ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

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RE: Future LCD – Surgical Dressings (L33831)

Dear Drs. Mamuya, Hoover, Brennan, Gurk and Hughes

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are expressing our grave concerns regarding the future Surgical Dressing LCD (L33831) since it is clinically unworkable for our members and its implementation will be disruptive to patient care. The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. A list of our members can be found on our website: www.woundcarestakeholders.org.

The practice of wound care is not limited to one particular medical specialty--instead, many different specialists treat patients with chronic wounds. These practitioners include but are not limited to the following: surgeons (e.g. vascular surgeons, plastic surgeons, and foot and ankle surgeons), vascular medicine physicians, podiatrists, phlebologists, nurse practitioners, physical therapists, nurses, registered dietician nutritionists, and primary care physicians who are in the full time practice of managing patients with wounds.

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Over the years we have served as a resource to the DMEMACs on draft surgical dressings and other DMEPOS draft LCDs to ensure that stakeholders such as clinicians in various sites of service, manufacturers and supplier/distributors are engaged in helping to answer questions and provide information so that a clinically appropriate policy would be written. We were advised by the DMEMACs that we would be contacted to serve as a resource again to resolve many of the concerns that we addressed in both our oral and written comments. Imagine our surprise and disappointment when we were told at the recent HCPCS Public meeting that the LCD was to be released that day without any of our clinical input.

Since the future LCD is almost identical to the draft, we still have very serious clinical concerns which affect our clinical association members. We submit again that the future LCD and policy article does not conform to current clinical practice, lacks clarity and contains conflicting language leading to confusion in wound care practice of the clinical community. None of this was resolved in the DMEMACs comments and response summary.

Therefore, here are our issues that are in the future LCD that must be clarified or resolved in order so not to harm Medicare beneficiaries if the policy is implemented. **We strongly believe as we stated in our 2015 comments that this future LCD should not be implemented, but withdrawn and then allow the Alliance members to work with the DMEMAC medical directors to craft an alternative LCD based on current clinical literature and clinical practice.**

REMOVAL OF CLINICAL JUDGMENT IN THE DRAFT LCD LANGUAGE

The Alliance clinical associations believe their first obligation is to their patients and it is important that they have the flexibility to use the wound care products and procedures appropriately to heal their patient's wounds. Typically, their decision to use a product is based on the wound appearance and its characteristics as well as their goals for healing. Clinicians need to have the ability to use their clinical judgment in cases to change the dressing on the wound depending on how it is healing.

It should be noted that the practice of wound care has changed since this surgical dressing policy was written in 1993.[1] At this point, nearly 25 years after that date, significant changes have occurred with surgical dressing construction and wound treatment. Particularly after the passage of Section 4009 of the 21st Century Cures Act—which requires Medicare contractors to provide an evidence-based rationale to explain their coverage determinations—simple reliance on decades-old dressing categories and coverage criteria is no longer sufficient. The DMEMACs must instead work collaboratively with knowledgeable stakeholders like the Alliance to update the LCD in a manner consistent with the current state of clinical practice and current evidence. The following are some changes that should be currently taken into account:

- Many of the categories of dressings do not reflect the combined nature and features of most dressings available on the market today. In fact, the decision to place a dressing in a category, as instructed by the future LCD is based on the 'predominant' component…..reflects that these dressings are multi-functional/ multi-components and have advanced beyond the foam or hydrocolloid of 1993.

- The Alliance has created wound care quality measures through the US Wound Registry QCDR. Physicians and clinicians are using these and other measures as part of their outcomes data. By the DMEMACs restricting choice of surgical dressings and the use of more modern dressings, chronic wounds may not heal in an appropriate timeframe.[2]
- In writing this policy, the DMEMACs must take into account more than the ulcer since that the wound care patient has co-morbidities which directly impact wound healing. Non-healing wounds occur among patients with diabetes, peripheral vascular disease (nearly as common as coronary artery disease and stroke), or as a result of unique medical problems (e.g., sickle cell anemia, vasculitis), or in association with immunosuppression (e.g., AIDS, steroid use or transplantation medications).
- Similarly, current research has now shown that wound healing is a complicated process directly influenced by the status of the local wound environment and also by the overall physical condition of the individual. The process of wound healing involves metabolic, structural, biochemical and patient factors in a unique way. Wound healing is not a single event; it is a result of a complex series of overlapping processes. There are guideline- suggested interventions but there are many combinations of individual wound characteristics which contribute to the complexity of healing a wound. The order and combinations of treatments used are varied and may be directed anywhere along the wound healing cascade.

The following three situations below illustrate our concerns: on frequency limitations, dressings not covered to treat partial thickness wounds, exudate tied to dressing coverage.

THE FUTURE LCD IMPOSES STRICT FREQUENCY LIMITATIONS ON ALL DRESSINGS

- *Concern*: These limitations discard the importance of clinicians' judgment and the variability of individual circumstance, and they are inconsistent with the standard of practice and evidence demonstrating that higher frequencies than those specified in the Future LCD are often reasonable and necessary.

- *Specific changes that the Draft/Future LCD made to the current LCD:*
  We have given examples below from our clinician associations why removal of the flexibility of the term "usual" along with the clinician's judgment is problematic and how if this policy is implemented as is would disrupt patient care.

    - Alginate: Removes "usual" dressing change is up to once per day
        - **There are wounds that initially require more than one dressing change per day due to copious exudate related to the location (an edematous lower extremity), surface area or infection causing not only larger amounts with foul odor, but also higher potential for environmental contamination.**

    - Composite: Removes "usual" dressing change is up to 3 times per week
        - **The choice of a composite dressing is to maximize a combination of dressing attributes to improve the wound condition, reduce contamination and positively impact the patient's quality of life. Frequency will be driven by a variety of factors arrived at by the clinician's assessment of the wound. For example, a dressing changed after one day**

may be assessed to have only a small amount of exudate, which can be due to the patient's positioning or dependency of an extremity, but cumulatively over a couple of days that same amount of exudate may be assessed as moderate to large for the same reasons.

- Contact Layer: Removes "usual" dressing change is up to once per week
  - **Contact layers are generally used to protect the surface of a wound from trauma and to prevent pain on removal. They also may be used to confine a medication to the wound bed. While some may be able to be left in place and the secondary dressing changed only, depending on the wound bed and reason for use they may need to be changed as often as daily. It must be noted that the frequency is not driven by exudate levels.**

- Foam Dressing: Removes "usual" dressing change is up to once per day
  - **As with the other dressings, the amount and character of the exudate will drive the frequency of the dressing change especially in the early stages of the management of a given wound.**

- Gauze, non-impregnated: Removes "usual" dressing change is up to 3 times per day without a border and once per day with a border
  - **There are variants in the gauze category that will drive dressing change frequency. Clinicians always strive to reduce the frequency of dressing changes, but as examples, the use of gauze will often be as a secondary dressing, to deliver a solution to the wound bed, or cover a prescription drug of some sort.**

- Gauze, impregnated other than H2O: Removes "usual" dressing change is up to once per day
  - **The frequency of dressing change of impregnated gauze will be dependent upon what it is impregnated with and the goal of the therapy.**

