



## ADVANCED WOUND CARE COLLAGEN DRESSINGS MEDIFIL® II AND SKIN TEMP® II

### Introduction of Human BioSciences, Inc.

Human BioSciences, Inc. takes pride in being a key-leading distributor, manufacturer, and multinational biotechnology company in the advanced wound care product industry for almost thirty-years. Medifil® II and Skin Temp® II collagen products are manufactured in the USA. HBS's meticulous manufacturing methods, processes, and quality systems deliver highest quality, biologically active products at a lower cost. Kollagen™ Technology enables products to have a longer shelf life of 5 years.

### Proprietary Manufacturing: Kollagen™ Technology

The goal with collagen technology dressings are to reduce protease activity, while converting the wound to a healing state. Collagen advanced wound care dressings are proving to be a catalyst in wound chronicity by stimulating tissue growth, promoting autolysis, encourage angiogenesis, collagen deposition, and moving wounds towards re-epithelialization.

Human BioSciences, Inc. (HBS) products are made using a proprietary manufacturing technique called Kollagen™ Technology. This biotechnology process provides highest quality collagen products by retaining the collagen triple helical protein molecule shape and keeping in its "purest" form through our carefully designed manufacturing process. Understanding functional properties such as the biological activity of biomolecules and modalities are essential in selecting the appropriate collagen dressing and its technology. HBS's Kollagen™ Technology provides the "only" intact collagen products to the tissue regeneration arena.



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HBS products are 100% non-hydrolyzed type I bovine (cattle) native collagen. Non-hydrolyzed collagen retains significantly more of its native triple helical shape, thereby allowing for better stability of the molecule and scaffolding moving wounds towards healing trajectory. Human BioSciences, Inc. has carefully bioengineered a proprietary Kollagen™ technology process to ensure collagen molecules retain bioactivity and keep collagen in its *purest* form, therefore this process binds and inactivates excessive MMPs found in chronic wounds.

## Introduction of Collagen's Vital Role

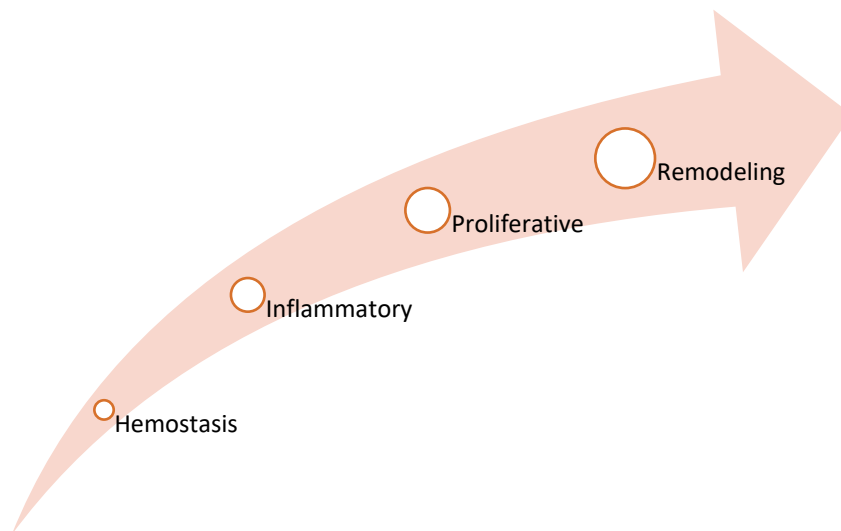
Collagen products are used in medicine for many purposes including wound care dressings and other matrices for tissue regeneration. Collagen is the most abundant protein in the human body constituting 85% of the dry weight of the skin. There is a total of 19 types of collagen proteins in the human body including type I, III, and V being the primary constituents of skin, thus are the most important for tissue regeneration. Type I is the most abundant of all three collagen types. It occupies more than 90% of the tissue and is the most dominant. This type is most used in assisting in the wound healing process. Huma BioSciences, Inc. extracts Type I bovine collagen from cattle hide. However, collagen can be extracted from any animal source.

