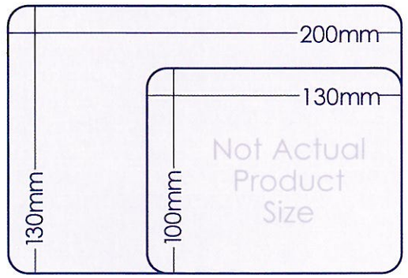
Product Ordering Information



Catalog Number	Description
35202-05	CardioWrap® Bioresorbable Adhesion Barrier Film, 100mm x 130mm x 0.02mm, 5-Pack
35502-05	CardioWrap® Bioresorbable Adhesion Barrier Film, 100mm x 130mm x 0.05mm, 5-Pack
35204-05	CardioWrap® Bioresorbable Adhesion Barrier Film, 130mm x 200mm x 0.02mm, 5-Pack
35504-05	CardioWrap® Bioresorbable Adhesion Barrier Film, 130mm x 200mm x 0.05mm, 5-Pack

Frequently Asked Questions

Why would surgeons use PLa bioresorbable polymer films instead of other bioresorbable films/technologies?
MAST Biosurgery PLa technology enables CardioWrap® Bioresorbable Adhesion Barrier Film to maintain its mechanical integrity and strength well throughout the critical healing period. This is in contrast to other bioresorbable films that begin losing mechanical integrity within days, and even hours after implantation.

What handling characteristics should surgeons expect?
CardioWrap® Bioresorbable Adhesion Film can be cut (with sterile scissors) into a custom-shaped size and placed around anatomic structures. The CardioWrap® Bioresorbable Adhesion Film maintains mechanical integrity during the surgical procedure allowing the product to be easily placed and repositioned as often as is necessary. The material can then be anchored in place as the surgeon chooses, depending on specific patient needs.

References

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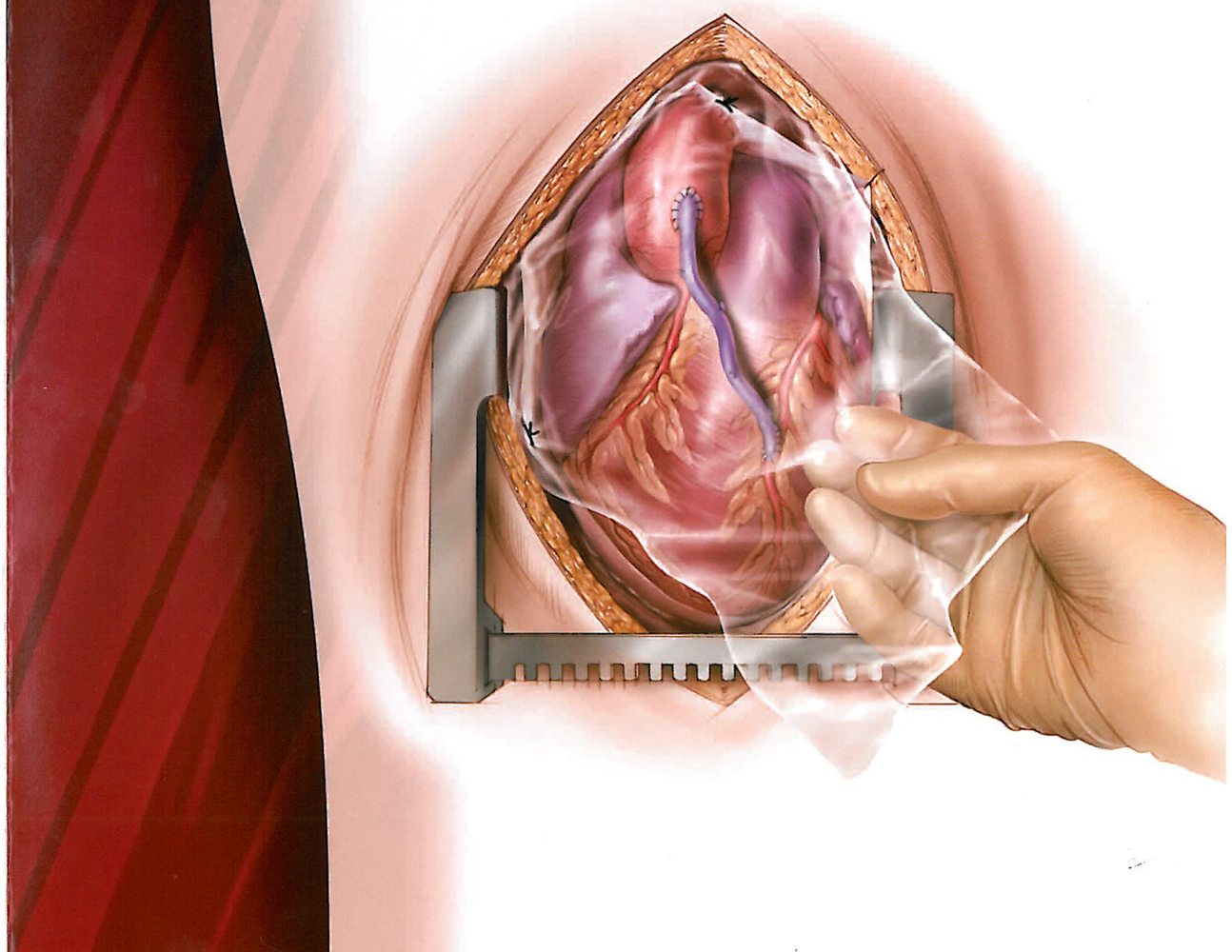
CardioWrap®

