

COCOHEAL[®]

Bio-cellulose Occlusive Wound Dressing

SCIENTIFIC DATA ON PRODUCT
PERFORMANCE



**ADVANCED WOUND
MANAGEMENT**

ISO 13485 CERTIFIED

PATENTED

CDSCO/MDA APPROVED

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Accelerated Wound Healing

Cocoheal works on the principles of moist wound healing which is shown to have at least 50% faster healing rate

Versatile

Cocoheal is versatile enough to be used for multiple wound conditions such as burns, diabetic ulcers, pressure ulcers, ischemic wounds, venous ulcers etc

Infection Prevention

The coconut derived monolaurin infused into Cocoheal is known to be a wide spectrum anti-microbial and helps prevent infection from external sources

Absorbs Exudates

The nano-porous structure of Cocoheal helps absorb exudates from wound bed

Autolytic Debridement

The Occlusive nature of Cocoheal helps in autolytic debridement of necrotic tissue at wound site

Reduced Scars and inflammation

The moist environment maintained by Cocoheal helps faster re-epithelization while reducing scar formation and inflammation

Soothing

The application of Cocoheal to wound site provides an instant relief by providing a cool and soothing effect



Benefits of Cocoheal

- Protects wound and provides a selective barrier effect.
- Reduces risk of infection from external sources.
- Maintains optimal moisture content at wound site and minimizes risk of over drying of wound.
- Provides a soothing effect at wound site and helps to greatly relieve pain.
- Absorbs and holds exudates within its matrix while donating moisture to the wound bed.
- It promotes autolytic debridement by liquifying necrotic tissue and discharging it through the exudates and maintains an optimal pH at wound site.
- Its unique hydrophilic properties helps it adhere to the wound and conform well to the bed but does not macerate the healing tissues and helps painless removal of dressing.
- It is translucent and helps to observe the healing wound without removal of dressing.
- In case of deep wounds, the dressing can be cut into strips and packed into the wound cavity.
- Increases re-epithelization and reduces scar formation.
- It is 100% bio-degradable

Indications of Use

COCOHEAL bio-cellulose occlusive wound dressing is indicated for use on minor burn, radiation burns, dry to moderately exudating wounds such as cuts, pressure, ulcers (partial and full-thickness) traumatic injuries, abrasions, skin graft donor site and other skin breaks which are not showing signs of normal healing.

On acute surgical wounds post suture removal for reduced scaring.

Contraindications

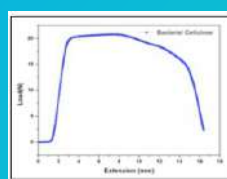
Contraindicated for use on individuals with an allergy to monolaurin, on third-degree burns, infected wounds, to control heavy bleeding or wounds with heavy exudates.

COCOHEAL bio-cellulose occlusive wound dressing is a patented, first of its kind product developed through biologic process for healing chronic wounds such as diabetic foot ulcers, burns, pressure ulcers, ischemic ulcers etc. It works on the latest concept of moist wound healing. It is an all-natural moisture dressing composed of 98% moisture and is incorporated with coconut derived monolaurin for faster wound healing and skin regeneration. It has a high nano-porous structure and acts as a temporary skin substitute. The monolaurin infused within the cellulose matrix is classified as GRAS (Generally regarded as Safe) by USFDA and aids in the skin regeneration while providing broad-spectrum protective effect from external infections.

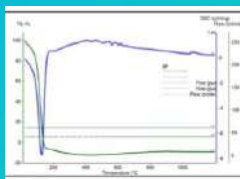
COCOHEAL is an indigenous product developed with support from the Government of India's Science & technology department's research fund. It is approved by the Indian Drug Control Authority CDSCO and ISO 13485 certified

Stability

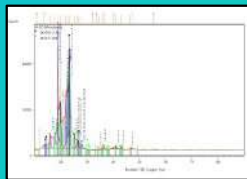
Cocoheal bio-cellulose dressing has been extensively tested for all critical physical properties to establish the stability of the product throughout its lifecycle. It has been tested for parameters such as Tensile Strength, Thermogravimetric analysis, X-Ray diffraction (XRD) and Thermal Degradation. The findings has ensured that the material meets the required strength, Physical & thermal stability and elasticity to deliver superior performance.