- Hydrocolloid: Removes "usual" dressing change is up to 3 times per week
  - **These dressings are best left in place for as long as possible but the amount and character of the exudate and the location of the wound will always drive the frequency of change and can only be decided upon by assessment and patient tolerance.**

- Hydrogel: Removes "usual" dressing change without adhesive border of fillers is up to once per day, with wound covers with adhesive border up to 3 times per week. Utilization reduction by capping at 3 units per wound in 30 days, whereas before higher utilization was covered if documentation substantiated medical necessity
  - **Hydrogel dressings are the optimal method for hydration or maintenance of a wound with minimal to no exudate. The size and location of the wound will drive the amount needed but most are going to require once a day dressing changes. Hydrogel dressings with adhesive borders often can be extended to 3 times weekly as the nature of the dressing reduces the potential for drying out.**

- Specialty Absorptive: Removes "usual" change is up to once per day without an adhesive border and every other day with a border
    - **The specialty absorptive dressings answer a need for the absorption of drainage that is not only in larger amounts but also more viscous in nature and often requires at least daily changes with or without border.**

- Transparent film: Removes "usual" change is up to 3 times per week
    - **Wounds with even minimal exudate will collect fluid under a film dressing often requiring at least every other day changes**

- Wound Filler: Removes "usual" change is up to once per day
    - **Wound filler products vary in their ability to absorb, but if being utilized may require daily dressings especially early in treatment.**

- Wound Pouch: Removes "usual" change is up to 3 times per week
    - **A wound draining either an amount of exudate or exudate that is severely caustic to the skin is best managed with a pouching system. The frequency of change will depend on amount and type of exudate as well as location of the wound on the body.**

- Tape: Removes "usual" utilization units
- Self-adherent bandage: Removes "usual" frequency of replacement is no more than one per week

- *Recommendation:*
  We would suggest that the following language be included in the policy: "Medicare expects that most covered surgical dressings will require changing no more frequently than the number of changes identified in the Dressings section, but additional changes may be covered, subject to documentation supporting the reasonable and necessary nature of the additional changes."

THE FUTURE LCD SUGGESTS CERTAIN DRESSINGS WILL NOT BE COVERED TO TREAT PARTIAL-THICKNESS WOUNDS

- *Specific changes that the Draft/Future LCD makes to the current LCD: Specific dressings that are not affirmatively covered to treat partial-thickness wounds:*
    - Alginate: covered for full-thickness wounds (e.g., stage III or IV ulcers)
    - Collagen: covered for full-thickness wounds (e.g., stage III or IV ulcers)
    - Foam: covered for full-thickness wounds (e.g., stage III or IV ulcers)
    - Hydrogel: covered for full-thickness wounds (e.g., stage III or IV ulcers)
    - Specialty absorptive: covered for full-thickness wounds (e.g., stage III or IV ulcers)

- *Concern:* These limitations are inconsistent with the standard of practice and evidence demonstrating that surgical dressings are often reasonable and necessary to treat partial-thickness wounds. If the policy was

implemented as written, only hydrocolloid and transparent film dressings would be available to treat patients with partial thickness wounds.

This is problematic since these dressings have more of a mechanical function to protect the wound versus clinicians having the ability to use dressings that have the properties to keep the wound progressing in the active phases of healing. In addition, there is great variability in what may be described as a partial thickness wound. A skin tear can start as a partial thickness wound; however they often progress into full thickness wounds once any necrotic tissue is debrided. In frail patients with poor skin tone and turgor, the continued use of only a transparent film or hydrocolloid can worsen the wound as the epidermis is stripped and torn with dressing changes. In addition, co-morbid conditions cause increased edema and exudate that must be managed with the wound. The more advanced dressings are necessary here to effectively treat the wound.

- *Recommendations:*
    - In **Appendix 1**, we have provided alginate and hydrogel manufacturer IFUs and in **Appendix 2** for collagen manufacturers IFUs. These include treating partial and full thickness wounds. Therefore, we would recommend that the final LCD include coverage for partial and full thickness wounds for these dressings.
    - We would also recommend elimination of the staging terms (see our recommendations later in our comments)

THE FUTURE LCD RESTRICTS COVERAGE FOR COLLAGEN, HYDROGEL, AND COMPOSITE DRESSINGS BASED ON THE AMOUNT OF EXUDATE OF THE WOUND

- *Specific changes that the Draft/Future LCD makes to the current LCD:*
    - Collagen: Only covered for wounds with light to moderate exudate—not covered for wounds with heavy exudate
    - Composite: Only covered for moderately to highly exudative wounds
    - Hydrogel: Only covered for wounds with minimal or no exudate

- *Concern:* These limitations are inconsistent with the standard of practice and evidence demonstrating that these dressings are often reasonable and necessary to treat wounds of all exudate levels.
- *Recommendations:*
    - We recommend that these three types of surgical dressings be covered for all levels of wound exudate.

NEW COVERAGE AND UTILIZATION CRITERIA ARE AMBIGUOUS AND INCONSISTENT

The proposed language is inconsistent in a number of places, leading to restrictive and uncertain guidelines, and possibly prevents any deviation from the LCD even when reasonable and necessary. With the best interest of the patient in mind, there are times that stepping outside of the LCD will lead to the most clinically appropriate avenue of care. The ambiguity and inconsistency with language regarding utilization creates an inability to put

the patients' needs first. This limitation will most certainly lead to a marked increase in re-hospitalizations and concerns with care coordination. Specific examples include but are not limited to the following:

COLLAGEN DRESSING OR WOUND FILLER (A6010, A6011, A6021-A6024)

Language in the Policy: ***Collagen Dressing or Wound Filler (A6010, A6011, A6021-A6024):*** *A collagen-based dressing or wound filler is covered for* ***full thickness*** *wounds (e.g., stage III or IV ulcers) wounds with light to moderate exudate, or wounds that have stalled or have not progressed toward a healing goal. They can* ***stay in place up to 7 days****, depending on the specific product. Collagen based dressings are not covered for wounds with heavy exudate, third-degree burns, or when an active vasculitis is present*

Concerns and Clarifications:

- The above statements are in conflict with the collagen dressing products Indications for Use (IFU) statements in the following manners: (see **Appendix 2** for IFUs of collagen)
    - Most products have IFU indications for a variety of wound types including partial to full thickness wounds and all exudate levels.
    - The various collagen products have different frequency of use indications. Since wounds progress at different rates, each stage requires a different frequency of dressing changes. The various frequency of use also depends on:[3-6]
        - the way the collagen dressing is constructed and performs,
        - its ability to absorb the exudate and interact with matrix metalloproteinases (MMPs),[*] and
        - the biocompatibility and biodegradable capabilities of the dressings, which occur at different rates (i.e. every 72 hrs. to every 7 days)
    - Collagen dressings can be used on all exudate levels, therefore the comment about use on light to moderate exudate levels is not clinically correct. Many of the products' IFUs indicate that they can be used for heavily exudating wounds.

