Integra®
Dermal Regeneration Template

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 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 Dermal Regeneration 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 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 6 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 less than 1% of the safety population.

Incidence of adverse events occurring in ≥1% of the safety population in the Postapproval Study are as follows:

Adverse Events	n/N (%)
Sepsis	50/216 (23.1%)
Death	30/216 (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.

Adverse events reported in the previous studies are as follows:

Coded Symptom	Multicenter N=149 (% frequency)	Anatomic Site N=59 (% frequency)	Meshed vs Sheet N=20 (% frequency)
Death	37 (24.8%)	19 (32.2%)	3 (15%)
Sepsis	17 (11.4%)	4 (6.8%)	1 (5.0%)
Apnea	13 (8.7%)	5 (8.5%)	0 (0.0%)
Pneumonia	10 (6.7%)	0 (0.0%)	0 (0.0%)
Heart Arrest	7 (4.7%)	6 (10.2%)	0 (0.0%)
Kidney Failure	5 (3.4%)	4 (6.8%)	0 (0.0%)
Respiratory Distress	3 (2.0%)	0 (0.0%)	0 (0.0%)
Infection	2 (1.3%)	0 (0.0%)	0 (0.0%)
Lung Disease	2 (1.3%)	0 (0.0%)	0 (0.0%)
Dyspnea	1 (0.7%)	1 (1.7%)	0 (0.0%)
Adrenal Insufficiency	1 (0.7%)	0 (0.0%)	0 (0.0%)
Agitation	1 (0.7%)	0 (0.0%)	0 (0.0%)
Convulsion	1 (0.7%)	0 (0.0%)	0 (0.0%)
Hematemesis	1 (0.7%)	0 (0.0%)	0 (0.0%)
Hemoptysis	1 (0.7%)	0 (0.0%)	0 (0.0%)
Liver Cirrhosis	1 (0.7%)	0 (0.0%)	0 (0.0%)
Nonadherence	1 (0.7%)	0 (0.0%)	0 (0.0%)
Shock	1 (0.7%)	0 (0.0%)	0 (0.0%)
Skin Discoloration	1 (0.7%)	0 (0.0%)	0 (0.0%)
Asystole	0 (0.0%)	0 (0.0%)	1 (5.0%)
Cerebral Artery Infarct	0 (0.0%)	1 (1.7%)	0 (0.0%)
Metastatic Ovarian Cancer	0 (0.0%)	1 (1.7%)	0 (0.0%)
Peritonitis	0 (0.0%)	1 (1.7%)	0 (0.0%)
Sarcoidosis	0 (0.0%)	0 (0.0%)	1 (5.0%)
Third Degree Burn	0 (0.0%)	1 (1.7%)	0 (0.0%)
Multisystem Failure	0 (0.0%)	3 (5.1%)	0 (0.0%)

With the exceptions of wound fluid accumulation, positive wound cultures and clinical wound infection, none were directly related to the use of INTEGRA template.

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 Contracture Reconstruction 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 (loss of INTEGRA)	1/30 (3.3%)	6/127 (4.7%)
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.

SUMMARY OF CLINICAL STUDIES

Burn Patients

INTEGRA template has been evaluated in over 1,200 wound sites in 444 burn patients in a series of 4 studies:

- Multicenter Safety and Efficacy Clinical Trial (Pivotal)
- Anatomic Site Study
- Meshed vs. Sheet INTEGRA template Study
- Postapproval Study

Demographic, safety and effectiveness data for INTEGRA template are summarized in the table below.