Bioresorbable Adhesion Barrier Film

The Clear Choice



MAST BIOSURGERY™ CARDIOWRAP®

Bioresorbable Adhesion Barrier Film

Re-do cardiothoracic procedures are often made more complicated by the need to dissect through scar tissue and adhesions that have formed subsequent to the initial procedure.

This results in:

- Increased operating room time
- Increased risk of injury to the patient by impeding the identification of critical anatomy, which may lead to catastrophic hemoraging during the procedure[1,2]

The CardioWrap® Bioresorbable Adhesion Barrier Film creates a protective barrier between opposing cardiac tissues to control the in-growth of scar tissue and subsequently control adhesions during the critical healing period. Control of the early formation of adhesions in the area adjacent to the CardioWrap Adhesion Barrier film may prove advantageous where clear tissue planes may result in simplified dissection and lowered risk to local anatomy.

MAST Biosurgery'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 CardioWrap® Bioresorbable Adhesion Barrier Film is made from an amorphous bioresorbable copolymer 70:30 Poly(L-lactide-co-D,L-lactide). It is transparent and offers an ultra-thin profile to allow for intra-operative placement and repositioning without obscuring surgical visualization.

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 CO_2 and H_2O 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 CardioWrap® 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[4,5,6] and up to 8 weeks for reinforcing weak tissues.[7]

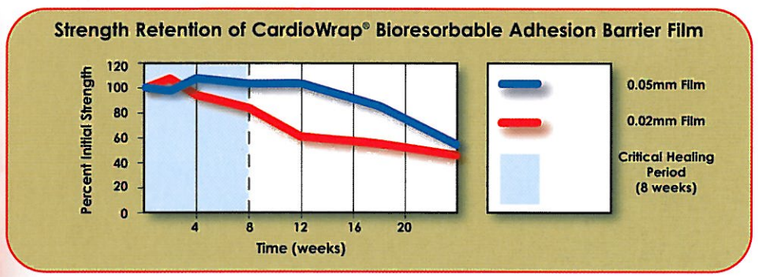


FIGURE 1.
Strength retention of the 0.05mm (blue) and 0.02mm (red) CardioWrap® Bioresorbable Adhesion Barrier Film over time. Both film configurations show significant mechanical strength throughout the critical healing period (light blue).

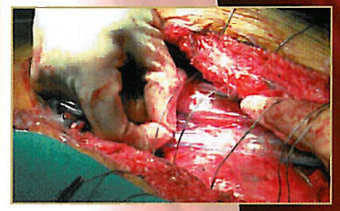
Since 2004, MAST Biosurgery has been manufacturing polymer implants, which have been successfully utilized in a wide variety of surgical applications in cardiac surgery, general surgery, gynecologic surgery, surgical oncology, and orthopedic surgeries.

Indications

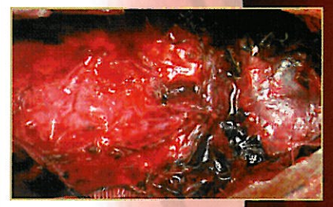
CardioWrap® Bioresorbable Adhesion Barrier Film is currently being marketed for the following indications:

- Separate opposing tissues and prevent the in-growth of scar tissues and the formation or reformation of adhesions immediately adjacent to the barrier film.
- Aid in re-operation procedures by promoting the formation of a surgical dissection plane immediately adjacent to the barrier film.
- Prevent the formation or reformation of adhesions and promote a surgical dissection plane in the pericardium, epicardium, and retrosternal anatomical regions.

Device Placement



35 Days Post Op



Features & Benefits of CardioWrap®

Features	Benefits
PLa	• Safe resorbtion and metabolization with minimal risk of inflammatory reaction • Demonstrated efficacy in reducing adhesion quantity and tenacity
Impermeable	• Maintains a physical adhesion barrier • Retains tensile strength for 6-8 weeks ensuring tissue separation during the critical wound healing period
Repositionable in a wet environment	• Easily repositioned if already in contact with anatomy • Will not stick to surgical gloves or instruments
Can be cut, trimmed or folded	• Enables CardioWrap® to be placed precisely where it is needed, around different anatomical structures and repairs
Transparent	• Allows for constant visualization of the entire surgical field, resulting in easy intra-operative placement and repositioning of the product.
Can be anchored in place with sutures, clips, or surgical tacks	• Ensures the device does not migrate from the desired area of protection