- We have concerns from a documentation standpoint on how the utilization of "stay in place up to 7 days" could be misinterpreted by those adjudicating the claims by thinking that this means 7 days and not more frequently. If the collagen product's IFU states dressing should be re-applied every 72 hours and it is

[*] Role of MMPs in wound healing: Due to a number of potential stimuli (local tissue ischemia, bioburden, necrotic tissue, repeated trauma, etc.), wounds can stall in the inflammatory phase contributing to the chronicity of the wound. One key component of chronic wounds is an elevated level of matrix metalloproteinases (MMPs). At elevated levels, MMPs not only degrade nonviable collagen but also viable collagen. In addition, fibroblasts in a chronic wound may not secrete tissue inhibitors of MMPs (TIMPs) at an adequate level to control the activity of MMPs. These events prevent the formation of the scaffold needed for cell migration and ultimately prevent the formation of the extracellular matrix (ECM) and granulation tissue. Collagen based wound dressings are uniquely suited to address the issue of elevated levels of MMPs by acting as a 'sacrificial substrate' in the wound. It has also been demonstrated that collagen breakdown products are chemotactic for a variety of cell types required for the formation of granulation tissue. In addition, collagen based dressings have the ability to absorb wound exudates and maintain a moist wound environment.

clinically appropriate, how will this be reviewed based on the current LCD language? There is immense administrative burden for the provider, biller and DME MAC to monitor this language.

- We have the following questions and issues that need clarifying:
  - *Language from policy: A collagen based dressing or wound filler is covered for full thickness wounds (PU stage II, IV) wounds with light to moderate exudate, or wounds that have stalled or have not progressed.*

    - What documentation will be required for stalled wounds? Or is this assumed if the wound is chronic?

    - Does this mean that collagen dressings will only be covered for full thickness wounds? (clinical practice and IFUs do not support this)

      Most products have IFU indications for partial thickness, and many clinicians use collagen dressings on partial thickness wounds. Does this language mean that they can no longer do this if they are sending the patient to the DME to obtain product for mid-week changes?

    - How will the level of exudate need to be documented? In the medical record? On the prescription?

  - *Language from policy: Dressing can stay in place up to 7 days, depending on the specific products.*

    - Please clarify that the dressings are changed depending on specific product.
    - Please clarify that there are not restrictions on the number of dressings changed in 7 day period.
    - We request clarification on these issues:
      - If a collagen dressing product has a IFU up to 5 to 7 day, can this be changed every 5 days? Or once / week?
      - If a collagen dressing product IFU states up to 72 hours can these be billed for every 48 hours? In the beginning of wound treatment, the frequency of dressing changes will occur more often and will occur less often as the wound treatment progresses. How will the DMEMACs take this into consideration for allotment of dressings?
      - How will the DMEMACs monitor this policy implementation? Claims audits?

Recommendation: As stated in our 2015 comments, we would recommend that: [7-14]

- Collagen dressings be covered for both full- and partial-thickness wounds
- Remove the examples for wound stages or place full list of staging options. Please see our general comments regarding staging- There are various scales/classification systems available to stage pressure, diabetic foot and venous ulcers.
- Delete "*They can **stay in place up to 7 days,** depending on the specific product"* and add instead "The frequency of change should be dictated by the condition of the wound and be determined by the physician/health care provider treating the wounds as wound change over the course of time as they go through the healing process."

CONTACT LAYER (A6206-A6208)

Language in the Policy: Contact Layer (A6206-A6208): *Contact layer dressings are used to line the entire wound to prevent adhesion of the overlying dressing to the wound. They are* ***not*** *reasonable and necessary* ***when used with any dressing that has a non-adherent or semi-adherent layer as part of the dressing****. They are not intended to be changed with each dressing change. Dressing change is up to once per week.*

Concerns and Clarifications:

- The future LCD states that they are not covered when used with SEMI-adherent products. Those still adhere so why would they not be allowed for such use.

HYDROGEL DRESSING (A6231-A6233, A6242-A6248)

Language in the Policy: Hydrogel dressings are covered when used on full thickness wounds with minimal or no exudate (e.g., stage III or IV ulcers). Hydrogel dressings are not reasonable and necessary for stage II ulcers. Dressing-change for hydrogel wound covers without adhesive border or hydrogel wound fillers is up to once per day. Dressing change for hydrogel wound covers with adhesive border is up to 3 times per week

Concerns/Clarifications: [15]

- The future LCD states that hydrogel dressing are not reasonable and necessary for stage II ulcers but the statement above that states "hydrogel dressings are covered when used on full thickness wound with minimal to no exudate". As stated above, a stage II Wagner ulcer is full thickness by definition.
- The future LCD also states there is a limit of three units per wound in 30 days; we question where the scientific evidence is in the bibliography that can justify this number?

MISCELLANEOUS- "the frequency of recommended dressing changes…"

Language in Policy: *The frequency of recommended dressing changes depends on the type and use of the surgical dressing. When combinations of primary dressings, secondary dressings, and wound filler are used, the change frequencies of the individual products should be similar.* ***For purposes of this policy, the product in contact with the wound determines the change frequency. It is not reasonable and necessary to use a combination of products with differing change intervals.*** *For example, it is not reasonable and necessary to use a secondary dressing with a weekly change frequency over a primary dressing with a daily change interval. Such claims will be denied as not reasonable and necessary.*

Issues:

- From a clinical perspective, there are many instances where multiple products need to be applied to treat the wound characteristics effectively. For example, partial thickness wounds can be both extremely painful and highly exudative (venous ulcers). A reasonable treatment plan would be to use a contact

layer to treat the wound pain and an alginate/foam over that. The absorptive dressing may need daily changes but the contact layer may not. Both are needed to address the wound properly.

- In addition, the frequency of dressing changes does NOT depend on the type and use of the surgical dressing but rather on the wound itself and how it is presented (i.e. – how big is the wound and where it is located, is it a heavy exudating wound etc.).
- This eliminates all options of secondary dressing OTHER THAN GAUZE, based on the other changes proposed in the LCD and gauze is not considered the standard of care

Recommendations:

- Delete the paragraph and add: "Should the frequency of dressing change of the primary dressing be greater than that typically allowed for the secondary dressing, then supportive documentation is required to justify clinical rationale for utilization."

THE FUTURE LCD CONCLUDES THAT THE SAFETY AND EFFECTIVENESS OF SILVER AND HONEY IN SURGICAL DRESSINGS HAS NOT BEEN ESTABLISHED

- *Concern:* This conclusion is inconsistent with evidence demonstrating that these components are effective in surgical dressings, as well as clinicians' experience using these dressings. As stated in our 2015 surgical dressing comments, honey impregnated and silver dressings have been cleared by the FDA as safe and effective. In addition, there is scientific evidence for medical grade honey impregnated dressings that was sent to the PDAC by clinical associations in 2014, which led the PDAC to confirm that the HCPCS codes that these dressings were originally in based on their substrate was correct.

  In terms of silver dressings, there have been many published articles and posters addressing the clinical evidence of these products. We have included them again in our bibliography.[16-31] We are concerned that in the future final LCD, out of 13 articles that we provided to you in our 2015 comments, only one was included in the bibliography. (Jørgensen B, Price P, Andersen KE, et al. The silver-releasing foam dressing, Contreet Foam, promotes faster healing of critically colonised venous leg ulcers: a randomised, controlled trial. *Int Wound J* 2005; 2:64-73.)

  Recommendation: As we stated in our 2015 comments, we request that this section be deleted.

