stops growing – allow granulation tissue to grow on the scaffolding

If the wound is rendered “chronic” the question is: “Where are we in the wound healing phase and where is it stuck?”

### Acute vs Chronic Wounds

Will you start with the wound and slap a product on it? No - you see where it is in the process. If the wound is progressing, you let that happen. If stuck somewhere in a healing phases then advanced wound care products, can be used. More specifics on this below.

We concentrate on wounds that are not progressing – Chronic >30 days.

### Global Wound Complications

1. Infections
2. Fluid loss
3. Temperature loss
4. Debility

Infections – leave a wound open long enough it's going to get infected – increased pain, swelling, redness and drainage – yellow/green discharge – complications = sepsis, limb loss

Fluid loss – dehydration reduces the body's blood volume, reduce oxygen and nutrient delivery to the wound bed – impairs wound healing – interrupts cell function. Patients with burns lose large amounts of water through evaporation from open wounds. Wound covering is the first line of defense for maintenance of body fluid balance (important to know for burn wound care).

Temperature loss – Not as big an issue for local/smaller wounds

Debility – Inability to work (can't bare weight on their foot/wound) – Pain (quality of life issue – biggest complaint – significant issue – can't function)– Immobilization (diff wounds require immobilization for off loading – compliance issue) – Mental and Emotional (psychological impact is severe– depression – loneliness – impact on social life – empathy) – Inhibits quality of life

### Wound types

Pressure ulcer – usually for bed ridden patients or in wheelchairs – biggest thing that needs to be done is pressure off-loading. Grafts may stimulate tissue growth, but most important treatment is pressure off-loading.

Venous ulcer – Occur due to venous hypertension from malfunctioning veins. The high pressure causes the wounds to keep from healing. Veins have valves in them – if the valves are not working the blood will fall backwards with gravity. First and primary treatment = compression. Will not heal until you get rid of that venous hypertension.

Diabetic foot ulcer – Very difficult wound to heal due to multiple different issues. Pressure causes these. Usually starts with trauma – i.e. step on something. Diabetes complicates the healing/neuropathy/etc – don't have feeling in the foot. They use antibiotics and does nothing. White stuff is macerated tissue. Need to absorb the drainage. Are you staying off your feet (pressure off-loading)? Pressure off-loading helps.

Surgical wounds – Mostly from an incision separating (Dehiscence) or from infection or poor healing. Acute wound may not heal in 4 weeks. Treat different wounds differently.

Trauma leg wounds – these can be extremely variable but constitute a large # of wounds. Need to clear out all of the bad stuff and get to the bottom to see what you have.

Burn wound – damage from heat/sun/rad.

Hematoma – necrosis on top – remove it – find hematoma (usually large below the necrotic tissue); work your way down and see what you have. Can't just treat the top of it – remove and work your way down.

Gangrene – necrosis in your foot or finger.

Complications of open wounds

Osteomyelitis – bone exposed creating infection – have to do something with the bone – pressure off loading or removal.

Peri wound dermatitis – irritated tissue – allergic reaction causing dermatitis and eating the skin around the wound. Must figure out what is causing it and fix it.

Infection & Biofilm

Systemic treatment - part of overall wound care

Nutrition – protein necessary for wound healing. Must be assessed and addressed or wound healing will be delayed.

Trauma and Surgical Care – Surgical intervention is used when significant tissue loss or infection is noted. Must debride thoroughly first.

Disease Control

Arterial disease-Need blood flow to heal wounds-Assess it-If you debride a wound without good blood flow you just make it bigger

ABI-Check blood pressure at their ankle (numerator) and arm(denominator)

Venous pressure relief

Work up

Edema control

Ablation – cauterize the vein to address venous hypertension

(see above notes on Venous Ulcers). Use catheter in procedure.

Blood Glucose control (for Diabetic Foot Ulcers) High blood sugar decrease healing

Monitor Hg A1C (Hemoglobin A1C) for DM control. Normal<6.2. If 9 or 16... May not come down right away even if you manage sugar. Understand that this must be addressed.

## Other medical pathologies

Autoimmune disease – Vasculitis most commonly seen. This causes a chronic wound.

Skin cancer-Normal Standard of Care - Need to follow the normal standard of care and clear the way before you use a product. See the wound after debridement.

Address venous....compression....off-loading etc.

FOLLOW AND EXHAUST NORMAL STANDARD OF CARE (NSOC) BEFORE YOU USE THE PRODUCT.

IF THE WOUND IS CHRONIC, WHERE IS THE WOUND STUCK AND WILL THE PRODUCT HELP AND/OR WHAT ELSE NEEDS TO HAPPEN. i.e. inflammation is part of the healing process but if the wound is stuck at the inflammatory phase what needs to be done to make it progress?

## Infection Control

Important part of the NSOC. Some docs will use anti-biotics but if the actual organism is not identified through culture or PCR testing then the anti-biotics may not work.

There are multiple products on the market to control infection and Biofilm.

What if a wound is healing even though there are bacteria present? Do you use antibiotics to address the bacteria? No, you don't need to. We have lots of bacteria in our bodies. If the bacteria are not stalling the healing process, then you don't need to. Treat infections for sure prior to use of our product because it won't heal if you don't.

## Local Wound Care

### Surgical

Debridement – sharp – blunt - ultrasound

Incision and Drainage - abscess

Excision – i.e. skin cancer/MOHS

Biopsy – used to help diagnose diff wounds with unique characteristics

### Skin grafting

Primary and secondary closure – closing wound is seldom successful but many try – secondary is to allow it to heal with local wound care.

