Integra® Dermal Regeneration Template

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 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 type 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.

Incidence of adverse events occurring in >1% of the safety population in the Post-approval Study are as follows:

Adverse Events	n/N (%)
Sepsis	50/216 (23.1%)
Death	30/126 (13.9%)
Infection	6/216 (2.8%)
Thrombophlebitis	6/216 (2.8%)
Kidney Failure	6/216 (2.8%)
Necrosis	5/216 (2.3%)
Hemorrhage	5/216 (2.3%)
Heart Arrest	4/216 (1.9%)
Apnea	4/216 (1.9%)
Pneumonia	4/216 (1.9%)
Allergic Reaction	3/216 (1.4%)
Fever	3/216 (1.4%)
Multisystem Failure	3/216 (1.4%)
Atrial Fibrillation	3/216 (1.4%)
Gastrointestinal Hemorrhage	3/216 (1.4%)
Kidney Abnormal Function	3/216 (1.4%)

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.

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 and a Retrospective Reconstruction Contracture Survey involving 89 patients and 127 anatomic sites.

Incidence of Adverse Events in the Reconstructive Contracture Surgery Study and Retrospective Contracture Reconstruction Survey

	Reconstructive Surgery Study N = 30 Sites	Retrospective Contracture Reconstruction Survey N = 127 sites
Adverse event	**n/N (%)**	**n/N (%)**
Infection	0/30 (0.0%)	26/127 (20.5%)
Fluid under Silicone Layer	0/30 (0.0%)	18/127 (14.2%)
Partial graft loss (Integra)	0/30 (0.0%)	2/127 (1.6%)
Failure to take (Integra)	0/30 (0.0%)	8/127 (6.3%)
Shearing/Mechanical shift	1/30 (3.3%)	6/127 (4.7%) (loss of Integra)
Hematoma	5/30 (16.7%)	3/127 (2.3%)
Granulation tissue formation	0/30 (0.0%)	4/127 (3.1%)
Delayed Healing	0/30 (0.0%)	1/127 (0.8%)
Separation of the Silicone Layer	0/30 (0.0%)	1/127 (0.8%)
Seroma	0/30 (0.0%)	1/127 (0.8%)
Pruritis	0/30 (0.0%)	1/127 (0.8%)
Epidermal autograft loss >15%	2/30 (6.7%)	7/127 (5.5%)
Epidermal autograft loss <15%	7/30 (23.3)	9/127 (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.

For more information or to place an order, please contact:

United States
USA 800-654-2873 ▪ 888-980-7742 fax ▪ International +1 609-936-5400 ▪ +1 609-750-4259 fax ▪ **integralife.com**

Integra and the Integra logo are registered trademarks of Integra LifeSciences Corporation in the United States and/or other countries. ©2020 Integra LifeSciences Corporation. All rights reserved.
Printed in the USA. OK 1768494-1-EN