References
This patient education brochure is presented courtesy of Wright with the assistance of Joseph Dileo, DPM

Patient results may vary. Please consult your physician to determine if these products are right for you.

For prescribing information, including warnings and contraindications, please consult the product labeling summary provided on the back inside cover of this brochure, or visit www.graftjacket.com.

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Prescribing Information & Precautions

The GRAFTJACKET® Ulcer Repair Matrix is processed from donated human dermis supplied from U.S. tissue banks utilizing the guidelines of the American Association of Tissue Banks (AATB) and applicable Food and Drug Administration’s (FDA) rules and regulations. FDA regulation of human tissue does not include review and approval of safety or effectiveness.

Donor tissue undergoes several levels of testing and screening to assure its safety. However, existing tests cannot provide absolute assurance that human source material will not transmit disease.

GRAFTJACKET® products should not be used in patients with certain conditions:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Matrix</th>
<th>XPRESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients diagnosed with autoimmune connective tissue diseases;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Patients without adequate blood supply at the ulcer site, unless specifically prescribed by a physician;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Patients with sensitivity to specific antibiotics listed on the package;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Patients with any disease condition that would limit the blood supply and compromise healing;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Patients with poor nutrition and/or poor general medical condition;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Patients with current infection that should be treated by a doctor first;</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Because of the particle size, GRAFTJACKET® Flowable Soft Tissue Scaffold should not be used in the periorcular, forehead or glabellar areas.</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Consult your doctor to see if GRAFTJACKET® products are right for you.

Warning
Careful controls the company has put in place reduce the risk of getting disease from the GRAFTJACKET® tissue. However, GRAFTJACKET® products cannot be guaranteed to be free of all possible diseases. The potential risk of cancer or reproductive risks are unknown.
but basically the wound just refuses to heal despite the physician’s best efforts. In these cases, GRAFTJACKET® Matrix can be used to help encourage the body to heal itself.

6. What is off-loading?
When treating an ulcer, it is very important to off-load or take the pressure off the affected area. This can be done with special dressings, foot wear, braces, and/or casts. By off-loading the wound, you allow the body to help repair itself more quickly.

7. How can diabetic foot ulcers be prevented?
Prevention is the best medicine for foot ulcers. Recommended guidelines for prevention include regular visits to your physician, monitoring and controlling your blood sugar levels, checking your feet on a daily basis, and wearing appropriate shoes and socks to help prevent callus formation.

8. What Composes GRAFTJACKET® Products?
GRAFTJACKET® products are collagen scaffolds from donated human skin. These scaffolds act as a three-dimensional structural to aid in repair of your ulcer. The GRAFTJACKET® material is incorporated by your body and eventually converted to your own tissue. Studies show that GRAFTJACKET® Matrix aids in repair of deep wounds with only one application.

9. What is a tunneling wound?
A tunneling wound is a tract or extension deep into the soft tissues. These tunnels can often retard healing of wounds. Sometimes, even after a wound has healed, a remaining tunnel that was not treated can lead to a breakdown of the wound and a new ulcer forms. Additionally, tunnels provide easy access for bacteria to potentially cause a deep infection, which can be very difficult to manage.

10. How is a tunneling wound treated?
There are not many options available to your doctor to treat tunneling wounds. Often the only recourse he/she has is to expose the tunnel by surgical means. Of course, this creates a larger wound and may be just as difficult to heal.

GRAFTJACKET® XPRESS Scaffold is a new technology that allows your doctor to graft the tunneling wound without surgical exposure. This means less surgery for you and, potentially, quicker recovery.

Introduction
Your doctor is recommending that you have GRAFTJACKET® Ulcer Repair Matrix or GRAFTJACKET® XPRESS Flowable Soft Tissue Scaffold applied to your ulcer in order for it to be treated and heal properly. With this product, even very difficult foot ulcers can be treated, with the ultimate goal being recovery and repair of the wound.

Diabetes and You
Sometimes we may have illnesses that put us at an increased risk for developing a foot ulcer such as diabetes. Diabetes affects over 18 million people in the U.S. It often results in poor circulation in your hands and feet and decreases your sensation to pain. This condition can affect the way you heal if you are injured.

