Integra®

Dermal Regeneration Template

Limit uncertainty with a proven Dermal Regeneration System

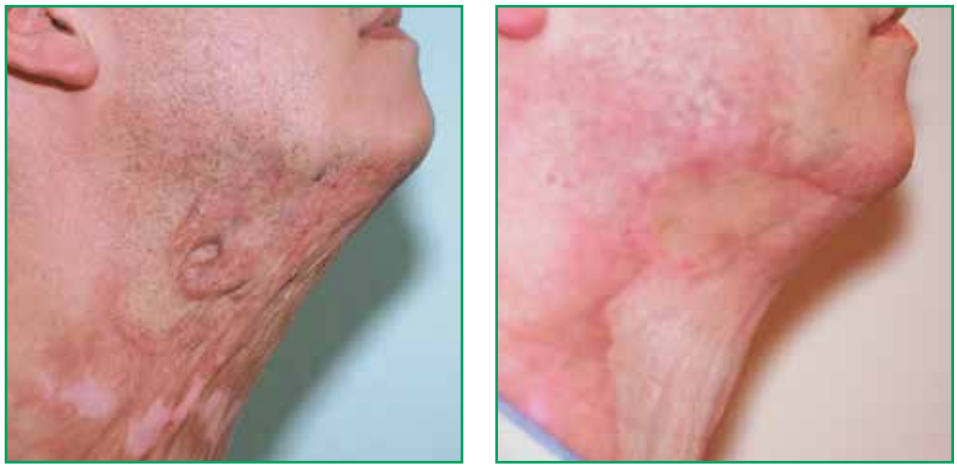
INTEGRA®
LIMIT UNCERTAINTY

Outcomes

Case 1

Left: Two-year-old neck scar contracture before Integra template treatment

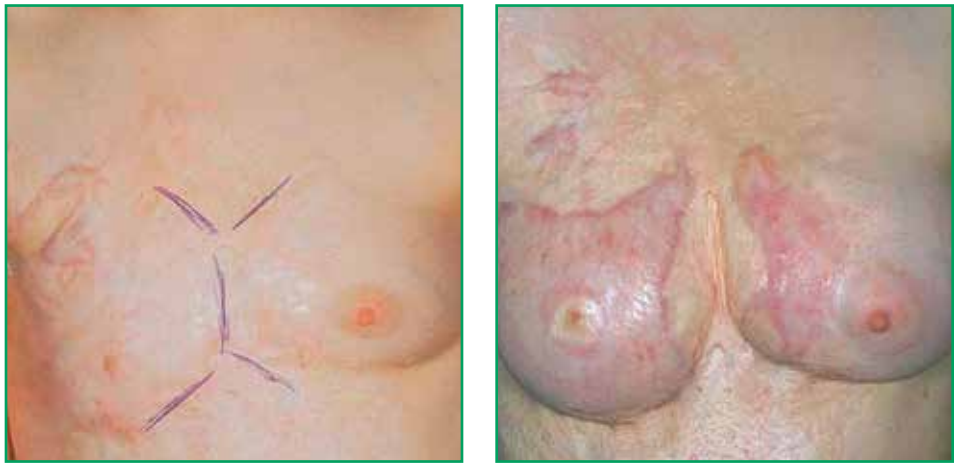
Right: Neck 1.5 years after contracture release and treatment with Integra template



Case 2

Left: 14-year-old chest scar contracture before Integra template treatment

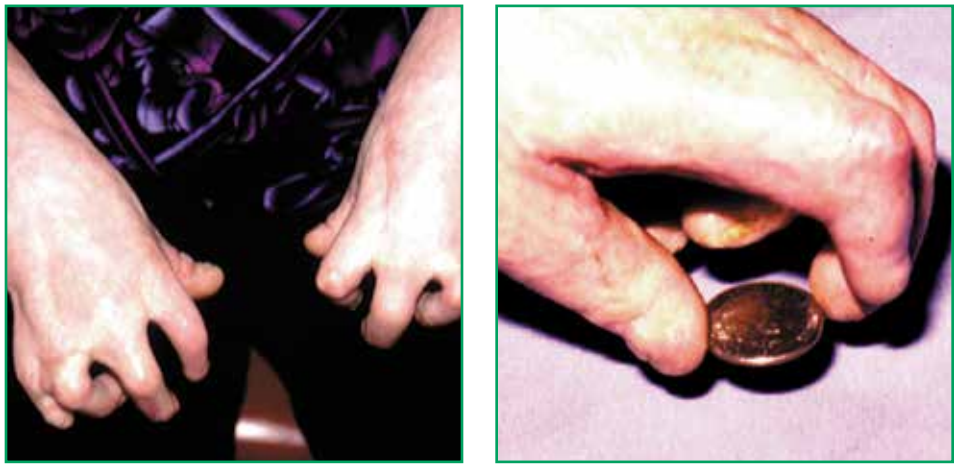
Right: Chest 1 year after contracture release and treatment with Integra template



Case 3

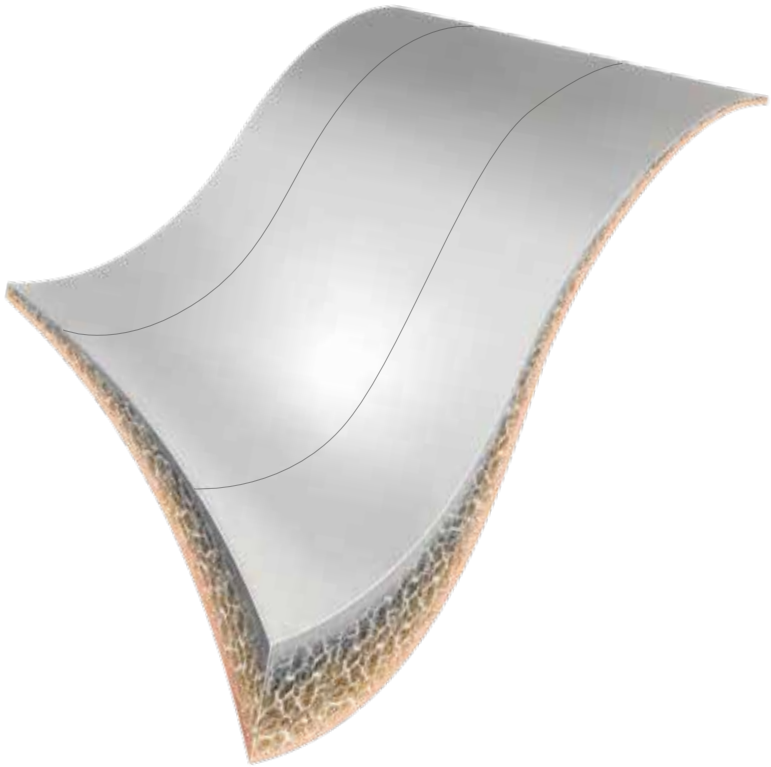
Left: Hand scar contracture before Integra template treatment