Data Across Studies

Variable		Multicenter Study	Anatomical Site Study	Meshed vs. Sheet Study	Postapproval Study
Year		**1983-1989**	**1985-1992**	**1989-1992**	**1997-2000**
Number of Patients		149	59	20	216
Number of Wound Sites		207	130	59	841
Age:	(Mean ± SD) Range	32.0 ± 21.5 <1 – 88Y	49.2 ± 21.2 19 – 93Y	30.1 ± 15.6 4 – 59Y	34.7 ± 23.9 4 M – 87Y
Gender:	Male	112 (75.2%)	33 (55.9%)	16 (80%)	151 (69.9)%
	Female	37 (24.8%)	26 (44.1%)	4 (20%)	65 (30.1%)
Race:	Caucasian	98 (65.8%)	56 (94.9%)	14 (70.0%)	151 (69.9%)
	Black	32 (21.5%)	0 (0.0%)	6 (30.0%)	38 (17.6%)
	Hispanic	15 (10.1%)	3 (5.1%)	0 (0.0%)	20 (9.2%)
	American Indian	3 (2.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)
	Asian	1 (0.7%)	0 (0.0%)	0 (0.0%)	4 (1.8%)
	Other	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)
% BSA Total Burn:	(Mean ± SD) Range	45.7 ± 18.6 14.5 – 88.5	49.8 ± 24.6 1 – 97	53.6 ± 19.4 30 – 90	36.5 ± 24.7 <1 – 95
% BSA Full-Thickness:	(Mean ± SD) Range	31.8 ± 20.8 0 – 88.5	42.5 ± 24.0 1 – 95	35.4 ± 22.4 0 – 78	27.9 ± 24.4 0 – 95
% Inhalation Injury		42%	62.5%	50%	45%
Mean Take		65.1%*	77.6%	80.6%	76.2%
Median Take		80%*	95%	100%	98%
Infection		55%	14%	25%	16.3%
Mortality		24.8%	32%	15%	13.9%

**paired comparative wound sites.*

Multicenter Safety and Efficacy Clinical Trial (Pivotal Study)

In the pivotal multicenter clinical trial, 149 patients were evaluated for safety and 106 patients (with 136 comparative wound sites) were included in an assessment of efficacy. The demographic profile was: mean age 32.0, age range <1 to 88 years, gender: 112 males and 37 females and a mean %TBSA burn of 45.7% with a range of 14.5%-88.5%. Take, which was defined as the median fractional area of the wound site to support epidermal growth, was the main efficacy variable and was bimodally distributed. In the multicenter trial, INTEGRA template had successful take (take >10%) in 69% of the wound sites (94 of 136). For this group of wound sites with successful take, the mean take was 81%, and the median take was 90%. Over 80% of the wound sites in this successful take group had greater than 60% take. INTEGRA template failed to take (take ≤10%) in 31% of the wound sites (42 of 136 comparative wound sites). For this group, the mean take was 1.7% and the median take was 0%.

The INTEGRA template neodermis provided a viable surface for the successful transplantation of thin, meshed and spread epidermal autograft. The take of epidermal autograft was bimodally distributed. In the multicenter trial, epidermal autograft had successful take (take >10%) in 90.5% of the sites (95 of 105 comparative wound sites). For this group of wound sites with successful take, the mean was 84% and the median take was 90%. Over 80% of the wound sites in this successful take group had greater than 65% take. Epidermal autograft failed to take (take <10%) in 9.5% of the sites (10 of 105 comparative wound sites). For this group, the mean take was 1.7% take and the median take was 0%.

No significant difference was seen between the total time for burn healing for wounds treated with INTEGRA template and for wounds treated with temporary wound covers. The healing time of thin epidermal autograft on the INTEGRA template neodermis was comparable to that of conventional autograft. Donor sites for thin epidermal autograft healed faster and allowed for more cycles of reharvesting than conventional donor sites.

Histological Evaluation

Three hundred thirty-six serial biopsies were obtained from 131 patients participating in the multicenter clinical trial ranging from 7 days to 2 years after application of INTEGRA template. A histological study of the wound healing in the burned areas was conducted. An intact dermis was achieved with regrowth of apparently normal reticular and papillary dermis. No scar formation appeared in the biopsies of patients examined.

Anatomic Site Study

In the noncomparative single-center anatomic site study, 59 patients (130 wound sites) were evaluated for safety and 41 patients (104 wound sites) were evaluated for efficacy parameters. The demographic profile was: mean age, 49.2, age range 19-93 years, gender: 33 males and 26 females and a mean %TBSA burn of 49.8% with a range of 1%-97%. The mean take of INTEGRA template was 77.6%, and the median take was 95%. The mean take of the epidermal autograft was 77.8% and the median take was 85%. Median take was similar for the various anatomic locations evaluated. However, the small number of patients and noncomparative nature of the study prevented conclusions from being made.

