

Integra®

Dermal Regeneration Template System

IDRT

IDRT Meshed

IDRT Single Layer

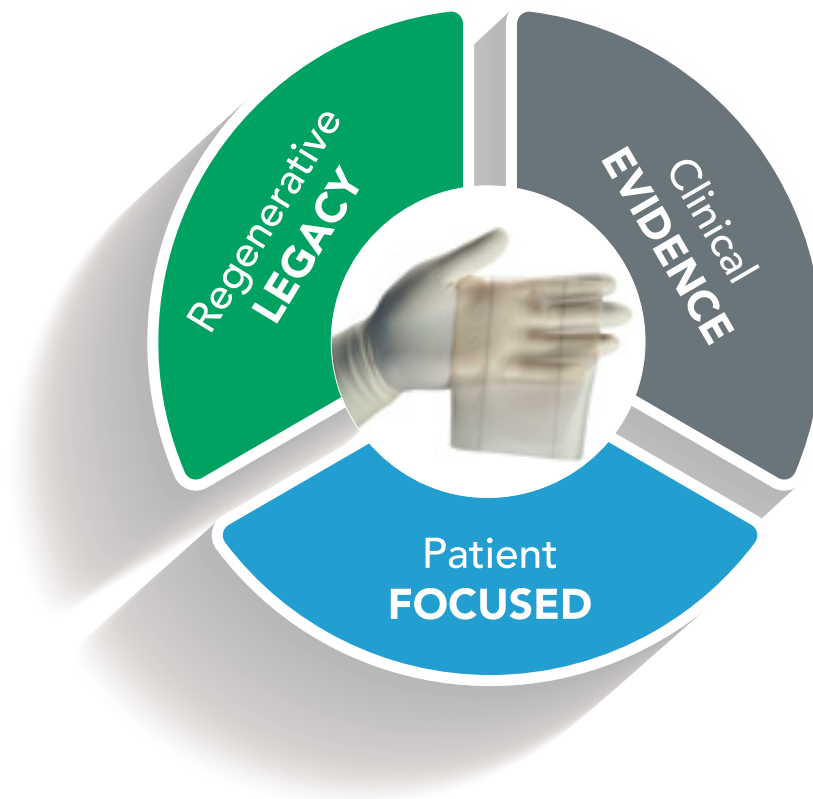
IDRT Single Layer Thin

Limit uncertainty
with a clinically proven
Dermal Regeneration System



INTEGRA®
LIMIT UNCERTAINTY

Integra® Dermal Regeneration Template : a leading solution in the treatment of severe wounds with 25+ years of clinical history¹



- ✓ The only FDA-approved product for dermal regeneration²
- ✓ PMA for severe burns treatment, scar contractures repair, and since 2016 for diabetic foot ulcers treatment³
- ✓ A complete portfolio of options:
 - Single Layer
 - Single Layer Thin
 - Bi-Layer
 - Bi-Layer Meshed

1. Heimbach D, Luterman A, Burke J, et al. Artificial dermis for major burns: a multi-center randomized clinical trial. Ann Surg. 1988;208:313–320
2. Food and Drug Administration, 1996. PMA filing for Integra® Dermal Regeneration Template (P900033). Accessible at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P900033> (last accessed on 12th July 2016)
3. Driver VR, Lavery LA, Reyzelman AM, Dutra TG, Dove CR, Kotsis SV, Kim HM, Chung KC. A clinical trial of Integra Template for diabetic foot ulcer treatment. Wound Repair Regen. 2015 Nov 12;23(6):891–900