The skin is the largest organ and approximately is two-thirds collagen. The collagen molecule is made up of various amino acid chains. Collagen has a unique composition of Gly-X-Y containing approximately 14% hydroxyproline. Collagen's structural material provides integrity, strength, and flexibility. The structure is determined by three helices intertwined forming a superhelix molecule. Therefore, molecules cross-link together giving rise to fibrils, fibers, and tissues.

Collagen also plays a vital role in all phases of wound healing providing not only structural support, but cellular functions including shape, differentiation, migration, and synthesis of proteins. The role of collagen in healing is vital due to its integral component. The collagen reaction consists of host cells like macrophages that regulate the entire healing process. Collagen provides an environment for cells which actively form the tissue regeneration. Remodeling occurs when the collagen deposited into the wound that imparts strength to the new tissue over time.



## Collagen Works in Every Phase of Wound Healing

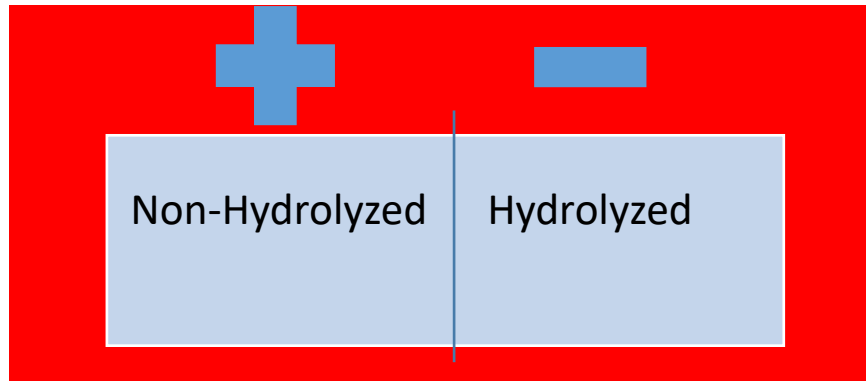


### Non-Hydrolyzed Collagen vs. Hydrolyzed Collagen

HBS's products are non-hydrolyzed collagen in its "purest form". Non-hydrolyzed collagen retains significantly more native triple helical protein structure, therefore allowing superior stability of the molecule and scaffolding in wound healing. It is vital that collagen retains its triple helix shape to enhance thermal durability, mechanical strength, and ability to engage in precise interactions with other biomolecules.

When collagen molecules lose their triple helix shape by fragmentation, the role transitions into more of a renewed state by activating monocytes therefore creating more macrophages etc. Collagen particles or powders that are nonhydrolyzed may enable better scaffolding and cell migration for developing granulation tissue.

Hydrolyzed collagen's main disadvantage is it cannot form scaffolds by itself due to low molecular weight of peptides but can be mixed with other copolymers such as cellulose and chitosan. It is "dead-protein". This type of collagen is produced primarily from connective that is not bioavailable. The derived source must undergo hydrolysis, and aggressive chemical process, therefore is composed of amino acids that are 'post-collagen'.



Hydrolyzed Collagen is broken down into its component amino acids, glycine, proline, and hydroxyproline, therefore, no longer retains its native triple helical structure or “purest form”. Hydrolyzed collagen fragment in the form of particles or powder create more active sites in the wound bed to support binding of fibronectin and improved fibroblast activity.

### **Human BioSciences, Inc. Products: Properties and Features**

Properties and features for products Medifil® II collagen particles and Skin Temp® II collagen sheets are not only cutting-edge technology, but also compatible, multifaceted, and effective.

