

Storage and Handling

1. How should allografts be stored, and what is their shelf life?

Allografts are designed for room temperature storage in a dry, light-protected area. Shelf-life ranges from 2-5 years, depending on the product. Reference the Instructions for Use (IFU) that comes with every shipment.

Source Material and Safety

2. What type of source material is used? Is all tissue tested for disease?

Our products use human amniotic membrane tissue from donated placentas via elective C-sections. All tissue is rigorously tested for diseases (e.g., HIV, hepatitis) per FDA HCT/P standards.

3. What are the latest FDA regulations affecting amniotic skin substitute products?

FDA regulates our HCT/P products under 21 CFR Part 1271, focusing on minimal manipulation and homologous use.

Preparation and Application

4. Can the skin substitute be cut to size, overlapped, or used in multiple pieces?

Yes, cut with sterile tools, overlap edges, or use pieces for coverage. Try to minimize wastage and always document it as to why there was wastage, how much, etc. We also carry fenestrated grafts.

5. How is the skin substitute prepared and applied (e.g., hydration, trimming, which side faces up)

Hydrate if dehydrated (e.g., saline for 1-5 min), trim to fit, apply amnion side down. Reference Instructions for Use (IFU) for products.

Clinical Usage and Compatibility

6. Are there any contraindications with certain medications, therapies, or patient conditions?

Contraindications for our line include active infections, hypersensitivity to human amniotic tissue, or untreated underlying conditions like osteomyelitis.

7. Can amniotic allografts be used on wounds with exposed bone or tendon?

Yes, products in our line are effective for wounds with exposed structures, acting as a protective barrier to promote regeneration.

8. Can the skin substitute be used on infected wounds or with specific patient conditions (e.g., allergies)?

Not for active infections; control first. Avoid in allergies to human tissue for our line.

Evidence and Outcomes

9. What are the outcomes from recent clinical trials on amniotic allografts for wound healing?

Recent studies on amniotic allografts similar to our products show closure rates of 70-85% in chronic wounds within 8-12 weeks, with reduced pain and infection. For example, trials on

dehydrated amniotic membranes like those in our line demonstrate accelerated granulation and epithelialization in DFUs and VLU's.

10. Are there clinical studies or evidence supporting the effectiveness of the skin substitute?

Evidence for amniotic allografts in our line shows accelerated healing, e.g., studies on Human Cellular Tissue Products report 70-85% closure in chronic wounds.

Patient Selection and Monitoring

11. How do you assess if a patient is a good candidate for amniotic allograft therapy?

Candidates for our products have chronic wounds failing 4 weeks of standard care, with adequate perfusion and no infection. Document vascular status (e.g., ABI) and wound metrics for successful reimbursement. We provide you with documentation checklists/templates to set you up for success.

12. What follow-up monitoring is recommended after applying an amniotic allograft?

Weekly evaluations for integration, size reduction, and complications are advised. Photograph and measure wounds, adjusting as needed per protocols.

Reimbursement and Billing Support

13. What support do you provide for reimbursement and billing queries?

Our third-party billing specialists provide comprehensive support with Q-coding, customized documentation templates, and appeals processes to ensure full compliance with CMS requirements. They utilize three distinct departments—or specialized review funnels—to meticulously check for errors and potential issues prior to submission, thereby maximizing reimbursement success rates. Their service fee is a competitive 3-4%.

14. What happens if a claim for skin substitutes doesn't meet clinical criteria?

Our 3rd party billers will respond with an appeal.

Shipping and Logistics

15. Can products be shipped to homes?

Products can be shipped to: Practice, Home of Provider, or any FedEx location for pickup.

16. What is the cost of shipping?

Depending on time of day needed for delivery and distance, between \$40-\$120. All products shipped by FedEx.

Pricing and Discounts

17. What's the invoice discount?

We can most likely beat what you're currently getting. Be careful, as 50% or more discount runs the risk of getting clawed back.

-----Summary of flow/pitch-----

- Invoice terms is 45 days, We want providers to pay their invoice once they are reimbursed.**
- We can most likely beat the discount there getting now, Over 50% is playing with fire when it comes to clawbacks.**
- IVR through portal or fax**
- Orders can be placed through portal, email, or fax**
- Manufacturer Assurance**
- 3rd party specialty billers for fast and reliable reimbursement. (they bill daily)**
- Clawback insurance, policies issued per treatment, coverage is for 6 years from treatment date, covering Medicare statute of limitations. A rated reinsurer. Cost is 6% of reimbursement amount.**
- Med advantage is a roll of the dice, that's why we always run a pre authorization. If patient has diabetes, we have a product named Actigraft plus which is on the NCD and will cover 20 treatments.**
- No stock / Inventory Issues**
- Facilitate overnight shipping.**
- We deliver updates through email on upcoming regulations and information related to the space.**
- Minimum orders, dependent on product, typically 2x2**