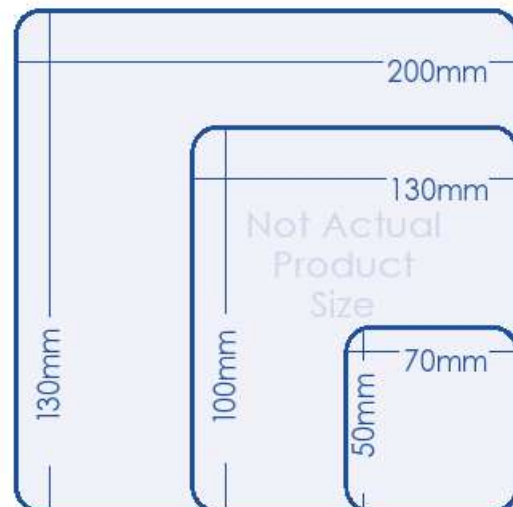


Features	Benefits
PLA	<ul style="list-style-type: none"> • Safe resorption and metabolization with minimal risk of inflammatory reaction • Demonstrated efficacy in reducing adhesion quantity and tenacity
Impermeable	<ul style="list-style-type: none"> • Maintains a physical barrier between opposing soft tissues • Retains tensile strength for 6-8 weeks ensuring tissue separation during the critical wound healing period
Repositionable in a wet environment	<ul style="list-style-type: none"> • Easily repositioned if already in contact with anatomy • Will not stick to surgical gloves or instruments
Can be cut, trimmed or folded	<ul style="list-style-type: none"> • Enables SurgiWrap™ to be placed precisely where it is needed, around different anatomical structures and repairs
Transparent	<ul style="list-style-type: none"> • Allows for constant visualization of the entire surgical field, resulting in easy intra-operative placement and repositioning of the product if needed
Can be anchored in place with sutures, clips, or surgical tacks	<ul style="list-style-type: none"> • Ensures the device does not migrate from the desired area of protection

Product Ordering Information



MAST Catalog Number	Description
25201-01	50mm x 70mm x 0.02mm, Single (1) Pack
25501-01	50mm x 70mm x 0.05mm, Single (1) Pack
25202-01	100mm x 130mm x 0.02mm, Single (1) Pack
25202-05	100mm x 130mm x 0.02mm, Five (5) Pack
25502-01	100mm x 130mm x 0.05mm, Single (1) Pack
25502-05	100mm x 130mm x 0.05mm, Five (5) Pack
25204-01	130mm x 200mm x 0.02mm, Single (1) Pack
25204-05	130mm x 200mm x 0.02mm, Five (5) Pack
25504-01	130mm x 200mm x 0.05mm, Single (1) Pack
25504-05	130mm x 200mm x 0.05mm, Five (5) Pack