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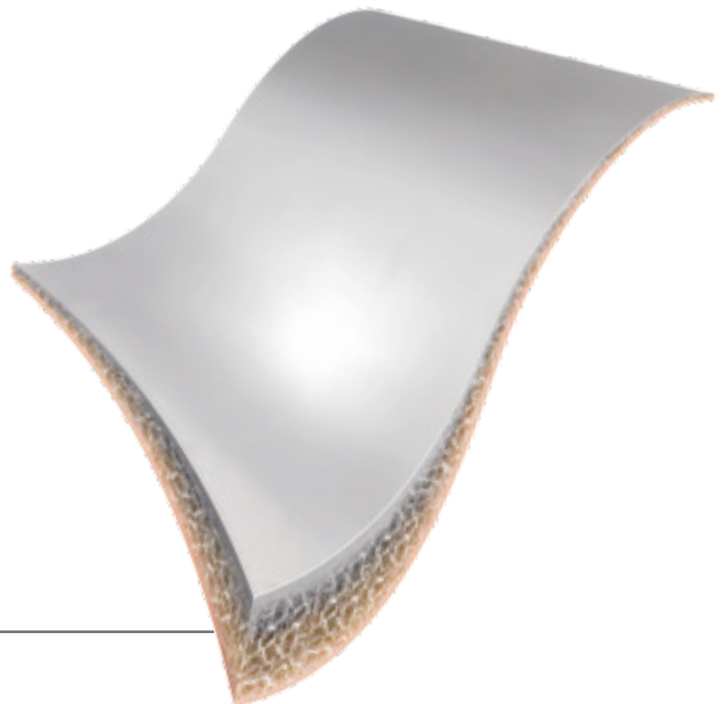
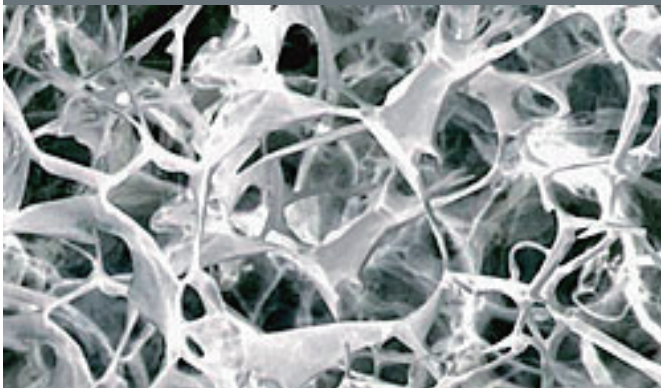
Dermal Regeneration Template

The technology behind Integra® Dermal Regeneration Template

The Integra® Dermal Regeneration Template is made up of a porous matrix of fibers of 90% cross-linked Type I atelocollagen and 10% glycosaminoglycan (chondroitin-6-sulfate).

3D Matrix Layer

- Cross-linked collagen and glycosaminoglycan (chondroitin-6-sulfate)
- Functions as an extracellular matrix
- Promotes cellular growth and collagen synthesis
- Biodegrades while being replaced by autologous dermal tissue



The inner three-dimensional layer membrane acts as a scaffold for the definitive dermal regeneration and guarantees immediate coverage of the wound lesion.

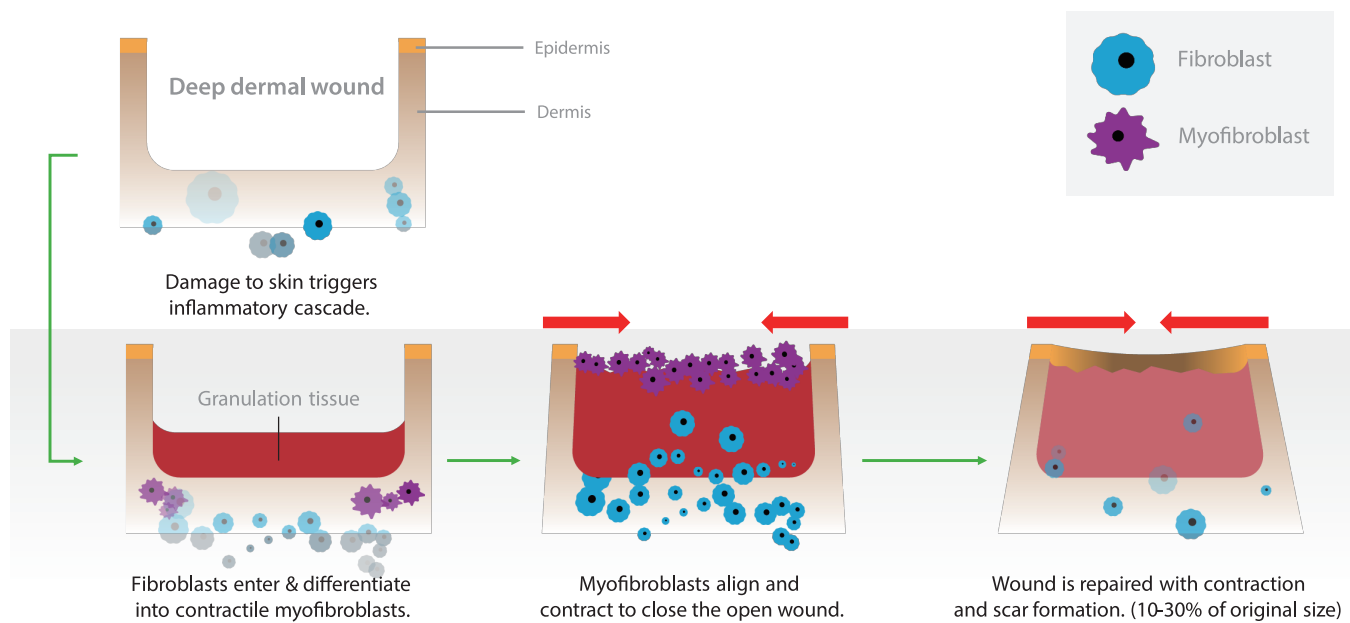
The matrix is manufactured with a controlled porosity with pore size dimensions ranging from 20 to 120µ designed to support organized neo-dermis regeneration.⁴

