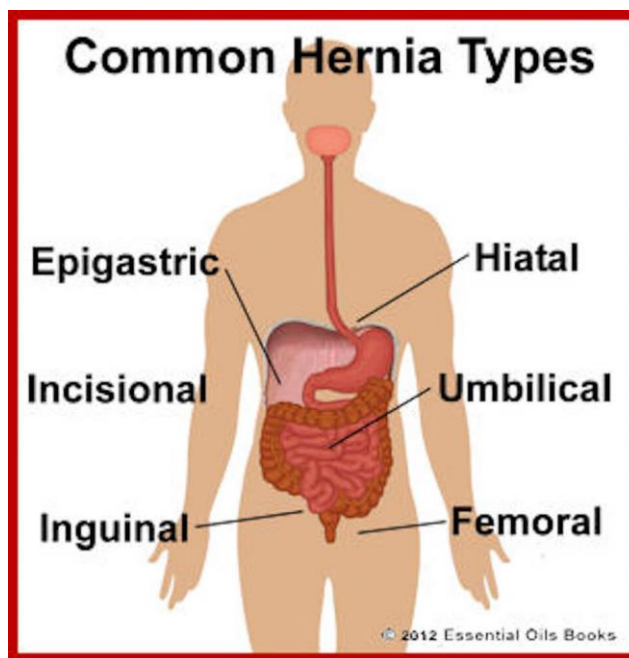


Usage of **SURGICOLL-MESH®**



FOR APPLICATION IN SOFT TISSUE REPAIR & RECONSTRUCTION



ADVANCED BIOTECH PRODUCTS (P) LTD.

Manufacturing:

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Sales & Marketing Office:

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Phone: 044 – 24744650 Website: www.advanced-biotech.com

Under the technology from:



Fremont, CA, USA

ABOUT 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 10 to 51% 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 condition



FOR SOFT TISSUE REPAIR & RECONSTRUCTION

BURN RECONSTRUCTIVE SURGERIES:



Testimonial by the Doctor:

“This has been a very critical case of major burn injury by electric shock in a young male adult patient lead to pressure sore ulcer. During Feb-Mar 2020, after debriding the wound, **Surgicoll-Mesh®** was applied. Rapid formation of granulation tissue in the affected areas was observed. **Surgicoll-Mesh®** effectively relieved pain since the day applied and the patient walked home harmoniously on day-7 after application.”

Technical reasons for the success of Surgicoll-Mesh:

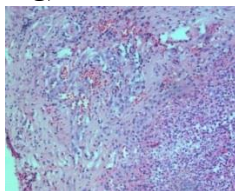
Surgicoll-Mesh® is highly bio-active due to its high purity of Type-I collagen which is phosphorylated to provide relevant tissue regeneration along with maximum wound healing benefits.

Its clinical effectiveness is evidenced through the infiltration of blood capillaries into the **Surgicoll-Mesh®** matrix within 4 to 5 days after application. As a result, **Surgicoll-Mesh®** heals wounds significantly faster (at least 60%) than most other advanced tissue repair products in the market.

Note: The patient was quite comfortable on day-7 and relieved himself from the hospital. Hence, no follow-up pictures are available.

After 5 days of Collagen application

Acute inflammatory cells (neutrophils), fibroblasts and blood vessels proliferate into collagen matrix (indicative of early healing). Notice no signs of immunogenicity.



Formation of neo-vascularization on Day 5 documenting the early healing process.

Courtesy of Dr. VRD, MS, M. Ch.

Head of the Department – Plastic & Burn Surgery
KMC Hospital, Chennai, India



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FAST SKIN REPAIR & REMODELING



Day 1



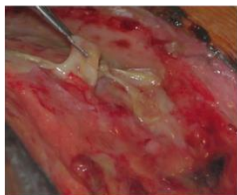
Day 1



Day 2



Day 3



Day 4 & 5

FAST NEO-VASCULARIZATION

Evidenced by incorporation of "Surgicoll-Mesh Equi" into the surgical defective tissue on day 4 & 5

These results also assessed by histology & electron microscopy

BURN RECONSTRUCTION



Day-0



Surgical Opening



Day-1: Surgicoll-Mesh Equi applied and stapled



21 days upon Skin-graft application over Surgicoll-Mesh Equi on day 5

Good Graft take, Firm adherence & early recovery

Ref: A Clinical Breakthrough in Wound Cover "Bioengineered Collagen" - A Cost Effective and Expeditious Permanent Skin Substitute
International Society for Burn Injuries, Switzerland, 2010



