Provider Screening Tool

Patient Name:
Date of Birth:
Date:
Facility:
Wound type:

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1. ☐ At least $1cm^2$ in dimension
2. ☐"Failed to adequately respond" to **last 4 weeks** of conservative treatment measures?
    a. Wound is worsening / stable / improving very slowly or less then expected?
    b. Currently trying and failing pressure-reducing intervention (eg, frequent turning, foam, footwear)
    c. has received treatment of Application of dressings (last 30 days)
    d. had received Debridement of necrotic tissue was performed
3. ☐ Obtain Face Sheet and Active Medication list
4. ☐ Note the duration of ulcer – in weeks (will need it later)
5. ☐ Need Labs (last 30 days): CMP, CBC, Pre-alb. If DM, HbA1C.
6. ☐ Smoking Status (Smoker, Previous Smoker, Non-Smoker). If current smoker, counsel to stop (6 weeks prior)
7. ☐ X-Ray (if foot/ankle)
8. ☐ Arterial Duplex Doppler with ABI and Venous Doppler – (if foot/ankle)
9. ☐ ABI
10. ☐ Venous Doppler
11. ☐ Test sensation with a sharp end of an applicator snapped in two – if DFU

EXCLUSIONS to remember:

☐ **No h/o Biologic used for this wound in past 1 year!**
☐ *No Evidence of active infection or osteomyelitis*?
☐ *No Evidence of necrotic tissue that cannot be debrided*?
☐ *No Active Charcot deformity or major structural abnormality (Chronic is ok)?*
☐ *No known or suspected malignancy of ulceration (other malignancy is ok, except see below…)?*
☐ *Not actively receiving radiation therapy or chemotherapy?*
☐ *Not taking medications considered to be immune system modulators/suppressants?*
☐ *No autoimmune connective tissue disease diagnosis?*
☐ *If the DFU patient has no loss of sensation or atrophy (peripheral neuropathy), they could be enrolled with PAD if they have those findings*

If Ulcer located on Leg/ankle/foot:
Circulation must be Adequate with Diagnostic Testing:

☐ **Arterial Doppler (last 30 days)**
☐ Note ABI **MUST BE ≥ 0.6 and ≤ 1.4**) Result:
☐ Note Doppler arterial waveforms (Triphasic, Biphasic at the ankle of the affected leg)
☐ Pedal pulses: Result: Date:
☐ CFT: Result Date:
☐ **Venous Doppler** (last 30 days)
☐ **X-Ray of the foot/ankle with a negative finding of osteomyelitis**

If Diabetic Ulcer:

Note if Type 1 ☐ , or Type 2 ☐
☐ **MUST have diabetic neuropathy** to qualify for biologic with a Diagnosis of Diabetes
- identify if peripheral neuropathy present: Paresthesia ☐ , Numbness on foot ☐
- Need one for Dx: Insensate ☐ / reduced sensation to touch ☐ / reduced sensation to filament ☐ / atrophy of intrinsic musculature ☐ / atrophy of skin & sub Q ☐ / weakness of musculature ☐ / contracture of joints ☐
- *EXCEPTION if: diagnosis of PAD*

☐ Note if under Medical Management (Y or N):
☐ Note name of Primary Provider (PMD):
☐ Note HbA1C result (last 30 days)

If Venous Stasis Ulcer:

☐ **Venous Doppler** (Last 30 days)
☐ Failed 30 day Compression Tx (eg, ace wrap, uniboot)

Also

1. ☐ **Obtain consent**
2. ☐ **Pre-Application documentation** (+/- debridement form)

Office needs:

1. ☐ Pre-Application documentation +/- debridement form
2. ☐ Face sheet for IVR
3. ☐ 3-4 weeks of prior documentation if not available in the system
4. ☐ **Preferred shipping location (option 1: office, 2: FEDEX location near you)**

INITIAL CMN – Pre-Treatment

Product Requested (XCellerate)

☐ 2cm x 2cm ☐ 4cm x 4cm

☐ 2cm x 4cm ☐ 4cm x 7cm

Date:

Pt Name:

Location / Facility:

Room:

31 – Skilled

32 – LTC / NH / Non-Skilled / Domicile

Wound Type:
pressure / non-pressure / diabetic / neuropathic / venous / arterial / ischemic / vasculitic / traumatic / s/p burn / s/p surgical

Baseline Measurements: L_____cm x W_____cm x D_____cm
AREA: _____ SQ cm [Including Undermining]

Stage / Grade:
Full Thickness

- The ulcer extends through the dermis ☐
- without tendon, muscle, capsule, or bone exposure. ☐
- with tendon, muscle, capsule, or bone exposure. ☐

- Stage or Grade: _____

WAGNER CLASSIFICATION SYSTEM
for diabetic foot ulcers (DFU's)

Grade	Description of Ulcer
0	No ulcer, but high risk foot
1	Superficial ulcer
2	Deep ulcer; No bony involvement or abscess
3	Abscess with bony involvement (X-Ray)
4	Localized gangrene (e.g. toe, heel, etc.)
5	Extensive gangrene involving whole foot

Location: _____
Right / left
Toe / foot / ankle / leg
Dorsal / plantar

Duration of the ulcer: _____ weeks

Arterial Perfusion
Pulses: **DP – L 0 1 2 3 4 R 0 1 2 3 4**
PT – L 0 1 2 3 4 R 0 1 2 3 4
Non-palpable

CFT <= 3 sec is normal
- CFT: _____ seconds

Must have adequate circulation/oxygenation to support tissue growth/wound healing (ABI >= 0.60, TBI > 30mmHg)
- ABI or TBI value _____
- **Arterial Doppler** Wave Pattern: Triphasic □ Biphasic □ Monophasic □
- **Venous Duplex Doppler**: Results: Normal □ Venous reflux □ Incompetent Perforator □ Venous Thrombosis □

For Diabetic ulcers:
- Current medical management of diabetes (description):

_____

- Type 1 ☐ *or* Type 2 ☐
- Presence of neuropathic disease? Yes ☐
- Controlled ☐ *or* **not** controlled ☐

Neuropathic Changes (circle all that apply): *Must be noted for DFU*

Insensate / reduced sensation to touch / reduced sensation to filament / atrophy of intrinsic musculature / atrophy of skin & sub Q / weakness of musculature / contracture of joints

Venous Ulcers - VLU:

Compression: Class 3 High Compression Garment ☐ Unna Boot ☐ Compression Stockings ☐ Multilayered Elastic compression ☐
Mixed Venous / Arterial Disease / CHF Disease needing modifications / Loosened Compression ☐

CEAP Classification: Ulcer # 1 2 3 Ulcer Duration: 0-None; 1-Mild- <3 mo; 2-Moderate-3-12 mo; 3-Severe->12 mo
Active ulcer size: 0-None; 1-Mild- <2cm; 2-Mod- 2-6cm; 3-severe- >6cm

Venous Duplex Scan: Results: Normal □ Venous reflux □ Incompetent Perforator □ Venous Thrombosis □

Chronic Wound: This wound has met the conditions (see below) of a Chronic Wound? Yes ☐

- Wounds not responding to standard/conservative wound care treatment for **>= 30 days** by means of closure; Has remained open despite appropriate standard/conservative advanced care; ☐

& / OR

- Has remained the same size or depth or has increased in size or depth; ☐

AND

- Has no indication that improvement is likely ☐

A Failed Response is defined as an ulcer or skin deficit that has failed to respond to appropriate wound-care measures, has not closed, has increased in size or depth, or has not changed in baseline size or depth with no indication that improvement is likely (such as increasing granulation, increasing epithelialization, or progress towards closing).

