MEDIHONEY®
Wound and Burn Dressing

PREPARE

A Natural Choice in Wound Care

The global leading brand of medical grade Manuka honey offering versatility and effectiveness for acute and chronic wounds and burns.[1-3]

INTEGRA®
LIMIT UNCERTAINTY

Changing expectations and clinical outcomes in wound care

Dramatic changes have been seen in the field of advanced wound care within the last two decades. The practice of moist wound healing has significantly improved outcomes and has helped clinicians make knowledge-based decisions affecting the healing process.

MediHoney® dressings, containing Active *Leptospermum* (Manuka) Honey (ALH), address many factors that delay healing, helps to promote a moist wound environment that aids and supports autolytic debridement.

MEDIHONEY®
Wound and Burn Dressing

Aids and supports autolytic debridement and a moist wound healing environment in acute and chronic wounds and burns[5-8]

What is Active *Leptospermum* (Manuka) Honey (ALH)?

- The most studied variety of medical grade honey for the management of wounds and burns[1-3]
- It is derived from the nectar of a *Leptospermum* species
- With its unique properties, it demonstrates significantly faster healing when compared with conventional dressings[4,6]
- Osmotic activity pulls fluid to the surface of the wound[1]

MediHoney® – Controlled Sourcing, Rigorous Processing

- Controlled using a rigorous set of systems and standards, including independent monitoring and auditing, to help ensure quality and batch-to-batch consistency
- Ultra filtrated and sterilized by gamma irradiation, removing any bacterial spores without loss of product effectiveness[3]
- Comes from a traceable source and is free of pesticides and antibiotics[3]

How MediHoney® Helps Provide an Environment Conducive to Healing

- A moisture-balanced environment conducive to wound healing in multiple etiologies[3]
- High osmotic potential, contributes to moist wound environment[5]
- Medical grade Manuka honey has a low pH of 3.5-4.5
- Has a long history of safe use in the care of wounds and burns[3]

Making an Impact on Wound Healing

Wounds and burns may be challenging to manage due to a multitude of co-morbidities and cascading factors. These factors include necrotic tissue, bacterial imbalance, recurring physical trauma, and altered levels/composition of wound exudate. Wound bed preparation is the principal step in helping to keep the wound free and clean of non-viable tissue that can delay healing.

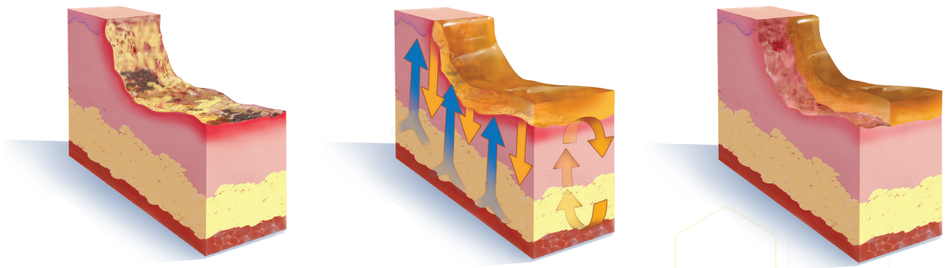
Factors that Impact Wound Healing

CAUSE OF STALLING	MEDIHONEY® PROPERTY	RELEVANCE
Non-viable/Necrotic Tissue	High osmolarity	Osmotic activity aids in creating a moist wound environment An increased flow of wound fluid helps to soften and liquefy necrotic material, while the body's own enzymes work to further break down the necrotic tissue
High pH	Low pH	Lowering pH has been associated with wound healing benefits

Goal Oriented Strategies

Goal oriented strategies for wound healing can help you to maintain control over your patients' wound environment and get them on to healthy healing. Appropriate goals such as maintaining the physiologic wound environment (e.g., debridement, cleansing, prevention/management of infection) and providing systemic support (e.g., edema reduction, nutrition, hydration) are foundational to the process.

The key properties of MediHoney offer you versatility and performance to support your wound management goals. It aids and supports autolytic debridement and the removal of non-viable tissue from the wound environment. Additionally, MediHoney has a low pH.



