

DIABETIC SKIN ULCER

INTEGRA™ MATRIX WOUND DRESSING • INTEGRA™ BILAYER MATRIX WOUND DRESSING



SOFT TISSUE SOLUTIONS

CASE STUDIES

COLLAGEN
SOFT
TISSUE

Case Study 1

CASE STUDY 1 - TYPE II DIABETIC FOOT

Type of Wound: Diabetic Foot Ulcer

Patient: 58 year-old male

A 58-year old male with a history of Type-II diabetes for 8 years presents with left foot swelling and ulceration for three months. Each time swelling occurred during this period, he would purchase a self-prescribed course of oral Ampicillin at the local pharmacy abroad and the swelling would recede. When he returned to mainland United States, he had another episode of swelling that did not respond to Ampicillin and presented to the ER with erythema, edema, and extensive ulceration at the left 1st interspace with a deep space abscess. Debridement in the OR was performed on 2 occasions in conjunction with IV antibiotics (Image #1), followed by application of Integra™ Bilayer Matrix 26 days later (Images #2 and 3). A wound VAC was placed over the Integra graft intraoperatively and maintained for two weeks at continuous pressure of 125 mm/Hg (Image #4). The silicone layer was removed at two weeks (Images #5, and 6) and the wound VAC was continued for an additional two weeks. The wound continued to progress and was completely epithelialized at 160 days (Image #7). Long-term follow-up at nine months showed no recurrence with normal skin lines returning (Images #8 and 9).

Image 1



Image 2



Image 3



Image 4



Image 5



Image 6



Image 7



Image 8



Image 9



Case Study 2

CASE STUDY 2 - TYPE II DIABETIC FOOT

Type of Wound: Diabetic Foot Ulcer

Patient: 61 year-old male

A 61 year-old male, with a medical history notable for Type II diabetes, hypertension and hypercholesterolemia, presented with an ulcer on the lateral aspect of the left midfoot. On physical exam, there was an abscess which tracked medially across the entire plantar midfoot (Image #1-2). The patient was admitted emergently for antibiotics, and the wound was debrided and abscess drained in the OR (Image#3). The right lower extremity was subsequently revascularized. The tunneled track was filled with the single layer Integra™ Matrix and covered and fixated with the Integra™ Bilayer Matrix 31 days later (Image #4). The graft was completely integrated by post-op day 50 (images #5 and 6), with complete closure at post-op day 113 (Image #7). The patient was fitted for a custom-molded brace for ambulation. Wound closure has been maintained without incident for 2 years (images #8 and 9).

Image 1



Image 2



Image 3



Image 4



Image 5



Image 6



Image 7



Image 8



Image 9



Case Study 3

CASE STUDY 3 - TYPE II DIABETIC FOOT

Type of Wound: Diabetic Foot Ulcer

Patient: 67 year-old male

A 67-year old male with a history of Type II diabetes and HIV, with a history of abscess and osteomyelitis of the left 5th metatarsal head, with subsequent resection of the metatarsal head. Approximately two years later he developed a contracted 4th hammertoe with retrograde plantar flexion of the 4th metatarsal (Image #1). A grade II ulcer developed as a result of the increased pressure sub-4th metatarsal head (Image #2). Local care and off-loading with orthotics did not resolve the problem. The ulcer was not clinically infected and there was no evidence of osteomyelitis radiographically and intraoperatively. Contraction of the digit was addressed with K-wire fusion of the hammertoe in conjunction with a Weil 4th metatarsal osteotomy that was fixated with Integra Spin Screws (Images #3 and 4). The ulcer was simultaneously debrided and Integra™ Bilayer Matrix was sutured externally (Image #5). At 32-days post-operatively, there was increased uptake of the graft (Image #6). Complete epithelization was achieved at 67 days, and one-year follow-up shows no regression of ulceration or contracture (Image #7). The patient is fully active and uses custom-molded orthotics with ambulation.