Tensile Test



Thermal Test



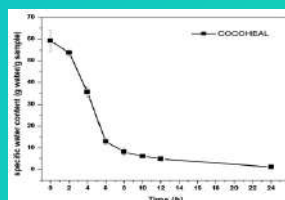
X-ray Diffraction

Tensile Strength	17.8 MPa
Pyrolytic Decomposition	450°C
Elongation at Break	109%
Crystallinity	74%

Exudate Absorption & Moisture holding Capacity

Superior Hydrostatic properties are a requirement for wound dressing to ensure it is capable of holding enough moisture to deliver at the wound bed at a controlled rate. The dressing should be capable of absorbing and holding exudates from the wound bed. It is also critical that the dressing has good hydrophilic properties such that it adheres and conforms well to the contours of the wound site. Cocoheal bio-cellulose dressing is found to have one

of the highest moisture holding capacity among wound dressings and is capable of holding moisture upto 60 times its weight. It is also found to have a Moisture Vapor Transmission rate of 11088.31 g/m²/24h



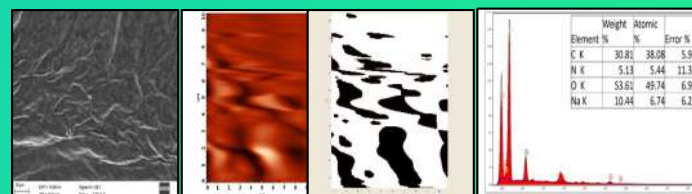
Water Holding Capacity



Contact Angle of less than 90 degree

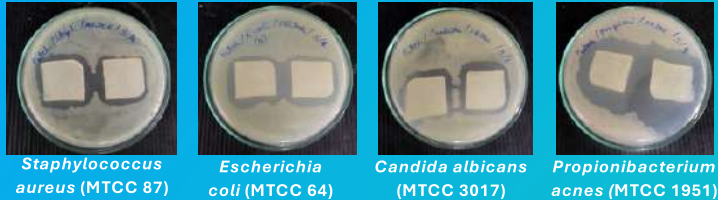
Permeability

Nano-characterization studies has been carried out on Cocoheal to study its structural construct using Scanning Electron Microscope, Atomic Force Microscope and Energy-dispersive X-ray spectroscopy (EDS). It has been identified that Cocoheal has highly uniform meso-porous and uniform matrix made of naturally occurring polysaccharides with nano-fiber diameters of 20 nanometers. EDS has confirmed high purity of the nano-fibers with no elemental impurities. These results establishes the high water holding and exudate absorption capacity of Cocoheal dressing. It also helps in gaseous exchange and to replenish oxygen to the wound site.



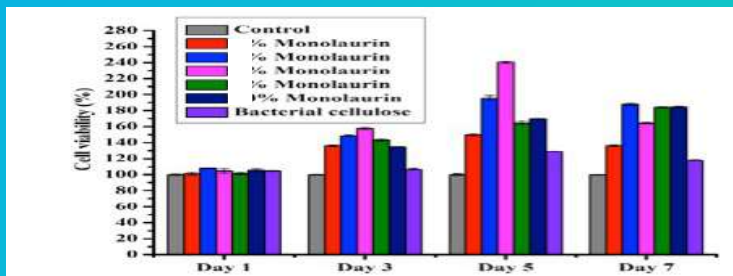
Anti-microbial Properties

The coconut derived compound Monolaurin found in Cocoheal, has been tested for its anti-microbial properties through zone of inhibition studies on clinically isolated pathogens and it has shown to have a wide-spectrum effect on these organisms.



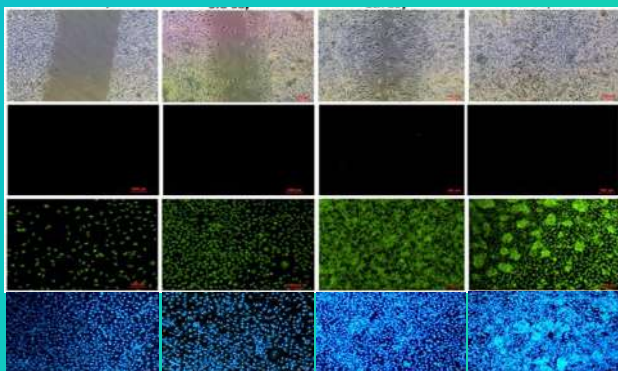
Accelerated Cell Regeneration

Cocoheal has been tested for bio-compatibility through in-vitro studies on L929 fibroblast cell lines. It was established that the cells viability increased by upto 220% when compared to the control. This result establishes that the monolaurin and bio-cellulose works synergistically to accelerate cell proliferation while still maintaining anti-pathogenic properties.