Wound bed with slough, eschar and elevated pH

High osmolarity pulls wound fluid and helps to liquify necrotic tissue

Non-viable tissue is removed

Supporting your wound management goals

The Role of MediHoney® (Active *Leptospermum* Honey) in Debridement

1

AUTOLYTIC DEBRIDEMENT

During autolysis, the body breaks down tissue or cells. A moist environment, supported by MediHoney dressings, aids the body's process of bringing wound fluid to the surface with endogenous enzyme, thus loosening and liquefying necrotic tissue.

2

HIGH OSMOLARITY

The high sugar content of honey facilitates movement of fluid from an area of higher concentration, across a membrane, to an area of lower concentration. Osmotic potential draws fluid through the wound, to the surface, helping to liquefy non-viable tissue.

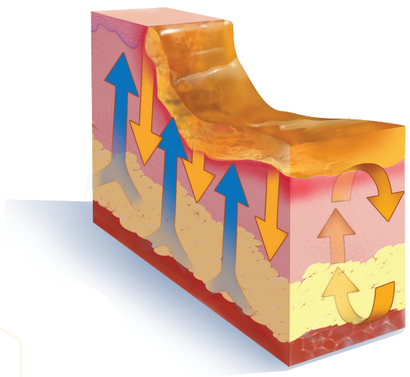
3

LOW pH

The failure of a chronic wound to heal has been correlated with alkaline pH levels ranging from 7.15 to 8.94.[10] MediHoney has a low pH of 3.5–4.5. Maintaining more acidic pH levels within the wound environment can help to keep a wound on track towards healing.

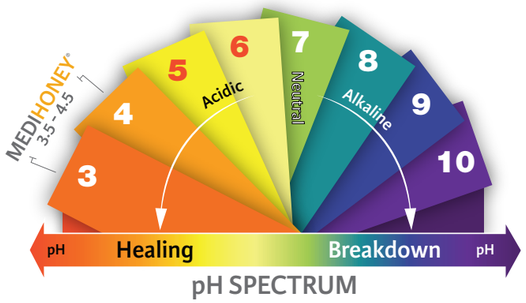
Key Properties

HIGH OSMOLARITY



MediHoney aids and supports autolytic debridement

LOW pH LEVEL



MediHoney has a low pH of 3.5-4.5

Clinical Evidence Demonstrates Manuka Honey's Effectiveness in Helping Wounds Heal

Manuka honey-impregnated dressings in the treatment of neuropathic diabetic foot ulcers

A 63 PATIENT RCT

Kamaratos, et al, Diabetes Center at Tzanio General Hospital in Greece, performed a prospective, randomized, double-blinded, controlled study.[4]

INCLUSION CRITERIA

Patients with type II diabetes with Wagner Grade 1 and 2 lower limb neuropathic ulcers.

PRIMARY OUTCOMES

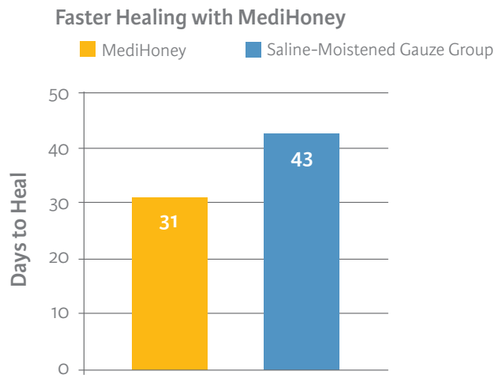
To investigate the effect of Manuka Honey (MediHoney) impregnated dressings in the healing and microbiology of neuropathic diabetic foot ulcers over a 16 week period.

METHODS

- Patients were randomly entered into 2 groups – MediHoney group and saline-moistened gauze group.
- Bedside debridement was conducted upon initial visit and when judged clinically necessary thereafter.
- Dressing changes were performed daily and then with declining frequency as wound healing progressed.
- At the initial visit, swab cultures were taken from all patients after wound debridement. Swab cultures were continued on a weekly basis.
- Off-loading of the affected limb was applied in all patients.