#### **Medifil® II and Skin Temp® II Properties and Features**

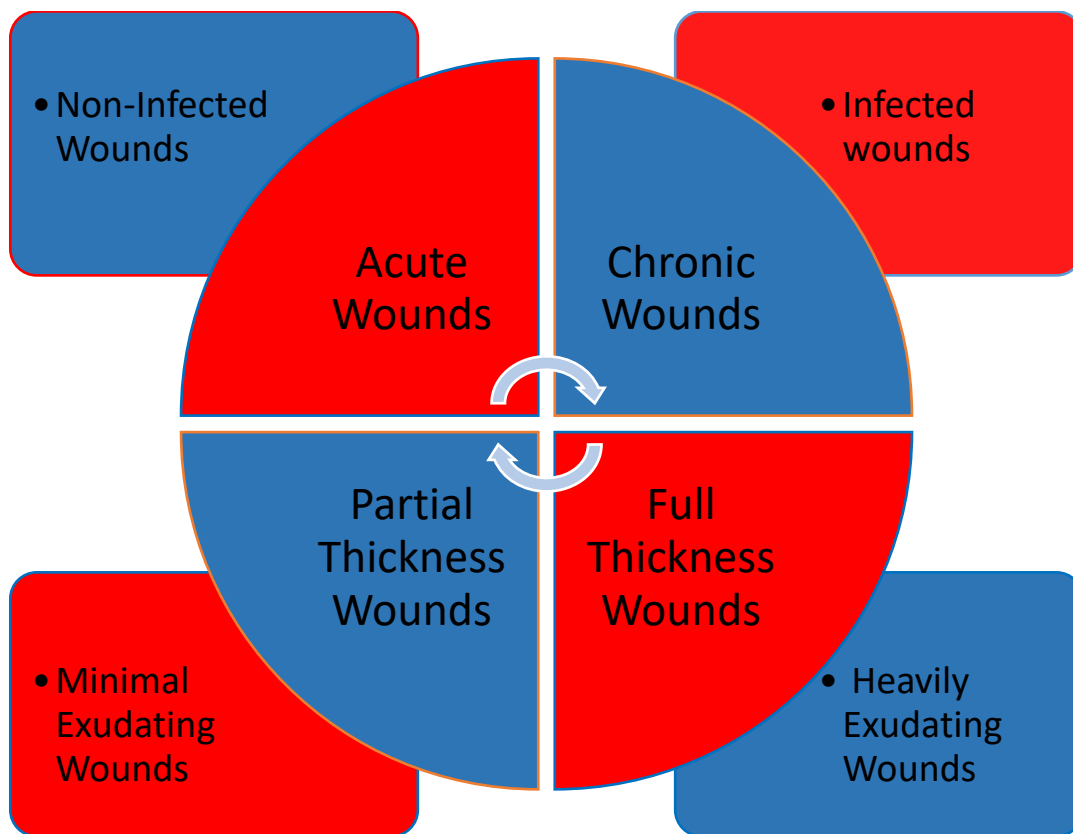
- Promotes angiogenesis
- Faster healing rates
- Decreases MMP levels found in chronic wounds
- Compatibility with topical agents and other secondary dressings
- Absorbent properties
- Hemostatic properties
- Maintains moist-wound healing
- Cuttable – collagen sheets
- Easy use in undermining and tunneling – collagen particles
- Compatibility with topicals and dressings
- Various sizes
- 5-year shelf life

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## Clinical Indications: Medifil® II and Skin Temp® II

Indications for Medifil® II and Skin Temp® II include acute and chronic wounds, partial and full-thickness wounds, non-infected and infected wounds, and minimal to heavily exudating wounds. Do not use on third-degree burns or patients with bovine sensitivities. Easy application and product compatibility with other topical agents and or dressings. If there is undermining and or tunneling in deeper wounds, gently push product into the spaces loosely.



## Human BioSciences, Inc. Products

Human BioSciences, Inc. provides highest quality and lowest priced collagen products. Directly contact [info@humanbiosciences.com](mailto:info@humanbiosciences.com) or toll-free (888)565-5243.

<p>Medifil® II Collagen Particles HCPCS A6010 1 gram vials OR 1 gram pouches.</p>
<p>Skin Temp® II Collagen Sheets 2"x2" HCPCS A6021 3"x4" HCPCS A6021 8"x12" A6023</p>

## Application and Purpose

The dressing change frequency is based on the wound assessment, exudate amount, physician order, and dressing manufacturer guidelines. Depending on the dressing, the product may have different wear times available, i.e. 1-7 days. Most wounds require a secondary dressing such as transparent film, composite, hydrocolloid, gauze, foam etc. The purpose is to deliver evidence-based advanced wound care while utilizing established and developed medical standards to optimize wound healing outcomes.