Right: 5 weeks after release and treatment with Integra template patient regained functional use of hand



Integra Template Promotes Regeneration of Dermal Tissue

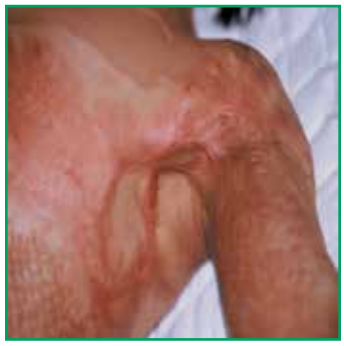
Integra® Dermal Regeneration Template (Integra Template) has two layers: a thin outer layer of silicone and a thick inner matrix layer of pure bovine collagen and glycosaminoglycan (GAG). Both collagen and GAG are normal components of human skin. In Integra, the collagen is obtained from bovine tendon collagen and the glycosaminoglycan is obtained from shark cartilage.

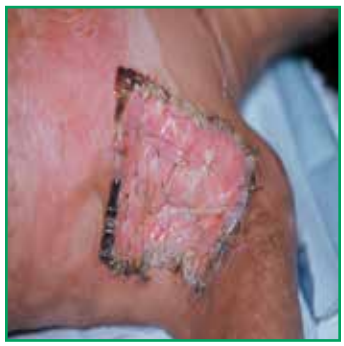


Integra Template Indication

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.





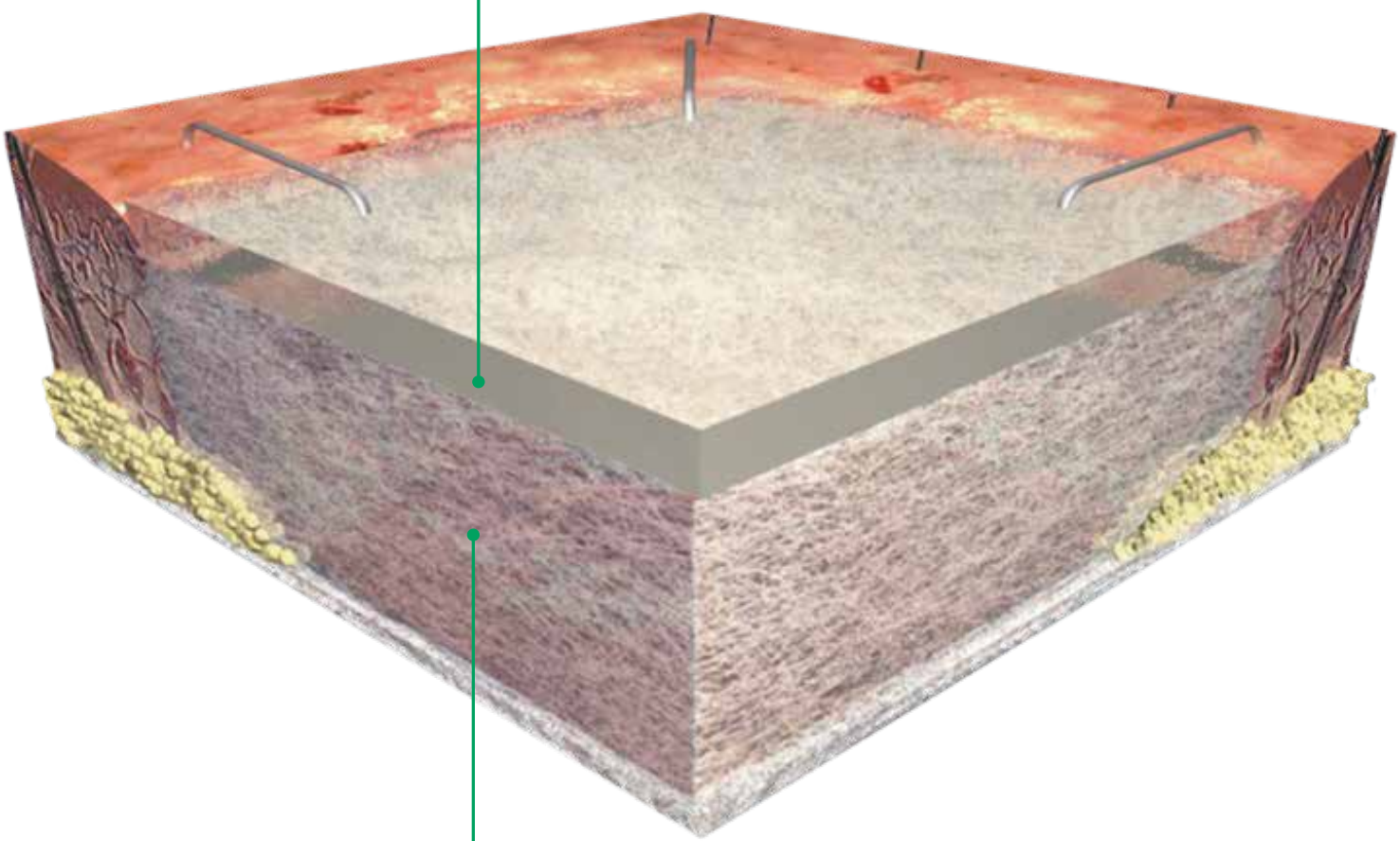
- Integra template is soft and pliable, facilitating greater range of motion even in difficult anatomic areas [2,7]
- Integra template grows with the patient [2,5]
- Integra template helps to restore function and joint mobility [5,7]

Structure of Integra Template

Designed to promote organized regeneration of dermal tissue

Silicone layer

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



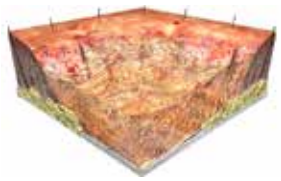
3-Dimensional matrix layer

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

How Integra Template Works

Day 0: Contracted scar

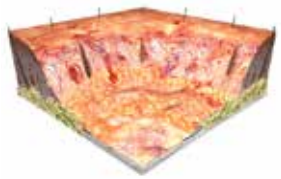
Scar contracture caused by tissue injury.