RESULTS

- Mean duration of healing time was 31 (± 4 days) in the MediHoney group vs 43 days (± 3 days) in the control group. This was statistically significant at p=<0.05.
- None of the patients in the MediHoney group required treatment with antibiotics while 9 (29%) in the control group required antibiotics, two of whom were hospitalized for 28 days.



	Required Antibiotics	Required Hospitalization
MediHoney Group	0	0
Saline-Moistened Gauze Group	9	4

Case Studies Demonstrating MediHoney® is Clinically Used on a Variety of Etiologies

PRESSURE ULCER

Nancy Chaiken, ANP-C, CWOCN
Swedish Covenant Hospital, Chicago, IL

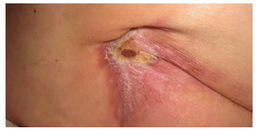
56 year-old female with Stage IV sacral pressure ulcer measuring 8.0 x 10.0 cm. Moderate amount of serosanguineous exudate. Peri-wound erythema and adherent, loose, necrotic slough tissue around wound base. Patient pain score 10/10.

WEEK 1 MediHoney Paste was applied and covered with a calcium alginate absorbent cover dressing daily.

WEEK 9 Minimal sharp debridement was performed as needed and MediHoney Paste covered with calcium alginate dressing continued to be applied. Wound measured 6.0 x 8.0 x 1.0 cm. Healthy granulation tissue was apparent with small amount of fascia exposed. Patient's self-report of pain scores gradually improved.

WEEK 16 Wound closure was achieved.





VENOUS LEG ULCER

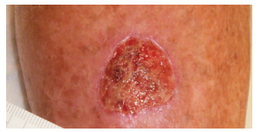
Jennifer A. Gardner PT, DPT, MHA, CWS & Tara Murphy RN, BSN
Underwood-Memorial Hospital, Woodbury, NJ

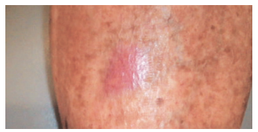
88 year-old female with traumatic wound on anterior lower leg complicated by venous insufficiency. Patient had multiple co-morbidities including cancer and was concurrently undergoing radiation treatment. MediHoney Gel was initiated in combination with elastic tubular bandage. The wound came to full closure in a two week time period.

DAY 1 2.5 x 2.5 cm.

WEEK 1 Wound closed.

WEEK 2 Follow up visit, wound remained closed.





DIABETIC FOOT ULCER

Steven J. Kavros, DPM
Gondavascular Wound Healing Center, Mayo Clinic, Rochester. MN

68 year-old male with diabetes, peripheral neuropathy, ESRD and CCLI. Wound located on the plantar aspect of the forefoot without bone exposure. Dense fibrin tissue, slough and limited granulation tissue were initially present. Weekly debridement and additional adjunctive therapies continued in the patient's wound care protocol.

DAY 1 MediHoney Calcium Alginate dressing was applied and changed every other day.

WEEK 4 Patient responded well with dressing changes every other day. Wound reduced in volume by 25%.

WEEK 8 Wound reduced in volume by 85%.



RHEUMATOID ARTHRITIS

Nancy Chaiken, ANP-C, CWOCN
Swedish Covenant Hospital, Chicago, IL

53 year-old male with history of RA, morbid obesity, myocardial injury, Hepatitis C and newly diagnosed esophageal cancer. MRSA positive foot wound of 2½ year duration. 8.0 x 8.0 x 1.0 cm full thickness wound. Large amounts of serious exudate, necrotic slough tissue, peri-wound erythema and pain.

WEEK 1 MediHoney Paste was applied, and covered with a dressing and secured with a conforming gauze bandage daily.

WEEK 4 Application of MediHoney Paste was continued. The wound measured 7.0 x 7.0 x 1.0. There was a decrease in exudate, necrotic slough, peri-wound erythema and patient's pain as well as an increase in granulation tissue.

MONTH 4 Complete closure achieved despite continual chemotherapy for esophageal cancer.