Meshed vs. Sheet Study

A pilot study was conducted on 20 patients (59 wound sites) to compare 2:1 meshed (but not expanded) and sheet INTEGRA template. The demographic profile was: mean age, 30.1, age range 4-59 years, gender: 16 males and 4 females and a mean TBSA of 53.6% with a range of 30-90%. The mean take of INTEGRA template in this study was 80.6% and the median take was 100%, while the mean take for the epidermal autograft was 86.5% and the median take was 95%. However, due to the small number of patients and study design, statistical conclusions could not be drawn.

Postapproval Study

A Postapproval Study of INTEGRA template evaluated the safety and effectiveness in 216 patients, 841 wound sites. There were 222 patients enrolled in the study, however 6 patients did not meet entry criteria (3 did not sign the patient informed consent form, 3 did not receive INTEGRA template) resulting in 216 patients entered into the study. The demographic profile was: mean age 34.7, age range 4 months to 87 years, gender: 151 males and 65 females and a mean %TBSA burn of 36.5% with a range of <1% to 95%. Effectiveness was measured by graft take. Overall mean percent take for INTEGRA template was 76.2% and the median percent take for INTEGRA template was 98%. The mean take of epidermal autograft was 87.4% with median take of 95%. The rate of infection in the study patients was 16.3% (13.2% superficial and 3.1% invasive). Patient mortality was 13.9%. Data analysis indicated that mortality was related to patient age, percent total body surface area burned, presence of inhalation injury, and presence of infection at a non-INTEGRA template treated wound site. Invasive infection at an INTEGRA template wound site was not a significant risk factor for mortality.

SUMMARY OF CLINICAL STUDIES

Contracture Reconstruction Patients

Reconstructive Surgery Study

This study evaluated the clinical and histologic outcomes in 20 consecutive patients (30 anatomic sites) whose scars and contractures were treated with INTEGRA template. Patients' mean age was 27.6 years, with an age range of 4-54 years. Patient follow-up ranged from 3 to 24 months. The mean take was derived from the adverse event data and was calculated to be 94.2% for INTEGRA template and 86.3% for epidermal autograft. Efficacy was evaluated using the Vancouver Burn Scar Assessment scale by an independent review panel, a visual analog scale of patient satisfaction and histological evaluations of patient biopsies. The Vancouver Burn Scar Assessment scale ranges from 0 (normal) to 15. The mean preoperative Vancouver Burn Scar Assessment was 13.3 and the mean postoperative score was 9.0. For the patient satisfaction assessments, patients or their parents completed a questionnaire at least 3 months after the second stage of the reconstruction. A visual analog scale was used in which a score of 0%=preoperative scar and a score of 100%=normal skin with no scar. Patients/parents reported mean scores of 72% for range of movement, 62% for softness, 59% for appearance, 27% for pruritis and 14% for dryness.

Retrospective Contracture Reconstruction Survey

This survey requested information from physicians already using INTEGRA template on the use of the product for contracture reconstruction. Information was received from 13 of 19 physicians surveyed who reported on 89 patients and 127 anatomic sites. The demographic profile for the reported patients were: mean age 24.8, age range <1 to 72, gender 52 males and 37 females. The safety results of this survey are provided in tabular form in the adverse event section.

INFORMATION FOR USE

INTEGRA template facilitates the formation of a neodermis by the body. The collagen dermal portion serves as a template for the infiltration of fibroblasts, macrophages, lymphocytes, and capillary endothelial cells which form the neovascular network. As healing progresses, the collagen-GAG layer is resorbed and new collagen is deposited by the fibroblasts to form the neodermis. Upon adequate vascularization of the neodermis and the availability of the donor autograft, the silicone layer is removed and a thin, meshed layer of epidermal autograft is placed over the neodermis. Cells from the epidermal autograft grow and form a mature epidermis thereby closing the wound, and resulting in a functional dermis and epidermis.

Patient Evaluation and Selection of Sites for Application of INTEGRA Template

As the extent of the patient's thermal injury is evaluated, all burn areas requiring prompt excision and grafting should be identified. INTEGRA template may be applied to all excised wound sites.