Diabetic Foot Ulcers
A common complication with diabetes is a foot ulcer. These ulcers may form when you get a cut or blister on your foot. When you do have an injury to your foot, it is very important to see your doctor. He/She is able to determine the stage of your wound and the best treatment options. If the wound is not properly cared for, it can become a hard-to-heal or chronic ulcer. These ulcers can become infected and can possibly lead to amputation. Early intervention with good wound care and grafting can often lead to better healing and prevention of infection and possible amputation.

Prevention is the Best Medicine for Diabetic Foot Care
Preventing Diabetic Foot Ulcers
Good, thorough foot care and blood glucose monitoring are your best defense against forming foot ulcers. Other important guidelines include:

- Control your diabetes through diet and insulin intake
- Regularly check your blood sugar levels
- Regularly check your feet for calluses and breaks in the skin
- Wear footwear that fits properly and covers your entire foot
- See your doctor as soon as possible if you injure your foot, or a wound forms

Taking the time to regularly check yourself can often save you the pain and cost of more serious complications, such as a foot ulcer.

What Exactly is GRAFTJACKET® Matrix?

GRAFTJACKET® Ulcer Repair Matrix and GRAFTJACKET® XPRESS Scaffold are both substances donated from human dermis that contain collagen fibers that have special building blocks to aid in repairing your foot ulcer. These building blocks work much like the inside of a new building under construction. The shape, the strength, and the look all begin with and depend on how the structure is made on the inside of the building. The goal of using the GRAFTJACKET® product is to allow the body to repair itself.

Frequently Asked Questions

1. What is a diabetic foot ulcer?
A diabetic foot ulcer is an open wound that is found in approximately 15 percent of patients with diabetes. Foot ulceration remains the most common reason for hospital admission among diabetic patients.

2. How do foot ulcers form?
Poor circulation and lack of feeling in the foot, which are common problems resulting from diabetes, combine with outside factors such as increased pressure, friction, or trauma and may result in an open wound.

3. Why do diabetics lack feeling in their feet?
Over time, elevated blood sugar levels (hyperglycemia) can lead to damage of nerves in the feet. Patients that experience higher than normal levels of blood sugar can lose sensation, particularly a sensation to pain. Often, you may not even be aware of a problem because of a lack of feeling in your feet. This is why your physician will recommend you check your feet daily.

4. Why are diabetic foot ulcers such a problem?
Diabetes is the leading cause of non-traumatic amputations in the U.S. In fact, roughly two-thirds of all amputations are performed on diabetics. In 1997, there were approximately 86,000 such amputations. Of note, 85% of all amputations in the diabetic were preceded by a foot ulcer. Once you find a foot ulcer, you should seek medical care immediately. It is extremely important to treat this open wound to reduce the risk of infection and amputation.

5. How is a foot ulcer treated?
The most important goal in treating a foot ulcer is to obtain quick healing. The faster the wound is healed, the less chance there is for infection. The following are the basic steps in treating a foot ulcer:

• Removing dead, devitalized skin and tissue (debridement)
• Applying medication/dressings
• Maintaining regular dressing changes
• Relieving pressure from wound (off-loading)

Sometimes wounds can become "sick" and not heal normally. These are often referred to as chronic or non-healing wounds. Many factors may be involved,
How Well Does GRAFTJACKET® Matrix Work And Is It Safe?

GRAFTJACKET® material has been implanted in 700,000 cases and is rigorously screened and tested to reduce the risk of infectious disease. Clinically, the GRAFTJACKET® Matrix has demonstrated some excellent results when treating deep, chronic diabetic foot ulcers:

Study 1: Rate of Wound Closure & Complete Healing*

The first study divided 40 patients into two groups (20 per group). Each group received similar treatment, including sharp debridement (thorough cleaning of the wound), weekly dressing changes and instruction not to walk or put pressure on the ulcer. The patients in the test group additionally had one application of the GRAFTJACKET® Matrix. Patients were followed weekly to determine the rate of healing at 4 weeks and complete healing at 12 weeks.