References

1. Salzman H, Gabella G, Davis C, Mubars SE, Boulos P, Laurent GJ, and Herick SE: Presence and distribution of sensory nerve fibers in human peritoneal adhesions. *Annals of Surgery* 234(2): 256-61, 2001
2. Howard FM: Chronic pelvic pain. *Obstetrics & Gynecology* 101(3): 394-611, 2003
3. Tulandi T, Collins JA, Burrows E, Jarrell JF, McInnes EA, Wilson W, and Simpson CW: Treatment-dependent and treatment-independent pregnancy among women with peritoneal adhesions. *Am J Obstet Gynecol* 162: 35-7, 1990
4. Ellis H, Moran B, Thompson J, Parker M, Wilson M, Mendes D, McGuire A, Lower A, Hawthorn B, O'Brien F, Buchan S, and Crowe A: Adhesion-related hospital readmissions after abdominal and pelvic surgery: a retrospective cohort study. *Lancet* 353:1476, 1999
5. Ahtook S, Pfaff E, and Tulandi T: Adhesion-related smallbowel obstruction after gynecologic operations. *Am J Obstet Gynecol* 180: 313-15, 1999
6. Montz FJ, Holschneider CH, Sob S, Schuchit LC, and Monk BJ: Small bowel obstruction following radical hysterectomy: risk factors, incidence, and operative findings. *Gynecol Oncol* 53:114-20, 1994
7. Mendes D and Ellis H: Intestinal obstruction from adhesions—how big is the problem? *Ann R Coll Surg Engl* 72: 60-63, 1990
8. Coleman MG, McClain AD, Moran BJ: Impact of previous surgery on time taken for incision and division of adhesions during laparoscopy. *Dis Colon Rectum* 43:1297-99, 2000
9. Van Der Krabben AA, Dijkstra FF, Hieuwenhuijzen M, Beijnen MM, Schaapveld M, and Van Gooij H: Morbidity and mortality of laparoscopic enterotomy during adhesiolysis. *Br J Surg* 87: 467-71, 2000
10. Audebert AJ, Gamel V: Role of microlaparoscopy in the diagnosis of peritoneal and visceral adhesions and in the prevention of bowel injury associated with blind trocar insertion. *Fertil Steril* 73(3):631-5, 2000
11. Gabbay S, Guindy AM, Andrews JP, Amato JJ, Seaver P, Khan MY: New outlook on pericardial substitution after open heart operations. *Ann Thorac Surg* 48: 803-812, 1989
12. Hechtel M, Mees U, Hill AC, Egbert B, Coker GT, Estbridge TD: Evaluation of a novel synthetic sealant for inhibition of cardiac adhesions and clinical experience in cardiac surgery procedures. *The Heart Surgery Forum* 4: 204-210, 2001
13. Malm T, Bowald S, Bylock A, Busch C: Prevention of postoperative pericardial adhesions by closure of the pericardium with absorbable polymer patches. An experimental study. *J Thorac Cardiovasc Surg* 104: 600-607, 1992
14. Okuyama H, Wang CY, Rose EA, Rodgers KE, Pines E, d'Zerega GS, Oz MC: Reduction of rethoracic and pericardial adhesions with rapidly resorbable polymer films. *Ann Thorac Surg* 68: 913-918, 1999
15. Rodgers K, Cohn D, Holovsky A, Pines E, Diamond MP, d'Zerega G: Evaluation of polyethylene glycol / poly(lactic acid) films in the prevention of adhesions in the rabbit adhesion formation and reformation sidewall models. *Fertility and Sterility* 69: 403-408, 1998
16. Yamaoka T, Takahashi Y, Fujisato T, Lee CW, Tsuji T, Ohita T, Murakami A, Kimura Y: Novel adhesion prevention membrane based on a bioresorbable copoly(ester-ether) comprised of Poly-L-lactide and Pluronic: in vitro and in vivo evaluations. *J Biomed Mater Res* 54: 470-479, 2001
17. Cuono C: Scars and Keloids: Plastic Surgery Principles and Practice. St. Louis: Mosby 1411-1428, 1990



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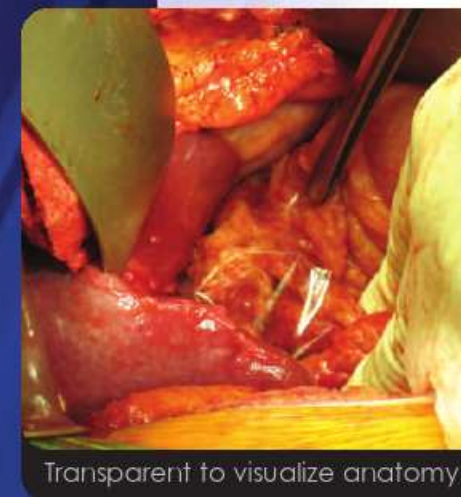
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III-SW-IT-100 Rev A



SurgiWrap

Bioresorbable Adhesion Barrier Film



Transparent to visualize anatomy



Insert through a trocar



Repositionable in a wet field

**prevents adhesion formation,
 creates a surgical plane of dissection,
 and reinforces soft tissue**



MAST BIOSURGERY™ SURGIWRAP®

Bioresorbable Adhesion Barrier Film

Post-operative adhesions are an almost inevitable occurrence after most surgical procedures. They are a major cause of morbidity and mortality, and cause considerable expense to both healthcare systems and society.

Surgical Challenge

Commonly, adhesion formation is a post-surgical sequelae of visceral tissue repair following surgical abdominal/pelvic procedures. The clinical significance of postoperative adhesions is associated with many complications including:

- Pelvic or Abdominal Pain^(1,2)
- Fertility Impairment in Women^(2,3)
- Bowel Obstruction^(4,5,6,7)
- Complication in Surgical Re-entry

There is a substantially high risk for patients undergoing secondary abdominal or pelvic re-operations as adhesion formation resulting from previous surgical procedures may complicate the re-entry by:^(8,9,10)

- Extended operating time due to surgical difficulties and adhesiolysis
- Substantial blood loss
- Incidental/inadvertent enterotomies
- Entero-cutaneous fistulas
- Resection of damaged tissue

Similar reactions after surgery occur over the entire body. In the chest, re-operations are often made more complicated by the need to dissect through scar tissue and adhesions that have formed subsequent to the initial procedure. This may result in:

- Increased operating room time
- Increased risk of injury to the patient because of impeding the identification of critical anatomy, which may lead to catastrophic hemorrhaging during the procedure.^(11,12)

Reoperative cardiac procedures are becoming increasingly common, exposing more patients to the hazards associated with postoperative pericardial and retrosternal adhesions.⁽¹³⁾



