

REPEL-CV[®] Adhesion Barrier vs. GoreTex[™] Pericardial Membrane

*A comparison between the GoreTex complications
and the innovativeness of REPEL-CV*

SyntheMed, Inc.

SyntheMed, Inc. 200 Middlesex Essex Turnpike, Suite 210
Iselin, New Jersey 08830, USA www.synthemed.com

REPEL-CV[®] Adhesion Barrier vs. GoreTex[™] Pericardial Membrane

The GoreTex pericardial membrane (W.L. Gore & Assoc.) is used in some centers to act as a protective barrier for patients that will require a reoperation through a median sternotomy. The rationale for the use of the GoreTex membrane is that it forms a barrier between the cardiac structures (right atrium, right ventricle, coronary arteries, conduit, etc.) and the undersurface of the sternum. Hence, when the sternal re-opening is created, in theory the surgeon should find the membrane and then dissect in a plane on top of the membrane to open the sternum prior to beginning the dissection around the cardiac structures.

However, based on references in the clinical literature and comments from surgeons, there are some disadvantages with the use of the GoreTex pericardial membrane:

Although GoreTex acts as a protective barrier, it is associated with a range of serious disadvantages.

- The body mounts an inflammatory response in recognition of permanent foreign materials like GoreTex. The resultant fibrotic response encapsulates the implant as well as increases epicardial fibrosis.
- GoreTex does not reduce the extent or severity of postoperative cardiac adhesions but rather causes two different levels of adhesions; one level on the sternal side and one level on the cardiac side. Even after a successful sternal re-entry there are adhesions underneath the GoreTex membrane (cardiac side) that must be carefully dissected away from the heart. Because of the layer of GoreTex and the new layer of adhesions on the cardiac surface, this can be a challenging aspect of the surgical procedure.
- The extent and severity of adhesion formation on the cardiac side of the GoreTex membrane are increased due to the foreign body reaction to the material and the tissue planes underneath the GoreTex membrane are destroyed thereby prolonging the dissection time and exposing the patient to surgical risks when the anatomy is not clearly delineated or distorted.
- In general it takes a significantly longer time to put the GoreTex membrane in place than with REPEL-CV. Surgeons frequently anchor the GoreTex membrane with between 8 and 12 sutures because the GoreTex membrane needs to be carefully anchored to the pericardium so that it does not pull away. Should the GoreTex membrane pull away, the surgeon would have a false sense of security at the time of sternal re-entry.
- Careful positioning of the GoreTex membrane is required. It also requires a more precise cutting of the size of the GoreTex. If the GoreTex is too large it will buckle and become redundant. If the GoreTex membrane is too small it can actually cause cardiac tamponade.
- The GoreTex membrane is not transparent and therefore it is not possible to view the cardiac structures beneath the membrane. In addition, because it is sutured in a more exacting fashion, bleeding beneath the GoreTex membrane could cause tamponade.

- It is a permanent foreign body and therefore there is some increased risk of infection. This would be particularly true for the patient whose sternum has been left open in the intensive care unit for more than 2 or 3 days, especially where a silastic patch has been used to cover the sternal opening.

In contrast to the complications experienced with GoreTex:

- REPEL-CV Adhesion Barrier (SyntheMed, Inc.) is specifically designed to reduce post-operative adhesions in cardiac surgery and has been proven through controlled clinical trials to be safe and effective.
- REPEL-CV is resorbed in a timely manner and does not elicit a fibrotic encapsulation response.
- REPEL-CV is a soft, compliant transparent film which is easy to use and does not obstruct the surgeon's view of the surgical field.
- REPEL-CV decreases the extent and severity of postoperative cardiac adhesions and thus provides a more clearly defined anatomy with discernable landmarks and planes of dissection. The reduction in adhesions facilitates a safer re-entry resulting in the procedure being less challenging for the surgeon and less risky for the patient, i.e., decreasing the morbidity and mortality rates associated with reoperative cardiac surgery (e.g., inadvertent vascular or cardiac entry, which can result in fatal hemorrhage is minimized, surgical time is decreased, less blood loss and potentially less time on cardiopulmonary bypass).
- REPEL-CV is very loosely anchored and blood and serous fluid can easily communicate around the edges of REPEL-CV thereby reducing the risk of postoperative tamponade.

In summary, GoreTex membrane provides a barrier between the cardiac structures and the undersurface of the sternum that is difficult to penetrate at the time of sternal re-entry. This makes the sternal re-entry safer. The disadvantages are the dense adhesions on the cardiac side of the GoreTex membrane which makes it difficult to visualize cardiac structures and require time to dissect, the longer time period that it takes to insert the GoreTex, the potential for infection, and the concern about tamponade.

In contrast, REPEL-CV decreases the extent and severity of postoperative cardiac adhesions and thereby provides a more clearly defined anatomy with discernable landmarks and planes of dissection. REPEL-CV completely resorbs in approximately one month and does not have to be dissected out during the reoperation. Thus, making the procedure less challenging to the surgeon and less life threatening to the patient.

REPEL-CV significantly reduces the formation of post-operative adhesions.

GoreTex membrane stimulates the formation of post-operative adhesions.