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FRESH.
LIVING.
PROVEN.

Affinity®, the ONLY fresh, placental amnion allograft retaining living cells,has been shown to support improved time-to-wound closure in RCT and real-world data, when used as a protective barrier.[1-8]

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WOUNDS CAN'T WAIT

Without proper and timely care, non-healing wounds can lead to serious complications, creating a major burden for patients as well as the healthcare system.

Diabetic Foot Ulcers (DFUs) and surgical wounds are the most common and most expensive types of wounds.[9]

Faster healing of DFUs is critical, since they put patients at risk for serious complications, including osteomyelitis and amputation.[10,11]

Venous Leg Ulcers (VLUs) are a substantial threat to quality of life for patients and require immediate attention.[12-15]

Affinity®, as a protective barrier, has been shown to support improved time-to-wound closure in DFUs.[5]

Choose Affinity for non-healing wounds.

I. EFFICACY
As shown in an RCT[5] and real-world case series,[6-8,16] Affinity, as a protective barrier and ECM scaffold, helps wounds of various types and sizes move from non-healing to closed.

II. COMPOSITION
Unlike any other amnion on the market today, Affinity retains the fresh characteristics of placental tissue, including living endogenous cells, growth factors and cytokines, native 3-dimensional ECM structure, and the spongy layer.[2-4,17,18]

III. PRESERVATION
Through our proprietary, AlloFresh™ preservation method, Affinity is never dehydrated or frozen, and is the closest choice to native, unprocessed, human amniotic tissue.[2,18-21]

Affinity, the ONLY fresh, placental amnion allograft retaining living cells.[1-4]

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RANDOMIZED CONTROLLED TRIAL

PROVEN SUCCESS WITH NON-HEALING DFUs

Affinity®, the ONLY fresh, placental amnion allograft retaining living cells, increased the frequency and probability of DFU wound closure compared to standard of care (SOC) alone, when used as a protective barrier.[1-5]

60%

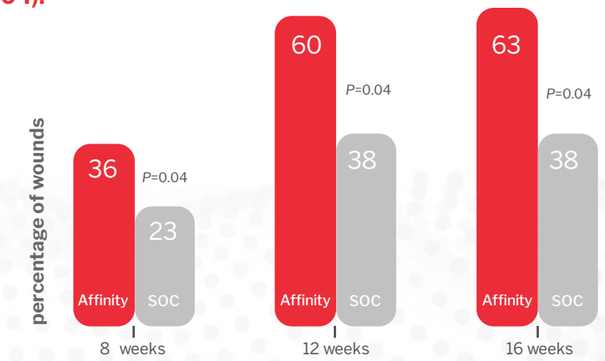
In a prospective, multicenter, randomized controlled trial (RCT;N=76), 60% of DFUs closed at 12 weeks compared to 38% with SOC (*P*=0.04).[5]

Median time to DFU closure with Affinity was 11 weeks[5]

SOC failed to attain this endpoint at 16 weeks[5]

Significantly more DFUs were closed with Affinity than SOC at 8, 12, and 16 weeks (*P=0.04).**

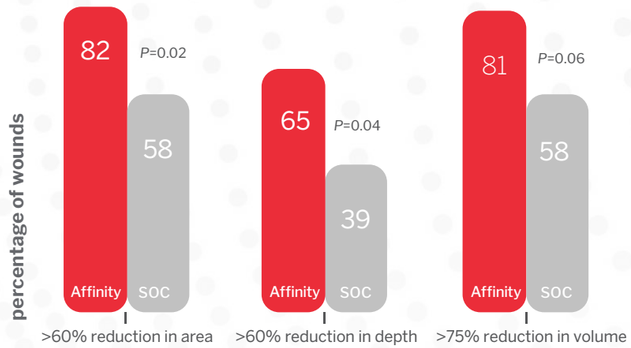
Frequency of wound closure



Affinity, as a protective barrier and ECM scaffold, was shown to support healing in a prospective, multicenter RCT.[5]

Significantly more DFUs achieved >60% reduction in wound area (*P*=0.02) and depth (*P*=0.04) with Affinity than SOC.