REFERENCE TO STAGING SYSTEMS SHOULD BE REMOVED FROM THIS FUTURE LCD

- The future LCD contains the 2016 NPUAP staging system which we submit should be removed. This staging system refers only to pressure ulcers and this policy includes using surgical dressings to treat diabetic foot ulcers and venous stasis ulcers which have different grading or staging systems such as Wagner scale, wound, ischemia and foot infection (WIfI), University of Texas for DFU and CEAP for

venous ulcers. Thus, it does not make sense clinically to include only the NPUAP staging system since those clinicians who treat DFU and VLU are confused by reference to the staging in the utilization parameters.

- To illustrate more fully, in the collagen dressing section using the terms (e.g. stage III or IV) is confusing. As stated above, there are many wound ulcer classification tools and they are specific to wound ulcer type. For example, Stage III or IV is specific for pressure ulcers and does not classify diabetic foot ulcers which may use a Wagner scale. For a DFU, Wagner 2 is *Ulcers extend into tendon, bone, or capsulea.* When only some of the classification/ staging tools are placed in the policy and are not complete, it causes confusion to the clinical community as well as claims administrators and ALJ when they don't see specific criteria.

We would recommend that the NPUAP staging system be removed since it does not apply to all types of chronic wounds and is not consistently used by all providers. We would suggest just using full thickness or partial thickness wounds when describing the chronic wounds.

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We therefore respectfully request that implementation of the future LCD be delayed for implementation pending the opportunity for all stakeholders to provide clinical evidence and expert input. The Alliance stands ready to work with you to craft an LCD that provides needed clarity around criteria and meets the clinical needs of this deserving Medicare population.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

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31. Sibbald G, et al.Bacteriology, Inflammation, and Healing: A Study of Nanocrystalline Silver Dressings in Chronic Venous Leg Ulcers. Advances in Skin & Wound Care. 2007. Oct., 549 558. (n=15) Clinical trial

Appendix 1

Hydrogel and Calcium Alginate IFUs

Product	Manufacturer	Type
Calcium Alginate Dressing	Hollister Woundcare	Calcium Alginate
Hydrogel Impregnated Sponge	Hollister Woundcare	Hydrogel
Calcicare Calcium Alginate Dressing	Hollister Woundcare	Calcium Alginate

hollisterwoundcare

STERILE
STERILE
ES TERIL

Restore

INSTRUCTIONS/MODE D'EMPLOI/INSTRUCCIONES

Calcium Alginate Dressing
Pansement d'alginate de calcium
Apósito de Alginato de Calcio

Calcium Alginate Dressing

Indications for Use

For the management of moderate to heavily exuding, partial- to full-thickness wounds including:

- Pressure Ulcers (Stages I-IV)
- Arterial Ulcers
- Venous Stasis Ulcers
- Post-Surgical Incisions
- Donor Sites
- Trauma Wounds
- Diabetic Ulcers
- Dermal Lesions

Contraindications

Calcium Alginate Dressings should not be used on dry or lightly exuding wounds or on patients with sensitivity to calcium alginate or with other known allergic skin conditions.

Directions for Application

Preparing the Wound Area

Before applying a dressing, the wound area should be thoroughly cleansed with Restore Wound Cleanser or normal saline, if appropriate.
If necessary, the wound should be debrided.

Applying the Dressing

The dressing may be trimmed to fit the wound size.
Apply dressing to wound surface; deep wounds should be loosely packed with rope dressing.
Cover the Calcium Alginate Dressing with an appropriate secondary dressing and secure.

Removing the Dressing

Remove the secondary dressing and discard.
Next, remove the Calcium Alginate Dressing. If any portion of the dressing adheres to the wound bed, use Restore Wound Cleanser or normal saline to loosen the dressing before removal.
If needed, gently rinse away remaining gel or dressing fibers.
Apply new Calcium Alginate Dressing following steps above.

Graphical Symbols
Symboles graphiques
Simbolos Graficos

USA: 1-800-323-4060/FAX Order: 847-680-1017
CANADA: 1-800-263-7400/FAX Order: 1-800-432-8846
ÉTATS-UNIS: 1-800-323-4060
Commande par telecopieur: 847-680-1017
CANADA: 1-800-263-7400
Commande par telecopieur: 1-800-432-8846
www.hollisterwoundcare.com

hollisterwoundcare

Manufactured for:
Hollister Wound Care, LLC
Libertyville, Illinois 60048
Distributed in Canada by:
Distribue au Canada par:
Hollister Limited

Printed in U.K.
Imprime au Royaume-Uni.
Impreso en el R.U.

907688-A407

VALID FOR TWO DAYS FROM PRINT DATE

Hydrogel Impregnated Sponge

Indications: Maintenance of a moist environment in stages II-IV pressure ulcers, stasis ulcers, 1st and 2nd degree burns, skin tears, cuts and abrasions.

Directions: Cleanse wound, if indicated. Open pouch by peeling apart at top edge using aseptic procedure. Remove sponge from package and cover or pack wound with sponge. Cover with secondary dressing as required. Change sponge every 24 to 72 hours, or as required to maintain moist environment.

Warnings: For external use only. Avoid contact with eyes. If condition worsens or does not improve within seven days, consult a physician. Keep out of reach of children. In case of ingestion, seek professional help.

Ingredients: Water, glycerin USP 99.7%, sodium polyacrylate, propylene glycol USP, hyaluronic acid, sodium metabisulfite FCC, methylparaben NF, propylparaben NF.

Graphical Symbols
Symboles graphiques
Símbolos Gráficos

USA: 1-800-323-4060/FAX Order: 847-680-1017
CANADA: 1-800-263-7400/FAX Order: 1-800-432-8846

ÉTATS-UNIS: 1-800-323-4060
Commande par télécopieur: 847-680-1017
CANADA: 1-800-263-7400
Commande par télécopieur: 1-800-432-8846

www.hollisterwoundcare.com

hollisterwoundcare
An alliance of Hollister Incorporated and Laboratorios URGO

Manufactured for:
Hollister Wound Care, LLC
Libertyville, Illinois 60048

Distributed in Canada by:
Distribué au Canada par:
Hollister Limited
Aurora, Ontario L4G 1G3

Printed in USA.
Imprimé aux États-Unis.
Impreso en EE.UU.

907691-A407

Restore
Hydrogel Impregnated Sponge
Hydrogel Éponge imprégnée
Hydrogel Esponja impregnada
STERILE
STERILE
STERILE

Hollister®

US Calcium Alginate Dressing, Silver

CA Pansement d'alginate de calcium, argent

ES Apósito de alginato de calcio, plata

INSTRUCTIONS
MODE D'EMPLOI
INSTRUCCIONES

CalciCare™

STERILE R
Sterilization using irradiation
Stérilisation par irradiation
Esterilizado por medio de irradiación

Consult Instructions for Use
Consulter le mode d'emploi
Consulte las instrucciones de uso

Do not use if package is damaged
Ne pas utiliser si l'emballage est endommagé
No utilizar si el envase está dañado

Single Use
Usage unique
No las use más de una vez

Do not re-sterilize
Ne pas restériliser
No la vuelva a esterilizar

Keep dry
Garder au sec
Consérvelos secos

Keep away from heat
Garder à l'abri de la chaleur
Manténgalos alejados del calor

To be stored at 25°C/77°F
Conserver à 25°C/77°F
Conservar a 25°C/77°F

Rx Only

Federal (USA) Law restricts this device to sale by or on the order of a physician or other healthcare practitioner licensed under state law to order this product.