AT-RISK LIMBS

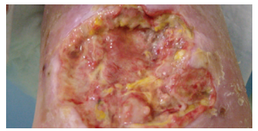
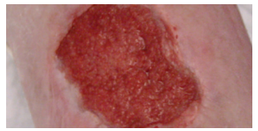
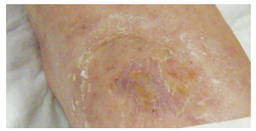
Paul Liguori, MD & Kim Peters, RN, CWS
Whittier Rehabilitation Hospital, Bradford, MA

72 year-old diabetic, neuropathic female with reddened area on the dorsal surface of the foot was presented at the hospital and diagnosed with cellulitis. Wound bed covered with thick slough. Peri-wound edema, erythema and warmth.

WEEK 1 MediHoney® Calcium Alginate dressings were initiated with an absorbent cover dressing changed daily.

WEEK 9 Frequency of MediHoney Calcium Alginate was reduced to 1x daily. Wound bed was clean and undermining was present. NPWT was initiated to enhance growth of granulation.

WEEK 16 At-risk limb achieved optimal outcome – total wound closure.

IV INFILTRATE WOUND

Roxana Reyna RNC, WWC
Driscoll Children's Hospital, Corpus Christi, TX

A 4 week-old male with a history of failure to thrive, IV infiltrate and cellulitis to the left foot, which had been treated for 7 days with antibiotic ointment and covered with non-stick gauze BID. Upon beginning of MediHoney treatment, dressings were changed every 3 days until discharge, then every 5 days until closed.

DAY 1 Initial assessment.

DAY 3 24 hrs. after MediHoney Paste applied.

MONTH 2 Wound closure.



POST SURGICAL WOUND IN PATIENT UNDERGOING RADIATION

Scott Moore, NREMT-P, RN. Certified ACLS, PALS, BLS ONS
Chemotherapy and Biotherapy, Edmund Oncology Center, Edmond, OK

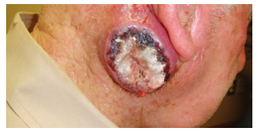
Rapidly growing Squamous Cell Carcinoma of the right post-auricular area. Excessive malodor and exudate present. Patient under going radiation therapy (IMRT).

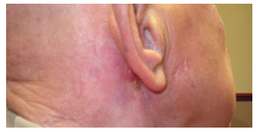
WEEK 1 Absorbent cover dressing was initiated.

WEEK 3 MediHoney Calcium Alginate was initiated.

WEEK 4 MediHoney Calcium Alginate dressings with super absorbent dressing was initiated. IMRT resulted in necrotic tissue sloughing. Excess exudate managed with frequent cover dressing changes (1-2 x daily). Malodor was eradicated.

WEEK 8 Complete wound closure with minimal scar tissue.





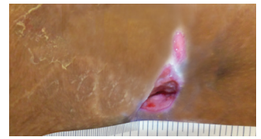
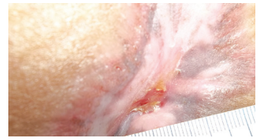
STAGE IV PRESSURE ULCER

Aaron Wodash RN, WCC
Augustana Care Center, Minneapolis, Minnesota

79 year-old female with stage IV pressure ulcer at left ischial tuberosity. Enzymatic debrider and NPWT were utilized, but wound healing was not progressing. MediHoney® Calcium Alginate dressings were initiated on Day 0. The wound came to closure in less than 9 weeks.

WEEK 1 4.0 cm x 2.0 cm.

MONTH 2 Wound closed.

SACRAL PRESSURE ULCER

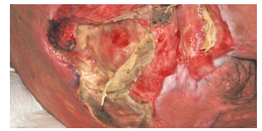
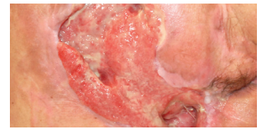
Cecilia Gray, RN, MSN, CNS, CWON & Fatima Ishii, RN, BS, CWON
Los Angeles County and University of Southern California Medical Center, Los Angeles, CA

A 51 year-old male paraplegic with chronic sacral and ischial pressure ulcers previously treated with surgical muscle flaps. History of osteomyelitis, receiving long-term antibiotics.[11]

DAY 0 Sacral pressure ulcer 10.0 x 12.0 x 5.0 cm.