Was there a pervious failed response to amniotic skin substitute(s)? Yes ☐ No ☐. If yes, date(s): _____

Has the wound previously been healed using Amniotic skin substitute(s)? Yes ☐ No ☐. If yes, date(s): _____

[Greater than 1 year] Yes ☐ No ☐. If yes, date(s): _____

Description of all failed previous treatments & why failed >=4 weeks:

Debridement □ Advanced Wound Dressings □

_____

_____

Pertinent Medical Conditions: DM □ CHF □ HTN □ CAD □ PAD □ Dementia □ Contracture □ See Attachment □

_____

_____

Are condition(s) listed above controlled? Yes ☐

If **SMOKER:** Smoking cessation counseling was performed? Yes ☐

If currently smoking, to the best of my knowledge patient ceased smoking 4 weeks prior to treatment. Yes ☐

Current Medication(s): See Attached Medication Sheet ☐

_____

_____

Location of Grafting (circle): Domiciliary LTC NF Bed / Skilled SNF Part A Bed / Home / Board & Care / Hospice / Acute Hospital / Wound Center – Acute Care / Office

Name of Skin Substitute / Amniotic Membrane: _____ is being used as part of a comprehensive and organized WOUND MANAGEMENT PROGRAM.

Rational for amniotic membrane:

This ls a human amniotic membrane, stemmed collagen drive from the placenta during which the human fetus grows and develops in the mother's uterus. The human amniotic membrane consists of multiple layers, some of them were manipulated, dehydrated, nonviable cellular amniotic membrane allograft, there is multiple extracellular matrix proteins. Growth factor cytokines and other specialty proteins present in the amniotic tissue to provide a barrier of membrane and enhance the healing.

The closure of the wound is necessary to avoid sepsis, hospitalization and amputation/death. The failure of the progression towards closure necessitates the use of amniotic membrane. All the other reasons for the failure of active aggressive conservative care have been ruled out. The patient has adequate arterial and venous perfusion. Diet and caloric intake is sufficient. There is no sign of dehydration. There is no sign of active, acute infection. The wound base is simply not responding to an environment conducive to wound closure. As such, as noted above, I find that the amniotic membrane serial application is necessary to further wound closure. There may not be significant signs of healing within the first 4 applications, but this is not an indication of failure of this treatment.

***Description of the treatment plan*: Rational for this membrane**
Application of amniotic membrane: Weekly ×10 applications, if less than anticipated 50% take is identified, but as long as there is positive signs of healing after 4 weeks.

Physical Exam Findings pertinent to Skin Subs Grafting:

The use of amniotic membrane on Partial-orfull-thickness ulcers, not involving tendon, muscle, joint, capsule or exhibiting exposed boneor sinus tracts, with a clean granularbase, **unless** theCTP package label indicates the CTP is approved for use involving tendon, muscle, joint, capsule or exhibiting exposed bone or sinustracts, witha clean granular base.

The manufacturer allows for the use of the amniotic membrane on exposed bone, tendon, muscle, joint, capsule, sinus tract: Yes ☐

Wound Description:

- **Significant** Progress towards closing — Yes No ☐
- **Insignificant** Progress towards closing — Yes ☐ No ☐
- Involvement tendon, muscle, joint capsule, exposed bone, exposed sinus tracts — Yes ☐ No ☐
- Epithelial tissue without improvement _____ % — Yes ☐ No ☐
- Granulation without improvement _____ % — Yes ☐ No ☐
- Skin deficit of wound/ulcer >= 1.0 cm^2 — Yes ☐
- Must be clean and free of necrotic debris or exudate [after debridement] — Yes ☐
- Must have a clean, granular base [after debridement] — Yes ☐
- Free of surrounding callus tissue and devitalized tissue [after debridement] — Yes ☐
- Must be free of infection and underlying osteomyelitis — Yes ☐
- Advanced wound dressings creating moist environment (for last 30 days) — Yes ☐

The wound is with EITHER (select one):

Full thickness tissue loss ☐

Partial Thickness Tissue Loss ***without*** retention of epithelial appendages ☐

*Note: Partial thickness loss **with the retention of epithelial appendages** is NOT a candidate for grafting or replacement, as epithelium will repopulate the deficit from the appendages, negating the benefit of grafting.*

Describe the treatment of the underlying disease process contributing to the ulcer:

Off-loading □ Turning/repositioning □ Air Loss Surface □ Encourage food intake □ Protein Supplement □ Debridement □ Moist Healing □ Hydration □

_____

_____

Adequate control of exacerbating factor, including but not limited to those listed below? **Yes** ☐

