



# Hope for healing your **DIABETIC FOOT ULCER**



Everything to know about  
a unique advanced treatment  
for healing your diabetic foot ulcer

Organogenesis

**Apligraf**<sup>®</sup>

Living Cellular Skin Substitute

# NO NEED TO FEEL HOPELESS

Apligraf® is a unique product for treating diabetic foot ulcers. It contains living cells, proteins produced by the cells, and collagen, which are important for healing.



## Apligraf® has been used to treat many thousands of patients

Your doctor has given you this brochure because you have a **DIABETIC FOOT ULCER (DFU)**. This is a serious wound that requires proper care and attention to avoid complications such as infection, which may require hospitalization, and possibly amputation.

- ▶ There are 2 main causes for diabetic foot ulcers. Most often, they result from **LACK OF FEELING IN THE FEET** (neuropathy; noo-ROP-a-thee). This condition can result in injury because normally painful sensations, such as stepping on a pin, cannot be felt and therefore may not be properly treated. Continuing to walk on the injured foot may cause an ulcer to develop. **POOR CIRCULATION** in your legs and feet can also cause the skin to break down, forming an ulcer.
- ▶ The standard treatment for healing diabetic foot ulcers is typically a combination of **SURGICALLY REMOVING DEAD SKIN, BANDAGING** the wound, and **STAYING OFF** the injured foot. However, this may take a long time and doesn't always work.
- ▶ When a diabetic foot ulcer (DFU) lingers for weeks, months or even years without healing, it can seem hopeless. It's frustrating when your body just does not heal, no matter what treatments you try. But there is real hope for healing your ulcer with Apligraf, using the latest in **BIOTECHNOLOGY** for wound care.
- ▶ Apligraf is made up of **LIVING CELLS**, proteins produced by the cells, and collagen. The living cells and proteins are similar to those found in human skin. Apligraf does not contain certain things found in human skin such as pigment cells, cells from the immune system, blood vessels, hair follicles, or sweat glands. Apligraf is not another ointment or dressing. It is an **ADVANCED TREATMENT** that helps promote healing of DFUs.

This brochure will familiarize you with Apligraf. Plus, you'll find out how to take better care of yourself and your condition to prevent these ulcers from coming back.



To learn more about your **DIABETIC FOOT ULCER**, please talk to your doctor.

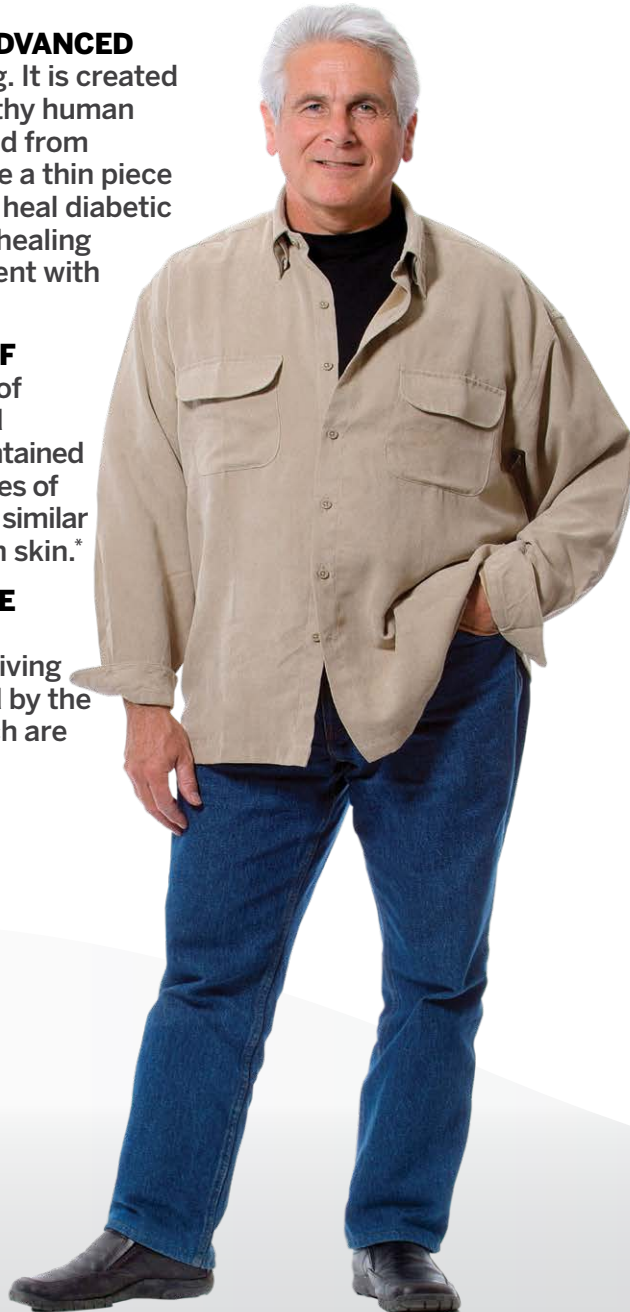
To learn more about Apligraf, please ask your doctor or visit [www.organogenesis.com](http://www.organogenesis.com)