WEEK 2 MediHoney was applied every 3 days, the wound displayed 100% granulation tissue.

WEEK 10 Six weeks prior, this sacral pressure ulcer had decreased to a 1.0 cm x 1.0 cm red granulating wound managed with a foam dressing. He told his clinicians he had slept and stayed in his wheelchair for 3 weeks straight without offloading or repositioning. Upon discharge to hospice care, the wound measured 5.0 x 8.0 x 1.0 cm with 2.5 cm undermining from 9 o'clock to 12 o'clock and 100% granulation tissue after 21 dressing changes.


POST SURGICAL WOUNDS AT PIN SITES

Michael S. Kerzner, DPM,
Dept. of Orthopedic Surgery, Duke University Medical Center, Durham, NC.

Prospective study of 19 patients aimed to demonstrate the safety and efficacy of a novel method of pin-site care utilizing Leptospermum Honey (LH) Fenestrated Dressings – Medihoney® HCS. Patients underwent deformity correction with Open reduction with external fixation (OREF).

Translucent nature of the dressing enables wound progression monitoring without disruption to the wound site. Dressings were replaced weekly. Fine wire ringed fixators were removed at an average of 12.1 weeks.

SURGERY Fenestrated dressing is applied at metal-cutaneous interface.

WEEK 3 No evidence of surrounding cellulitic infection after weekly dressing application.

FRAME REMOVAL No patients required early pin removal or a debridement procedure related to their pin-sites.



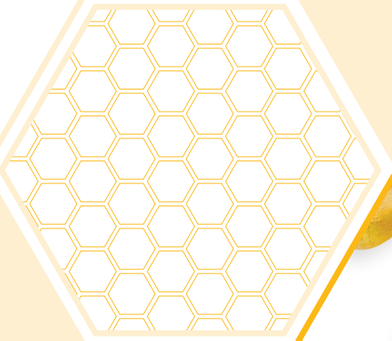
MEDIHONEY®
Wound and Burn Dressing

MediHoney is the global leading medical-grade honey-based product line for the management of acute and chronic wounds and burns.[1-3] Derived from the *Leptospermum* species, these unique dressings have properties that can be beneficial throughout all phases of the wound healing.

MediHoney® Gel
(ALH content - 80%)

- 80% ALH and 20% natural gelling agents
- Provides increased stability at the site of the wound due to its natural gelling agent

USAGE SUGGESTIONS:
- For lightly to moderately exudating wounds



MediHoney® Paste
(ALH content - 100%)

- For use in hard-to-dress wounds, where tunneling or undermining occurs

USAGE SUGGESTIONS:
- For lightly to moderately exudating wounds
- An optional accessory applicator tip comes in each box, to help facilitate application into tough-to-reach areas

MediHoney® Dressings can be used from the start of wound management through to wound closure

MediHoney® HCS (Hydrogel Colloidal Sheet)
(ALH content - 63%)

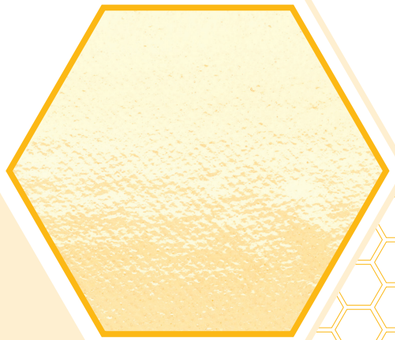
- Combines the benefits of ALH with the handling capability of Super Absorbent Polymer (SAP) technology
- Absorbs 2.5x the amount of fluid of leading hydrocolloids[3]
- Is cooling and soothing upon application
- Two versions: Adhesive and Non-adhesive

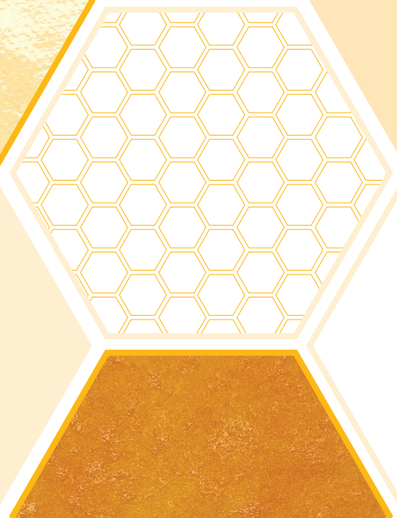
USAGE SUGGESTIONS:
- For non-draining to lightly exuding wounds