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SACRAL PRESSURE SORE



Stage 4 pressure
sore



10 Days Post "Surgicoll-Mesh
Equi" application



Completely healed using
"Surgicoll-Mesh Equi"

Complete Recovery in 6 weeks

Courtesy: Dr. Vinoth Philip , MD, DNB, Plastic Surgeon, Tirunelveli

KELOID EXCISION AND CLOSURE



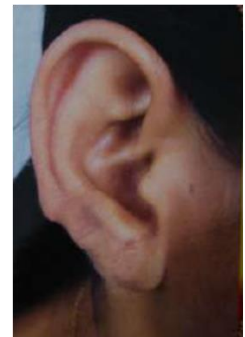
Day- 0



Day- 1: Insertion of Surgicoll-Mesh equi
into the wound



Day- 15



5 years- No
Recurrence

*Postulate that Surgicoll-Mesh equi acts to interrupt abundant collagen deposition
and thus prevent hypertrophic scars and keloids*

BREAST RECONSTRUCTION:

In breast reconstructive surgery, to facilitate the expansion of the submuscular pocket for direct-to-implant breast reconstruction and two-stage breast reconstruction, **Surgicoll-Mesh®** can be used as a sling, interposed between the lateral pectoral edge and the thoracic wall. Following capsular elevation, **Surgicoll-Mesh®** can be placed in-between tissues and frequently fixed with marionettes sutures (ref 6).

It can also be used for:

- ✓ Symmastia correction



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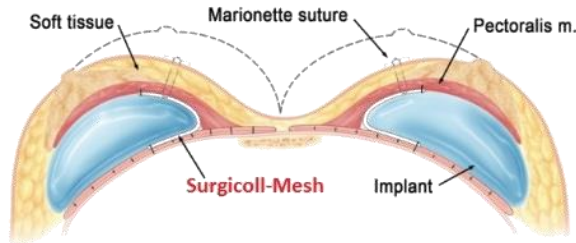
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Website: www.abpdermal.com

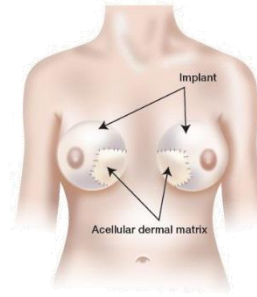
- ✓ Mask rippling and Camouflage surface irregularities
- ✓ Inframammary fold malposition or bottoming out correction
- ✓ TRAM flap procedure

Symmastia correction

Symmastia is an implant displacement problem that occurs when the skin and muscle between the breasts over the sternum (breastbone) detaches and the two pockets of tissue that hold the breast implants come together to form one pocket.

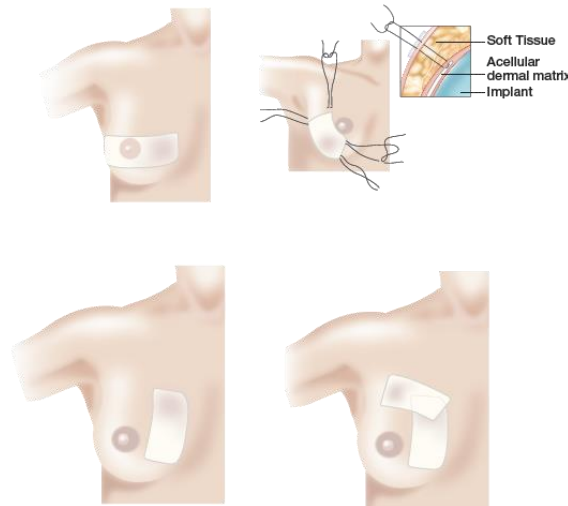


Placement of Surgicoll-Mesh to correct symmastia



Medial placement of Surgicoll-Mesh

Placement of a sling of **Surgicoll-Mesh®** in the subpectoral position, between the lateral and inferior borders of the pectoralis major and the chest wall, to complete the inferior lateral part of the implant pocket, with either a tissue expander or a permanent breast implant (ref 7).