Image 1



Image 2



Image 3



Image 4



Image 5



Image 6



Image 7



Case Study 4

CASE STUDY 4 - TYPE II DIABETIC FOOT

Type of Wound: Diabetic Foot Ulcer

Patient: 54 year-old male

A 54-year-old male with multiple medical problems most notable for diabetes on hemodialysis, hypertension, coronary artery disease, and peripheral vascular disease, presented upon referral with a 3 month history of dry gangrene of the right halux. He recently had an arthrectomy of the right popliteal artery, and subsequently developed the gangrene. An MRI showed evidence of an abscess extending from the area of dry gangrene demarcation to the plantar vault with a swelling and malodor (Image #1). The patient was admitted for IV antibiotics and emergent surgery, where an amputation of the right hallux and first metatarsal head were performed. A secondary surgery was performed 23 days later where the wound was further debrided and pulse irrigated, and Integra™ Bilayer Matrix graft was applied (Image #2). Image #3 shows the graft partially integrated after 26 days, with Images #4 and 5 showing enhanced granulation and wound contracture. Complete closure was obtained 133 days after graft application (Image #6).

Image 1



Image 2



Image 3



Image 4



Image 5



Image 6



Case Study 5

CASE STUDY 5 - TYPE II DIABETIC FOOT

Type of Wound: Diabetic Foot Ulcer

Patient: 80 year-old male

An 80-year old male with a medical history notable for Type-II diabetes presented to the emergency room with a right foot ulcer draining plantarly and medially for 1 week. The ulcers had been present for approximately 10 years, and had been only treated conservatively. On physical exam, there was extreme pain on palpation of the right foot with malodor and copious yellow-gray drainage. The patient had previous digital amputations bilaterally. Upon evaluation, the prognosis of the right foot is very guarded with a very high possibility for a below-the-knee amputation. Non-invasive flow studies (NIFS) showed a right Ankle-Brachial Index (ABI) of 0.90 DP and 0.96 PT. A wide excisional debridement was performed, with follow-up washout and debridement 6 days later (Images #1-4).

Image 1



Image 2

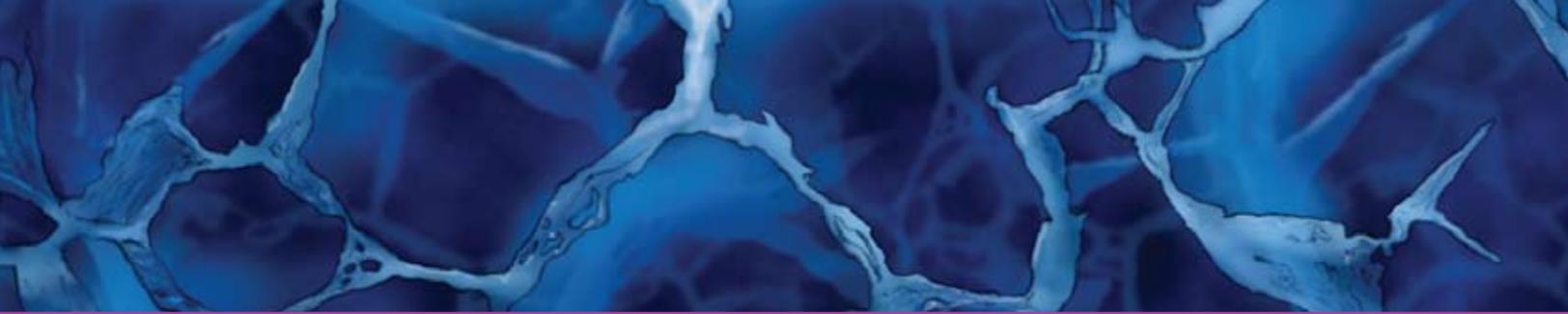


Image 3



Image 4





A PICC line was placed for long-term IV antibiotics for treatment of osteomyelitis with Vancomycin and Imipenem. Approximately one month later, the wound bed was prepared, and Integra™ Bilayer Matrix was applied as per standard protocol (Images #5-8). IV antibiotics were completed and non-weight bearing status was obtained through the use of a wheelchair. There was adequate wound epithelialization at 113 days after Integra application for the patient to advance to ambulation in custom molded shoes and inserts (Images #9-11). There was complete epithelialization of the wound at 155 days after application of the Integra (Image #12) with maintenance of wound closure at 15-months post-operatively.