## What is Apligraf®?

Apligraf is a **UNIQUE, ADVANCED TREATMENT** for healing. It is created from cells found in healthy human skin and collagen derived from cows. In fact, it looks like a thin piece of real skin. It is used to heal diabetic foot ulcers that are not healing after 3 weeks of treatment with standard therapies.

Apligraf has **2 TYPES OF CELLS** – an outer layer of protective skin cells and an inner layer of cells contained within collagen. Both types of cells contain substances similar to those found in human skin.\*

Apligraf plays an **ACTIVE ROLE IN HEALING** by providing to the wound living cells, proteins produced by the cells, and collagen, which are important for healing.



\*Apligraf does not contain certain things found in human skin, such as pigment cells, cells from the immune system, blood vessels, hair follicles, or sweat glands.

## How does Apligraf® compare to other wound care products?

- ✓ **FDA APPROVED**  
Apligraf is an FDA-approved product. In multiple controlled clinical studies, it has been shown to be an effective and safe wound treatment. Many wound care products cannot make such claims.
- ✓ **BETTER HEALING COMPARED TO BASIC WOUND CARE**  
Studies showed that Apligraf heals more wounds than standard treatment alone. And does it faster.
- ✓ **ACTIVE VERSUS PASSIVE WOUND HEALING**  
Many wound treatments passively manage the wound. Apligraf plays a more active role by delivering to the wound living cells, proteins produced by the cells, and collagen, which are important for healing.
- ✓ **A LIVING PRODUCT RESEMBLING OUR OWN SKIN**  
Apligraf is the product approved for both diabetic foot ulcers and venous leg ulcers, containing 2 different types of skin cells combined with collagen.
- ✓ **EASY**  
Apligraf typically requires no maintenance. Dressings are usually changed once a week by your doctor or nurse depending on your wound type. It is very important to keep your follow-up visits and to follow your doctor's directions carefully. If you have any signs of infection such as tenderness to the touch, redness, pain, heat, and/or swelling, contact your doctor immediately.



## Is Apligraf® safe?

Apligraf has been used to treat many thousands of patients.

When used with standard therapy, Apligraf has been shown to heal more diabetic foot ulcers than standard therapy alone. Of course, it is better to prevent a diabetic foot ulcer than to have to treat one.

No allergic reactions have been reported in studies with more than 1,000 patients. However, you should tell your doctor immediately if you have any allergy symptoms.

In a study of patients treated with Apligraf, the most common health problems were related to an open ulcer, the skin, or diabetes. These potential problems were usually temporary or treatable by a doctor. The health problems in the Apligraf patients were similar to those found in patients treated with standard therapy (moist gauze and removal of weight from the foot).