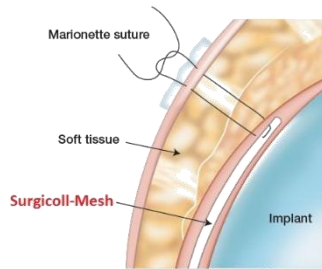


Different placement of the Surgicoll-Mesh: (a) centre, (b) lower lateral, (c) medial and (d) upper medial areas.

Breast Rippling

Rippling occurs when the breast implant shows visible folds or wrinkles underneath your skin. Using **Surgicoll-Mesh®** can be placed at the bottom of the breast to reinforce weak or inadequate tissue. This can help position the breasts in the desired location and reduce the presence of wrinkles and ripples on the skin surface (ref 8).



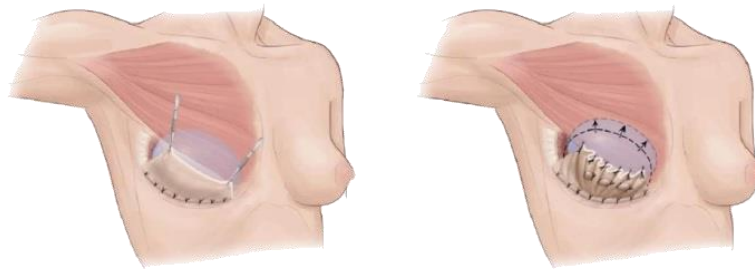


Placement of Surgicoll-Mesh to correct rippling

Correction of Inframammary Fold

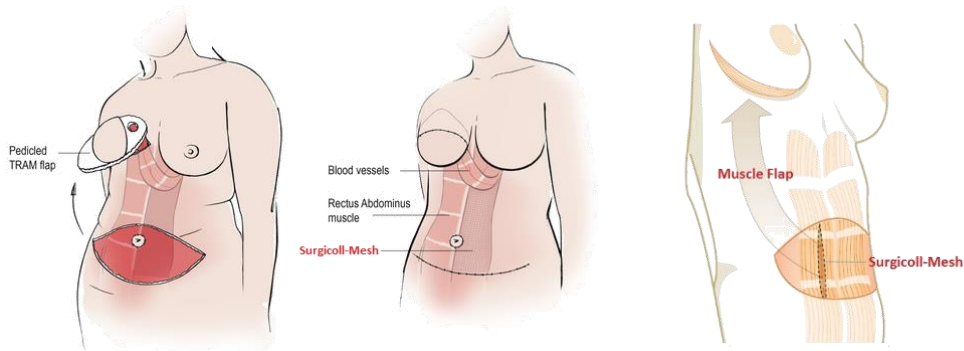
Surgicoll-Mesh® sutured to the infra-mammary fold and draped over the implant with the superior edge approximating the inferolateral margin of the pectoralis major (Fig on left).

Suture plication of the **Surgicoll-Mesh®** to help maintain a higher position of the implant on the chest wall (Fig on right). This includes plication of the **Surgicoll-Mesh®** as needed, not only at the periphery but within the central areas (ref 9).



TRAM Flap Procedure

In TRAM Flap procedure for breast reconstruction, **Surgicoll-Mesh®** can be used to achieve reinforcement of the entire abdominal wall (ref 10).



PELVIC FLOOR RECONSTRUCTION SURGERIES:

Types of Pelvic Organ Prolapses (ref 11):

- ✓ **Vaginal prolapse:** This is a prolapse of the vagina.
- ✓ **Urethrocele:** This is a prolapse of the urethra (the tube that carries urine).
- ✓ **Cystocele:** This is a prolapse of the bladder into the vagina, the most common condition.
- ✓ **Uterine prolapse:** uterus descends toward or into the vagina



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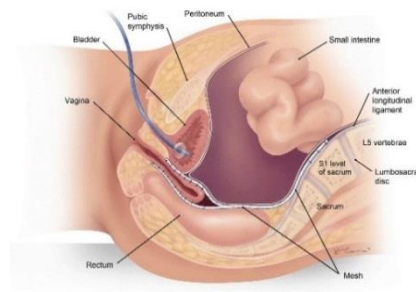
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- ✓ **Enterocoele:** This is a small bowel prolapse.
- ✓ **Rectocoele:** This is a rectum prolapse.