- ✓ Acute or Chronic Wounds
- ✓ Minimal to Heavy Exudate
- ✓ Partial or Full Thickness Wounds
- ✓ Non-Infected or Infected Wounds
- ✓ Compatible with topical agents and dressings
- ✓ Do not use on third-degree burns
- ✓ Do not use in patients with bovine sensitivities



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## Documentation to Support Medical Necessity

When ordering wound care or surgical dressings, it is vital that documentation supports the medical necessity for products billed to Centers of Medicare and Medicaid Services (CMS) for reimbursement. Below are helpful tips to ensure documentation supports current guidelines provided by CMS.

### *Documentation Criteria to Support Medical Necessity in Billing Reimbursement*

1. Weekly wound assessment (every 7 days)
  2. Wound location
  3. Wound type – pressure, diabetic, venous, arterial, surgical, trauma, and other.
  4. Depth of tissue involvement – partial-thickness, full-thickness, undermining, tunneling, exposed structure.
  5. Exudate amount – dry, scant, minimal, moderate, heavy, copious
  6. Exudate consistency – color, odor
  7. Wound bed tissue type(s) or color(s)
  8. Periwound, wound edges, and surrounding skin
  9. Pain level – location, duration, frequency
- Dressing size is determined by wound measurements that may or may not include periwound. A larger dressing may be used if the clinical rationale supports product size.
  - Physician progress note/wound note must substantiate advanced wound care products and frequency of change.

Wound photos can be used as an adjunct to documentation. Always follow your policy and procedures.

- Physician detailed written order must be signed and dated for each product billed, including # of dressings and directions for us. Orders may be placed every 30 days per Medicare Part B guidelines.
- The physician will monitor wound progress and treatment plan weekly and make changes to treatments as appropriate if no wound healing progress >2 weeks.



## Conclusion

A complete wound assessment is imperative in the clinical rationale and justification of appropriate dressing usage. Healthcare clinicians should be familiar with their facility formulary, dressing categories, indications, and contraindications. Collagen dressings that have been shown to move chronic complex wounds towards healing trajectory when used in conjunction with wound bed preparation, moist-wound healing, offloading/redistribution, and ongoing education. Healthcare professionals should take into consideration when selecting advanced wound care products, the quality, product properties, affordability, and availability.

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# Our **Kollagen™** technology sets the standard for **Wound Care**

based on intact collagen – the body's natural healing material



## SkinTemp® II Collagen Sheets

Bovine collagen scaffolds bioengineered with our proprietary Kollagen™ technology with a non-woven fabric backing for easy application



HCPCS: A6021, A6023

### Indications:

SkinTemp® II Collagen Sheets are indicated for the management of burns, sores, blisters, scrapes and ulcers as well as acute & chronic wounds; superficial, partial & full-thickness wounds; non-infected & infected wounds; minimal to heavily exuding wounds.

### Precautions:

- SkinTemp® II should not be used on third-degree burns.
- All open and unused portions must be discarded
- Do not use if sensitive to materials of bovine origin

## Medifil® II Collagen Particles

Bovine collagen fibers bioengineered for advanced wound care applications using our proprietary Kollagen™ technology



HCPCS: A6010

### Indications:

Medifil® II Collagen Particles are indicated for the management of burns, sores, blisters, scrapes and ulcers as well as acute & chronic wounds; superficial, partial & full-thickness wounds; non-infected & infected wounds; minimal to heavily exuding wounds.

### Precautions:

- Do not pack the wound tightly; allow for expansion of the particles
- Apply collagen particle 1/4" to entire wound bed surface area.
- Treatment of underlying condition (venous or arterial flow, pressure, etc.) should proceed concurrently with the use of Medifil® II
- Medifil® II is insoluble collagen and should never be used as an injectable soluble collagen
- All open and unused portions must be discarded
- Do not use if sensitive to materials of bovine origin

All products are reimbursable  
in the USA

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