SURGICAL APPLICATION

Scheduling Surgery for INTEGRA Template Application

INTEGRA template must be applied to a viable wound bed following surgical excision of burn wounds. Surgery may be scheduled as soon as the patient is stabilized. Surgery should be staged as appropriate.

Perioperative Antibiotics

Perioperative antibiotics are recommended to be administered according to the clinical judgment of the practitioner.

Opening the package

In the operating room, peel open the outer package and remove the inner foil package using sterile technique. Invert the foil pouch a few times. Holding the package vertically, with the notched end up, carefully cut off the top of the foil pouch with sterile scissors and pour off the isopropyl alcohol, taking care to retain the INTEGRA template in the package. Empty the INTEGRA template from the foil pouch and place into a sterile basin for washing.

Rinsing INTEGRA Template with Saline Solution

INTEGRA template must be thoroughly rinsed in sterile normal saline solution prior to application. The recommended rinsing procedure is to soak each INTEGRA template device in 2L sterile, pyrogen-free, normal saline solution. Each sheet of INTEGRA template requires two soaks and each soak should last at least 5 to 10 minutes. A third basin with new sterile saline solution may be used to hold the product until application.

Meshing INTEGRA Template

INTEGRA template can be meshed at 1:1 ratio before the application, but must not be expanded. Meshing may improve the ability of INTEGRA template to conform to irregular surfaces and may improve take on exudating wounds.

Wound Excision

Excision must be made to the level of viable tissue and meticulous hemostasis must be achieved before application of INTEGRA template.

Excisional techniques for INTEGRA template sites can be fascial, sequential, or tangential. It is absolutely critical to the successful take of INTEGRA template that excision be complete and that no devitalized tissue remains.

Complete hemostasis must be achieved before application of INTEGRA template. The presence of hematoma will cause loss of INTEGRA template in the affected area. Broad area cauterization that could decrease wound bed viability should be avoided.

Shaping INTEGRA Template to Fit the Wound

INTEGRA template should be shaped accurately to fit the excised wound margins to minimize scarring at these margins. It should not be overlapped onto non-excised areas or onto other sheets of INTEGRA template. It is easily cut with sterile scissors by placing the sheet of INTEGRA template over the excised wound bed and cutting exactly to the edge.

Applying INTEGRA Template to the Wound

It is critical that the collagen template layer be in direct contact with the excised wound. The silicone layer (identified by the black threads) must be placed out (away from the wound bed). Do not apply upside down, the black threads must be clearly visible.

For optimal cosmetic results, place the INTEGRA template so that the suture lines between INTEGRA template sheets lie in Langer's lines. This will minimize the final appearance of the suture lines.

The INTEGRA template sheets are secured by staples or sutures placed in an interrupted fashion under slight tension. If the INTEGRA template has been meshed, care must be taken not to spread the mesh. Care should be taken to achieve a primary closure between INTEGRA template and adjacent unburned skin or between sheets of INTEGRA template. Suture or staple each sheet of INTEGRA template in place independently. The INTEGRA template sheets may also be affixed to one another to assure that there is no gap between sheets. Adjust the area to ensure that there is no undue tension on an individual piece of INTEGRA template. The material should readily adhere and conform to the wound surface. Any air bubbles should be carefully removed by moving them to the edge of the sheet. Dressings should be applied over INTEGRA template according to the protocol of the practitioner.

Postoperative Care

Postoperative care, like that used following treatment with full sheet or meshed autograft, should include monitoring for hematomas, wound infection and patient sepsis.

The outer dressing should be changed as necessary. However, the inner dressing need not be disturbed unless there are problems requiring intervention. The attachment of the silicone layer should be examined. An antibacterial dressing may be used or the outer dressing can be soaked in an appropriate antimicrobial solution.

There should be no hydrotherapy immersion of the patient following INTEGRA template application while the silicone layer is in place.

Mechanical dislodgment of INTEGRA template should be avoided. Ambulation and physical therapy can be instituted according to the condition of the patient and judgment of the practitioner. All INTEGRA template sites must be securely covered with dressings before ambulation and/or physical therapy.

Staples or sutures should remain in place until the time of epidermal autografting. The staples or sutures help secure the silicone layer and decrease the likelihood of premature silicone layer separation.

