Treatment Options Within Reach

Integra®
Dermal Regeneration Template

Information for Patients and their Families

burn treatments
reconstruction options

To find out if INTEGRA Dermal Regeneration Template is a good option for you or someone you know, ask your doctor or visit www.integraskin.com

INTEGRA Dermal Regeneration Template is a bilayer skin replacement system used for treating burn injuries. It can also improve the quality of life for individuals who suffer from limited mobility caused by severe scarring.

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Dermal Regeneration Template

What is INTEGRA Dermal Regeneration Template?

INTEGRA Dermal Regeneration Template (INTEGRA Template) is a bilayer skin replacement system that helps the body to grow new skin.

INTEGRA Template is composed of two layers:

- An outer layer of silicone.
- An inner layer that combines a protein (collagen) with a carbohydrate (glycosaminoglycan). Both substances are found in natural human skin.

What is INTEGRA Template Used For?

INTEGRA Template is used for:

- The immediate treatment of severe burn injuries.
- The surgical replacement of scar tissue to improve function or mobility (scar contracture release).

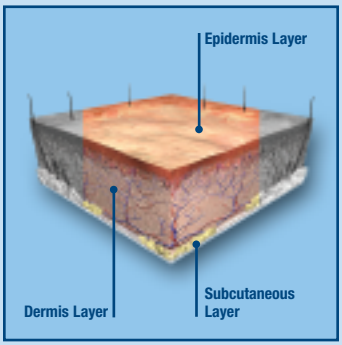
INTEGRA Template is used in the immediate treatment of severe burns to minimize the need for full-thickness skin grafts.

INTEGRA Template is also used to repair scar contractures (loss of motion or flexibility) that are the result of severe burn injuries.

BURN INJURIES

There are three categories of burns, classified by the amount of damage caused to the two layers found in human skin: the *epidermis* and the *dermis* (Figure 1).

- **First degree burns** affect only the epidermis (the outer layer of skin).
- **Second degree burns** penetrate deeper and damage the epidermis and part of the dermis (the inner layer of skin).
- **Third degree burns** (also called full-thickness burns) involve the loss of both epidermis and dermis, extending down into sub-cutaneous tissue.



Severe burns are treated initially by removing the damaged skin to prevent infection. Usually this is followed by autografting — a procedure in which skin tissue is transplanted from one place on a person's body (donor site skin) to another. Frequently, patients who suffer severe burns do not have sufficient donor site skin to cover the burn wounds immediately.

Using INTEGRA Template to Treat Burns

After removing damaged skin, the surgeon applies the INTEGRA Template to the wound and secures it with surgical sutures or staples, sealing the wound and preventing further fluid loss. The wound is then covered with several layers of bandages.

The inner layer of INTEGRA Template provides a support structure that enhances the growth of new dermal tissue. As the new dermis grows, the inner layer is absorbed into the body. The outer layer keeps bacteria from entering the wound bed by immediately sealing the wound.

When the dermal regeneration process is complete, usually in 14 to 28 days, the silicone layer is removed. At this point, instead of a thick epidermal/dermal graft that may cause scarring at the donor site, an ultra-thin graft of the patient's epidermal tissue is applied surgically to the new dermal tissue.

SCAR CONTRACTURES

Scar tissue, unlike dermal tissue, is hard, inflexible, and does not grow with normal body growth. It can shrink as it matures. In cases where scarring results in the loss of flexibility or range of motion, it is referred to as a **scar contracture.** Scar contractures often form as a full-thickness burn or skin graft heals.

Using INTEGRA Template to Treat Scar Contractures

Because INTEGRA Template supports the growth of new dermal tissue rather than scar tissue, it can be used to treat scar contractures. The procedure is the same as that for burns, except that the surgeon begins by removing scar tissue rather than recently burned tissue. With INTEGRA Template, the new dermal tissue is soft, pliable, and grows as the patient grows.

Commonly Asked Questions
About INTEGRA Template

What are the benefits of using INTEGRA Template?

INTEGRA Template is the first dermal replacement product that mimics the functions of human skin. It provides immediate wound closure and permanent regeneration of the inner layer of skin.