Reduction in wound area and depth



In a randomized controlled trial (RCT), the efficacy of Affinity vs. SOC was assessed in 76 patients with refractory diabetic foot ulcers (DFUs) of more than four weeks' duration. Digital planimetry† was used to accurately capture DFU area, depth, and volume.[5]

* Debridement, infection elimination, dressings, and offloading by total contact casting.
† Silhouette® laser-assisted wound measurement device.

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In a multicenter, retrospective case series, including patients with multiple comorbidities, positive outcomes were achieved for DFUs managed with Affinity® (N=50).[16]

78%

of DFUs reached complete closure by week 12.

Median time to complete closure was 55 days

96% of DFUs attained area reduction of >60% by week 12

Frequency of closure increased at each 4-week interval

Affinity, as a protective barrier, was used to support a healing environment for hard-to-heal DFUs where:

- 54% of patients received SOC for >4 weeks prior to starting Affinity
- 60% had >1 comorbidity
- 26% were amputees with type 1 or 2 diabetes, in combination with Charcot foot, PVD, or renal failure/dialysis
- Mean area of DFUs was 3.5 cm^2, and all DFUs were Grade 2 or higher on the Wagner Scale

Real-world data has shown that a variety of wounds managed with Affinity reduced in size to closure.[5]

≥65%

wound size reduction at 3 weeks.

Study author: Lambert • Study type: retrospective case series • Wound types: mixed

93.9%

wound size reduction at 6 weeks.

Study author: Sabo • Study type: prospective case series • Wound types: mixed

100%

of wounds closed at 9 weeks.

Study author: Carpenter • Study type: retrospective case series • Wound types: mixed

In retrospective case studies, Affinity, as a protective barrier and ECM scaffold, demonstrated positive results in diabetic foot ulcers (DFUs), venous leg ulcers (VLUs), and other wound types.[6-8,16]

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THE ONLY FRESH, PLACENTAL AMNION ALLOGRAFT RETAINING LIVING CELLS[1-4]

The living-cell characteristics of Affinity®, combined with its 3-dimensional extracellular matrix (ECM) structure, support an optimal healing environment when used as a protective barrier.[2,4]

Our proprietary, hypothermic process preserves components of the native amniotic tissue, supporting the body's natural healing process.[2-4,18,19]

Living cells

Including epithelial cells and fibroblasts[3,4,21]

Native 3-dimensional ECM scaffold

With multiple ECM proteins retained from native human placental tissue that supports the formation of granulation tissue[2,4,22]

Growth factors/cytokines

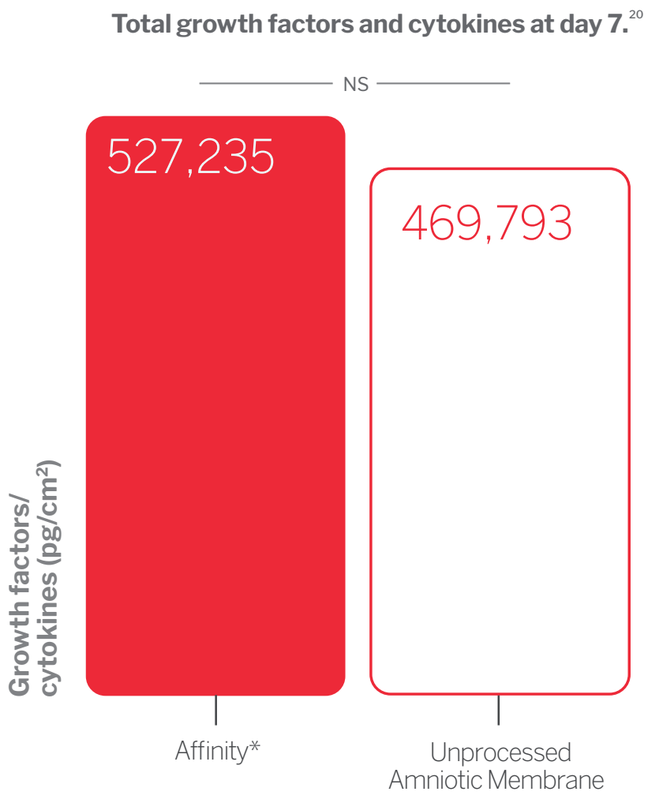
Analytical testing has shown the level of these factors is similar to that of unprocessed amniotic membrane[4,17]