EPIDERMAL AUTOGRAFTING

Identifying the Neodermis

The area of INTEGRA template take (neodermis formation) should be evaluated before application of the epidermal autograft. Neodermis may be recognized by a yellow-orange color with occasional areas of light red. The neodermis should be firmly attached to the underlying tissue. The silicone layer should easily separate from the underlying neodermis.

Removal of Silicone Layer for Epidermal Autograft

The silicone layer of INTEGRA template may be removed when the collagen layer has been replaced by neodermis, usually 14 to 21 days after application of INTEGRA template. Removal of the silicone layer and grafting may take place immediately after formation of the neodermis, if epidermal autograft is available. The removal of the silicone layer may be postponed until donor sites for epidermal autograft area are available.

The clinician must be careful when removing the silicone layer. The silicone layer can usually be removed using only forceps. Generally, it should peel off easily. Difficulties in removal may indicate that neodermis formation is incomplete. However, if the silicone is difficult to remove, a forceps and scalpel may be used to gently separate the silicone layer from the neodermis. 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.

Harvesting and Preparation of the Epidermal Autograft

Epidermal autograft can be taken from sites unsuitable for conventional autograft, for example small areas from which a large intact sheet would be impossible. If possible, the area should be matched for color and type of skin.

A thin epidermal autograft should be taken at a thickness just sufficient to provide punctate bleeding of the donor site, typically 0.004–0.006 inches (0.10 mm–0.14 mm). Dermal tissue is not needed in the epidermal autograft, and should be minimized.

Typically, the thin epidermal autograft may be meshed up to a 5:1 ratio. The meshed epidermal autograft may be fragile and care should be taken in handling the graft.

Application of the Epidermal Autograft to the Neodermis

The epidermal autograft should be placed over the neodermis by spreading the meshed autograft. It should be spread as evenly as possible over the neodermis without leaving large open areas.

Completion of the epidermal autograft procedure should follow the standard protocol for full sheet or meshed autograft. The epidermal autograft should be anchored by sutures or staples. The dressing over the epidermal autograft should be similar to that used over conventional meshed autograft.

POTENTIAL POSTOPERATIVE PROBLEMS

Wound Colonization or Infection

Wounds having excessive discharge may require more frequent dressing changes and may require the use of appropriate antimicrobial intervention. After a diagnosed infection is controlled, either INTEGRA template or a thin epidermal autograft may be applied.

Patient Sepsis

The dressings should be removed and wound sites inspected for infection (INTEGRA template or autograft). Appropriate diagnostic and therapeutic procedures should be followed.

Hematoma

Areas of hematoma should be monitored and aspirated or excised as required. New INTEGRA template or autograft may be applied to the excised sites.

Poor Take of INTEGRA Template

If INTEGRA template is not incorporated into the wound bed, carefully remove the INTEGRA template and examine the wound bed. Areas of poor INTEGRA template take may be treated by reapplication of INTEGRA template or by application of conventional autograft.

Fluid Accumulation and Premature Silicone Layer Separation

Fluid accumulation or premature silicone layer separation must be treated to prevent infection or granulation tissue. Small areas of fluid accumulation under the silicone layer may be aspirated and cultured. If the silicone layer separates from the wound bed after neodermis formation begins, only the loose area of the silicone layer need be removed.

Inflammation

INTEGRA template grafts do not become inflamed unless there is a bacterial complication. This should be treated based on the clinical judgment of the practitioner.

HOW SUPPLIED

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

INTEGRA template is available in the following sizes:

- 4 inch x 5 inch (10 cm x 12.5 cm)
- 4 inch x 10 inch (10 cm x 25 cm)
- 8 inch x 10 inch (20 cm x 25 cm)

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 packaged in a foil pouch containing approximately 250 mL of 70% isopropyl alcohol. Each sterile foil pouch is packaged in a sealed outer chevron-style pouch.

Store flat under refrigeration at 35°–46°F (2°–8°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.

PRODUCT INFORMATION DISCLOSURE

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SYMBOLS USED ON LABELING

Do not reuse after opening	LOT Lot number
See instructions for use	Expiration date
Rx ONLY Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner	CE 0123 Product complies with requirements of directive 93/42/EEC

INTEGRA™

FDA APPROVED

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RMS# 51000-1204-6