- **Regenerates a natural and functional dermis.**
- **Thinner donor sites with less scarring and faster healing.**
- **Grows with the patient.**

"Patients treated with INTEGRA Template have reported excellent joint function, minimal or no scarring, better cosmetic appearance, and the feel of normal skin," according to Paul Glat, MD, pediatric plastic surgeon at St. Christopher's Hospital for Children, Philadelphia, PA.

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Who can benefit from treatment with INTEGRA Template?

INTEGRA Template may be useful for anyone with:

- Deep burns that require surgical removal of burn tissue and skin grafting to cover the wound.
- Restricted mobility to parts of the body affected by scar contractures.

INTEGRA Template has been used successfully in:

- Infants less than a year old to people over 88 years old.
- Both men and women.
- In people from a wide variety of ethnic backgrounds.

Is INTEGRA Template safe to use for anyone?

INTEGRA Template can be used safely in most people of any age or ethnicity. However,

- INTEGRA Template should not be applied to anyone with a known hypersensitivity (allergy) to bovine collagen, chondroitin, or silicone.
- INTEGRA Template should not be used for a burn wound where infection is present.

INTEGRA Template is FDA approved, and its effectiveness and safety have been shown in a number of clinical trials.

There have been no clinical studies evaluating the use of INTEGRA Template in pregnant women.

What can a patient do to help his or her wounds heal safely?

To enhance the safety of INTEGRA Template in healing burn wounds or correcting scar contractures, it is essential to follow the instructions of your healthcare provider.

- Attend all scheduled appointments in order to check your progress and assess the treated wound area. While you are in the hospital, the physicians and nurses will monitor and treat all of your INTEGRA Template sites. After you are discharged, dressings will be changed on return visits to the hospital clinic or by a home health care nurse.
- Be aware of any signs that indicate infection, such as fever, any changes in the INTEGRA Template sites, swelling, odor, discharge or pain. Call your physician immediately if you notice any signs of infection.
- The INTEGRA Template site **MUST** be kept completely dry. This is important, as it may not be possible to take a bath, shower or swim without wetting the wound.
- Eat a well-balanced diet so your body will have the nutrients that it needs to aid in healing. Burns and other wounds heal best when patients are in good general health.
- Avoid tobacco products, because nicotine can hinder blood flow to the wound site.

Consult your healthcare provider if you have any questions about bathing, diet or any other problems concerning wound healing.

Brief Summary

Consult Package Insert For Full Prescribing Information

DESCRIPTION

INTEGRA Dermal Regeneration Template (INTEGRA Template) is a bilayer membrane system for skin replacement. The dermal replacement layer is made of a porous matrix of fibers of cross-linked bovine tendon collagen and glycosaminoglycan (chondroitin-6-sulfate) that is manufactured with a controlled porosity and defined degradation rate. The epidermal substitute layer is made of a thin polysiloxane (silicone) layer to control moisture loss from the wound. INTEGRA Template is aseptically processed. The inner foil pouch and product should be handled using sterile technique. INTEGRA Template should not be sterilized, as this would alter the intrinsic properties of the product.

INDICATIONS

INTEGRA Template is indicated for the postexcisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. INTEGRA Template is also indicated for the repair of scar contractures when other therapies have failed or when donor sites for repair are not sufficient or desirable due to the physiological condition of the patient.

CONTRAINDICATIONS

Use of INTEGRA Template is contraindicated in patients with known hypersensitivity to bovine collagen or chondroitin materials. INTEGRA Template should not be used on clinically diagnosed infected wounds.

WARNINGS

Excision of the wound must be performed thoroughly to remove all coagulation eschar and nonviable tissue. INTEGRA Template will not "take" to nonviable tissue. Leaving any remaining nonviable tissue may create an environment for bacterial growth. Hemostasis must be achieved prior to applying INTEGRA Template. Inadequate control of bleeding will interfere with the incorporation of INTEGRA Template.