Image 5



Image 6



Image 7



Image 8



Image 9



Image 10



Image 11



Image 12



Case Study 6

CASE STUDY 6 - TYPE II DIABETIC FOOT

Type of Wound: Diabetic Foot Ulcer

Patient: 53 year-old male

A 53-year old male with a history of uncontrolled Type II diabetes presented with a one month history of enlarging heel ulcer with purulent drainage after a puncture wound on a metal surface (Image #1). Plain film x-rays showed no break in the calcaneal cortex, however, a Technesium bone scan showed increased uptake in the late phase. The patient had operative debridement of necrotic tissue, and inspection of the calcaneus showed hard bone with no evidence suggestive for osteomyelitis. The patient was placed on IV antibiotics, and a second debridement and pulse irrigation was performed (Images #2 and 3) five days later. The depth of the soft tissue void was 1.5cm (Image #4) and was completely filled subsequent to debridement with the single layer Integra™ Matrix (Images #5 and 6), and then covered with Integra™ Bilayer Matrix sutured externally to the skin (Images #7) and a light compressive dressing applied (Images #8).

Image 1



Image 2



Image 3



Image 4



Image 5



Image 6



Image 7



Image 8





The patient was placed on a six-week course of IV antibiotics. [Image #9](#) shows graft uptake with an intact silicone layer at 2-weeks postoperatively. At four weeks, the silicone layer detached, and continued integration of the graft was appreciated ([Image #10](#)). Additional superficial debridement and application of Integra™ Bilayer Matrix were performed three more times over the next four months to ensure full and rapid healing ([Image #11](#)). Complete epithelialization of the wound was present at 153 days ([Image #12](#)). Two-year follow-up shows no further breakdown of the ulcer with periodic hyperkeratotic tissue that needs debridement ([Images #13 and 14](#)).

Image 9



Image 10



Image 11



Image 12



Image 13



Image 14



Case Study 7

CASE STUDY 7 - TYPE II DIABETIC FOOT

Type of Wound: Diabetic Foot Ulcer

Patient: 55 year-old male

A 55-year old male with a history of uncontrolled Type-II diabetes, hypertension, end-stage renal disease on hemodialysis, presents with ulceration of the left foot with gas gangrene. He underwent a transmetatarsal amputation which progressed to dehiscence of the entire wound. He was treated with local wound care with topical debridement agents without success. Below-knee amputation was considered, and he was referred for attempt at limb salvage. Wound cultures positive for pseudomonas and staphylococcus. Goal-directed IV antibiotics was initiated for 2 weeks prior to initial debridement and application of Integra™ Bilayer Matrix (Images #1-4), and maintained for 4 additional weeks. The silicone layer detached at 20 days (Image #5).

Image 1



Image 2



Image 3



Image 4



Image 5





The wound showed uptake of the graft with formation of neo-dermis (Images #6 and 7). Two additional applications of Integra™ Bilayer Matrix were applied at 51 and 99 days post-operatively (Image #8) with progression of healing (Image #9). Complete epithelialization of the wound was achieved at 161 days (Image #10 and 11).

Image 6



Image 7



Image 8



Image 9



Image 10



Image 11



Integra™ Matrix Wound Dressing

Integra™ Bilayer Matrix Wound Dressing

Indications for Use:

• INTEGRA™ MATRIX WOUND DRESSING

Description

INTEGRA™ Matrix Wound Dressing is an advanced wound care device comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan. The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

Indications

INTEGRA™ Matrix Wound Dressing is indicated for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. This device is intended for one-time use.

Contraindications

This device should not be used in patients with known sensitivity to bovine collagen or chondroitin materials. The device is not indicated for use in third degree burns.

Precautions

Do not resterilize. Discard all opened and unused portions of INTEGRA™ Matrix Wound Dressing.

Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.

Discard device if mishandling has caused possible damage or contamination.