En vertu de la loi fédérale des États-Unis, ce dispositif ne peut être vendu que sur ordonnance d'un médecin ou d'un autre professionnel de la santé dûment autorisé conformément à la législation de l'État.

La ley federal (de EEUU) limita la venta de este dispositivo a médicos o bajo prescripción medica y a otros profesionales de la salud autorizados por la ley del estado a pedir este producto.

Hollister

US CalciCare Calcium Alginate Dressing, Silver

Product Description

CalciCare calcium alginate dressing, silver is a sterile, reinforced, non-woven pad composed of a high G (guluronic acid) calcium alginate, carboxymethylcellulose (CMC) and ionic silver complex (Silver Sodium Hydrogen Zirconium Phosphate), which releases silver ions in the presence of wound fluid. As wound fluid is absorbed the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing. The dressings are reinforced for intact removal.

The silver ions protect the dressing from a broad spectrum of microorganisms over a period of up to fourteen (14 days), based on in-vitro testing. Odor reduction results from the antibacterial effect in the dressing. CalciCare calcium alginate dressing, silver is an effective barrier to bacterial penetration.

The dressing protects the wound and aids autolytic debridement therefore facilitating wound healing.

Indications

CalciCare calcium alginate dressing, silver is indicated for moderate to heavily exuding partial to full thickness wounds such as:

- post-operative wounds
- trauma wounds (dermal lesions, trauma injuries or incisions)
- leg ulcers
- pressure ulcers
- diabetic ulcers
- graft and donor sites
- 1st and 2nd degree burns

This product can also be used under compression bandages.

As the product contains alginate, it may assist in supporting the control of minor bleeding in superficial wounds.

The dressing is suitable for use, under medical supervision, on wounds that are critically colonized. The dressing is indicated for external use only.

Contraindications

CalciCare calcium alginate dressing, silver is not indicated for use on the following:

- individuals with a known sensitivity to alginates or silver
- to control heavy bleeding
- direct application on dry or lightly exuding wounds

Precautions

Systemic antimicrobial therapy should be considered when wound infection is evident. CalciCare calcium alginate dressing, silver may be used, under medical supervision, in conjunction with systemic antibiotics.

The dressing may adhere if used on dry or very lightly exuding wounds. If the dressing is not easily removed, moisten it with sterile saline solution prior to removal.

The dressing performance may be impaired by excess use of petroleum-based ointments.

Avoid contact with electrodes or conductive gels during electronic measurements, e.g. electrocardiograms (ECG) and electroencephalograms (EEG).

The dressing must be removed prior to patients undergoing Magnetic Resonance Imaging (MRI) examinations.

In the event of clinical infection, topical silver does not replace the need for systemic therapy or other adequate infection treatment.

Clinicians/Healthcare Professionals should be aware that there is very limited data on prolonged and repeated use of silver containing dressings, particularly in children and neonates.

INSTRUCTIONS FOR USE

Site Preparation

- Debride when necessary and irrigate the wound site in accordance with standard protocols.
- Remove excess solution from surrounding skin.

Dressing Selection

- Select a size of dressing that is slightly larger than the wound.

Dressing Application

1. Cut (using sterile scissors) or fold the dressing to fit the wound. Loosely fill deep wounds, ensuring the dressing does not overlap the wound margins.
2. Apply to wound bed directly. Discard any remaining dressing material due to the risk of contamination.
3. Cover and secure CalciCare calcium alginate dressing, silver with a nonocclusive secondary dressing.

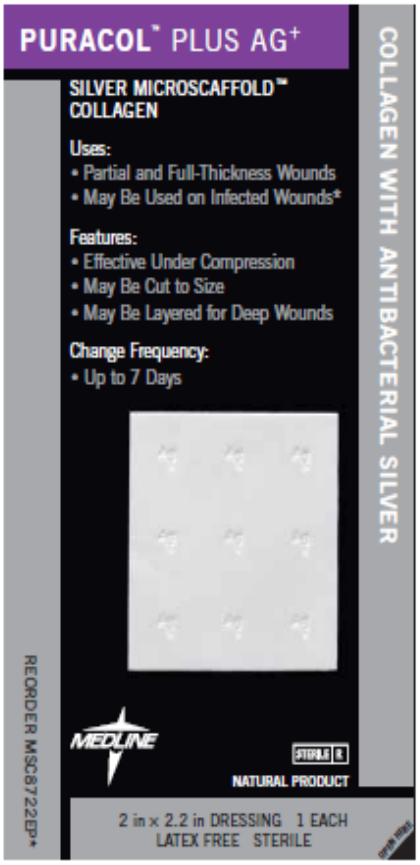
Dressing Change and Removal

1. Dressing change frequency will depend on wound condition and the level of exudate. Initially it may be necessary to change the dressing every 24 hours.
2. Reapply the dressing when the secondary dressing has reached its absorbent capacity or whenever good wound care practice dictates that the dressing should be changed.
3. Gently remove the secondary dressing.
4. If the wound appears dry, saturate the dressing with sterile saline solution prior to removal.
5. Gently remove the dressing from the wound bed and dispose of according to local procedures and guidelines.
6. Irrigate the wound site in accordance with standard protocols prior to application of a new dressing.

Appendix 2

"Collagen Indications for Use (IFUs)"

Product	**Manufacturer**
Puracol Plus AG+	Medline
Endoform Dermal Template	Hollister Woundcare
Fibracol Plus	Acelity
Promogran Prisma	Acelity
Promogran	Acelity
Biostep AG	Smith & Nephew



PURACOL™ PLUS AG+

SILVER MICROSCAFFOLD™ COLLAGEN

Puracol™ Plus is made of pure native collagen and helps provide an ideal environment for wound healing. May be used under compression or with infected wounds.*

Indications
Light to heavily draining, partial and full-thickness wounds.

Directions for Use

1. Remove Puracol™ Plus AG+ from the package.

2. The dressing should come in contact with on the wound. If necessary the dressing may be moistened with saline.

3. Cover with a secondary dressing.

NOTE: Puracol™ Plus AG+ may be cut if necessary.

Removal Instructions
Gently remove secondary dressing. As the dressing moistens it will form a gel, which rinses out of the wound easily. Puracol™ Plus AG+ is completely biodegradable.

Frequency of Dressing Change
Puracol™ Plus AG+ may remain in place for 7 days or be replaced at the discretion of a healthcare professional.

General Precautions and Observations
Puracol® Plus AG+ may be used when visible signs of infection are present in the wound, with proper medical treatment addressing the underlying causes.* Puracol® Plus AG+ may be used under compression therapy. Should any signs of irritation or sensitivity appear, discontinue use and consult a healthcare professional. Puracol® Plus AG+, an antibacterial wound dressing, is made of pure collagen and hydrated silver chloride at a concentration of 1.2%. Silver ions in the dressing have demonstrated an antibacterial effect against tested organisms in vitro: Pseudomonas aeruginosa, Staphylococcus aureus (MRSA), Escherichia coli and Staphylococcus epidermidis. RX Only.

