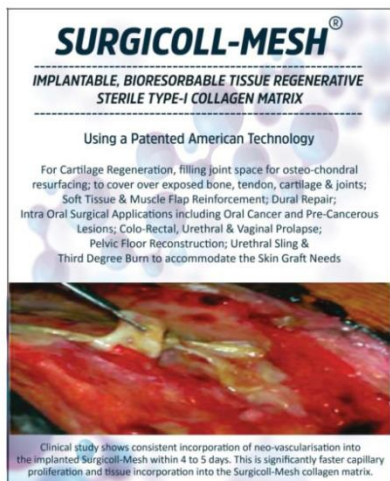




INFORMATIONAL MATERIAL PACKAGE ON

SURGICOLL-MESH®

**IMPLANTABLE, BIORESORBABLE, TISSUE REGENERATIVE
STERILE, TYPE-I COLLAGEN MATRIX
A Patented American Technology**



Manufacturing Address:

PL. 111 to 114 SIDCO Pharma Estate, Alathur 603 110.

Sales & Marketing Office:

#77, 1st Cross St, Ragavan Colony
Chennai - 600 083. TN, INDIA. Phone: 044 – 24744650
E-mail: info@advanced-biotech.com
Website: www.advanced-biotech.com

Under the technology from:



Fremont, CA, USA





Advanced Biotech Products (P) Ltd.

Head Office : 77, First Cross Street, Ragavan Colony, Ashok Nagar, Chennai, TN - 600083, India.

Factory : PL.111 to 114, SIDCO Pharma Estate, Alathur, TN - 603110, India.

PROPRIETARY ARTICLE CERTIFICATE (PAC)

(To be submitted by the indenter along with the indent)

Certified that to the best of our knowledge, the items indented vide indent No.....

Dated..... for **Surgicoll-Mesh** tissue regenerative innovative biological device products that are manufactured only by **M/s. Advanced Biotech Products P Ltd.** There is no other option of the Facility except to Purchase this item(s) as it is having unique features. (Please see the patented product features attached)

Further it is essential for the high quality R&D and Clinical treatments that cannot be met through any other similar tissue regenerative biological products currently available. Also the product is Proprietary through its US patents.

I/we shall be held responsible in case the certificate is found to be incorrect.

Signature of Indenting Officer / Project Leader

S. Gnanasekaran



Designation: Scientist and Managing Director / Project Leader

Date: 24 Feb. 2020

UNIQUE FEATURES OF

SURGICOLL-MESH[®]

Surgicoll-Mesh, an innovative, high purity Type-I collagen has the following description and unique features:

1. High functional efficiency.
2. Its bioactivity is further enhanced by phosphorylation.
3. High degree of wound healing and tissue regenerative features.
4. Evidenced by equivalent Product approved in the US market.
5. US Patented for its purity and clinical efficacy^{1,2}.
6. Prepared using USP/IP, WHO GMP standards with ISO 13485:2016 regulations for quality compliances

Indications of Surgicoll-Mesh:

- Intra Oral Surgical - Post-operative mucosal defect in oral cancer and pre-cancerous lesions, dental/OMF applications.
- Soft Tissue & Muscle Flap Reinforcement – As a patch used for suture line reinforcement, muscle supplement with sling, repair and anchorage of tendon damage, and Transverse Rectus Abdominis Muscle (TRAM) flap procedures.
- Chronic ulcers and Diabetic ulcer treatment.
- Third-Degree Burn to accommodate the Skin Graft needs
- Orthopedic Surgery - Osteochondral resurfacing, synovial tissue implant, repair of rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons.
- Cartilage Regeneration.
- Pelvic floor reconstruction, sacro-colposuspension and urethral sling.
- Colo-rectal, urethral & vaginal prolapse.
- Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias.
- Cardio-vascular - Atrial, ventricular and arterial patch repair, suture line buttress, intra-cardiac patch, thoracic wall etc.
- Neurosurgical - As a substitute for dura repair and nerve wrap.