Anatomy and Procedures Prone to Adhesions after Surgery

- **General Surgery** - Laparotomy, Colorectal surgery, Transplants, Liver Surgery, Adhesiolysis
- **Gynecologic Surgery/Obstetrics** - Infertility surgery, Myomectomy, C-Section, Endometriosis
- **Urologic Surgery** - Bladder Suspension, Transplant
- **Cardio Thoracic Surgery** - Open heart surgery, Bypass-surgery, LVAD-procedures
- **Reconstructive Surgery** - Soft tissue repair

Surgical Solutions

In addition to good surgical technique and increasingly minimally invasive surgical procedures, placing a physical barrier between opposing tissues to control the in-growth of scar tissue and subsequently control adhesions is an effective solution. Control of the early formation of adhesions in the area adjacent to the barrier may prove advantageous where clear tissue planes may result in simplified dissection and lowered risk to adjacent anatomy. So a temporary physical barrier will:

- Separate opposing soft tissues
- Create a surgical dissection plane
- Prevent formation of adhesions
- Reinforce soft tissues

The SurgiWrap® Bioresorbable Adhesion Barrier Film is designed to reinforce soft tissues to facilitate healing and to prevent adhesions of opposing tissues throughout the body. The SurgiWrap® film separates opposing tissues in order to prevent them from adhering to each other in regions immediately adjacent to the film. The SurgiWrap® film aids tissue healing by acting as a temporary support mechanism that holds soft tissues in place during the healing process.*

SurgiWrap® Bioresorbable Adhesion Barrier Film

- Separate opposing tissues in order to prevent them from adhering to each other in regions immediately adjacent to the film.
- Aids tissue healing by acting as a temporary mechanism that supports and holds soft tissues in place during the healing process.
- Act as a temporary physical barrier to:
 - Separate opposing tissues and prevent the in-growth of scar tissues and the formation or reformation of adhesions immediately adjacent to the film.
 - Aid in re-operation procedures by promoting the formation of a surgical dissection plane immediately adjacent to the film.
 - Reinforce soft tissues where weakness exists or to be used whenever temporary wound support is required.



What Is It?

SurgiWrap® Bioresorbable Adhesion Barrier Film's polymer material is fabricated from essentially the same lactic acid molecular building blocks that occur naturally in the human body. The polymers, which result from lactic acid derivatives, are generally referred to as PLA or polylactide. The SurgiWrap® Bioresorbable Adhesion Barrier Film is made from an amorphous bioresorbable copolymer 70:30 Poly(L-lactide-co-D,L-lactide).

How Does It Work?

The degradation of polylactide polymer (PLA) occurs in two phases:

- Water penetrates the implant and severs the polymer chains into smaller units
- Individual lactide molecules are metabolized in the liver into CO₂ and H₂O and excreted or exhaled

The 0.02mm and 0.05mm films retain significant tensile strength (greater than 80% and 100%, respectively) for the initial 8 weeks, and decreases in a controlled fashion through 24 weeks of aging (see Figure 1). Independent laboratory testing determined that the SurgiWrap® Bioresorbable Adhesion Barrier Film was capable of maintaining an impermeable barrier throughout the critical healing period, which has been described as several hours for adhesion formations^(14,15,16) and up to 8 weeks for reinforcing weak tissues.⁽¹⁷⁾

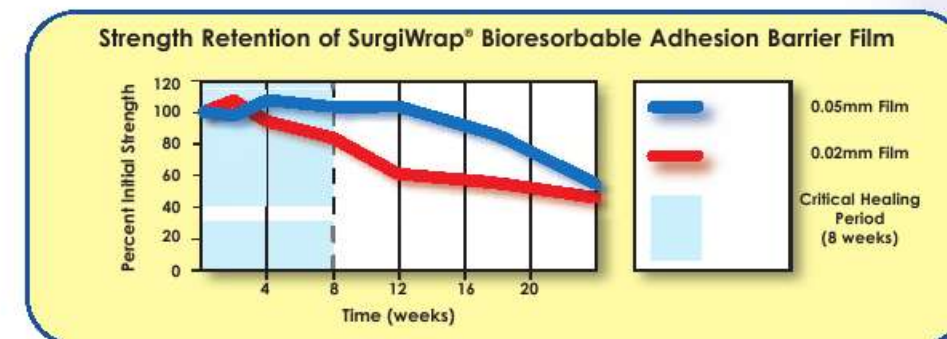


FIGURE 1. Strength retention of the 0.05mm (blue) and 0.02mm (red) SurgiWrap® Bioresorbable Adhesion Barrier Film over time. Both film configurations show significant mechanical strength throughout the critical healing period (light blue).

* See instructions for use for approved indications.