Day 0

Day 1: Excision of contracture scar

The contracture scar is completely excised to viable tissue.



Day 1

Day 1: Application

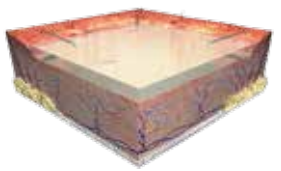
Integra template is applied to the excised viable wound bed. The first phase of Integration, imbibition, begins within minutes when wound fluids invade the matrix and fibrin fosters adherence to the wound bed.

Day 1

Day 7-14: Neodermal Formation

Fibroblasts, lymphocytes and macrophages migrate into the matrix. Later, endothelial cells begin forming the neovascular network.

As healing progresses, endogenous collagen is deposited by the fibroblasts, replacing the collagen/glycosaminoglycan layer of Integra template. The color of the neodermis starts to change from red to pale yellow.



Day 7-14

Day 21+: Complete Neodermal Formation and Silicone Removal

When the neodermis has formed and vascularization is adequate, the silicone layer is removed. Integra template is incorporated without rejection and biodegrades, leaving autologous dermis in place.[9]

Day 21+

Day 21+: epidermal autograft

A thin (approximately 0.004”–0.006”) epidermal autograft (sheet or meshed and expanded) is applied over the neodermis.

Day 21+

Day 28-56: Regenerated Skin

Engraftment and wound closure is complete. Neovascularization is well established. In a clinical trial evaluation, the neodermis was indistinguishable histologically from collagen in normal dermis.[4]

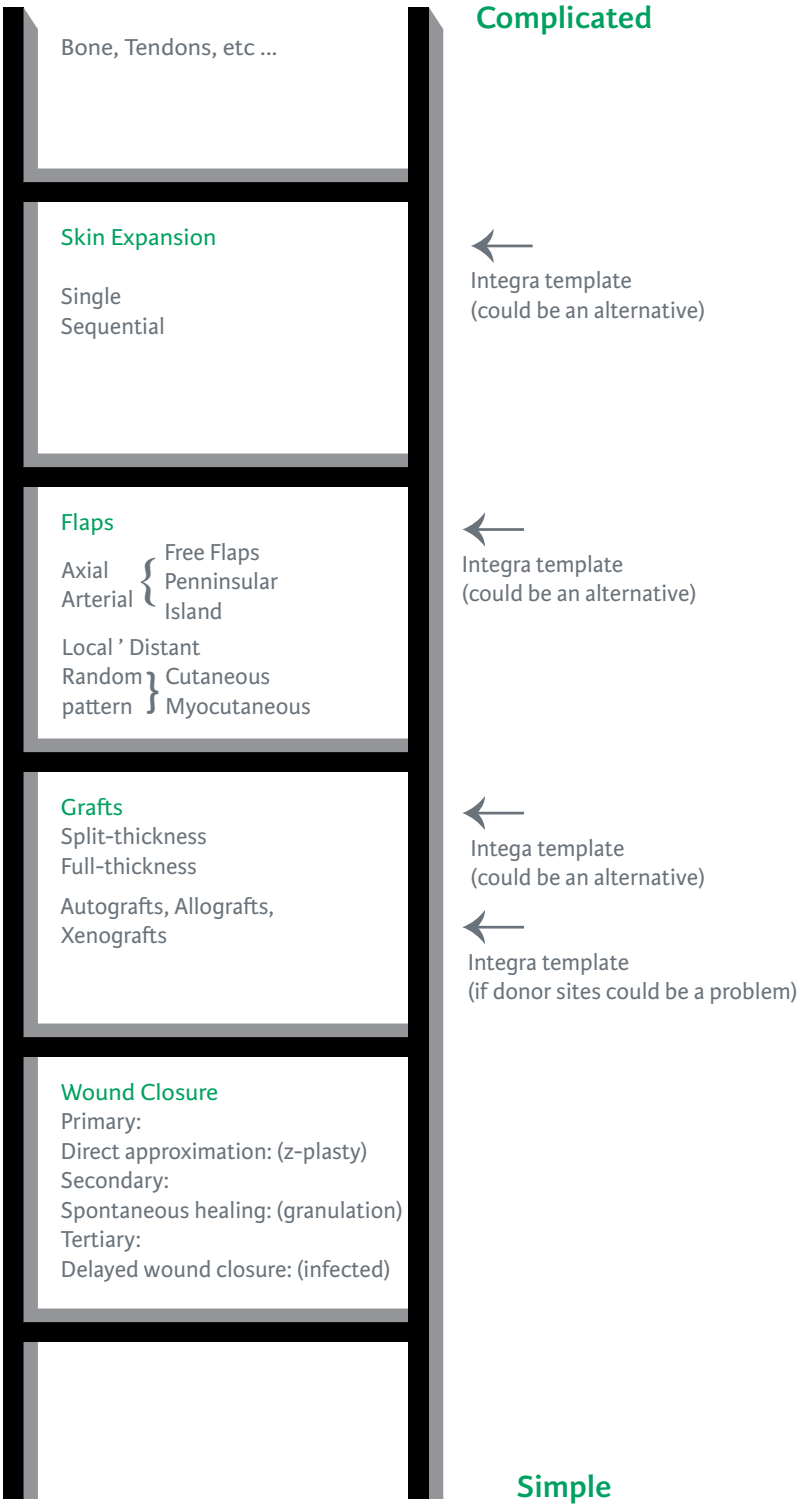
Day 28-56

Integra Template as an Alternative

The unique bilayer system provides immediate wound closure and promotes dermal regeneration