Integra® Dermal Regeneration Template favors cellular and capillary growth, minimizes the inflammatory response and, due to crosslinking, it delays the matrix degradation by collagenase.

4. 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.

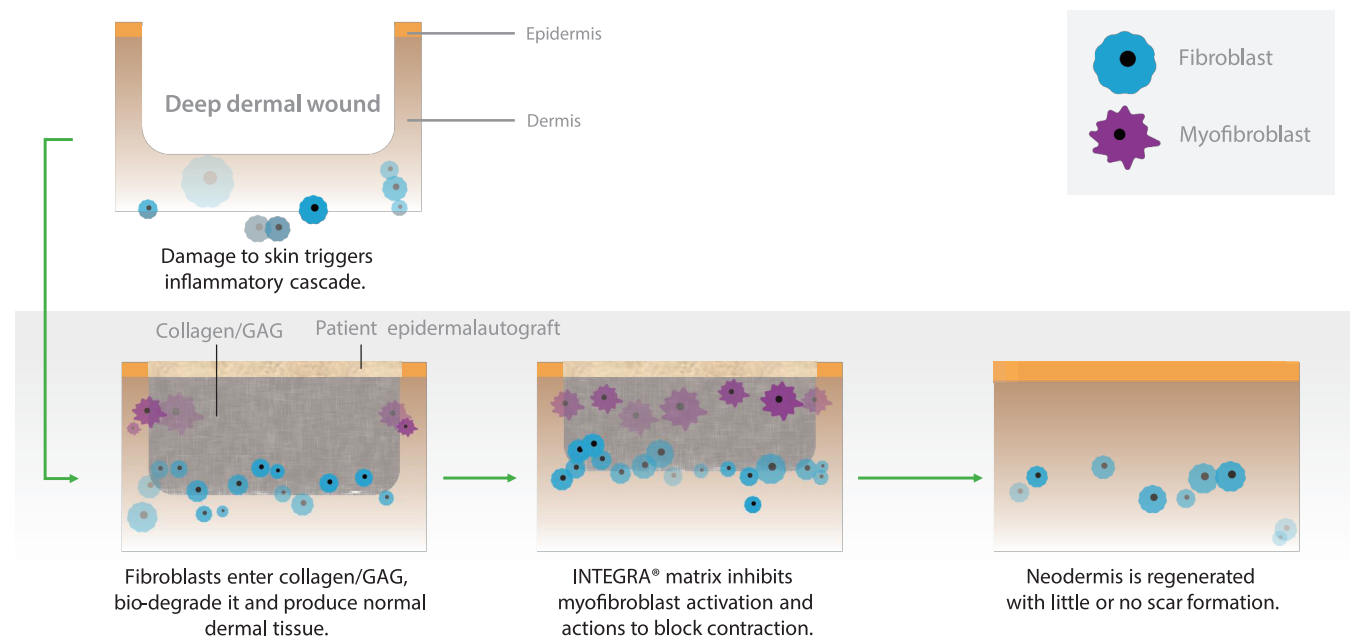
Normal Wound

Healing Process



Integra® Dermal Regeneration Template

Healing Process

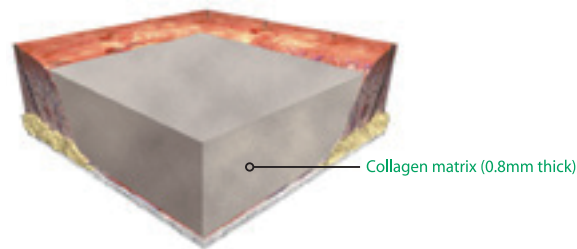


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Dermal Regeneration Template

Integra® Dermal Regeneration Template Single Layer (IDRT SL)

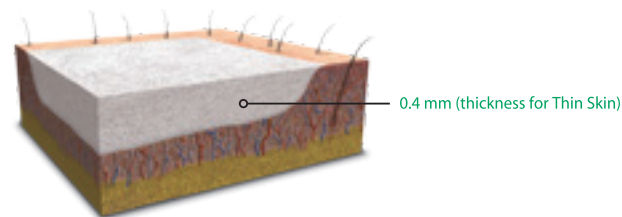
It has been designed for use in a one-stage procedure for moderately depressed wounds. This is when applied with an epidermal graft at the same time as the surgery.