Advantage of using Surgicoll-Mesh:

- **High purity Type-I Collagen:** Surgicoll-Mesh consists of native un-crosslinked pure Type-I collagen (>97% pure) free of immunogenic proteins, lipids, and elastin^{3,4}.
- **Faster Healing:** Collagen phosphorylation attracts cells, regenerates tissue, and stimulates blood capillaries/granulation within 4 to 5 days⁵.
- **Innovative Technology:** Better than intact tissue-based membranes which contain > 49% elastin and other immunogenic molecules.
- **Easy Application:** No washing needed prior to use. Can be Sutured and/or Stapled.
- **Pain Control:** Effectively reduces pain
- **Various Sizes:** Choose from our available wide range of standard sizes. For more details, [see Brochure](#).
- **Cost-Effective:** Accelerated wound healing and tissue remodeling with minimal applications.
- **Long Shelf Life:** Remains clinically usable for 3 years when stored in room temperature conditions



SURGICOLL-MESH® & HEMOCOLL® FOR USE IN DIABETIC FOOT ULCERS (DFU)

Introduction:

Diabetes is a growing challenge in India with estimated 8.7% diabetic population in the age group of 20 and 70 years¹. The overall perception of the delayed diabetic wound healing is neuropathy resulting in poor arterial blood supply and venous circulation.

However, high levels of blood glucose not only affect the nerves but also impedes the natural maturation of the healing/granulation tissue. This is a biochemical phenomenon called glycosylation of structural proteins.

We need to consider all the causes of Diabetic Ulcers at this point as shown below:

Understanding of the causes for Diabetic Foot Ulcers

Commonly recognized concepts of DFU

1. Nerve Damage

Damage to the nerve by increased level of glucose in blood may result in loss of sensation and the inability to feel any pain or pressure.

2. Poor Circulation

High blood glucose levels thicken the arteries and narrow its blood vessels, restricting the delivery of the blood and oxygen needed to support the body's natural healing abilities.

3. Infection

Suppressed immune system may facilitate pathogen proliferation eventually leading to an infection like non-healing diabetic ulcer.

4. Immune Suppression

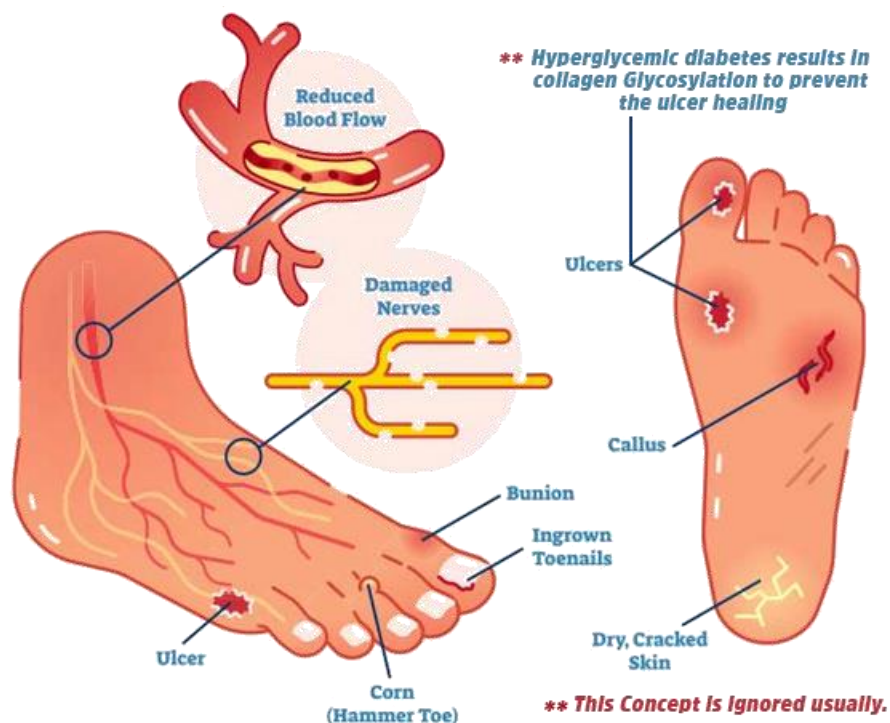
Diabetes may suppress the immune system that could impair the body's ability to fight-off an infection.