![Percentage (%) Wound Closure At 4 Weeks](chart)

<table>
<thead>
<tr>
<th>Percentage (%) Wound Closure At 4 Weeks¹</th>
<th>GRAFTJACKET® Matrix Used</th>
<th>Control: No GRAFTJACKET® Matrix Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average AREA of Ulcer Closed</td>
<td>73%</td>
<td>34%</td>
</tr>
<tr>
<td>Average DEPTH of Ulcer Closed</td>
<td>89%</td>
<td>25%</td>
</tr>
</tbody>
</table>

![Percentage (%) Patients Completely Healed* 12 Weeks²](chart)

<table>
<thead>
<tr>
<th>Percentage (%) Patients Completely Healed* 12 Weeks²</th>
<th>GRAFTJACKET® Matrix Used</th>
<th>Control: No GRAFTJACKET® Matrix Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>85% (17/20)</td>
<td></td>
<td>5% (1/20)</td>
</tr>
</tbody>
</table>

Study 2: Patients Completely Healed*³

A second study included a series of 17 consecutive patients with deep ulcers. These patients were treated with sharp debridement, a single application of GRAFTJACKET® Matrix, and standard off-loading (no pressure on ulcer). These patients were followed for 20 weeks to determine complete healing and the average time to complete healing.

<table>
<thead>
<tr>
<th>GRAFTJACKET® Matrix</th>
<th>Deep Ulcers Healed</th>
<th>Average Time For Healing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>14/17 (82%)</td>
<td>9 weeks</td>
</tr>
</tbody>
</table>

*Complete healing is defined as closure of the wound with no drainage.

What is GRAFTJACKET® XPRESS Flowable Soft Tissue Scaffold?

GRAFTJACKET® XPRESS Scaffold is the same collagen material as the “sheet” form of GRAFTJACKET® Matrix, but is broken into very small particles that allows it to be applied with a syringe into tunnels or extensions that sometimes may be found with a foot ulcer. This means that your doctor can use a very small incision or no incision at all to apply the graft and allow the body to repair your ulcer.

Is GRAFTJACKET® Matrix Right for You?

If you have a wound that is slow to heal, especially if it is deep, GRAFTJACKET® products may be right for you, if:

- You have had an ulcer for 6 weeks or more
- Your ulcer has not responded to conventional treatment
- Your ulcer is considered deep
- Other grafts have failed
- Your wound has tunnels or extensions
- You prefer one application to several

How are GRAFTJACKET® Products Applied?

Once you and your doctor have agreed to the GRAFTJACKET® product therapy, your doctor will schedule you for a surgical visit. This may take place in the hospital operating room, as an outpatient procedure, or even in your doctor’s office.
Depending on the extent of the surgery, your doctor may use a general anesthesia (put you to sleep), or may simply use a local (injection of pain-numbing drug at the site). Your doctor will then prepare the wound by removing all the dead tissue and applying the GRAFTJACKET® product of choice.

If the wound is like a “crater”, the GRAFTJACKET® Ulcer Repair Matrix (sheet form) may be used to graft the wound and aid in repair.

If the wound is more of a “tunneling” wound, the GRAFTJACKET® XPRESS Scaffold may be used by applying the graft through a syringe into the wound and filling the “tunnel”.

What Happens After Application?
After your procedure, your doctor will instruct you on dressing changes and off-loading. In general, the GRAFTJACKET® product treatment requires once-a-week dressing changes, and you will be asked to be non-weight bearing for a few weeks. This may seem restrictive, but these recommendations are in your best interests. The weekly dressing changes will help keep the graft in good condition so that your wound will heal properly. Also, it is very important not to put any weight on the wound to give the GRAFTJACKET® material the best opportunity to aid in repair. At any time, if you notice excessive drainage or issues of concern, please contact your physician.

The graft will be incorporated into the wound over a period of weeks and gradually converted into your own tissue. Please note that there are multiple factors within your wound that may cause the graft to become incorporated at a decreased rate. Clinical studies have shown that one application of GRAFTJACKET® product may be sufficient, as compared to other procedures that may require multiple applications and may be less effective.

Case Study Example

*The time for closure of your ulcer may vary.*