INTEGRA™ Matrix Wound Dressing should not be applied until excessive exudate, bleeding, acute swelling and infection are controlled. Debridement or excision must be done thoroughly to remove any remaining necrotic tissue that may cause infection. The following complications are possible with the use of wound dressings.

If any of the conditions occur, the device should be removed: infection, chronic inflammation (initial application of wound dressings may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain or swelling.

• INTEGRA™ BILAYER MATRIX WOUND DRESSING

Description

INTEGRA™ Bilayer Matrix Wound Dressing is an advanced wound care device comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan and a semi-permeable polysiloxane (silicone layer). The semi-permeable silicone membrane controls water vapor loss, provides a flexible adherent covering for the wound surface and adds increased tear strength to the device.

The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

Indications

INTEGRA™ Bilayer Matrix Wound Dressing is indicated for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic and vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.

This device is intended for one-time use.

Contraindications

This device should not be used in patients with known sensitivity to bovine collagen or chondroitin materials. The device is not indicated for use in third-degree burns.

Precautions

Do not resterilize. Discard all opened and unused portions of INTEGRA™ Bilayer Matrix Wound Dressing

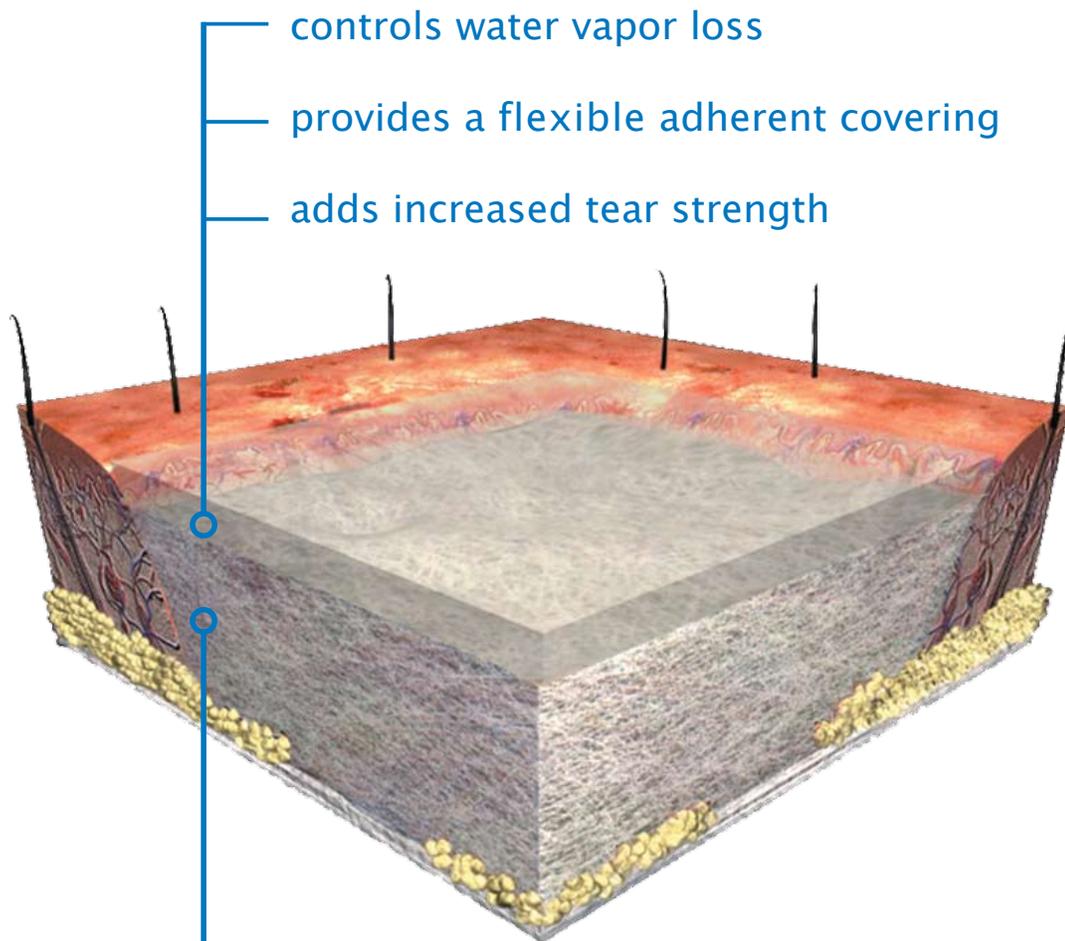
Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.