Unrecognized concept of DFU

5. Glycosylation of wound bed collagen

In hyperglycemic patients, Glycosylation of the newly formed wound bed collagen hinders the normal enzymatic (lysyl oxidase) maturation leading to non-healing. The hyperglycemic glucose may be absorbed by Surgicoll-Mesh for faster healing of the ulcer wound.





Diagrammatic representation of Hyperglycemic Diabetology

Treatment options for DFU:

Normal materials that are used to cover an ulcer:

1. Non-biological synthetic polymeric sheets and sponges
2. Cotton gauze
3. Vaseline

All such materials are able to protect wound as a wound cover and may absorb the secreted fluid (exudate). Upon usage of such non-biological scaffold materials, cells may not feel comfortable when they come in contact. Accordingly, this would un-necessarily delay the wound healing process because the exudation will continue until the cells are comfortable with the surrounding environment.

On the other hand, **Surgicoll-Mesh** biological dressing may provide a better result. However, all biological materials are not the same. Using an advanced biological skin substitute like **Surgicoll-Mesh** will not disturb the cells on the surface of the wound involved in the tissue granulation process.

All biological skin substitutes may NOT be ideal biocompatible matrices:

Two main categories of Biological matrices:

1. **Reconstituted Collagen membranes:** This includes products made from collagen extracted from animal tissues. Only a few such products are highly biocompatible and bioactive. **Surgicoll Mesh** happens to be one such unique product.
2. **Intact tissue membrane derived products:** These products are made from intact tissue membranes of amnion, pericardium, intestinal wall, urinary bladder etc. These membranes are contaminated with approximately 10 to 49% elastin, type-III collagen, lipids and other proteoglycans which are all highly immunogenic. They have to be cross-linked to minimize their immunogenicity and on the other hand loses the bioactivity and wound healing abilities if the material is not chemically modified or cross-linked, it can effectively be used in tissue regeneration and in the granulation process.



Etiology of Diabetic Ulcers:

- High levels of blood glucose leads to slow healing of DFU
- High levels of blood glucose makes collagen Glycosylated
- Glycosylation is the covalent addition of the excess blood glucose to collagen

Impact of Glycosylation:

- Glycosylation prevents the normal collagen maturation of healing wounds
- Glycosylation inhibits lysyl oxidase that matures collagen to heal the wound (Fig. 1 below)
- This is the reason why the diabetic patient's foot ulcer doesn't heal easily.
- How an innovative, patented, **SURGICOLL-MESH** collagen helps

Surgicoll-Mesh's NANOTECHNOLOGY could help heal DFU faster!

- **Surgicoll-Mesh**, as an uncross-linked biocompatible collagen, when tightly applied over the wound, it would osmotically absorb glucose.
- Such glucose pulling of **Surgicoll-Mesh** collagen would reduce the glycosylation of the collagen produced in the wound-bed.
- When the collagen in the wound is relieved from glycosylation, it matures and the Diabetic wound heal faster.
- This provides a scientific explanation for the successful use of **SURGICOLL-MESH** to treat the non-healing **DIABETIC FOOT ULCERS**.

Treatment of Diabetic Foot Ulcer



**One-month
post traumatic ulcer
with gangrene of 4th toe**



**Application of
Surgicoll-Mesh**



**31 Days Post
Application**

Indications of Hemocoll:

Hemocoll is intended for the surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical includes:

- Cardiovascular surgery
- Neurosurgery
- Uro-surgery
- General surgery
- Trauma surgery
- Intracranial bleeding, and
- Control post-surgical.