- uncontrolled blood pressure
- uncontrolled diabetes,
- uncontrolled nutrition / hydration factors
- active infection,
- active Charcot
- arthropathy of the ulcer extremity,
- vasculitis,
- smoking w/o physician attempt to affect smoking cessation

Anticipated Outcomes (circle all that apply): complete closure / partial closure / potential reopening / amputation avoidance / increased function & activities / Need to close to reduce chance of serious infection, sepsis, hospitalization, amputation or death

NON-Coverage

- *NOT covered if previous course of skin sub applications was unsuccessful.*
- *Retreatment of healed ulcers are NOT covered. (> 75% size reduction and < 0.5 cm^2)*
- *Simultaneous use of more than one product is NOT covered, nor is Combination Therapy with any skin substitute product.*

- *Contraindicated if known hypersensitivity to component of the skin substitute (i.e. allergy to any of the contents). SEE IFU*
- *Billing CPT codes for surgical wound preparation is ONLY COVERED at the initial application of skin substitute graft.*
- *Non-graft wound dressings or injected skin substitute codes are NOT covered.*
- *When billing for Skin Subs, active wound care management (i.e. CPT code 97602) procedures are NOT covered.*
- *Removal of current graft and/or simple cleansing of wound are NOT Billable along with skin replacement treatment*
- *When billing for Skin Subs, active wound care management (i.e. CPT code 97602) procedures are NOT covered. Removal of current graft and/or simple cleansing of wound are NOT COVERED along with skin replacement treatment.*
- *Max 10 applications PER WOUND – even if more than one product is used.*
- *Max 12 weeks total treatment period PER WOUND*
- *Min 12 months since last treatment period PER WOUND*

Informed Consent: Document if the patient is competent, and/or has the support services necessary to participate in follow-on care (check those that apply).

- Patient is competent & has been given informed consent, with risks and complications explained completely, by the provider who will be performing the procedure. ☐
- Patient is incompetent. The patient's _____ has been given informed consent, with risks and complications explained completely, by the provider who will be performing the procedure. ☐
- Decision-maker can not be contacted or does not respond. The facility consent for treatment is in effect and will allow for the use of the biologics. The primary doctor and the wound consultant agree on its use and are aware of the risks and complications. If when the decision maker responds, they will be made aware of the application, risks and complications. ☐
- The orders for the post application treatment will be communicated to the treatment nurse and documented in the patient's chart. ☐
- The nurses have been adequately trained in the post application care of the wound. ☐

Must include 3-4 week of prior notes

Date:

Pt Name:

Facility:

Room:

31 – Skilled

32 – LTC / Non-skilled / Domicile

Product Requested (XCellerate)

☐ 2cm x 2cm ☐ 4cm x 4cm

☐ 2cm x 4cm ☐ 4cm x 7cm

Treatment #1

Has the patient changed location / room since the Pre-Treatment Visit / IVR? Yes ☐ No ☐

The patient is in a LTC / Domiciliary bed? Yes ☐ No ☐

The patient has not been hospitalized in the intervening time from the pre-Treatment visit Yes ☐

Has the patient failed to show sufficient improvement in the wound, with Advanced wound care, >= 30 days? Yes ☐

Ulcer Dimension: L_____cm x W_____cm x D_____cm
[Include Undermining]

AREA: _____ SQ cm

Stage / Grade:

Full Thickness

- The ulcer extends through the dermis ☐
- without tendon, muscle, capsule, or bone exposure. ☐
- with tendon, muscle, capsule, or bone exposure. ☐

- Stage or Grade: _____

Location (circle): _____
Right / left
Toe / foot / ankle / leg
Dorsal / plantar

Duration of the ulcer: _____ weeks

WAGNER CLASSIFICATION SYSTEM
for diabetic foot ulcers (DFU's)

Grade	Description of Ulcer
0	No ulcer, but high risk foot
1	Superficial ulcer
2	Deep ulcer; No bony involvement or abscess
3	Abscess with bony involvement (X-Ray)
4	Localized gangrene (e.g. toe, heel, etc.)
5	Extensive gangrene involving whole foot