MediHoney® Hydrogel Sheet
(ALH content - 45%)

- Combines the benefits of ALH with the handling capability of Super Absorbent Polymer (SAP) technology
- Absorbs 2.5x the amount of fluid of leading hydrocolloids[3]
- Is cooling and soothing upon application
- Two versions: Adhesive and Non-adhesive
- HCPCS A6242, A6243, A6245, A6246

USAGE SUGGESTIONS:
- For non-draining to lightly exuding wounds



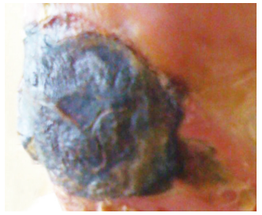


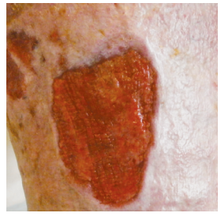
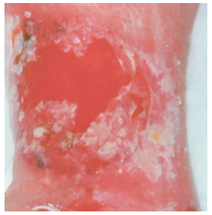
MediHoney® Calcium Alginate
(ALH content - 95%)

- Honey impregnated into a calcium alginate dressing
- As wound fluid enters the dressing, the honey is released while the dressing absorbs and forms a gel

USAGE SUGGESTIONS:
- May be used to pack wounds in the same fashion as a typical calcium alginate or other gelling fiber dressing
- For moderately to heavily exuding wounds

MediHoney® Dressing Selection Guide for Superficial, Partial and Full Thickness Wounds and Burns



TYPE OF WOUND	Eschar		Sloughy		Granulating	Epithelializing
OBJECTIVE	Soften and Remove Eschar		Remove Slough		Promote Granulation	Maintain Moist Environment
EXUDATE	Light	Moderate	Light to Moderate	Heavy	Light to Moderate	Light
MediHoney Dressing (Primary Dressing)	Gel Paste HCS	Gel Calcium Alginate	Gel Paste HCS	Calcium Alginate	Gel HCS	HCS
Xtrasorb® Dressing (Secondary Dressing)	Foam HCS	Classic	Foam HCS Classic	Classic	Foam HCS	N/A

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11. Gray C, Ishil F. Using Active Leptospermum Honey in the Debridement Process: 6 Challenging Cases from the Inner City. OWM 2015 (4): 63-66.

A Guideline for Care – MediHoney® Dressing Application and Removal

- Wash hands thoroughly
- Apply gloves
- Assess the wound. Look for signs of healing. Also look for any signs of increased redness, pain, swelling, or heat within or around the wound*
- Cleanse the wound and skin around the wound with sterile saline, sterile water, or other safe wound cleansers
- Dry the skin around the wound by patting gently with gauze
- Protect the skin around the wound to avoid maceration. Apply a skin protectant barrier wipe or barrier ointment as necessary. (An initial increase in exudates may occur)
- Choose a MediHoney dressing that is appropriate for the amount of drainage:
  - MediHoney Paste or MediHoney Gel for lightly to moderately exudating wounds that are hard to dress
  - MediHoney HCS for non-draining to lightly exudating wounds that are superficial to partial thickness wounds
  - MediHoney Calcium Alginate dressing for moderate to heavily exudating wounds
- Apply the appropriate MediHoney dressing to fit the wound. The MediHoney Calcium Alginate and HCS Non-adhesive dresings can be cut to fit within the wound edges.
- Apply an absorbent cover dressing to manage exudate (Xtrasorb® super absorbent dressings are recommended)
- Dressing change: Remove the dressing gently. If the dressing is difficult to remove, moisten with saline or water.