Spongy layer

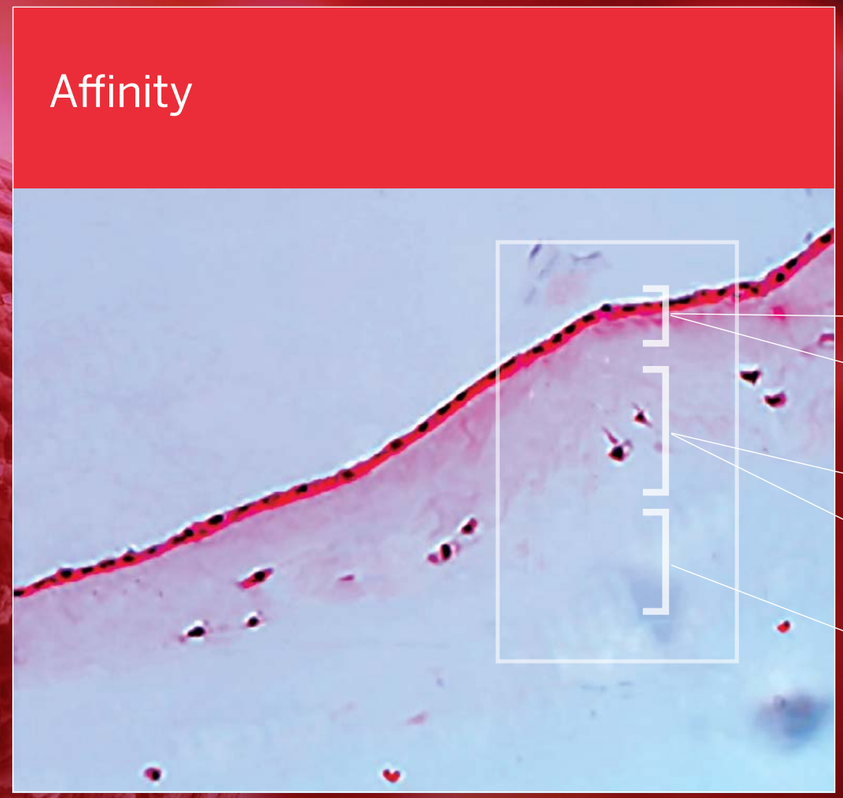
Contains proteoglycans, glycoproteins, and hyaluronic acid[20]

In analytical testing, Affinity® has been shown to retain a variety of growth factors and cytokines at a level similar to that of unprocessed amniotic membrane.[4,13]

Total growth factors and cytokines at day 7.[20]



*After ~30 days of storage in AlloFresh™ solution.
NS = Not Significant



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ALLOFRESH™ KEEPS LIVE CELLS VIABLE[3]

Affinity® undergoes the AlloFresh proprietary process, a gentle preservation method that hypothermically maintains living endogenous cells and retains native human tissue composition and architecture.[2-4,18,19]

- Gentle process maintains native human tissue characteristics[2-4,18,19]
- Avoids extremes of heat and cold[19]
- No dehydration or freezing[19]

NEVER DEHYDRATED OR FROZEN[19]

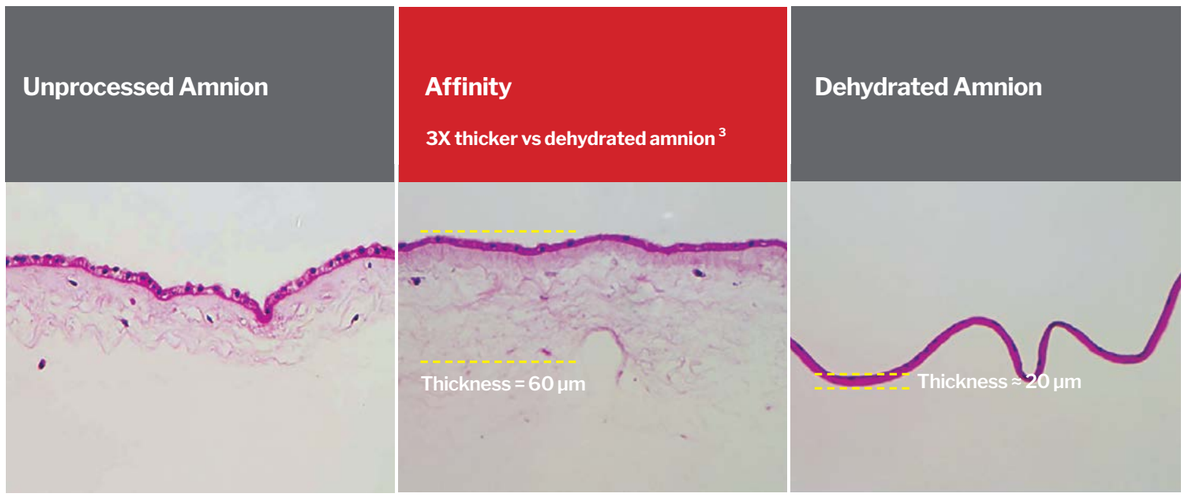
No cryopreservation.[19]