Storage
Protect from freezing. Avoid excessive heat. Do not store above 25°C/77°F. Sterile in unopened, undamaged package. Single use only. Do not resterilize.

Contraindications
Not intended for use on wounds with active vasculitis, 3rd degree burns, or on patients with a known sensitivity to collagen or silver.

1-800-MEDLINE (1-800-633-5463)
www.medline.com/woundcare
Puracol® and Microscaffold™ are trademarks of Medline Industries, Inc. Patent No. U.S. 7,624,869. Manufactured in Germany by Dr. Suwelack Skin & Health Care AG, Billerbeck, for Medline Industries, Inc., Mundelein, IL 60060 USA
RG10IVT

*These directions apply to the following item numbers: MSC8722EP and MSC8744EP.

endoform
dermal template
matrice dermique • matrix dérmica

INSTRUCTIONS / MODE D'EMPLOI / INSTRUCCIONES

2" x 2" (5cm x 5cm)
2" x 2" (5cm x 5cm) Fenestrated / Fenêtrée / Ranurada
4" x 5" (10cm x 12.7cm)
4" x 5" (10cm x 12.7cm) Fenestrated / Fenêtrée / Ranurada

hollisterwoundcare

Endoform Dermal Template

PRODUCT DESCRIPTION
Endoform dermal template is an advanced wound care dressing comprised of approximately 90% natural, non-reconstituted collagen with the balance being secondary extracellular matrix associated macromolecules including elastin, fibronectin, glycosaminoglycans and laminin. Endoform dermal template is derived from ovine (sheep) extracellular matrix and it retains the innate biological structure and function of the native extracellular matrix. When rehydrated with wound exudate or sterile saline, Endoform dermal template transforms into a soft conforming sheet, which is naturally incorporated into the wound over time.

INDICATIONS FOR USE
Endoform dermal template 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, and wound dehiscence)
- Traumatic wounds (abrasions, lacerations, first and second degree burns, and skin tears)
- Draining wounds

℞ Caution: Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

SUGGESTED INSTRUCTIONS FOR USE
These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

1) Wound Preparation
a) Prepare the wound bed by cleansing, irrigation and, if necessary, debridement to ensure the wound is free of debris, necrotic tissue or infected tissue.

2) Dressing Application
a) Select a sheet of Endoform dermal template which is slightly larger than the wound and apply aseptically.
b) Endoform dermal template can be applied as a whole sheet or trimmed so it contacts the wound margins. Multiple sheets can be used to cover the entire wound bed.
c) For ease of handling, apply Endoform dermal template by placing the dry material in the wound and rehydrating with exudate or sterile saline until moistened. Ensure that Endoform dermal template conforms to the underlying wound bed. When rehydrated, Endoform dermal template transforms into a soft conforming sheet.
d) To protect Endoform dermal template from adhering to the cover dressing, consider applying a non-adherent dressing, such as Restore contact layer, over Endoform dermal template.
e) Secure the dressing using an appropriate cover dressing, such as Restore border foam dressing featuring TRIACT ADVANCED technology or Restore Hydro-Shield foam dressing. If antimicrobial properties are warranted, consider using Hydrofera Blue dressings. The secondary dressing should be changed according to standard of care taking into account the level of exudate.
f) Endoform dermal template is naturally incorporated into the wound over time.

3) Endoform dermal template can be used in conjunction with compression therapy and negative pressure wound therapy under the supervision of a health care provider.

4) Dressing Changes
a) Carefully cleanse the wound surface in accordance with established procedures. It is not necessary to remove the residual Endoform dermal template that forms, as it contains extracellular matrix components that assist in wound healing. Depending on the exudate color, the residual product may appear as an off-white to golden gel.
b) Reapply Endoform dermal template every 5–7 days or as needed, until the wound has re-epithelialized. Duration of treatment is determined by the physician and depends upon the wound type and conditions.
c) It is not necessary to remove any residual Endoform dermal template during dressing changes. However, if the product has been overlapped onto the periwound area, and if desired, the remaining loose product that has not incorporated into the wound may be gently removed around the edges.
d) Change the cover dressing as needed, and when Endoform dermal template is re-applied.

PRECAUTION FOR USE
- Do not apply to wounds with uncontrolled clinical infection, acute inflammation, excessive exudate or bleeding.
- Endoform dermal template is supplied as a sterile dressing. Do not use if the pouch seal is broken.
- Discard Endoform dermal template if mishandling has caused possible damage or contamination.
- Single use product. Do not attempt to re-sterilize. Discard all unused portions. To help reduce the potential for infection and/or other complications, do not reuse.
- Always handle Endoform dermal template using aseptic technique.

CONTRAINDICATIONS
- Endoform dermal template is derived from an ovine (sheep) source and should not be used on patients with known sensitivity to ovine (sheep) derived material.
- Endoform dermal template is not indicated for use on third degree burns.

STORAGE
Endoform dermal template should be stored between 15°C/59°F–40°C/104°F in a clean and dry area.

HOW SUPPLIED
Endoform dermal template is packaged in boxes of 10 dressings:

REF.		
	529311	2" x 2" (5cm x 5cm)
	529312	2" x 2" (5cm x 5cm), Fenestrated
	529313	4" x 5" (10cm x 12.7cm)
	529314	4" x 5" (10cm x 12.7cm), Fenestrated

Graphic Symbols
Symboles Graphiques
Símbolos Gráficos

Single Use.
Usage unique.
No los use más de una vez.

Use by expiration date YYYY-MM.
À utiliser jusqu'au MM-AAAA
Fecha de caducidad.

Keep dry.
Conserver au sec.
Mantener seco.

Latex free.
Sans latex.
Sin látex.

Do not use if package is damaged.
Ne pas utiliser si l'emballage est endommagé.
No usar si el envase está dañado.

Rx Only
Prescription only.
Seulement sur ordonnance.
Venta únicamente con receta.

Store between 15°C/59°F–40°C/104°F.
Conserver à une température entre 15 et 40 °C (59 et 104 °F)
Almacenar a 15 °C (59 °F) a 40 °C (104 °F).

STERILE EO
Sterilized with ethylene oxide.
Stérilisé à l'oxyde d'éthylène.
Esterilizado con óxido de etileno.

See instructions for use.
Voir le mode d'emploi.
Consulte las instrucciones de uso.

Keep away from heat.
Garder à l'abri de la chaleur.
Mantener lejos del calor.