Features	Benefits
<ul style="list-style-type: none">• Features the same 3D technology as IDRT but without silicone layer• Designed to promote permanent regeneration of functional dermal tissue	<ul style="list-style-type: none">• Saves Operating Room time compared to autograft• Avoids additional surgery for the patient• Can be stacked with IDRT 'should' extra thickness 'be' required to bridge the defect• Solution for treating burns and reconstructive procedures of small lesions

Integra® Dermal Regeneration Template Single Layer Thin (IDRT SL Thin)

It combines the proven technology of the Integra® Dermal Regeneration Template Single Layer with the versatility of a thinner scaffold which can be applied using a one-step surgery technique to mildly depressed anatomical sites.



Features	Benefits
<ul style="list-style-type: none">• The Thin version is 0.4mm thick, half the thickness of IDRT SL• Cross-linked collagen-chondroitin-6-sulfate• Designed to promote permanent regeneration of functional dermal tissue	<ul style="list-style-type: none">• Saves Operating Room time compared to autograft• Avoids additional surgery for the patient• Can be stacked with IDRT SL and/or IDRT should extra thickness be required to bridge the defect and in deeper wounds• Solution for treating burns and reconstructive procedures of small lesions

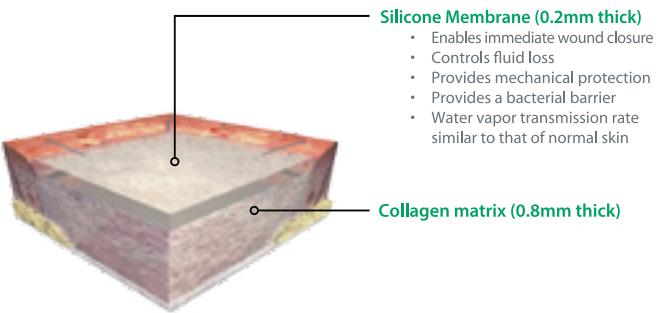
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Dermal Regeneration Template

Integra® Dermal Regeneration Template (IDRT)

It is a bilayer membrane system for skin replacement. It has been designed for the treatment of full thickness lesions in a two-step procedure.

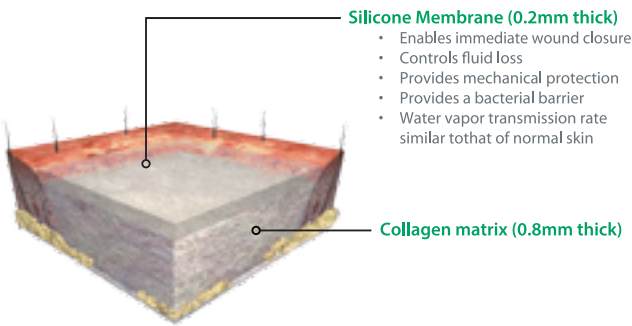
The temporary epidermal substitute layer on top of the matrix, is made up of a thin silicone layer to control moisture loss from the wound; after approximately 3 weeks it can be removed and the neo-dermis formed is covered with a split thickness skin graft to achieve final healing.



Features	Benefits
<ul style="list-style-type: none">• Tridimensional matrix• Tissue engineered design• Chondroitin-6-sulfate cross-linked with bovine collagen Type I• Atelocollagen• Bilayer configuration with silicon layer• Designed to promote permanent regeneration of functional dermal tissue	<ul style="list-style-type: none">• Allows cellular migration and capillary growth from the base and sides of the wound• Allows coverage over small avascular structures like bone and tendon• Reduces inflammatory response, promotes formation of organised dermal tissue avoiding scarring• Eliminates species specific properties• Early wound coverage limiting donor sites• Available in large sizes for burn and reconstructive surgery procedures

Integra® Meshed Dermal Regeneration Template (IMDRT)