At the time of this examination, prior to the debridement in preparation for amniotic membrane (check all present):

a. Infection ☐
b. Erythema ☐
c. Cellulitis ☐
d. Lymphangitis ☐

---

e. Necrosis ☐
f. Sinus tract, undermining ☐
g. Presence of biofilm ☐
h. Slough ☐
i. Granular, fibrotic tissue ☐
j. Drainage / Exudate ☐
k. Color change on peri-wound ☐
l. Exposed tendon / muscle / capsule / bone / joint [CIRCLE] ☐

If k. checked above, does skin substitute manufacturer allow for the application of their product on exposed tendon, muscle, capsule, bone, joint. Yes ☐

Describe any changes in the wound since Baseline Visit dated _____.

a. Reduction of dimension Yes ☐ Insignificant ☐ No ☐
b. Reduction of depth Yes ☐ Insignificant ☐ No ☐
c. Increased granulation Yes ☐ Insignificant ☐ No ☐
d. Increased epithelium growth Yes ☐ Insignificant ☐ No ☐

There has been **no change** to the following **Factors of Non-Healing**, from the Pre-Treatment visit:

a. Arterial perfusion to the lower extremity – Controlled ☐
b. Venous perfusion to the lower extremity – Controlled ☐
c. Diabetes coverage – Controlled ☐
d. Nutritional status – Controlled ☐
e. Hydration status – Controlled ☐
f. Pressure issues – Control ☐
g. Other metabolic issues – Controlled ☐
h. Infection & Colonization – Controlled ☐

Rational for graft has been discussed in the Pre-Treatment note? Yes ☐
Underlying disease processes contributing to failure of closure discussed in baseline visit? Yes ☐

Medical Necessity:

Advanced wound care treatment has failed to result in the closure of this wound? Yes ☐
All conservative therapies previously used in the failed response of the current wound:
Debridement □ *Alginate* □ *Hydrogel* □ *Collagen* □ *Foam* □ *Silvadene* □ *Santyl* □ *Medihoney* □

Provider treating the patient's systemic disease: _____

Review of pertinent medical problems: How treated / monitored. Reviewed at baseline visit? Yes ☐ No ☐

_____

Change of patient medication since the Pre-Treatment visit: _____ Yes ☐ No ☐

_____

If diabetic ulcer, have identified presence of neuropathy? Yes ☐

If venous insufficiency ulcer, have identified definitive presence of venous insufficiency? Yes ☐

The patient's arterial supply is sufficient. ABI >= 0.6 and/or TBI > 30mmHg? Yes ☐

Hx of smoking? Yes ☐ No ☐
Is patient presently a smoker? Yes ☐ No ☐
If currently smoking, have smoking cessation counseling and cessation measures prescribed? Yes ☐ No ☐
Has smoking ceased during last 4 weeks? Yes ☐ No ☐

Informed consent has been given, including risk and complications? Yes ☐ No ☐

Facility General Consent for Treatment to be used; & obtained Yes ☐ No ☐

Treatment alternatives have been discussed with the patient and/or decision maker? Yes ☐ No ☐

Patient is competent, and/or has support services necessary to participate in follow-on care? Yes ☐ No ☐

Anticipated patient outcomes from the serial applications using the Amniotic Skin Sub membrane (circle all that apply):

Graft take >= 50% / Return to an appropriate rate of healing / Eventual Closure of wound / Increase in activity

Reduced possibility of infection, sepsis, hospitalization, amputation of extremity, death

Application # 1

This is the initial application of the Human Amniotic Skin Substitute

Date: _____

Time: _____

Location of wound _____

Product name: _____

Ulcer Dimension: Length____cm x Width_____cm x Depth____cm on application **[Include undermining]**

Ulcer Dimension in sq cm: _____

Stage or Grade: _____

Graft Size: _____

Graft Area in sq cm: _____

Amount of graft used (%) _____

Amount of graft discarded (%) _____

Reason for wastage: _____

How product supplied ☐ Dehydrated / ☐ Packaged

Place all stickers used below, or write by hand:

Manufacturer Serial Number _____	Manufacturer Serial Number _____
Lot/ Batch _____	Lot/ Batch _____
Expiration Date _____	Expiration Date _____
Manufacturer Serial Number _____	Manufacturer Serial Number _____
Lot/ Batch _____	Lot/ Batch _____
Expiration Date _____	Expiration Date _____

Note: Where multiple sizes of a specific product are available, use the size that best fits the wound with the least amount of wastage.