Discard device if mishandling has caused possible damage or contamination.

INTEGRA™ Bilayer Matrix Wound Dressing should not be applied until excessive exudate, bleeding, acute swelling and infection are controlled. Debridement or excision must be done thoroughly to remove any remaining necrotic tissue that may cause infection. The following complications are possible with the use of wound dressings. If any of the conditions occur, the device should be removed: infection, chronic inflammation (initial application of wound dressings may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain or swelling.

Collagen Soft Tissue Technology

Semi-permeable silicone membrane



controls water vapor loss

provides a flexible adherent covering

adds increased tear strength

Collagen-glycosaminoglycan biodegradable matrix

provides a scaffold for cellular
invasion and capillary growth

scaffold is eventually remodeled
as the patient's cells rebuild the
damaged site

Also Available: Integra™ Flowable Wound Matrix

 **INTEGRA™**
Extremity Reconstruction



INTEGRA™ FLOWABLE WOUND MATRIX



Collagen Soft Tissue
Technology

FUNCTIONALITY-

AN ALTERNATIVE FOR FILLING DEEP
SOFT TISSUE AND TUNNELING WOUNDS

FLEXIBILITY-

SIMPLE, EASY APPLICATION

STABILITY-

PROVIDES A SCAFFOLD
FOR CELLULAR INVASION
AND CAPILLARY GROWTH

Ordering Information

To place an order for INTEGRA™ Bilayer Matrix Wound Dressing, INTEGRA™ Matrix Wound Dressing, or INTEGRA™ Flowable Wound Matrix Please call Customer Service at 800-654-2873

INTEGRA™ Bilayer Matrix Wound Dressing

A bi-layer advanced wound care device that is ideal for partial and full-thickness soft tissue trauma and chronic wounds.

U.S. Catalog No.	Size	Unit of Measure
BMW2021	2 in x 2 in	1 sheet/box
BMW202	2 in x 2 in	5 sheets/case
BMW4051	4 in x 5 in	1 sheet/box
BMW405	4 in x 5 in	5 sheets/case
BMW4101	4 in x 10 in	1 sheet/box
BMW410	4 in x 10 in	5 sheets/case
BMW8101	8 in x 10 in	1 sheet/box
BMW810	8 in x 10 in	5 sheets/case

INTEGRA™ Matrix Wound Dressing

A single layer advanced wound care device which is indicated for the management of wounds including tunneling wounds.

U.S. Catalog No.	Size	Unit of Measure
52021	2 in x 2 in	1 sheet/box
52025	2 in x 2 in	5 sheets/case
54051	4 in x 5 in	1 sheet/box
54055	4 in x 5 in	5 sheets/case
54101	4 in x 10 in	1 sheet/box
54105	4 in x 10 in	5 sheets/case
58101	8 in x 10 in	1 sheet/box
58105	8 in x 10 in	5 sheets/case

Also Available:

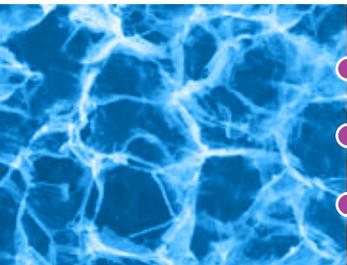
INTEGRA™ Flowable Wound Matrix

An alternative for filling deep soft tissue and tunneling wounds.

U.S. Catalog No.	Size	Unit of Measure
FWD301	3cc	1 syringe/box

DIABETIC SKIN ULCER

INTEGRA™ MATRIX WOUND DRESSING • INTEGRA™ BILAYER MATRIX WOUND DRESSING



 **INTEGRA™**
Extremity Reconstruction

**COLLAGEN
SOFT
TISSUE**

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