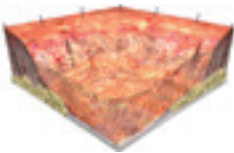

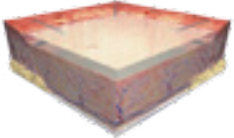
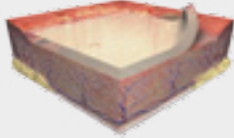
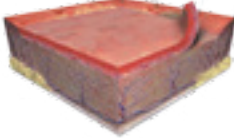
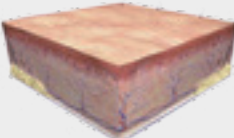
It combines the proven collagen technology of Integra® Dermal Regeneration Template and the feature of a pre-meshed configuration, and may be used in highly exudating wounds in conjunction with negative pressure wound therapy.⁵



Features	Benefits
<ul style="list-style-type: none">• The matrix is fully perforated at 1:1 ratio (not expandable)• Allows drainage of wound exudate and provides a flexible adherent covering to the wound surface• Designed to promote permanent regeneration of functional dermal tissue	<ul style="list-style-type: none">• Reduces Operating Room time compared to autograft, by removing the need to mesh• Designed to be used with negative pressure wound therapy devices.• Meshed design allows improved conformity to irregular wound beds• Available in large sizes for burn and reconstructive surgery procedures

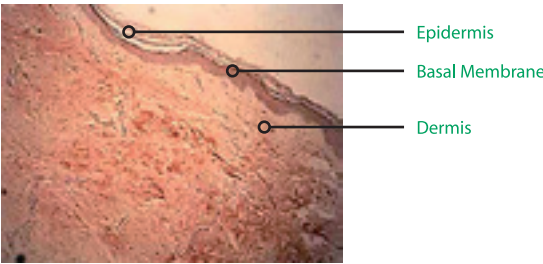
5. When using Integra Meshed Dermal Regeneration Template with Negative Pressure Wound Therapy, follow Warnings and Precautions for the specific Negative Pressure Wound Therapy device utilized.

How does Integra® Dermal Regeneration Template work in a two-step procedure?

Days	Results
Day 0: Contracted scar The burn injury or scar contracture is assessed and evaluated	
Day 1: Excision of non-viable tissue & application of the matrix The wound is cleaned and the damaged tissue or scar contracture is completely excised (removed) down to viable tissue in preparation for the application of the Integra® Dermal Regeneration Template. Integra® Dermal Regeneration 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 7-14: New dermis 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 21+: Complete neo-dermis 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.	
Day 21+: Epidermal autograft A thin (approximately 0.01 - 0.20 mm thick) epidermal autograft (sheet or meshed and expanded) is applied over the neodermis.	
Day 28-56: Regenerated Skin Successful engraftment completes the procedure yielding a permanent and lasting wound closure.	

Histological results

A histological analysis performed on 131 patients demonstrated that an intact dermis was achieved with no scar formation during the course of healing in any of the 336 serial biopsies (from 7 days to 2 years after application of the template).⁶



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

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Product Information

Integra® Dermal Regeneration Template (IDRT), Integra® Meshed Dermal Regeneration Template (IMDRT), Integra Dermal Regeneration Template Single Layer (IDRT SL) and Integra® Dermal Regeneration Template Single Layer Thin (IDRT SL Thin) are provided sterile under e-beam irradiation. The inner foil pouch and product should be handled using sterile technique. The product should not be re-sterilized.

Integra® Dermal Regeneration Template (IDRT)

Catalog Number	Size	Units/Box
32021	5cm x 5cm	1 Sheet
34051	10cm x 12.5cm	1 Sheet
34101	10cm x 25cm	1 Sheet
38101	20cm x 25cm	1 Sheet



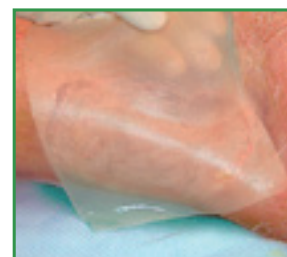
Integra® Meshed Dermal Regeneration Template (IMDRT)

Catalog Number	Size	Units/Box
MDRT2021	5cm x 5cm	1 Sheet
MDRT4051	10cm x 12.5cm	1 Sheet
MDRT4101	10cm x 25cm	1 Sheet
MDRT8101	20cm x 25cm	1 Sheet



Integra® Dermal Regeneration Template Single Layer (IDRT SL)

Catalog Number	Size	Units/Box
62021	5cm x 5cm	1 Sheet
64051	10cm x 12.5cm	1 Sheet
64101	10cm x 25cm	1 Sheet
68101	20cm x 25cm	1 Sheet



Integra® Dermal Regeneration Template Single Layer Thin (IDRT SL Thin)

Catalog Number	Size	Units/Box
62021T	5cm x 5cm	1 Sheet
64051T	10cm x 12.5cm	1 Sheet
64101T	10cm x 25cm	1 Sheet