Bio-Compatibility

The bio-compatibility properties of Cocoheal was studies using scratch test method, where fibroblast cells were grown in-vitro on Cocoheal bed. It was identified that the fibroblast cells proliferated, closing the scratch region within a time frame of 7days. MTT assay carried out post this study established that there was no dead fibroblast cells on the bed of Cocoheal. These findings establish the excellent bio-compatibility of the product.



Scratch test, live-dead staining, Hoechst fluorescence staining

Bio-Degradability

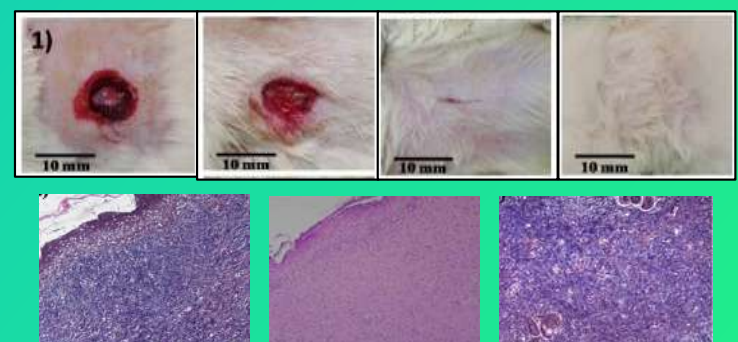
Most of the Advanced Wound Care products currently available in the market currently are of petro-chemical origin and not bio-degradable. Our Cocoheal bio-cellulose dressing is 100% bio-compatible and bio-degradable causing no harm to the environment in its production process or post its useful life time. In fact, we have identified that our dressing completely degrades in landfill within 60 days time, reaching only 5% of its initial mass, with no recycling efforts.



Bio-degradability tests in landfill

Healing on Animal Models

As part of our pre-clinical studies, wound healing properties of Cocoheal was tested on diabetic rat models. Our product was compared with an already well-established Advanced wound care product in the market. It was observed that the wound periphery started reducing from the 5th day of application for Cocoheal treated rats. On the 15th day, it was observed that the wound had completely healed with very minimal scar formation and complete hair growth on the healed wound. Whereas, on the competing product, the healing was incomplete on the 15th day with no visible hair follicle formation. Histopathological studies on the regenerated dermis layer were carried out following single blinded procedure. It was revealed that there was mature collagen formation with no evidence of inflammation. Healing scores were arrived at based on the quantity and type of collagen formation, rate of granulation and inflammatory response. It was observed that Cocoheal Bio-cellulose dressing scored better the commercially available product.



Wound healing & histopathological observation on rat models

Tunneling Ulcer

Gender: Male

Age: 71 Years

Wound Since: Jan 2023

Wound Type: Diabetic Ulcer

Observation: Patient with diabetics for 20 years. Was recommended for foot amputation after several grafting failures. Application of Cocoheal has helped towards complete closure of tunneling wound.



Day 0



Day 21



Day 39

Diabetic Cavity Ulcer

Gender: Male

Age: 67 Years

Wound Since: 3 Years

Wound Type: Diabetic Ulcer

Comorbidities: Blood pressure, kidney transplantation, Heart surgery with stent and tablet



Day 0



Day 6



Day 18

Radiation Burns

Gender: Male

Age: 64 Years

Wound Since: July 24

Wound Type: Radiation burns from cancer treatment

Observation: Patient was diagnosed with lymph node cancer and had to undergo radiation therapy for cancer treatment. In the process patient developed severe radiation dermatitis. Treatment with Cocoheal helped patient recover from the burns in a very short period.



Day 0



Day 9



Day 19

Burns

Gender: Male

Age: 53 Years

Wound Since: On date

Wound Type: 1st Degree burn

Observation: Re-epithelization was clearly visible on the 8th day. Patient felt comfortable with considerable pain reduction after application of Cocoheal Dressing



Day 0



Day 8

Thermal Burn

Gender: Male

Age: 40 Years

Wound Since: 1 Year

Wound Type: Silencer Burn

Background: Patient with diabetes for 8yrs got infected in right leg due to silencer burn. Was recommended for foot amputation after several treatment. Application of Cocoheal has helped towards healing of silencer burn wound in his leg.



Day 0



Day 20



Day 48

Diabetic Cavity Ulcer

Gender: Male

Age: 53 Years

Wound Since: 5 Years

Wound Type: Diabetic Ulcer

Observation: Patient with diabetic wound for 5 yrs in his right leg. He was recommended for skin transplantation. Followed various treatment for 3yrs . Application of Cocoheal has helped towards healing of diabetic wound in his leg.