USA: 1-888-740-8999 FAX Order: 1-847-680-1017
CANADA: 1-800-263-7400 FAX Order: 1-800-432-8846

www.hollisterwoundcare.com

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hollisterwoundcare

Manufactured for:
Hollister Wound Care
Libertyville, IL 60048 USA
Distributed in Canada by:
Distribué au Canada par:
Distribuido en Canadá por:
Hollister Limited
Aurora, Ontario L4G 1G3.
Made in New Zealand by:
Fabriqué en Nouvelle Zélande par:
Fabricado en Nueva Zelanda por:
Mesynthes Limited

Let's Promote™

FIBRACOL® PLUS

COLLAGEN WOUND DRESSING WITH ALGINATE

PANSEMENT AU COLLAGENE AVEC ALGINATE
APÓSITO DE COLÁGENO CON ALGINATO PARA HERIDAS
ALJİNATLI KOLAJEN YARA SARGISI

Natural product - approximate dimensions
Produit naturel - dimensions approximatives
Producto natural - dimensiones aproximadas
Doğal ürün - yaklaşık boyutlar

3.5"

LET'S HEAL™

EN Product Description

FIBRACOL® Plus Collagen Wound Dressing with Alginate is an advanced wound care device composed of collagen and calcium alginate fibers. FIBRACOL® Plus dressing contains 80% more collagen than our traditional FIBRACOL® Dressing. Its unique combination of natural biopolymers created by a patented process combines the structural support of collagen and the gel forming properties of alginates into a sterile, soft, absorbent, conformable topical wound dressing. In the presence of wound fluid FIBRACOL® Plus dressing maintains a physiologically moist microenvironment at the wound surface that is conducive to granulation tissue formation, epithelialization, and enables healing to proceed at a rapid rate. FIBRACOL® Plus dressing is versatile as a primary wound dressing, it can be cut to the exact size of the wound, multi-layered for the management of deep wounds and used in combination with either a semi-occlusive or non-occlusive secondary dressing.

Indications

FIBRACOL® Plus dressing is indicated for the management of exuding wounds including:

- Full-thickness and partial-thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Second-degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical incisions

Precautions

FIBRACOL® Plus dressing may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause. FIBRACOL® Plus dressing may be used under compression therapy with healthcare professional supervision.

Contraindications

FIBRACOL® Plus dressing is not indicated for wounds with active vasculitis, third-degree burns, or patients with known sensitivity to collagen or alginates.

Adverse Reactions

FIBRACOL® Plus dressing should not be used on patients with known sensitivities to collagen or alginates. Discontinue use if signs of sensitivity appear.

Directions for Use

- Debride when necessary and irrigate the wound site with normal saline solution.
- Remove excess solution from surrounding skin.
- For heavily exuding wounds, apply to wound bed directly. For wounds with minimal exudate, apply to moistened wound bed; this will initiate the gel forming process.
- Pack deep wounds loosely. The dressing can be cut to size with sterile scissors. The amount of FIBRACOL® Plus dressing to be used depends on the size of the wound and the amount of exudate.
- FIBRACOL® Plus dressing may be covered with either a non-occlusive secondary dressing and fixed to the skin with a non-irritating tape or a semi-occlusive dressing (e.g TIELLE® Hydropolymer Adhesive Dressing or TIELLE® Plus Hydropolymer Adhesive Dressing).
- Reapply FIBRACOL® Plus dressing when the secondary dressing has reached its absorbent capacity or whenever good wound care practice dictates that the dressing should be changed. A heavily exuding wound may require daily or twice daily dressing changes. More moderately exuding wounds will require less frequent changes (every 2 to 4 days or as directed by a healthcare professional).

Following the initial application, irrigate the wound with saline solution. Reapply FIBRACOL® Plus dressing as previously instructed.

Dressing Removal

After gently removing the secondary dressing, lift any FIBRACOL® Plus dressing that has not formed a gel and discard. Using normal saline, gently irrigate the wound to remove any residual gel.

Do not re-use.
Do not resterilize.
Do not use if package is damaged.
The use by date of this product is printed on the packaging.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a properly licensed healthcare practitioner.
This caution is not applicable outside the U.S.

Leaflet prepared: October 2011

LET'S HEAL™

PROMOGRAN PRISMA® MATRIX

Let's Promote™

USA Product description

PROMOGRAN PRISMA® Matrix is comprised of a sterile, freeze dried composite of 44% oxidized regenerated cellulose (ORC), 55% collagen and 1% silver-ORC. Silver-ORC contains 25 % w/w ionically bound silver, a well-known antimicrobial agent. In the presence of exudate, the PROMOGRAN PRISMA® Matrix transforms into a soft, conformable, biodegradable gel, and thus allows contact with all areas of the wound. PROMOGRAN PRISMA® Matrix, when covered with a semi-occlusive dressing, maintains a physiologically moist microenvironment at the wound surface. This environment is conducive to granulation tissue formation, epithelialization and optimal wound healing. PROMOGRAN PRISMA® Matrix provides an effective antibacterial barrier as demonstrated by the in-vitro reduction of bacterial growth with common wound pathogens such as, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli* and *Streptococcus pyogenes*. Reduction of bacterial bioburden in the dressing may result in reduced risk of infection. Literature reports of in-vitro testing indicate that collagen fibers provide a biodegradable matrix for cellular invasion and capillary growth. In laboratory testing, Collagen-ORC has been shown to absorb components of wound exudate.

PROMOGRAN PRISMA® Matrix is a primary dressing that can be cut to fit wound with scissors and used in combination with either a semi-occlusive or non-occlusive secondary dressing. Prior to application in dry wounds saline solution should be used to hydrate PROMOGRAN PRISMA® Matrix.

Indications for use

PROMOGRAN PRISMA® Matrix is intended for the management of exuding wounds.

Under the supervision of a health care professional, PROMOGRAN PRISMA® Matrix may be used for the management of:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full-thickness & partial thickness wounds
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds

PROMOGRAN PRISMA® Matrix may be used under compression therapy with healthcare professional supervision.

Precautions

PROMOGRAN PRISMA® Matrix may be used when visible signs of infection are present in the wound area, only when proper medical treatment addresses the underlying cause. PROMOGRAN PRISMA® Matrix is not intended to be a substitute for appropriate treatment of infection.

Clinicians/Healthcare Professionals should be aware that there are very limited data on prolonged and repeated use of silver containing dressings, particularly in children and neonates.

Contraindications

PROMOGRAN PRISMA® Matrix is not indicated for third-degree burns, or patients with known sensitivity to silver, ORC or collagen.

DIRECTIONS FOR USE

Storage

PROMOGRAN PRISMA® Matrix should be stored away from direct light. Over-exposure to light may cause some discolouration, however this does not affect the release of silver from the dressing. Store below 25 °C / 77 °F.

Prepare wound bed per your standard wound care protocol and debride when necessary.
For optimal effect, apply PROMOGRAN PRISMA® Matrix directly to the whole wound bed.

- For a wound with low or no exudate apply PROMOGRAN PRISMA® Matrix and hydrate with saline solution. This will initiate the transformation of the PROMOGRAN PRISMA® Matrix into a gel.
- After hydration, through exposure to wound exudate or saline, the PROMOGRAN PRISMA® Matrix gel will intimately come into contact with the wound surface.
- The biodegradable PROMOGRAN PRISMA® Matrix gel is naturally absorbed into the body over time.
- In order to maintain a moist wound healing environment PROMOGRAN PRISMA® Matrix must be covered with a semi-occlusive dressing (e.g. BIOCLUSIVE® Transparent Dressing, TIELLE® Hydropolymer Dressing or TIELLE® Plus Hydropolymer Dressing) or a non-occlusive secondary dressing and fixed to the skin with a non-irritating tape.
- After initial application, reapply PROMOGRAN PRISMA® Matrix to the wound daily or per physician recommendation. It is not necessary to remove any residual PROMOGRAN PRISMA® Matrix during dressing changes.