Various local treatments

Chemical debridement – Enzymatic

Wound dressings should be:

Moisten – don't want it too moist or too dry

Absorbent

Antimicrobial

Iodine/Silver based

Non-stick

Goal – Provide best wound environment for healing depending on what is currently happening with the wound. This changes frequently with the same wound.

Growth Factors and Biologic Products – Growth Factors – Cytokines

Skin Substitutes – Growth Factors/Placental Tissue/Cellular

Products/Collagen Matrix/PRP Gel

# Normal Standard of Care

## Including:

1. Wound debridement
2. Treatment of Systemic issues including  
Glucose control
3. Pressure off-loading for DFU
4. Evaluation and treatment of vascular  
disease, venous and arterial
5. Treating infection
6. Local wound care management
7. Nutritional




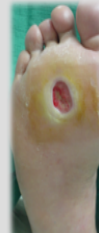
Advanced wound care products may be appropriate after conservative treatment has been exhausted and the patient's wound is not responding.



# Standard of Care

Medical records document that conservative pre-treatment wound management has been tried and failed to induce healing.  
**Standard of care at least 30 days DFU, 30-45 days VLU.**

Protocol for the use of advanced wound care product published by CMO of one manufacturer:

<p><b>Standard of Care – General All Wounds</b></p> <ul style="list-style-type: none"> <li>• Drainage controlled</li> <li>• Local wound care environment addressed</li> <li>• Cultures taken and Infection treated</li> <li>• Debridement; sharp or enzymatic as often as needed</li> <li>• Nutritional assessment and supplementation as needed</li> <li>• Systemic pathology addressed and currently under treatment</li> </ul>	<p><b>+ Standard of Care – Venous Stasis Wound</b></p> <ul style="list-style-type: none"> <li>• Venous incompetence study to evaluate for reflux</li> <li>• Arterial study to assess perfusion</li> <li>• Venous ablation as needed for venous hypertension</li> <li>• Edema control with compression and elevation</li> <li>• Address systemic factors affecting edema</li> <li>• Drainage controlled</li> </ul> 	<p><b>+ Standard of Care – Diabetic Wound</b></p> <ul style="list-style-type: none"> <li>• Arterial study to assess perfusion</li> <li>• Assess diabetic control and refer appropriately</li> <li>• Appropriate pressure offloading</li> </ul> 
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<p><b>The Stalled Wound</b></p> <ul style="list-style-type: none"> <li>• Standard wound care has been used.</li> <li>• There is a lack of wound improvement despite the standard of care discussed above. (i.e. infection, necrosis, excess drainage, and pressure)</li> <li>• Wound base lacks growth clinically.</li> <li>• Wound is likely halted in the inflammatory stage.</li> </ul>	<p><b>Indication for use of advanced wound care product</b></p> <ul style="list-style-type: none"> <li>• To use when wound is stalled – as previously defined.</li> <li>• Apply to stimulate growth through providing a better wound environment and helping the wound heal itself.</li> <li>• All other current therapy must continue for best success.</li> <li>• Most insurances typically require documentation of standard of care treatment. If you can document that this standard of care treatment was done prior to your evaluation, then you may proceed with the application of the advanced wound care product.</li> </ul>
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Why not do NSOC for 60-90-120+ days? Because if a wound is stalled and not healing, continuous debridement of non-viable tissue, as an example, simply increases the wound size. The wound is not improving and will worsen. The longer a wound is open, the more serious it becomes and the harder it is to close it. So no, more standard of care is not better if the wound is stalled and not healing. The industry and Medicare recognize this and also understand that chronic non-healing wounds often lead to hospitalizations and amputations.

Major amputations come with a mortality rate of 2 years on average. The cost of a chronic non-healing wound can accelerate to very large numbers the longer it is open. This is why Medicare will pay for advanced wound care products like once the NSOC is completed and has not induced healing.

**TIMING IS IMPORTANT.** If the NSOC yields results and the wound is closing within the industry standard of 50%, give or take, then there is no need for a membrane.

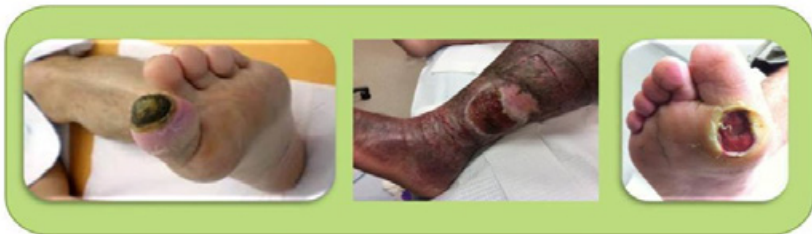


Your customer will have a mix of wounds that respond to NSOC and wounds that do not.

**Rapid Closure = Decreased Risk & Decreased Costs**  
**TIME = TISSUE**

**The longer an ulcer remains unhealed:**

- Greater risk for infection
- Greater risk for hospitalization (cost burden, quality of life)
- Greater risk of limb amputation



International Consensus on the Diabetic Foot, p12

**ACUTE WOUND HEALING**

- No Infection
- Minimal Inflammation
- Normal Blood Supply
- Active Cell Function & Matrix Remodeling

Repair is **orderly**, sequential fashion



**Wound Resolution**

**CHRONIC WOUND HEALING**

- Persistent Infection
- Prolonged Inflammation
- Inadequate Blood Supply
- Impaired Cell Function & Matrix Remodeling

Repair is **delayed**, disorderly fashion



**Wound Chronicity**

- Bacteria/Biofilm
- High Protease Levels & Pro-inflammatory signals
- Vascular disease  
Failure to form new blood vessels
- Stem Cell/Fibroblast Depletion; Impaired Keratinocyte Migration