- Silicone layer water vapor transmission rate similar to that of normal skin[6,7]
- 3-dimensional matrix with optimized properties[2,11]
  - » Promotes cellular growth and organized regeneration of dermal tissue
  - » Minimizes inflammatory response
  - » Controlled degradation rate by collagenase
  - » Controlled pore diameter
  - » Controlled pore volume fraction
  - » Defined collagen fiber dimensions
  - » Specified collagen/glycosaminoglycan ratio (type 1 bovine tendon collagen/chondroitin-6-sulfate)

The Reconstructive Ladder

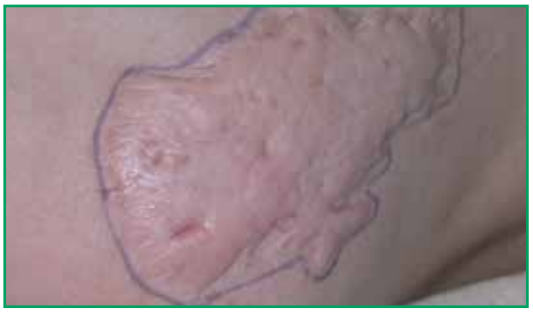


Integra Template Can Be Used as an Alternative for Standard Split-Thickness Autograft

- The Integra template neodermis is covered with a thin epidermal autograft (0.004”–0.006”)
- Donor site heals faster than a standard autograft site (10 days ± 6 days vs. 14 days ± 8 days)[3]

The benefits of thin donor sites[3]

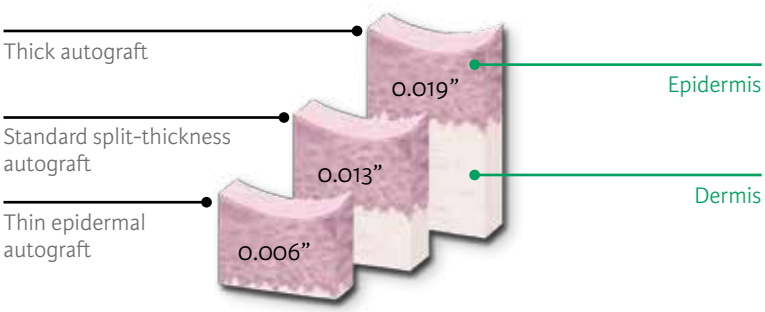
- Heal faster with minimal scarring[3]
- Can be reharvested more frequently than standard donor sites[3]
- Epidermal graft can be meshed and expanded up to 5:1, preserving additional donor areas



Donor Site of a Standard Split-Thickness Autograft

Donor Site of a Thin Epidermal Autograft

Integra Template Requires Thin Donor Sites

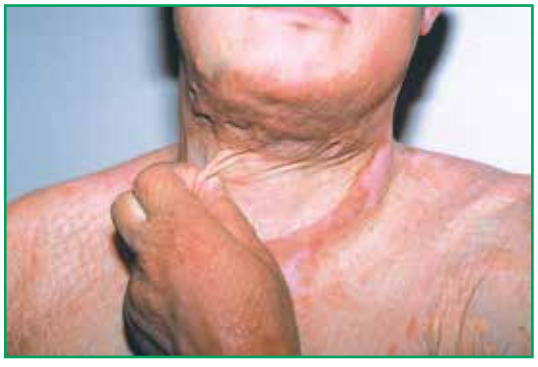


Depth of donor sites for epidermal autografts average less than half the thickness of standard donor sites[3]

Dermal Regeneration: The Lasting Advantage

Regeneration of functional dermis benefits the patient[5]

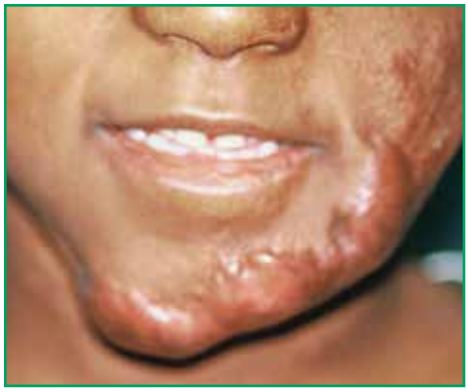
- Integra template acts as a scaffold to promote permanent regeneration of functional dermis
- Restoring the dermis is vital to restoring cosmetic appearance and proper function after closing a large skin defect
- Dermis provides skin elasticity, tear resistance and texture, and acts as a sliding layer over the subcutaneous fascia to allow mobility without adhesion



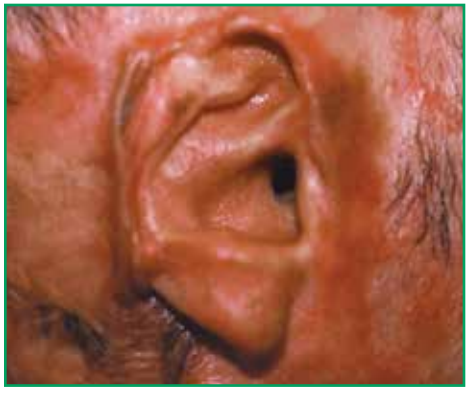
Additional Outcomes with Integra Template

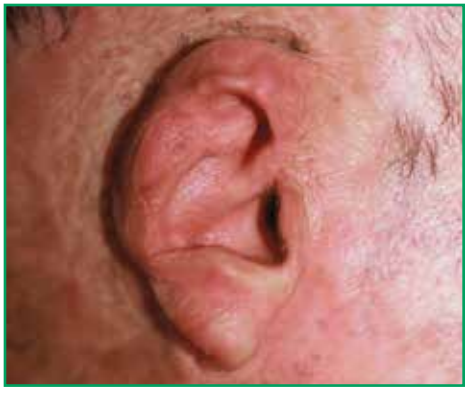
Integra template can successfully increase treatment options in a number of situations:

- Infants and children: when skin is thin and areas for harvesting are limited
- The elderly: when additional donor site wounds would cause unacceptable added stress to thin, friable skin
- Hypertrophic scarring: when there is a tendency to form hypertrophic or keloid scars
- Difficult grafting situations: when donor sites are limited due to the extent of the defect or patient condition, or when functional outcome is particularly important



Chin: release of contracted hypertrophic scar with Integra template in pediatric patient





Ear: reconstruction of ear contraction with Integra template in elderly patient

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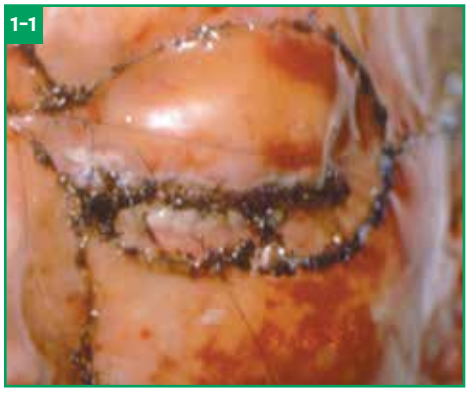
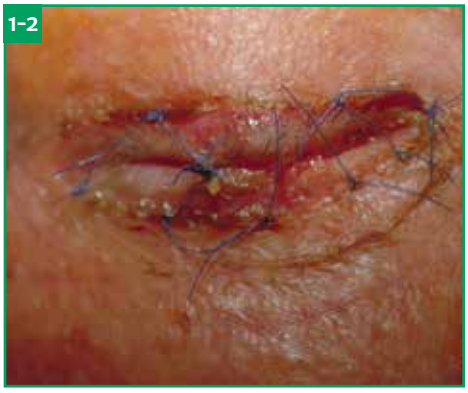
A 26-year-old patient with extensive full-thickness face burn. The entire face was treated with Integra template

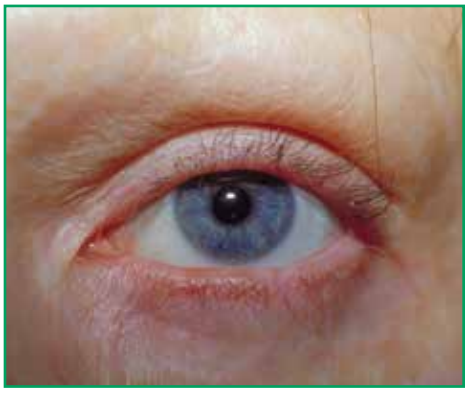
1-1 Left eye treated with Integra template

1-2 Six weeks after Integra template application, the eyelid has healed but still remains sewn shut

1-3 1 year post Integra template application, the eyelid is fully functional and the patient can open and close the eye







Eyelids: acute treatment and functional restoration with Integra template

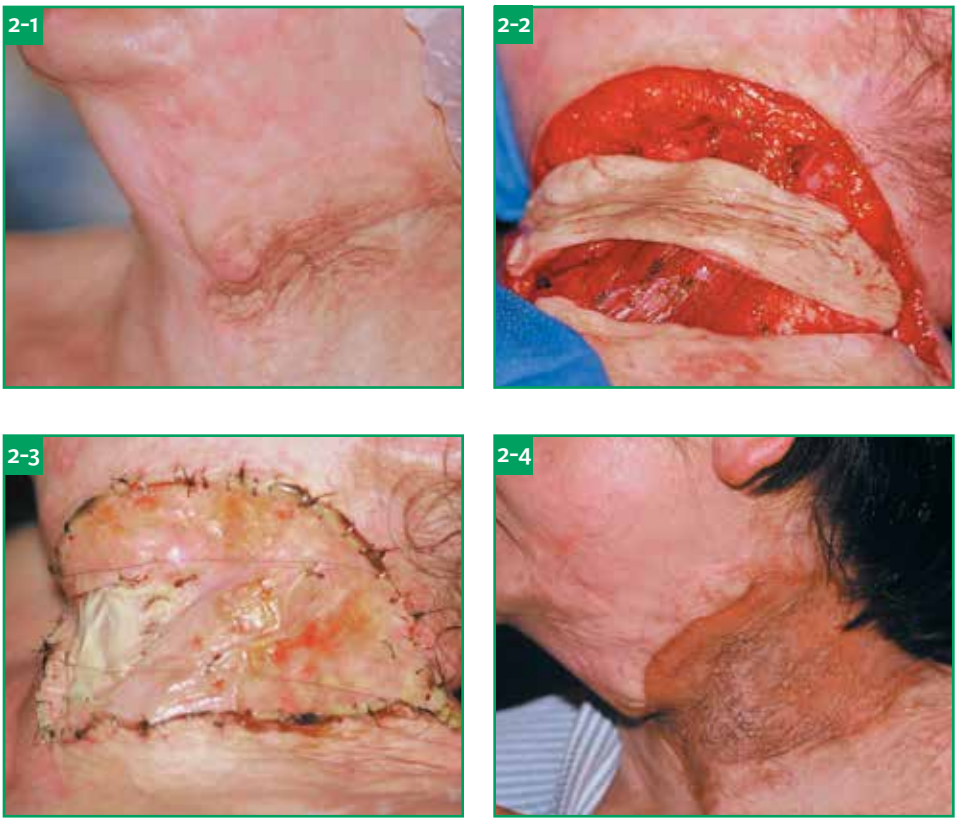
Neck Contracture Reconstruction After Conventional Treatment

2-1 Neck contracture after conventional treatment and prior to Integra template application

2-2 Release of contracted scar

2-3 Silicone has been removed after complete neodermal formation

2-4 Released neck 5 months after Integra template application—Hyperpigmentation will decrease over time