Op Note:

Wound was examined and found to be free of infection, purulent exudate or drainage. The wound and surrounding skin was prepped with Betadine. The procedure was performed under sterile conditions, with sterile field. The surgical debridement and preparation for the graft involved several instruments, scissors, scalpel, and curettes. The edges of the wound were debrided of devitalized tissue and small areas of undermining. A sterile curet was utilized for this portion of the debridement. The base of the wound was similarly debrided using a combination of curettes, scissor, and scalpel. Slough, devitalized tissue, and areas of necrosis were debrided. Bleeding was noted, there were no perforating veins or artery. Bleeding was mild oozing. Hemostasis was accomplished with pressure.

Based on the dimensions of the wound, the appropriate amniotic membrane graft was applied. This is speaking of the dehydrated human amnion/chorion membrane allograft. We are using the amniotic membrane allograft in the treatment of chronic wound to reduce scarring, modulate inflammation, provide a barrier, initiate stem cell recruitment, and initiate signaling of the progenitor cells to reverse the stalling of formation of healing tissue. The graft was oriented correctly.

The graft fit well and the edges of the graft were manipulated to fit the wound precisely; including the walls of the edges of the wound, and any undermining. There was no need to trim the graft, and there was no wastage. 2 ampules of adhesive liquid were applied to the periwound, with care to avoid any application to the graft itself. Steri-Strips were then applied to anchor the graft to the surrounding periwound. Xeroform and a nonstick gauze was then applied and Steri-Strips were also used in a crisscross application to hold that portion of the dressing. Gauze and loosened gauze were placed over the interior dressing, with fluff, Kling, and Coban as the exterior dressing. The nursing staff will remove the exterior dressing and reapply the exterior dressing on an every other day basis or as needed for drainage.

Throughout the procedure the patient maintained adequate perfusion. There was no pain nor did the patient react to the procedure.

The patient was off-loaded. Postoperative orders were written and verbally explained to the nursing staff in detail. Orders included the previously explained dressing changes, avoidance of weightbearing with offloading. Dressings can be removed will be the clean, and fluff. The interior dressing is not to be removed. The area is to be kept dry, the patient receiving sponge baths rather than showers. If the patient should develop any fever, chills, bleeding, severe pain I am to be contacted immediately 24/7

Tylenol for pain. I will return in 1 week for dressing change, debridement if necessary, and reapplication of the graft if appropriate. The application of the amniotic membrane graft in 1 week will be considered graft #2.

Depth of the debridement: Muscle / Tendon / Bone / Fascia

Exposed Structures: Fascia / Fat / Muscle / Tendon / Capsule / Bone / Joint / Ligament

Blood loss: Negligible / ____cc

Hemostasis: Pressure / SilverCel / Hemopatch / Silver nitrate

Anesthesia: None / Native Peripheral Neuropathy / Topical Lidocaine / Prilocaine / Injectable 2% Lidocaine

Premedication: None / Tylenol / Oral Pain Medication: _____

Pain: Pre-operative _____/ 10 Intra-operative _____/ 10 Post-operative _____ / 10

Signature: _____ Date: _____

Date:

Pt Name:

Facility:

Room:

31 – Skilled

32 – LTC / Non-skilled / Domicile

Treatment #_____

Product Requested (XCellerate)

☐ 2cm x 2cm ☐ 4cm x 4cm

☐ 2cm x 4cm ☐ 4cm x 7cm

Has the patient changed location / room since the Pre-Treatment Visit / IVR? Yes ☐ No ☐

The patient is in a LTC / Domiciliary bed? Yes ☐ No ☐

The patient has not been hospitalized in the intervening time from the pre-Treatment visit Yes ☐

Ulcer Dimension: L_____cm x W_____cm x D_____cm

AREA: _____ SQ cm

Stage / Grade:

Full Thickness

- The ulcer extends through the dermis ☐
- without tendon, muscle, capsule, or bone exposure. ☐
- with tendon, muscle, capsule, or bone exposure. ☐