✓ **Vaginal Prolapse:**

Weak muscles and ligaments supporting the pelvic organs may fall out of place and bulge down in the vagina. To treat POP, **Surgicoll-Mesh®** can be implanted to reinforce the weakened vaginal wall. Surgery can be done through the abdomen using mesh (ref 12).

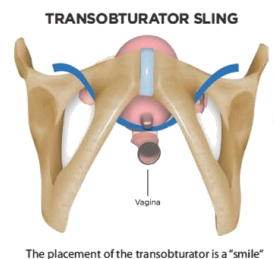
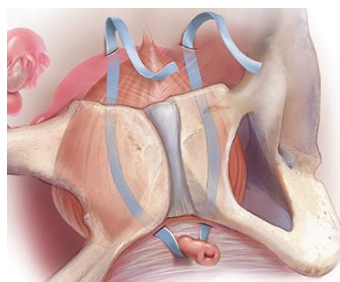
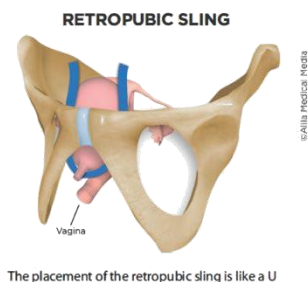
The length of the mesh should represent the length of the vagina, and the breadth should represent the wideness. The vagina is approximately 3 cm wide distally and up to 10 cm proximally between the ischial spines (ref 14).



Incorporation of mesh in Sacrocolpopexy (ref 13)

✓ **Urethrocele (Urethra Prolapse):**

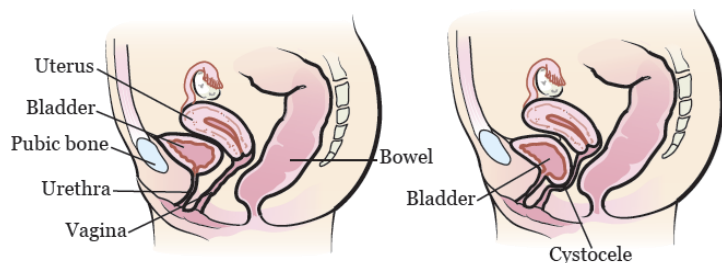
A urethrocele occurs when the tissues surrounding the urethra sag downward into the vagina (ref 15). **Surgicoll-Mesh®** urethral slings can be implanted through the vagina to support the bladder neck or the tube that carries urine from the body (urethra). This is known as a midurethral sling or a mesh sling procedure.



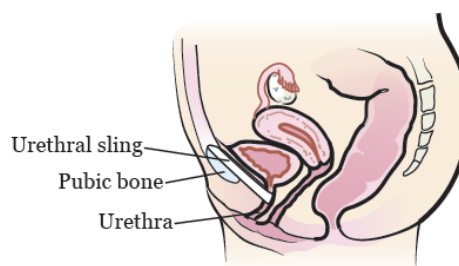
Urethral Sling Procedure

✓ **Cystocele (Bladder Prolapse):**

A cystocele occurs when the wall of the bladder presses against and moves the wall of the vagina (ref 15). **Surgicoll-Mesh®** urethral sling holds your urethra in its correct position. The sling is looped around your urethra and the ends are attached to the pubic bone.



Female anatomy without (left) and with (right) a cystocele.



Female anatomy with urethral sling

✓ **Uterine Prolapse:**

A uterine prolapse is when the uterus descends toward or into the vagina. It happens when the pelvic floor muscles and ligaments become weak and are no longer able to support the uterus (ref 16).

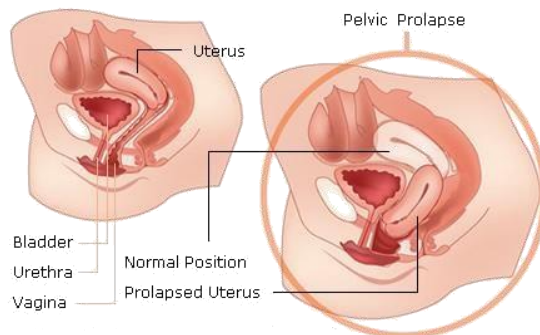
Uterus is supported in its natural position by attaching a piece of **Surgicoll-Mesh®** to connect the uterus to



the vertebral spinal bone (ref 17).