Reconstruction of neck scar contracture with Integra template

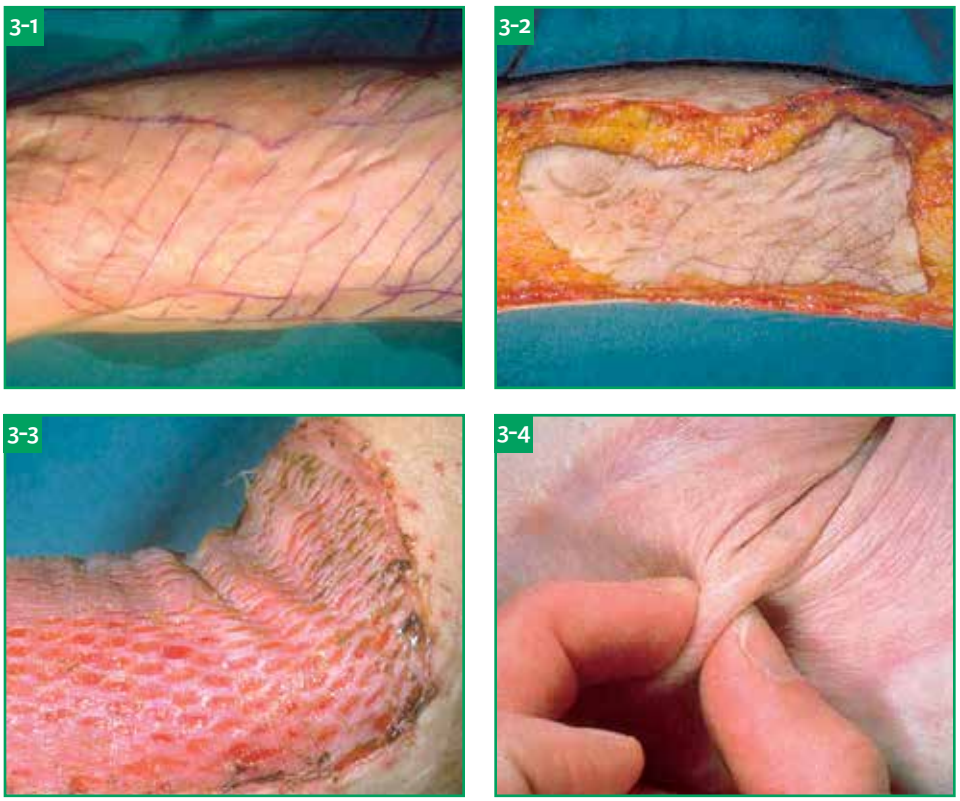
Pediatric Elbow Reconstruction of Contracted Scar

3-1 Scald burn on 18-month-old child resulted in a contracted scar at the elbow

3-2 At 13 years of age the scar was released and treated with Integra template

3-3 After neodermal formation and silicone removal, a thin meshed and slightly expanded autograft was applied over the neodermis

3-4 One year after Integra template application there was no contracture and pinching demonstrates tissue pliability



Reconstruction of elbow scar contracture with Integra template

Suggested Readings

Integra Basic Science

Silver FH, Yannas IV, Salzman EW. Glycosaminoglycan inhibition of collagen induced platelet aggregation. Thromb Res. 1978 Aug;13(2):267–77.

Silver FH, Yannas IV, Salzman EW. In vitro blood compatibility of glycosaminoglycan-precipitated collagens. J Biomed Mater Res. 1979 Sep;13(5):701–16.

Yannas IV, Burke JF. Design of an artificial skin. I. Basic design principles. J Biomed Mater Res. 1980 Jan;14(1):65–81.

Yannas IV, Burke JF, Gordon PL, Huang C, Rubenstein RH. Design of an artificial skin. II. Control of chemical composition. J Biomed Mater Res. 1980 Mar;14(2):107–32.

Dagalakis N, Flink J, Stasikelis P, Burke JF, Yannas IV. Design of an artificial skin. Part III. Control of pore structure. J Biomed Mater Res. 1980 Jul;14(4):511–28.

Yannas IV, Burke JF, Orgill DP, Skrabut EM. Wound tissue can utilize a polymeric template to synthesize a functional extension of skin. Science. 1982;215(4529):174–6.

Yannas IV, Lee E, Orgill DP, Skrabut EM, Murphy GF. Synthesis and characterization of a model extracellular matrix that induces partial regeneration of adult mammalian skin. Proc Natl Acad Sci U.S.A. 1989 Feb;86(3):933–7.

Orgill DP, Butler CE, Regan JF. Behavior of collagen-GAG matrices as dermal replacement in rodent and porcine models. Wounds. 1996;8(5):151–57.

King WW, Lam PK, Liew CT, Ho WS, Li AK. Evaluation of artificial skin (Integra) in a rodent model. Burns. 1997;23 Suppl 1(-HD-):S30–2.

Yannas IV. Studies on the biological activity of the dermal regeneration template. Wound Repair Regeneration. 1998;6:518–524.

Compton CC, Butler CE, Yannas IV, Warland G, Orgill DP. Organized skin structure is regenerated in vivo from collagen-GAG matrices seeded with autologous keratinocytes. J Invest Dermatol. 1998 Jun;110(6):908–16.

Butler CE, Orgill DP, Yannas IV, Compton CC. Effect of keratinocyte seeding of collagen-glycosaminoglycan membranes on the regeneration of skin in a porcine model. Plast Reconstr Surg. 1998 May;101(6):1572–9.

Orgill DP, Butler C, Regan JF, Barlow MS, Yannas IV, Compton CC. Vascularized collagen-glycosaminoglycan matrix provides a dermal substrate and improves take of cultured epithelial autografts. Plast Reconstr Surg. 1998 Aug;102(2):423–9.

Orgill DP, Yannas IV. Design of an artificial skin. IV. Use of island graft to isolate organ regeneration from scar synthesis and other processes leading to skin wound closure. J Biomed Mater Res. 1998;39(4):531–5.

Butler CE, Yannas IV, Compton CC, Correia CA, Orgill DP. Comparison of cultured and uncultured keratinocytes seeded into a collagen-GAG matrix for skin replacements. Br J Plast Surg. 1999 Mar;52(2):127–32.

Kremer M, Lang E, Berger AC. Evaluation of dermal-epidermal skin equivalents ('composite-skin') of human keratinocytes in a collagen-glycosaminoglycan matrix (Integra artificial skin). Br J Plast Surg. 2000 Sep;53(6):459–65.

