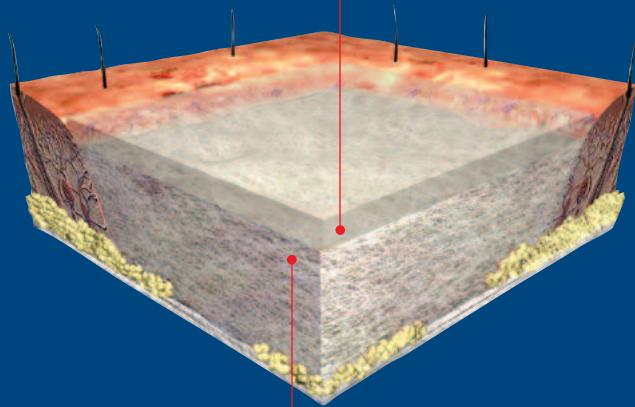


# Structure of INTEGRA template

## SILICONE LAYER

- Enables immediate wound closure
- Controls fluid loss
- Provides mechanical protection
- Provides a bacterial barrier
- Water vapor transmission similar to normal skin



## 3-DIMENSIONAL MATRIX LAYER

- Cross-linked collagen and glycosaminoglycan
- Functions as an extracellular matrix
- Promotes cellular growth and collagen synthesis
- Biodegrades while being replaced by autologous dermal tissue

The **first and only** FDA approved tissue engineered product for burn and reconstructive surgery



For product ordering information, technical questions or reimbursement issues please call **877-444-1122** or **609-275-9004**.

For further product information, please visit [www.integra-ls.com](http://www.integra-ls.com)

For patient information, please visit [www.integraskin.com](http://www.integraskin.com)

### FDA APPROVED

Integra LifeSciences Corporation  
311 Enterprise Drive, Plainsboro, New Jersey 08536

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ILS049-11/03

# Key Benefits

Benefits for reconstructive surgery

Induces organized regeneration of dermal tissue

Allows immediate physiologic closure of full-thickness wounds

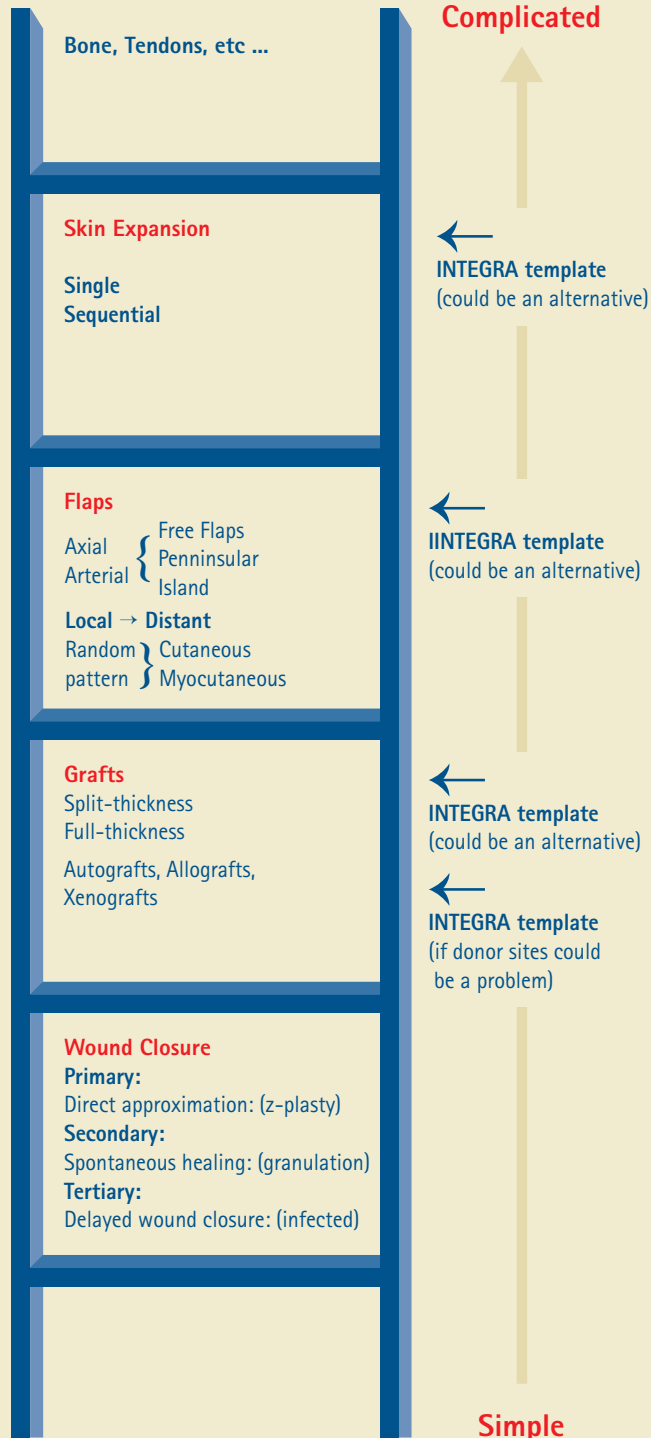
Enhances formation of new dermal tissue

Provides alternative to a full-thickness skin graft or skin flap

Minimizes the complications of deep donor sites



# The Reconstructive Ladder



**Bone, Tendons, etc ...**

**Skin Expansion**

Single  
Sequential

**Flaps**

Axial } Free Flaps  
Arterial } Penninsular  
          } Island  
Local → Distant  
Random } Cutaneous  
pattern } Myocutaneous

**Grafts**

Split-thickness  
Full-thickness  
Autografts, Allografts,  
Xenografts

**Wound Closure**

**Primary:**  
Direct approximation: (z-plasty)  
**Secondary:**  
Spontaneous healing: (granulation)  
**Tertiary:**  
Delayed wound closure: (infected)

## Brief Summary Consult Package Insert For Full Prescribing Information

### DESCRIPTION

**INTEGRA Dermal Regeneration 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 Dermal Regeneration Template** is aseptically processed. The inner foil pouch and product should be handled using sterile technique. **INTEGRA Dermal Regeneration Template** should not be sterilized, as this would alter the intrinsic properties of the product.

### INDICATIONS

**INTEGRA Dermal Regeneration 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 Dermal Regeneration Template** (**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 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. 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). 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.