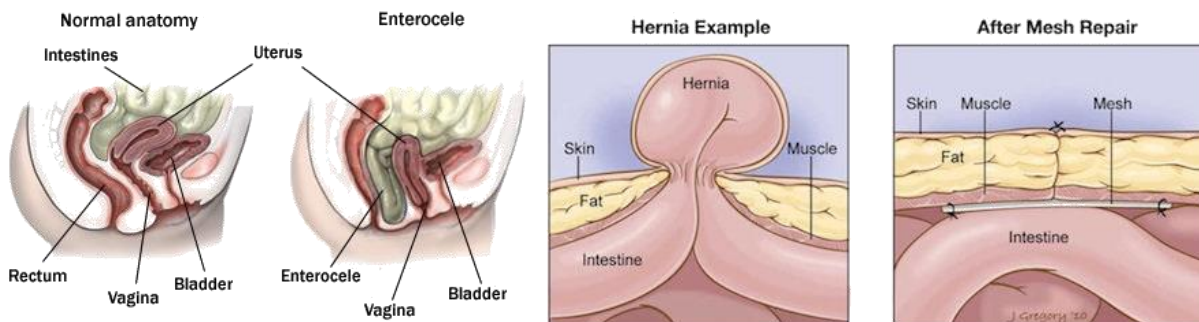
This can be done in two different ways:

- keyhole (laparoscopic) surgery – the operation is carried out through small incisions (cuts) in the lower abdomen
- open surgery – a larger incision is made in the lower abdomen.



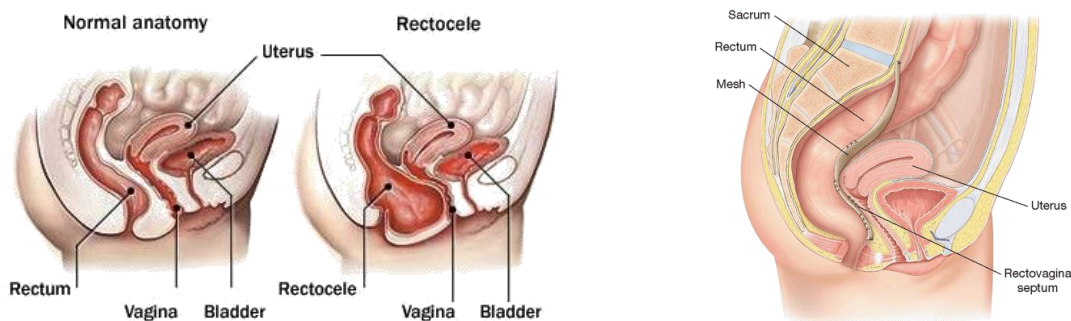
✓ **Enterocoele (Small bowel prolapse):**

An enterocoele (small bowel prolapse) occurs when the small bowel presses against and moves the upper wall of the vagina (ref 18). **Surgicoll-Mesh®** stabilizes and strengthens the area, supports organs and muscles, and acts as a scaffold for new tissue growth.



✓ **Rectocoele (Rectum prolapse):**

A rectocoele is a bulging of the front wall of the rectum into the back wall of the vagina (ref 19). The posterior mesh rectopexy involves insertion of **Surgicoll-Mesh®** behind a completely mobilized rectum and its fixation to the sacrum as well as to the sides of the rectum (ref 20).



Mesh Rectopexy



Complications of other meshes (ref 21):

Local irritation at wound site	Migration of the device
Infection	Pain
Urinary tract obstruction and urine retention	Recurrence of incontinence
Vaginal extrusion	Nerve damage
Erosion through the urethra	Swelling and redness at the wound site
Scarring	Vaginal discharge
Scar contracture	Fatigue
Inflammation	Shortness of breath
Fistula formation	Bleeding

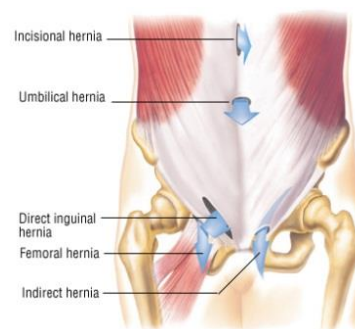
Surgicoll-Mesh® Available Sizes (in cms):

5x5	2x25	5x10	10x10	10x15	10x20	15x15
10x25	15x20	20x20	15x30	20x25	20x30	

HERNIA REPAIR:

Types of Hernias

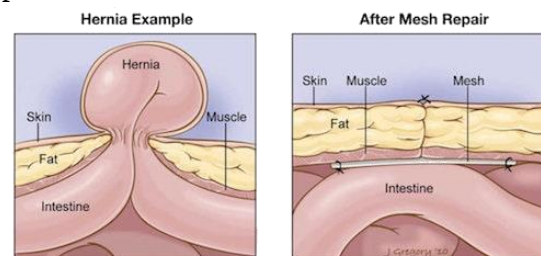
- ✓ **Inguinal:** occurs in the inner groin
- ✓ **Femoral:** occurs in the upper thigh/outer groin
- ✓ **Incisional:** occurs through an incision or scar in the abdomen
- ✓ **Ventral:** occurs in the general abdominal/ventral wall
- ✓ **Umbilical:** occurs at the belly button
- ✓ **Hiatal:** occurs inside the abdomen, along the upper stomach/diaphragm



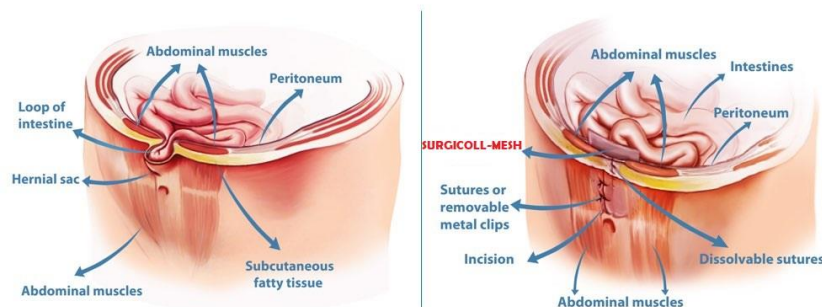
Abdominal Hernia:

Open Surgery:

An open incision is made in the abdomen at the hernia site and the protruded intestine or abdominal tissue is pushed back in place. Depending on the hernia's size, a component separation procedure (cutting through some of the abdominal wall muscles along the side of the body) may be performed. **Surgicoll-Mesh®** material is placed to reinforce the damaged site and reduce hernia recurrences. The skin is typically closed with dissolvable stitches and glue (ref 22).



Absorbable **Surgicoll-Mesh®** would meet the clinical need to provide the physical support. As this product gradually degrades over time, it will trigger the new tissue growth that is intended to provide strength to the damaged site.



Laparoscopic Surgery (ref 23):

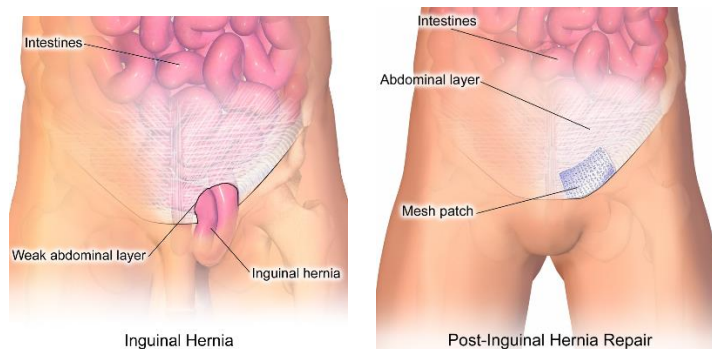
Several small incisions are made at locations away from the hernia site. A laparoscope (a thin lighted tube



with a camera on the tip) is inserted through one of the openings to help guide the surgery. **Surgicoll-Mesh®** material may be inserted to strengthen the weakened area in the abdominal wall.

Inguinal Hernia Repair:

The procedure involves making an approximate 10-cm incision in the groin. Once exposed, the hernia sac is pushed to the abdominal cavity or excised. The abdominal wall is then reinforced (ref 24) with **Surgicoll-Mesh®**.



Umbilical Hernia:

Hernia sac is removed and **Surgicoll-Mesh®** is placed on the site. It is attached using sutures to the stronger tissue surrounding the hernia. **Surgicoll-Mesh®** extends 3 to 4 cm beyond the edges of the hernia and the umbilicus is fixed back to the muscle (ref 25).



Complications of other meshes (ref 26):

Bowel obstruction	Migration of the device
Infection	Pain
Scarring	Bleeding
Bowel perforation	Recurrence
Inflammation	Swelling and redness at the hernia site
Fistula formation	Rejection

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