Day 0



Day 22



Day 38

Venous Ulcer

Gender: Female	Age: 60 Years	Wound Since: 9 months
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Wound Type: Varicose Veins

Observation: patient suffering from varicose veins for 9 months. Application of Cocoheal helped patient in healing wound within a span of 28 days.



Day 0



Day 28

Diabetic Cavity Ulcer

Gender: Male	Age: 62 Years	Wound Since: 4 months
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Wound Type: Diabetic Ulcer

Observation: Observation: Patient with diabetes and cardiac problem for 18 yrs got infected in right leg due to diabetes. Took prescriptions and ointment for the wound. Application of Cocoheal has helped towards healing of diabetic wound in his leg.



Day 0



Day 38



Day 78



Global Doctors Hospital

wholly owned by GDM Specialist Centre (Mont' Kiara) Sdn Bhd (754478-A)

Specialist Clinics, Day Surgery, Radiology & Imaging, Dental Specialist, Physical Medicine

25.6.24

To whom it may concern,

Mr. Parsi Siavash, a patient with underlying uncontrolled diabetes, unfortunately developed a severe diabetic foot ulcer in October. The wound was extensive and required meticulous care and advanced wound management strategies.

Initially, we started treating the wound with antiseptic solution and Aquacel dressings with oxygen therapy. While these treatments provided benefit and positive progress, it was in February, upon introducing Bio-cellulose to the regimen, that we witnessed remarkable progress. The healing process accelerated significantly, surpassing our expectations.

This case has reinforced our belief in a holistic approach to wound management. By combining appropriate nutritional support and effective diabetes management with an advanced wound dressing materials, we have seen tremendous benefits for our patients. Mr. Parsi's experience underscores the importance of integrating comprehensive care strategies to achieve optimal outcomes in wound healing. We are thrilled with his progress and are committed to continuing this approach for all our patients with similar conditions.

Please do not hesitate to contact me if you need any further information.

Thank you

Yours sincerely,

Dato Dr Surendranath K. Menon MBBS, MRCP(UK), FRCP AM
Consultant Resident Internal Physician
Global Doctors Hospital

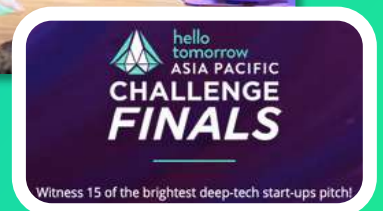
Product Development funded by Government of India's BIRAC and Startup India Grants

Ardor Biomed was recognized as one among **top 75 most innovative startups in India** creating substantial impact to the society by the Startup India initiative. Ardor's products were shortlisted to be displayed at the National Science Center, New Delhi, to recognize scientific achievements during 75th year of Indian Independence.



Ardor Biomed was recognized with the STAR STARTUP 2022 award by the prestigious Ramaiah Evolute program at Bangalore

Ardor Biomed has been shortlisted as the **only Indian startup among top 15 in Asia-Pacific region** to participate in the grand finale pitch fest to be held at Singapore on 5th Sept, 2022. Hello Tomorrow is a global non-profit on a mission to unlock the potential of deep technologies to help solve some of the world's toughest challenges. We have been recognized as a deep tech Pioneer by the scientific forum.



Innovation award was presented for CocoHeal by The Honorable President of India Smt. Droupadi Murmu, in the presence of Honorable Union Minister for Food Processing Industries, Shri Pasupati Kumar Paras and Secretary to department, Smt. Anita Praveen for utilization of Agro-product in medical segment.



AVAILABLE SIZES

5 cm X 5 cm

10 cm X 10 cm

15 cm X 20 cm

Instructions for use

1. Clean the wound bed and peri wound area using standard cleaning procedures.
2. Debride the wound bed through surgical or enzymatic procedures as deemed necessary.
3. Irrigate the wound bed post debridement with saline to remove any particles present and pat dry with gauze or cotton.
4. Open the Aluminum foil cover.
5. Remove the sterile poly pack from inside the Aluminum foil cover. Open the sterile poly pack and remove the COCOHEAL bio-cellulose dressing.
6. COCOHEAL bio-cellulose dressing can be trimmed to necessary size if required, using a sterile scissors.
7. Place the dressing on the wound bed, such that the dressing covers the entire wound bed and also up to 1 cm of the peri-wound area.
8. Ensure that the dressing is in full contact with the wound bed without any air pockets by applying a gentle force on the dressing with 2 fingers in a motion that starts from center of the dressing and radiating to the edges. Either side of the dressing may be used.
9. Optionally, COCOHEAL bio-cellulose dressing can be covered with gauze as a secondary dressing. The dressing has to be replaced every 2-3 days depending on the wound conditions.

