



Advanced therapy for wound care, 1974.

DO YOU SUFFER FROM LEG AND FOOT SORES?

**APLIGRAF® HEALS
30-50%
MORE FOOT OR LEG SORES
IN 1/3 LESS TIME
THAN CONVENTIONAL
WOUND CARE.***

When a foot or leg sore lingers for weeks, months or even years without healing, it's normal to feel hopeless. Perhaps you've tried other basic treatments, but they've been ineffective in healing your sore.

Now there's Apligraf®, an advanced wound care therapy, offering real hope for healing your sore by using the latest in biotechnology. Like human skin, Apligraf® consists of living cells, proteins and skin-healing substances. Apligraf® is not another ointment or dressing, it's designed as a living "skin patch" to replicate the function of healthy human skin by helping the skin naturally



Advanced therapy for wound care, today.

regenerate itself. And the application is painless.

Apligraf®, which can be used to treat diabetic foot sores or venous leg sores, is FDA approved and clinically proven to be safe and effective. It's been used in over 150,000 patients to date and is covered by most insurance plans.

Apligraf® is not available everywhere, so to find a wound care doctor who can apply Apligraf®, go to www.apligraf.com or call toll-free **1-866-637-4325** (HEAL)

HOPE FOR HEALING EVEN THE MOST PERSISTENT SORES.



APLIGRAF® ESSENTIAL PRESCRIBING INFORMATION

Numbers in parentheses () refer to sections in the main part of the product labeling.

DEVICE DESCRIPTION

Apligraf is supplied as a living, bi-layered skin substitute manufactured using neonatal foreskin keratinocytes and fibroblasts with bovine Type I collagen. (1)

INTENDED USE/INDICATIONS

Apligraf is indicated for use with standard therapeutic compression in the treatment of uninfected partial and/or full-thickness skin loss ulcers due to venous insufficiency of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy. (2)

Apligraf is indicated for use with standard diabetic foot ulcer care for the treatment of full-thickness foot ulcers of neuropathic etiology of at least three weeks duration, which have not adequately responded to conventional ulcer therapy and extend through the dermis but without tendon, muscle, capsule or bone exposure. (2)

CONTRAINDICATIONS

Apligraf is contraindicated for use on clinically infected wounds and in patients with known allergies to bovine collagen or hypersensitivity to the components of the shipping medium. (3, 4, 5, 8)

WARNINGS AND PRECAUTIONS

If the expiration date or product pH (6.8-7.7) is not within the acceptable range DO NOT OPEN AND DO NOT USE the product. A clinical determination of wound infection should be made based on all of the signs and symptoms of infection. (4, 5)

ADVERSE EVENTS

All reported adverse events, which occurred at an incidence of greater than 1% in the clinical studies are listed in Table 1, Table 2 and Table 3. These tables list adverse events both attributed and not attributed to treatment. (6)

MAINTAINING DEVICE EFFECTIVENESS

Apligraf has been processed under aseptic conditions and should be handled observing sterile technique. It should be kept in its tray on the medium in the sealed bag under controlled temperature 68°F - 73°F (20°C-23°C) until ready for use. Apligraf should be placed on the wound bed within 15 minutes of opening the package. Handling before application to the wound site should be minimal. If there is any question that Apligraf may be contaminated or compromised, it should not be used. Apligraf should not be used beyond the listed expiration date. (9)

USE IN SPECIFIC POPULATIONS

The safety and effectiveness of Apligraf have not been established in pregnant women, acute wounds, burns and ulcers caused by pressure.

PATIENT COUNSELING INFORMATION

VLU patients should be counseled regarding the importance of complying with compression therapy or other treatment, which may be prescribed in conjunction with Apligraf.

DFU patients should be counseled that Apligraf is used in combination with good ulcer care including a non-weight bearing regimen and optimal metabolic control and nutrition. Once an ulcer has healed, ulcer prevention practices should be implemented including regular visits to appropriate medical providers.

TREATMENT OF DIABETES

Apligraf does not address the underlying pathophysiology of neuropathic diabetic foot ulcers. Management of the patient's diabetes should be according to standard medical practice.

HOW SUPPLIED

Apligraf is supplied sealed in a heavy gauge polyethylene bag with a 10% CO₂/air atmosphere and agarose nutrient medium, ready for single use. To maintain cell viability, Apligraf should be kept in the sealed bag at 68°F - 73°F (20°C-23°C) until use. Apligraf is supplied as a circular disk approximately 75 mm in diameter and 0.75 mm thick. (8)

PATENT NUMBERS:

4,485,096 5,106,949 5,536,656

Manufactured and distributed by: Organogenesis Inc.

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*Falanga V, Sabolinski ML. A bilayered living skin construct (Apligraf®) accelerates complete closure of hard-to-heal venous ulcers. *Wound Repair Regen.* 1999; 7:201-207.

*Veves A, Falanga V, et al Graftskin, a human skin equivalent, is effective in management of a non-infected neuropathic diabetic foot ulcers. *Diabetes Care.* 2001;24:290-295.