** The healthcare provider should be notified if the wound worsens. Report increased redness, pain, swelling, or heat on or around the wound.*

Contraindications

- On third degree burns
- With patients that have a known sensitivity to honey or any other component parts specific to each dressing (please see package insert for more information).
- To control heavy bleeding

Precautions

- If the dressing is not easily removed, soak with sterile saline or water until it is removed without difficulty.
- Due to the dressing's low pH, some patients may notice a slight transient stinging. If stinging does not stop or persists and cannot be managed with an analgesic, remove dressing, cleanse area, and discontinue the use of MediHoney dressing.
- During initial use of the dressing (depending on wound exudate levels, interstitial fluid, and edema surrounding the wound), the dressings high osmotic potential may contribute to increased exudate, which could lead to maceration if the excess moisture is not managed appropriately. Manage additional moisture by adding an absorptive cover dressing and/or adjusting the frequency of dressing change. Protect the peri-wound skin by applying a skin barrier protectant to the surrounding skin.
- During the healing process it is common for non-viable tissue to be removed from the wound resulting in an initial increase in wound size. Although an initial increase in wound size may be attributed to the normal removal of non-viable tissue, consult a healthcare professional if the wound continues to grow larger after the first few dressing changes.

MediHoney®
Wound and Burn Dressing

PREPARE

MediHoney® Wound and Burn Dressing

	Reference	Description	Packaging Unit/Case	HCPCS
Gel	31805	0.5 oz tube	10/box, 4 boxes/case	A4649
	31815	1.5 oz tube	1/box, 12 boxes/case	A4649
	31840	14 oz tube	1/jar, 6 tubs/case	------
Paste	31505	0.5 oz tube	10/box, 4 boxes/case	A4649
	31515	1.5 oz tube	1/box, 12 boxes/case	A4649
	31535	3.5 oz tube	1/box, 12 boxes/case	A4649
Hydrogel Sheet *Non-Adhesive*	31620	2.4 in x 2.4 in	10/box, 5 boxes/case	**A6242**
	31640	4.3 in x 4.3 in	10/box, 5 boxes/case	**A6243**
Adhesive	31720	2.8 in x 2.8 in (4.3 in x 4.3 in with adhesive border)	10/box, 5 boxes/case	**A6245**
	31740	4.5 in x 4.5 in (6 in x 6 in with adhesive border)	10/box, 5 boxes/case	**A6246**
HCS *Surgical*	31738	1.75 in x 6.5 in (3 in x 8 in with adhesive border)	10/box, 5 boxes/case	A4649
Fenestrated (Non-Adhesive)	31618	1.8 in x 1.8 in	10/box, 5 boxes/case	A4649
Non-Adhesive	31622	2.4 in x 2.4 in	10/box, 5 boxes/case	A4649
	31644	4.33 in x 4.33 in	10/box, 5 boxes/case	A4649
	31612	8 in x 12 in	2/box, 5 boxes/case	A4649
Adhesive	31722	2.8 in x 2.8 in (4.3in x 4.3in with adhesive border)	10/box, 5 boxes/case	A4649
	31744	4.5 in x 4.5 in (6 in x 6 in with adhesive border)	10/box, 5 boxes/case	A4649
Calcium Alginate	31012	0.75 in x 12 in	5/box, 4 boxes/case	A4649
	31022	2 in x 2 in	10/box, 10 boxes/case	A4649
	31045	4 in x 5 in	10/box, 5 boxes/case	A4649


Gel


Paste


Hydrogel Sheet *(Non-Adhesive)*


Hydrogel Sheet *(Adhesive)*


HCS *(Surgical)*


HCS -*Fenestrated (Non-Adhesive)*


HCS (*Non-Adhesive)*


HCS *(Adhesive)*


Calcium Alginate

Integra LifeSciences Corporation intends to use reasonable efforts to provide accurate coding information, but this information should not be construed as providing clinical advice, dictating reimbursement policy or substituting for the judgment of a practitioner. It is always the Provider's responsibility to determine and submit appropriate codes, charges and modifiers for services that are rendered. Integra LifeSciences Corporation assumes no responsibilities or liabilities for the timeliness, accuracy and completeness of the information contained herein. Since reimbursement laws, regulations and payor policies change frequently, it is recommended that providers consult with their payors, coding specialists and/or legal counsel regarding coverage, coding and payment issues.

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