Shermak MA, Wong L, Inoue N, Nicol T. Reconstruction of complex cranial wounds with demineralized bone matrix and bilayer artificial skin. J Craniofac Surg. 2000 May;11(3):224–31.

Ojeh NO, Frame JD, Navsaria HA. In Vitro Characterization of an Artificial Dermal Scaffold. Tissue Eng. 2001 Aug;7(4):457–72.

Grant I, Green C, Martin R. Strategies to improve the take of commercially available collagen/glycosaminoglycan wound repair material investigated in an animal model. Burns. 2001 Nov;27(7):699–707.

Lam PK, Chan ES, Liew CT, Lau C, Yen SC, King WW. Combination of a new composite biocampatible skin graft on the neodermis of artificial skin in an animal model. ANZ J Surg. 2002 May;72(5):360–3.

Chu CS, McManus AT, Matylevich NP, Goodwin CW, Pruitt BA Jr. Integra as a dermal replacement in a meshed composite skin graft in a rat model: a one-step operative procedure. J Trauma. 2002 Jan;52(1):122–9.

Integra Clinical

Burke JF, Yannas IV, Quinby WC Jr, Bondoc CC, Jung WK. Successful use of a physiologically acceptable artificial skin in the treatment of extensive burn injury. Ann Surg. 1981;194(4):413–28.

Burke JF. Observations on the development and clinical use of artificial skin—an attempt to employ regeneration rather than scar formation in wound healing. Jpn J Surg. 1987;17(6):431–8.

Heimbach D, Luterman A, Burke J, Cram A, Herndon D, Hunt J, Jordan M, McManus W, Solem L, Warden G, Zawacki B. Artificial dermis for major burns. A multi-center randomized clinical trial. Ann Surg. 1988;208(3):313–20.

Tompkins RG, Hilton JF, Burke JF, Schoenfeld DA, Hegarty MT, Bondoc CC, Quinby WC Jr, Behringer GE, Ackroyd FW. Increased survival after massive thermal injuries in adults: preliminary report using artificial skin. Crit Care Med. 1989;17(8):734–40.

Stern R, McPherson M, Longaker MT. Histologic study of artificial skin used in the treatment of full-thickness thermal injury. J Burn Care Rehabil. 1990 Jan-Feb;11:1,7–13.

Michaeli D, McPherson M. Immunologic study of thermal injuries. J Burn Care Rehabil. 1990 Jan-Feb;11:1,21–6.

Sheridan RL, Hegarty M, Tompkins RG, Burke JF. Artificial skin in massive burns-results to ten years. Eur J Plast Surg. 1994;17:91–93.

Lorenz C, Petracic A, Hohl HP, Wessel L, Waag KL. Early wound closure and early reconstruction. Experience with a dermal substitute in a child with 60 percent surface area burn. Burns. 1997 Sep;23: 6,505–8.

Besner GE, Klamar JE. Integra Artificial Skin as a useful adjunct in the treatment of purpura fulminans. J Burn Care Rehabil. 1998 Jul–Aug;19:4,324–9.

Clayton MC, Bishop JF. Perioperative and postoperative dressing techniques for Integra Artificial Skin: views from two medical centers. J Burn Care Rehabil. 1998;19:4,358–63.

Pandya AN, Woodward B, Parkhouse N. The use of cultured autologous keratinocytes with Integra in the resurfacing of acute burns. Plast Reconstr Surg. 1998 Sep;102:3,825–8; discussion 829–30.

Cedidi, C., Hartmann, B., Schepler, H., Raff, T., Germann, G. Grafting of deeply burned problem zones in the lower extremity with a dermal substitute, Eur J Plast Surg. 1999;22:119–124.

Boyce ST, Kagan RJ, Meyer NA, Yakuboff KP, Warden GD. The 1999 clinical research award. Cultured skin substitutes combined with Integra Artificial Skin to replace native skin autograft and allograft for the closure of excised full-thickness burns. J Burn Care Rehabil. 1999 Nov-Dec;20:6,453–61.

Hunt JA, Moisidis E, Haertsch P. Initial experience of Integra in the treatment of post-burn anterior cervical neck contracture. British Journal Plastic Surgery. 2000 Dec;53(8):652–658.

Berger A, Tanzella U, Machens HG, Liebau J. Administration of Integra on primary burn wounds and unstable secondary scars. Chirurg. 2000 May;71(5):558–63.

Wang JC, To EW. Application of dermal substitute (Integra) to donor site defect of forehead flap. Br J Plast Surg. 2000 Jan;53(1):70–2.

King P. Artificial skin reduces nutritional requirements in a severely burned child. Burns. 2000;26:501–3.

Loss M, Wedler V, Kunzi W, Meuli-Simmen C, Meyer VE. Artificial skin, split thickness autograft and cultured autologous keratinocytes combined to treat a severe burn injury of 93% of TBSA. Burns. 2000;26:644–652.

Prystowsky JH, Nowygrod R, Marboe CC, Benvenisty AI, Ascherman JA, Todd GJ. Artificial skin (Integra Dermal Regeneration Template) for closure of lower extremity wounds. Vascular Surgery. 2000;34(6):557–567.

Fitton AR, Drew P, Dickson WA. The use of a bilaminate artificial skin substitute (Integra) in acute resurfacing of burns: an early experience. Br J Plast Surg. 2001 Apr;54(3):208–12.

Chan ES, Lam PK, Liew CT, Lau HC, Yen RS, King WW. A new technique to resurface wounds with composite biocompatible epidermal graft and artificial skin. J Trauma. 2001 Feb;50(2):358–62.

Chou T-D, Chen S-L, Lee T-W, Chen S-G, M.D.Cheng T-Y, Lee C-H, Chen T-M, Wang H-J. Reconstruction of Burn Scar of the Upper Extremities with Artificial Skin. Plastic and Reconstructive Surgery. 2001;108:378–384.

Moiemen NS, Staiano JJ, Ojeh NO, Thway Y, Frame JD. Reconstructive Surgery with a Dermal Regeneration Template: Clinical and Histologic Study. Plastic and Reconstructive Surgery. 2001;108:93–103.