PRECAUTIONS

There have been no clinical studies evaluating INTEGRA Template in pregnant women. Caution should be exercised before using INTEGRA Template in pregnant women. Such use should occur only when the anticipated benefit clearly outweighs the risk. In clinical trials, the use of INTEGRA Template was evaluated in a small number of patients with chemical, radiation, or electrical burns. A surgeon's decision to use INTEGRA Template on these wounds should be based on their evaluation of the wound and its suitability to excisional therapy, the likelihood that a viable wound bed will be created by excision, and whether the possible benefit outweighs the risk in this patient population. INTEGRA Template should be applied on the day of excision. Delaying the application of INTEGRA Template may substantially impair the take of the material. Appropriate techniques to minimize pressure and shearing should be used to reduce risk of mechanical dislodgement. Placing the patient in hydrotherapy immersion may interfere with proper incorporation of the INTEGRA Template and cause premature separation of the silicone layer and nonadherence of the template. Caution must be employed to not remove the newly formed neodermal tissue when removing the silicone layer. INTEGRA Template must NOT be excised off the wound. The extent of scarring associated with the use of this product has not been determined.

ADVERSE EVENTS

Burn Patients

INTEGRA Template has been found to be well tolerated in 4 prospective clinical trials involving 444 burn patients. There were no reports of clinically significant immunological or histological responses to the implantation of INTEGRA Template. There were no reports of rejection of INTEGRA Template. Adverse events reported in the INTEGRA Template clinical trials included death, sepsis, apnea, heart arrest, pneumonia, kidney failure, multisystem failure, and respiratory distress. With the exception of wound fluid accumulation, positive wound cultures, and clinical wound infection, none were directly related to the use of INTEGRA Template. Adverse events in the Postapproval Study were similar to those observed in the previous clinical trials and are common in populations of critically ill burn patients regardless of treatment used. There were no trends noted. There were six adverse events which were rated by the investigator as being related. These events were all single occurrences except for sepsis (2). Adverse events reported in less than 1% of the population were as follows: enlarged abdomen, accidental injury, hypothermia, peritonitis, hypotension, peripheral vascular disorder, arrhythmia, cardiomyopathy, cardiovascular disorder, congestive heart failure, pulmonary embolism, dyspnea, aspiration pneumonia, hypoxia, pleural effusion, respiratory distress syndrome, cholecystitis, gastrointestinal perforation, hepatorenal syndrome, intestinal obstruction, and pancreatitis. These adverse events occurred in ≤1% of the safety population. The adverse events occurring in ≥1% of the safety population in the Postapproval Study are as follows: sepsis (23.1%), death (13.9%), infection (2.8%), thrombophlebitis (2.8%), kidney failure (2.8%), necrosis (2.3%), hemorrhage (2.3%), heart arrest (1.9%), apnea (1.9%), pneumonia (1.9%), allergic reaction (1.4%), fever (1.4%), multisystem failure (1.4%), atrial fibrillation (1.4%), gastrointestinal hemorrhage (1.4%), kidney abnormal function (1.4%).

In these clinical trials, data were collected regarding wound infection. The consequences of infection at sites treated with INTEGRA Template included partial or complete loss of take (incorporation into the wound bed) of INTEGRA Template. Infection rates in sites treated with INTEGRA Template in the three clinical trials supporting the PMA ranged from 14 to 55%. The overall infection rate for the Postapproval Study was 16.3%.

Contracture Reconstruction Patients

The following adverse events were reported in a Reconstructive Surgery Study involving 20 patients with 30 anatomical sites: shearing/mechanical shift (loss of INTEGRA) (3.3%), hematoma (16.7%), epidermal autograft loss >15% (6.7%), and epidermal autograft loss <15% (23.3%). The following adverse events were reported in a Retrospective Contracture Reconstruction Survey involving 89 patients and 127 anatomic sites: infection (20.5%), fluid under silicone layer (14.2%), partial graft loss (INTEGRA) (1.6%), failure to take (INTEGRA) (6.3%), shearing/mechanical shift (loss of INTEGRA) (4.7%), hematoma (2.3%), granulation tissue formation (3.1%), delayed healing (0.8%), separation of the silicone layer (0.8%), seroma (0.8%), pruritis (0.8%), epidermal autograft loss >15% (5.5%), epidermal autograft loss <15% (7.1%). There were no infections reported in the Reconstructive Surgery Study and the reported infection rate was 20.5% in the Retrospective Contracture Reconstruction Survey. No deaths were reported.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or practitioner with appropriate training. Please refer to the clinical training materials for complete instructions. For additional information contact your Plastic and Reconstructive Sales Specialist or a Technical Representative at 877-444-1122 or 609-275-9004.

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FDA APPROVED

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INTEGRA™

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