Why Use Hemocoll:

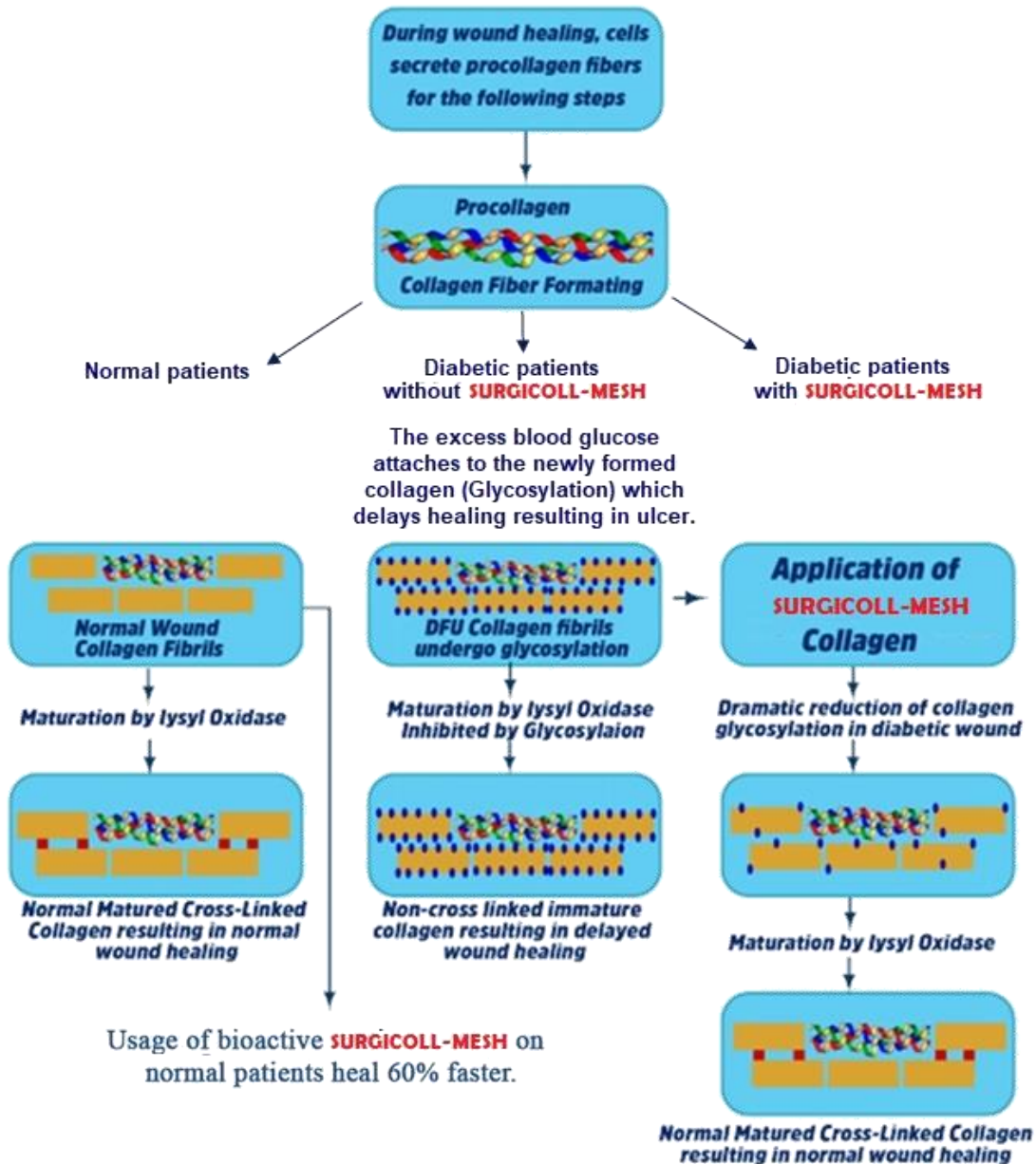
1. Hemostatic agent, effectively controls bleeding
2. Accommodable for deep tunneling wounds
3. Decrease hospital length of stay



SURGICOLL-MESH®

WHY IT WORKS BEST FOR DIABETIC FOOT ULCERS?

How Surgicoll-Mesh Nano-technology could heal a Diabetic Ulcer faster than other collagen products.



References:

<https://www.who.int/india/events/world-diabetes-day>