### The most common health problems were:

<b>A NEW FOOT ULCER</b>	<b>PAIN</b>
<b>SUSPECTED WOUND INFECTION</b>	<b>NON-WOUND INFECTION</b>
<b>A SKIN TEAR OR CUT</b>	<b>BRUISING</b>
<b>SKIN INFLAMMATION</b>	<b>SWELLING</b>
<b>BONE INFECTION</b>	<b>WORSENING ULCER</b>
<b>RASH</b>	<b>DRY SKIN</b>
<b>LOW BLOOD SUGAR OR HIGH BLOOD SUGAR</b>	

The incidence of other reported adverse events was similar for patients receiving Apligraf or standard therapy.



For a more complete description of Apligraf, or for more information about side effects, please read the Apligraf complete prescribing information contained in the back of the brochure or talk to your doctor.

Your doctor should not apply Apligraf if the wound is infected or if you are allergic to cow collagen or to any of the components in the Apligraf shipping gel.<sup>†</sup>

While the safety of Apligraf in DFU patients has not been studied beyond 6 months, Apligraf has been used to treat many thousands of patients. Patients treated with Apligraf have shown no increased risk for developing cancer; however, the long-term possibility has not been studied.

<sup>†</sup>Contains agarose, L-glutamine, hydrocortisone, human recombinant insulin, DMEM powder, HAM's F-12 powder, calcium chloride, sodium bicarbonate, adenine, selenious acid, ethanolamine, O-phosphorylethanolamine, and water for injection.

## How is Apligraf® applied?

Apligraf is a living product that must be ordered by your doctor. It may be applied in a hospital, in a Wound Care Center, or in your doctor's office.

**A** First, your doctor will clean your ulcer and possibly debride it (debriding removes dead, damaged, or infected tissue from a wound). Then Apligraf is placed directly on the ulcer.



**B** The wound is then covered with a non-adhesive dressing to keep it moist and to keep Apligraf in place.



**C** The area is then wrapped with other dressings that are changed weekly by the doctor or nurse.



The healing process now begins and improvement of the wound can usually be seen within weeks. If you have any signs of infection, such as tenderness to the touch, redness, pain, heat, and/or swelling, contact your doctor immediately.

## What happens after Apligraf® is applied?

Once Apligraf is applied, your doctor or nurse will give you instructions to follow while your wound is healing.

- ▶ Be careful not to disturb your wound or get it wet during the first week of healing.
- ▶ Within the first week, you may have a follow-up visit with your doctor to check the healing progress.
- ▶ After that, your doctor may schedule weekly follow-up visits until your wound is healed.
- ▶ It is very important to keep your follow-up visits and to follow your doctor's directions carefully.



It is important to keep your weight off your feet while your ulcer is healing. To do this your doctor may tell you to use a wheelchair, crutches, or a specially made protective shoe or cast during the first weeks after Apligraf is applied.



Once your ulcer has healed, your doctor may want you to wear special footwear to keep pressure off of the newly healed wound.

And do not forget that while Apligraf can treat your foot ulcer, it is not a treatment for diabetes or the health condition that caused the ulcer in the first place. Follow your doctor's advice on how to stay healthy in order to prevent your ulcer from coming back.

If you experience any signs of infection, such as tenderness to the touch, redness, pain, heat, and/or swelling, **CONTACT YOUR DOCTOR IMMEDIATELY.**



Apligraf has been clinically proven to be more effective than standard wound care alone for ulcers that haven't progressed toward healing after **THREE** weeks.<sup>1,2</sup>