- Stage or Grade: _____

Location (circle):

Right / left

Toe / foot / ankle / leg

Dorsal / plantar

Duration of the ulcer: _____ weeks

WAGNER CLASSIFICATION SYSTEM

for diabetic foot ulcers (DFU's)

Grade	Description of Ulcer
0	No ulcer, but high risk foot
1	Superficial ulcer
2	Deep ulcer; No bony involvement or abscess
3	Abscess with bony involvement (X-Ray)
4	Localized gangrene (e.g. toe, heel, etc.)
5	Extensive gangrene involving whole foot

At the time of this examination, prior to the debridement in preparation for amniotic membrane (check all present):

a. Infection ☐
b. Erythema ☐
c. Cellulitis ☐
d. Lymphangitis ☐

---

e. Necrosis ☐
f. Sinus tract, undermining ☐
g. Presence of biofilm ☐
h. Slough ☐
i. Granular, fibrotic tissue ☐
j. Drainage / Exudate ☐
k. Color change on peri-wound ☐
l. Exposed tendon / muscle / capsule / bone / joint [CIRCLE] ☐

If k. checked above, does skin substitute manufacturer allow for the application of their product on exposed tendon, muscle, capsule, bone, joint. Yes ☐

Describe any changes in the wound since Baseline Visit dated _____.

a. Reduction of dimension Yes ☐ Insignificant ☐ No ☐
b. Reduction of depth Yes ☐ Insignificant ☐ No ☐
c. Increased granulation Yes ☐ Insignificant ☐ No ☐
d. Increased epithelium growth Yes ☐ Insignificant ☐ No ☐

There has been **no change** to the following **Factors of Non-Healing**, from the Pre-Treatment visit:

a. Arterial perfusion to the lower extremity – Controlled ☐
b. Venous perfusion to the lower extremity – Controlled ☐
c. Diabetes coverage – Controlled ☐
d. Nutritional status & Controlled ☐
e. Hydration status – Controlled ☐
f. Pressure issues – Control ☐
g. Other metabolic issues – Controlled ☐
h. Infection & Colonization – Control ☐

Rational for graft has been discussed in the Pre-Treatment note? Yes ☐
Underlying disease processes contributing to failure of closure discussed in baseline visit? Yes ☐

Medical Necessity:

Advanced wound care treatment has failed to result in the closure of this wound? Yes ☐
All conservative therapies previously used in the failed response of the current wound:

Attestation:

The patient's wound is observed to have less than the 50% "take" of the amniotic allograft placed last week. However, there are small, but not significant signs of improvement from baseline, signs that the treatment with amniotic allograft is working. Therefore, the treatment with an additional application today will proceed.

Signature: _____ Date: _____

Provider treating the patient's systemic disease: _____

Review of pertinent medical problems: How treated / monitored. Reviewed at baseline visit? Yes ☐ No ☐

_____

Change of patient medication since the Pre-Treatment visit: _____ Yes ☐ No ☐

_____

If diabetic ulcer, have identified presence of neuropathy? Yes ☐

If venous insufficiency ulcer, have identified definitive presence of venous insufficiency? Yes ☐

The patient's arterial supply is sufficient. ABI >= 0.6 and/or TBI > 30mmHg? Yes ☐

Hx of smoking? Yes ☐ No ☐
Is patient presently a smoker? Yes ☐ No ☐
If currently smoking, have smoking cessation counseling and cessation measures prescribed? Yes ☐ No ☐
Has smoking ceased during last 4 weeks? Yes ☐ No ☐

Informed consent has been given, including risk and complications? Yes ☐ No ☐

Facility General Consent for Treatment to be used; & obtained Yes ☐ No ☐

Treatment alternatives have been discussed with the patient and/or decision maker? Yes ☐ No ☐

Patient is competent, and/or has support services necessary to participate in follow-on care? Yes ☐ No ☐

Anticipated patient outcomes from using the Amniotic Skin Sub membrane (circle all that apply):

Graft take >= 50% / Return to an appropriate rate of healing / Eventual Closure of wound / Increase in activity
Reduced possibility of infection, sepsis, hospitalization, amputation of extremity, death