Do not use if package is damaged.
The use by date of this product is printed on the packaging.
Do not resterilize.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a properly licensed healthcare practitioner.
This caution is not applicable outside the U.S.

Leaflet prepared: October 2011

LET'S HEAL™

Let's Promote™

PROMOGRAN®

MATRIX WOUND DRESSING
PANSEMENT À MATRICE

(USA) Product description

PROMOGRAN® Matrix Wound Dressing is an advanced wound care device comprised of a sterile, freeze dried composite of 45% oxidized regenerated cellulose (ORC) and 55% collagen. In the presence of exudate the PROMOGRAN® Dressing transforms into a soft, conformable, biodegradable gel, and thus allows contact with all areas of the wound. PROMOGRAN® Dressing maintains a physiologically moist microenvironment at the wound's surface. This environment is conducive to granulation tissue formation, epithelialization and rapid wound healing. PROMOGRAN® Dressing is a primary dressing that can be cut to fit wound with sterile scissors and used in combination with either a semi-occlusive or non-occlusive secondary dressing. Prior to application in dry wounds saline solution should be used to hydrate PROMOGRAN® Dressing.

Indications for use

PROMOGRAN® Dressing is intended for the management of exuding wounds including:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full thickness & partial thickness wounds
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds

PROMOGRAN® Dressing may be used under compression therapy with healthcare professional supervision.

Precautions

PROMOGRAN® Dressing may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause.

Contraindications

PROMOGRAN® Dressing is not indicated for wounds with active vasculitis, third-degree burns, or patients with known sensitivity to ORC or collagen.

DIRECTIONS FOR USE

Wound Bed Preparation

Prepare wound bed per your standard wound care protocol and debride when necessary. Wound bed should be clear of any visual signs of infection.

Application

- For optimal effect, apply PROMOGRAN® Dressing directly to the whole wound bed.
- For a wound with low or no exudate apply PROMOGRAN® Dressing and hydrate with saline solution. This will initiate the transformation of the PROMOGRAN® Dressing into a gel matrix.
- After hydration, through exposure to wound exudate or saline, the PROMOGRAN® gel matrix will intimately come into contact with the wound's surface.
- The biodegradable PROMOGRAN® gel matrix is naturally absorbed into the body over time.
- In order to maintain a moist wound healing environment PROMOGRAN® Dressing must be covered with a semi-occlusive dressing (e.g. BIOCLUSIVE® Transparent Dressing, TIELLE® Hydropolymer Dressing or TIELLE® Plus Hydropolymer Dressing) or a non-occlusive secondary dressing and fixed to the skin with a non-irritating tape.
- After initial application, reapply PROMOGRAN® Dressing to the wound up to every 72 hours depending upon the amount of exudate. It is not necessary to remove any residual PROMOGRAN® Dressing during dressing changes.

Adverse Reactions

PROMOGRAN® Dressing is contraindicated for patients with known hypersensitivity to the components of this product, i.e. ORC and Collagen. Discontinue use if signs of sensitivity appear.

Do not use if pouch is damaged.
The use by date of this product is printed on the packaging.
Do not resterilize.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a properly licensed healthcare practitioner.
This caution is not applicable outside the U.S.

Leaflet prepared: October 2011

PRODUCT: PROMOGRAN®.	**COLOURS:** PMS 2587 (Purple) & PMS Process Black.
CODE: PG004 & PG019	**DATE:** 11.10.2011
PRODUCT DESCRIPTION: MATRIX WOUND DRESSING.	**AVC #:** PM00175.e
LANGUAGES: English & French.	**BARCODE(S):** None.
SIZE: (Sheet Size) 128.25mm (H) x 348mm (W) (Folded: 64.125mm (H) x 87mm (W)).	**SYMBOLOGY:** N/A.
	VERSION NUMBER: 02.

smith&nephew

BIOSTEP® Ag

Collagen Matrix Dressing with Silver
Matrice de collagène avec argent
Apósito matriz de colágeno con plata

Sterile unless opened or damaged.
Stérile tant que l'emballage est intact.
Estéril mientras el envase se encuentre intacto.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured in the USA for/Fabriqué aux États-Unis pour/Fabricado en USA para:
Covalon Technologies Ltd.,
Mississauga (Ontario) L4Z 3E6 Canada

Distributed in USA by/
Distribué aux États-Unis par/Distribuido en USA por:
Smith & Nephew, Inc.
Largo, FL 33773 USA

www.smith-nephew.com

PI 02273-A

ENG

BIOSTEP® Ag Collagen Matrix Dressing with Silver is an advanced wound care dressing composed of collagen, sodium alginate, carboxyl methylcellulose, ethylenediaminetetraacetic acid (EDTA) and silver chloride.

Properties and mode of action

BIOSTEP Ag Collagen Matrix Dressing is a topically applied wound dressing designed to transform into a soft gel sheet on contact with wound exudate. It maintains a moist wound environment at the wound surface that aids in the formation of granulation tissue and epithelialization. The EDTA in the dressing binds the zinc which is essential to matrix metalloproteinases (MMP) function. The removal of zinc inhibits the activity of the MMPs creating a suitable environment for wound healing. The dressings act as an effective barrier to bacterial and fungal penetration. The silver content is intended to prevent colonization of the dressing. The dressings may be cut to shape and layered for the management of deep wounds.

Indications for Use

BIOSTEP Ag is indicated for management of full and partial thickness wounds including: pressure ulcers, diabetic ulcers, ulcers caused by mixed vascular aetiologies, venous ulcers, donor and graft sites, abrasions, traumatic wounds healing by secondary intention, dehisced surgical wounds, first and secondary degree burns.

Directions for use

- Prior to application, the wound bed should be debrided and then irrigated with an appropriate wound cleanser or water. The use of saline could affect the efficacy of the silver.
- The dressing should be cut to fit the wound size exactly. For heavily exudating wounds, the dressing should be applied directly to the wound bed. For dry wounds with minimal exudate, the wound bed should be moistened with water to begin the gelling process.
- BIOSTEP Ag should be covered with a suitable secondary dressing.
- Dressings may be left in place for up to 6 days depending on the level of exudate or as good nursing practice dictates.

Dressing Removal

- Remove secondary dressing with care. Gently remove BIOSTEP Ag Collagen Matrix Dressing with Silver ensuring that the dressing removal does not damage delicate newly-formed tissues.
- Cleanse the wound site using an appropriate wound cleanser or water prior to application of a new BIOSTEP Ag as per application instructions.

Contraindications

BIOSTEP Ag Collagen Matrix Dressing with Silver should not be used on patients with a known allergy or sensitivity to porcine collagen, to silver, any other ingredient or on third degree burns.

Active Ingredient

BIOSTEP Ag contains silver chloride whose purpose is to reduce the incidence of bacterial colonization within the wound dressing.

Precautions

- If sensitivity to BIOSTEP Ag develops, discontinue use.
- BIOSTEP Ag dressings may be used under compression therapy under the supervision of a health care professional.
- United States' federal law restricts this device to sale by or on the order of a physician.

Product Availability

Code	Size	Availability
#66800126	2" x 2" (5cm x 5cm)	10 Dressings per box
#66800122	4" x 4" (10cm x 10cm)	10 Dressings per box