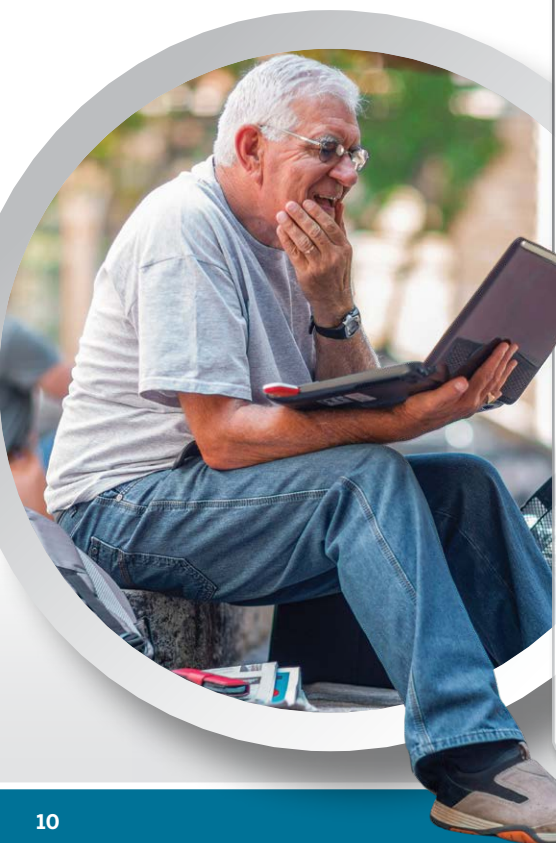
Apligraf **DELIVERS** to the wound **LIVING CELLS, PROTEINS** produced by the cells, and **COLLAGEN**, which are important for healing.

## Preventing your ulcer from coming back

As you know, treating diabetic foot ulcers can be challenging, both emotionally and physically. In addition, treatments like Apligraf do not cure the underlying health conditions that lead to these types of ulcers. This means that even after successful treatment of an ulcer, you are still at risk for another one if you don't improve your existing health condition. The most effective way to improve your quality of life is to do what you can to prevent a non-healing ulcer from starting or coming back.

### Diabetic Foot Ulcer Prevention

- Follow your doctor's advice on how to control your blood sugar
- Check your feet daily for cuts, blisters, red spots, or swelling. Tell your doctor immediately if you see any changes or injuries
- Have a podiatrist or other health care professional trim your toenails straight across and file the edges
- Always wear shoes when walking – never go barefoot
- Wear thick, soft socks – avoid mended socks or those with seams. Seams can rub and cause blisters or other skin injuries
- Before putting on your shoes, feel inside for pebbles or other small hard objects
- Don't wear high heels, sandals, or open toe shoes
- Don't try to remove calluses, corns, or warts by yourself – see your doctor for assistance in these cases



## Apligraf® is a proven advanced treatment for diabetic foot ulcers

### Q What kinds of ulcers does Apligraf treat?

A Apligraf is indicated to treat non-healing diabetic foot ulcers and venous leg ulcers that have not responded to conventional therapy.

### Q Does Apligraf really work better than traditional therapies for diabetic foot ulcers?

A Yes. When used in combination with good wound care, Apligraf has been proven to heal ulcers better than standard therapy and does it faster.

### Q How quickly will I see results with Apligraf?

A This depends on the nature of your ulcer and underlying medical condition. Apligraf begins to work as soon as it is placed on the wound. Improvement can usually be seen within weeks.

### Q How many applications of Apligraf will I need?

A Again, that depends on the nature of your ulcer and underlying medical condition. While some patients may heal with a single application, others might require several applications.

### Q What is a Wound Care Center?

A A Wound Care Center is a clinic specializing in the treatment of non-healing wounds and ulcers. They provide advanced wound healing techniques and state-of-the-art wound assessment, testing, and treatment.

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## Follow your doctor's or nurse's advice on how to prevent your ulcer from coming back



Ask your doctor for more information about **DIABETIC FOOT ULCERS** and Apligraf.



[www.organogenesis.com](http://www.organogenesis.com)  
**1.888.HEAL.2.DAY**  
(1.888.432.5232)

**Please see complete prescribing information enclosed, or visit [www.organogenesis.com](http://www.organogenesis.com)**

**References:** **1.** Falanga V, Sabolinski ML. A bilayered living skin construct (Apligraf<sup>®</sup>) accelerates complete closure of hard-to-heal venous ulcers. *Wound Repair Regen.* 1999;7:201-207. **2.** Veves A, Falanga V, Armstrong DG, Sabolinski ML: Apligraf Diabetic Foot Ulcer Study. Graftskin, a human skin equivalent, is effective in management of non-infected neuropathic diabetic foot ulcers. *Diabetes Care.* 2001;24:290-295.

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Empowering Healing