Application #_____

This is the subsequent application of the Human Amniotic Skin Substitute

Date: _____

Time: _____

Location of wound _____

Product name: _____

Ulcer Dimension: Length____cm x Width_____cm x Depth____cm on application **[Include undermining]**

Ulcer Dimension in sq cm: _____

Stage or Grade: _____

Graft Size: _____

Graft Area in sq cm: _____

Amount of graft used (%) _____

Amount of graft discarded (%) _____

Reason for wastage: _____

How product supplied ☐ Dehydrated / ☐ Packaged

Place all stickers used below, or write by hand:

Manufacturer Serial Number _____	Manufacturer Serial Number _____
Lot/ Batch _____	Lot/ Batch _____
Expiration Date _____	Expiration Date _____
Manufacturer Serial Number _____	Manufacturer Serial Number _____
Lot/ Batch _____	Lot/ Batch _____
Expiration Date _____	Expiration Date _____

Note: Where multiple sizes of a specific product are available, use the size that best fits the wound with the least amount of wastage.

Op Note:

Wound was examined and found to be free of infection, purulent exudate or drainage. The wound and surrounding skin was prepped with Betadine. The procedure was performed under sterile conditions, with sterile field. The surgical debridement and preparation for the graft involved several instruments, scissors, scalpel, and curettes. The edges of the wound were debrided of devitalized tissue and small areas of undermining. A sterile curet was utilized for this portion of the debridement. The base of the wound was similarly debrided using a combination of curettes, scissor, and scalpel. Slough, devitalized tissue, and areas of necrosis were debrided. Bleeding was noted, there were no perforating veins or artery. Bleeding was mild oozing. Hemostasis was accomplished with pressure.

Based on the dimensions of the wound, the appropriate amniotic membrane graft was applied. This is speaking of the dehydrated human amnion/chorion membrane allograft. We are using the amniotic membrane allograft in the treatment of chronic wound to reduce scarring, modulate inflammation, provide a barrier, initiate stem cell recruitment, and initiate signaling of the progenitor cells to reverse the stalling of formation of healing tissue. The graft was oriented correctly.

The graft fit well and the edges of the graft were manipulated to fit the wound precisely; including the walls of the edges of the wound, and any undermining. There was no need to trim the graft, and there was no wastage. 2 ampules of adhesive liquid were applied to the periwound, with care to avoid any application to the graft itself. Steri-Strips were then applied to anchor the graft to the surrounding periwound. Xeroform and a nonstick gauze was then applied and Steri-Strips were also used in a crisscross application to hold that portion of the dressing. Gauze and loosened gauze were placed over the interior dressing, with fluff, Kling, and Coban as the exterior dressing. The nursing staff will remove the exterior dressing and reapply the exterior dressing on an every other day basis or as needed for drainage.

Throughout the procedure the patient maintained adequate perfusion. There was no pain nor did the patient react to the procedure.

The patient was off-loaded. Postoperative orders were written and verbally explained to the nursing staff in detail. Orders included the previously explained dressing changes, avoidance of weightbearing with offloading. Dressings can be removed will be the clean, and fluff. The interior dressing is not to be removed. The area is to be kept dry, the patient receiving sponge baths rather than showers. If the patient should develop any fever, chills, bleeding, severe pain I am to be contacted immediately 24/7

Tylenol for pain. I will return in 1 week for dressing change, debridement if necessary, and reapplication of the graft if appropriate. The application of the amniotic membrane graft in 1 week will be considered graft #____.

Depth of the debridement: Muscle / Tendon / Bone / Fascia

Exposed Structures: Fascia / Fat / Muscle / Tendon / Capsule / Bone / Joint / Ligament

Blood loss: Negligible / ____cc

Hemostasis: Pressure / SilverCel / Hemopatch / Silver nitrate

Anesthesia: None / Native Peripheral Neuropathy / Topical Lidocaine / injectable Lidocaine

Premedication: None / Tylenol / Oral Pain Medication: _____

Pain: Pre-operative _____/ 10 Intra-operative _____/ 10 Post-operative _____ / 10

Signature: _____ Date: _____