While freezing can preserve growth factor/cytokine content and structural integrity, cryopreservation techniques may cause the loss of cell viability.[18]

No dehydration and sterilization.[19]

Dehydration may preserve some growth factor content, but it compresses the ECM and, in some products, devitalizes the living endogenous cells.[23,24]

Affinity retains the 3-dimensional structure of native human placental tissue and is significantly thicker than dehydrated amnion.[3]



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AFFINITY® PRODUCT DETAILS AND RESOURCES

Intended Use[25]

Affinity, as a protective barrier and ECM scaffold, may be used in a variety of partial- and full-thickness acute and chronic wounds.[4] Affinity will naturally be broken down and resorbed into the wound and is not intended to be removed.

- Trauma wounds
- Dehisced wounds
- Pressure injuries
- Venous leg ulcers (VLUs)
- Diabetic foot ulcers (DFUs)
- Dermal ulcers
- Post-Mohs defects
- Wounds with exposed bone/tendon

Application[25]

Preparation of the wound bed: Ensure that the wound is free of infection. Sharp debridement should be performed and extended to healthy, viable bleeding tissue. Hemostasis should be achieved, and heavy exudate controlled.

Remove

- Using aseptic technique, remove the inner tray from the outer tray.
- Peel back the foil lid from the inner tray, remove Affinity and place the product on the inner side of the foil lid.

Identify

- Identify which side is facing up by touching the surface with a sterile cotton swab.
- If the stromal or sticky side is up, then turn Affinity over, so that the stromal side is facing down on the foil lid. If the epithelial or non-sticky side is facing up, then you do not need to turn the product over.
- Rinse with a sterile irrigant prior to application.

Apply

- Slide Affinity onto the wound bed so that the stromal side is in contact with the wound bed.
- Forceps can be used to help with orientation.
- Trim Affinity as needed so that it is slightly larger than the wound bed.

Dressings and Re-Application Schedule*

- Anchor Affinity using preferred fixation method, such as sutures or adhesive strips, then cover Affinity with a primary nonadherent dressing.
- Apply a secondary dressing that controls drainage and provides a moist wound environment.
- Offload or compress appropriately based on wound type.

*Affinity can be applied at the onset or duration of the wound, with subsequent application at the discretion of the healthcare practitioner. Please confirm with your current applicable payer policies for up-to-date Affinity coverage requirements and policies.

Affinity Product Information

Product Number	Product Description	Total Size (cm^2)	Billable Units	HCPCS Code	UPC Number	Alternate ID
AF-1150	Affinity 1.5x1.5 cm	2.25	3	Q4159	857877005139	57877-0005-13
AF-1250	Affinity 2.5x2.5 cm	6.25	7	Q4159	857877005115	57877-0005-11

Storage

Affinity should be maintained at refrigerated temperature (between 1°C and 10°C).
See the full Instructions for Use for complete storage and handling instructions.

Reimbursement

- Affinity has broad Medicare coverage for a variety of wound types when medically appropriate.[26]
- Consult with your LCD (local coverage determination) for the specific wound types covered.
- Coverage benefits can be verified prior to treatment through our Benefit Verification Program.

CPT codes
15271-15278

Support programs and resources
1-888-432-5232

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WOUNDS CAN'T WAIT

Talk to your Organogenesis sales representative about Affinity®.

Or scan this code to contact us.

CIRCLE of CARE

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We're with you every step of the way.

Organogenesis' Circle of Care offers a comprehensive range of services, benefits, and support to help navigate the treatment journey.

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