

INTEGRA® DERMAL REGENERATION TEMPLATE



The new Integra®
Dermal Regeneration
Template (IDRT).

Now alcohol free for
faster, easier handling.

- New packaging for improved ease of preparation
- Storage at room temperature
- Rinsing time only 1-2 minutes
- Now available in a new, smaller 2" x 2" sheet

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 provided sterile and non-pyrogenic. The inner foil pouch and product should be handled using sterile technique. INTEGRA template should not be re-sterilized.

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 $\leq 1\%$ of the safety population. The adverse events occurring in $\geq 1\%$ 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 or to schedule training contact your Plastic and Reconstructive Sales Specialist or a Technical Representative at (877) 444-1122 or (609) 275-9004.



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For more information, visit:

www.ilstraining.com

(product training and certification).

www.integraskin.com (patient site).

www.integra-ls.com (corporate site).

We've
reduced the
time from
package to
patient.



From package to patient in under 2 minutes.

Our new physician-inspired packaging is user friendly and alcohol free, which means that IDRT can be rehydrated and ready to apply in under two minutes. It also stores safely at room temperature for up to 18 months from manufacture date, without refrigeration.

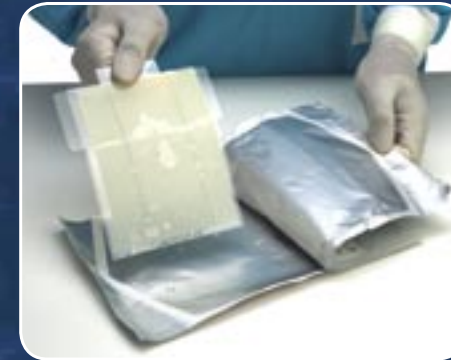
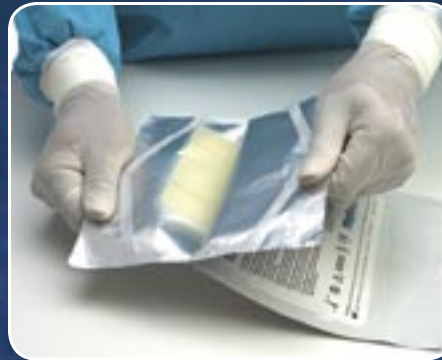


Always handle IDRT using aseptic technique. Peel open the outer pouch and remove the inner foil pouch using sterile technique.

INTEGRA® Dermal Regeneration Template Product Offering (U.S.A.)

CATALOG No.	DESCRIPTION	UNIT OF MEASURE
32021	INTEGRA Dermal Regeneration Template, 2"x2"	1 Sheet
32025	INTEGRA Dermal Regeneration Template, 2"x2"	5 Sheets/Case
34051	INTEGRA Dermal Regeneration Template, 4"x5"	1 Sheet
34055	INTEGRA Dermal Regeneration Template, 4"x5"	5 Sheets/Case
34101	INTEGRA Dermal Regeneration Template, 4"x10"	1 Sheet
34105	INTEGRA Dermal Regeneration Template, 4"x10"	5 Sheets/Case
38101	INTEGRA Dermal Regeneration Template, 8"x10"	1 Sheet
38105	INTEGRA Dermal Regeneration Template, 8"x10"	5 Sheets/Case

With IDRT's faster "three-step prep," you can spend less time rinsing and more time restoring.



1. OPEN PACKAGING
Place foil pouch flat on a sterile surface and peel it open. Remove product, including the protective polyethylene cover sheets.



2. REMOVE CARRIER SHEETS
While holding the product with the tab remove one polyethylene cover sheet. Turn the product and remove the second polyethylene cover sheet.



3. RINSE FOR 1-2 MINUTES
Using the tab, the product can now be placed into a basin containing sterile saline solution. Carefully remove the tab from the product. Rinse the product by immersion in sterile saline for 1-2 minutes. Keep product in the basin until application.