Thomas WO, Rayburn S, Leblanc RT, Powell RW, Luterman A. Artificial Skin in the Treatment of a Large Congenital Nevus. Southern Medical Journal. 2001;94(3):325–328.

Prystowsky JH, Siegeal DM, Ascherman JA. Artificial skin for closure and healing of wounds created by skin cancer excision. Dermatologic Surgery. 2001;27:648–55.

Giovannini UM, Teot L. Aesthetic complex reconstruction of the lower leg: application of a dermal substitute (Integra) to an adipofascial flap. Br J Plast Surg. 2002 Mar;55(2):171–2.

Ryan CM, Schoenfeld DA, Malloy M, Schulz III JT, Sheridan RL, Tompkins RG. Use of Integra artificial skin is associated with decreased length of stay for severely injured adult burn survivors. J Burn Care Rehabil. 2002 Sep–Oct;23(5):311–7.

Fang P, Engrav LH, Gibran NS, Honari S, Kiriluk DB, Cole JK, Fleckman P, Heimbach DM, Bauer GJ, Matsumura H, Warner P. Dermatome Setting for Autografts to Cover Integra. J Burn Care Rehabil. 2002 Sep–Oct;23(5):327–32.

Artificial Skin Review

Tompkins RG, Hilton JF, Burke JF, Schoenfeld DA, Hegarty MT, Bondoc CC, Quinby WC Jr, Behringer GE, Ackroyd FW. Increased survival after massive thermal injuries in adults: preliminary report using artificial skin. Crit Care Med. 1989;17(8):734–40.

Jaksic T, Burke JF. The use of "artificial skin" for burns. Annu Rev Med. 1987;38(-HD-):107–17.Tompkins RG, Burke JF. Progress in burn treatment and the use of artificial skin. World J Surg. 1990 Nov-Dec;14(6):819–24.

Tompkins RG, Burke JF. Burn wound closure using permanent skin replacement materials. World J Surg. 1992 Jan–Feb;16(1):47–52.

Helvig EI. Dermal replacement: an update. Semin Perioper Nurs. 1997 Oct;6(4):233–5.

Cameron S. Changes in burn patient care. Br J Theatre Nurs. 1997 Aug;7(5):5–7.

Schultz JT, Tompkins RG, Burke JF. Artificial Skin. Annu Rev Med. 2000;51:231–244.

Orgill, DP, Straus FH 2nd, Lee RC. The use of collagen-GAG membranes in reconstructive surgery. Ann N Y Acad Sci. 1999;888:233–48.

Winfrey ME, Cochan M, Hegarty MT. A new technology in burn therapy: Integra artificial skin. Dimens Crit Care Nurs. 1999;18(1):14–20.

Machens HG, Berger AC, Mailaender P. Bioartificial skin. Cells Tissues Organs. 2000;167(2-3):88–94.

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.

Integra®
Dermal Regeneration System

How Supplied

The sale of Integra template is restricted to clinicians who have completed a company sponsored training program.

The bilayer sheets consist of collagen with an outer removable silicone covering identified by black sutures as markers to ensure proper placement on the wound bed. Each sheet of Integra template is stored in phosphate buffer within a foil pouch. Each sterile foil pouch is packaged in a sealed outer chevron-style pouch. Store flat at 2°–30°C. Protect from freezing.

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 use.

For product ordering information, technical questions, or reimbursement issues please call 877-444-1122 or 609-275-0500.

Integra Dermal Regeneration Template

Catalog Number	Size	Units/Case
32021	2in x 2in (5cm x 5cm)	1 Sheet
32025	2in x 2in (5cm x 5cm)	5 Sheets/Case
34051	4in x 5in (10cm x 12.5cm)	1 Sheet
34055	4in x 5in (10cm x 12.5cm)	5 Sheets/Case
34101	4in x 10in (10cm x 25cm)	1 Sheet
34105	4in x 10in (10cm x 25cm)	5 Sheets/Case
38101	8in x 10in (20cm x 25cm)	1 Sheet
38105	8in x 10in (20cm x 25cm)	5 Sheets/Case

References

1. Singer AJ, Clark RAF. Cutaneous wound healing. N Engl J Med. 1999; 341:738–746.
2. Burke JF: Observations on the development and clinical use of artificial skin: An attempt to employ regeneration rather than scar formation in wound healing. Jpn J Surg. 1987:17(6) 431–438.
3. Heimbach D, Luterman A, Burke JF et al: Artificial dermis for major burns: A multi-center randomized clinical trial. Ann Surg. 1988 (Sept);208(3):313–320.
4. Stern R, McPherson M, Longaker MT: Histologic study of artificial skin used in the treatment of full-thickness thermal injury. J Burn Care Rehabil. 1990;11:7–13.
5. Sheridan RL, Hegarty M, Tompkins RG, Burke JF: Artificial skin in massive burns—results to ten years. Eur J Plastic Surgery. 1994;17:91–93.
6. Burke JF, Yannas IV, Quinby WC, et al: Successful use of a physiologically acceptable artificial skin in the treatment of extensive burn injury. Ann Surg. 1981 (Oct);194(4):413–428.
7. Berger A, Tanzella U, Machens HG, Liebau J, The use of Integra in primary burn wounds and unstable secondary scars. Chirurg. 2000; 71(5):558–563.
8. Tompkins RG, Hilton JF, Burke JF, Schoenfeld DA, Hegarty MT, Bondoc CC, Quinby WC, Behringer GE, Ackroyd FW. Increased survival after massive thermal injuries in adults: preliminary report using artificial skin. Critical Care Medicine. 1989; 17(8)734–740.
9. Data on file, Ethicon INC.
10. Besner G, Klamar J. Integra Artificial Skin as a Useful Adjunct in the Treatment of Purpura Fulminans. J Burn Care Rehabil. 1998;19:324–329.
11. Orgill DP, Butler CE, Regan JF. Behaviour of collagen-GAG matrices as dermal replacement in rodent and porcine models. Wounds: A Comp of Clin. Research and Practice. 1996;8(5):151–157.

For more information or to place an order, please contact:
Integra ▪ 311 Enterprise Drive, Plainsboro, NJ 08536
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