

WITTMANN PATCH®

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| STERILE | EO |
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Description

The Wittmann Patch consists of two adhering sheets of biocompatible polymeric material. One sheet consists of micro-hooks and the other of loops. The two sheets adhere to each other when compressed together. High tangential shearing forces are required to separate the two sheets. Testing has demonstrated that separation of the two sheets would occur only with forces greater than those that would disrupt normal, intact or sutured fascia. Peeling the top sheet away from the lower sheet opens the two sheets to access the abdominal cavity.

Indications

For temporary bridging of abdominal wall openings where primary closure is not possible and or repeat abdominal entries are necessary.

Contraindications

The Wittmann Patch is not designed or intended for use as a permanent implant.

Uses

The following information is provided for informational purposes only. It is intended to show how surgeons, who studied the device, used it in various applications. It is not intended to supersede the way the attending surgeon chooses to use it for a particular application.

The Wittmann Patch has been used to treat excessively increased intra-abdominal pressure, abdominal trauma, intra-abdominal infections, acute pancreatitis with and without infection, bowel ischemia, traumatic and non traumatic intra-abdominal hemorrhage, ruptured abdominal aortic aneurysms and the "difficult-to-treat abdomen" including multiple adhesions, enteric fistulas, loss of fascia and failed hernia repairs with meshes. It also has been used in abdominal organ transplantation to foster abdominal perfusion and treat complications.

| Use | Intra-Abdominal Infection | Infected Pancreatic Necrosis | Hemo-peritoneum/ Trauma | Difficult-to-Treat Abdomen | All Patients |
|--|---------------------------|------------------------------|-------------------------|----------------------------|--------------|
| Average Number Days Treated with Wittmann Patch | 6.7 | 8.1 | 4.1 | 3.8 | 6.2 |
| Average Number Openings with Wittmann Patch | 4.7 | 6.1 | 2.6 | 3.0 | 4.4 |
| Average Time (Days) between Entries using Wittmann Patch | 1.5 | 1.3 | 1.6 | 1.2 | 1.5 |
| Average Number of Wittmann Patches per Patient | 1.10 | 1.00 | 1.03 | 1.00 | 1.06 |

Warnings

FOR SINGLE PATIENT USE ONLY

Federal law restricts sale of this device to, by, or on the order of a physician. Use of this device should not otherwise affect the standard of care for the condition being treated. The Wittmann Patch should be opened at least once every 24 to 36 hours. There have been no prospective controlled studies to support device safety and effectiveness.

Adverse Reactions

Patients with severe abdominal trauma and abdominal compartment syndrome have a high mortality rate. Careful attention is required irregardless of whether the Wittmann Patch is being used.

Precautions

Continuous monitoring of clinical parameters should be performed as indicated. If intra-abdominal pressure exceeds acceptable clinical limits, the Wittmann Patch must be opened and or readjusted.

The Wittmann Patch requires use in accord with institutional standards for the critical care patients. Institutional standards typically include, but are not limited to, patient monitoring, pain control, and antibiotic therapy.

Re-use or re-processing of the Wittmann Patch poses a significant risk of cross-contamination in terms of microbiological agents, antigens, toxins, or chemical entities. The manufacturer knows of no effective method for cleaning and re-sterilization of the Wittmann Patch.

Contents

One 20cm x 40cm loop sheet and one 10cm x 40cm hook sheet. Contents are sterile unless enclosed package has been opened or damaged.

Instructions for use

The two sheets of the Wittmann Patch are placed on top of the wound to insure that the material covers the entire incision. The sheets are trimmed to the length of the incision and separated from each other.

Loop sheet

The larger, “fuzzy” flexible-backed loop sheet is sutured with running 0-loop nylon to the right abdominal fascia with the “fuzzy” loop side facing outwards. The backing covers the omentum and viscera. The free part is gently slipped underneath the opposite fascia (**Figure 1a**).

Hook Sheet

The smaller, more rigid hook sheet is sutured to the left fascia with running 0-loop nylon. The backing of the hook sheet must face outward (**Figure 1b**).

Closure

The closure is completed by gently pressing the hook sheet on to the loop sheet and trimming the overlapping edges (**Figure 1c**). A slight tension is exerted via the hook sheet, which helps prevent fascial retraction and eases re-approximation once increased intra-abdominal pressure has subsided.

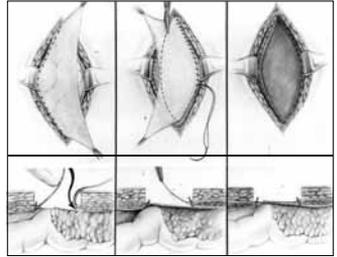


Figure 1 a, b, c. (from left to right)

Hypobaric Wound Shield

A Hypobaric Wound Shield (HWS) (**Figure 2**) is then applied to cover the wound and Wittmann Patch to help prevent contamination after the patient has left the operating room. The HWS also allows for detoxification of the peritoneal fluid that contains toxins and excessive cytokines and the other potentially harmful inflammatory proteins.

The Hypobaric Wound Shield is applied as follows:

1. Sterile gauze is applied to cover the wound and Wittmann Patch.
2. A sterile 6 mm (inner diameter) stiff drain with three side holes at the end, 10 feet long, is wrapped in the gauze on the end with the holes. The other end is attached to a suction pump.
3. The wound site is then covered with a self-adhesive plastic drape, which adheres to the surrounding skin. This hermetically seals the abdominal wound and allows for a slight negative or hypobaric pressure. The drain tube **MUST ALWAYS** be under suction without interruption once the plastic drape sticks to the skin.
4. Excess peritoneal fluid can be collected and measured losses replaced.

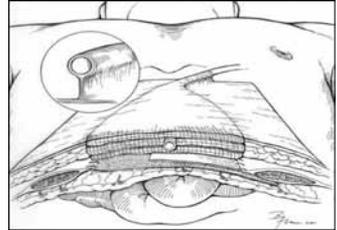


Figure 2 Cross section of the abdomen with Hypobaric Wound Shield

Reopening

At each re-laparotomy in the operating room, the hypobaric wound shield (plastic self adhesivedrape, gauze and drain tube) is removed after the abdominal wall has been prepped and draped to insure sterility. The **hook sheet** is then peeled off the **loop sheet**. Both sheets are folded back over the wound edges and the abdomen is explored. Upon completion of the operation, loop and hook sheets are refastened.

Pulling the fascial edges together via the hook and loop sheet may decrease the width of the abdominal wound. Decreasing wound width brings fascial wound edges closer together. The hook sheet can be trimmed further to allow for further progressive reapproximation of both fascial edges until final fascial suture between both sides becomes possible. Then, at the last operation, the hook and loop sheets are removed from the fascia and the abdomen is closed by directly suturing the two fascial borders.

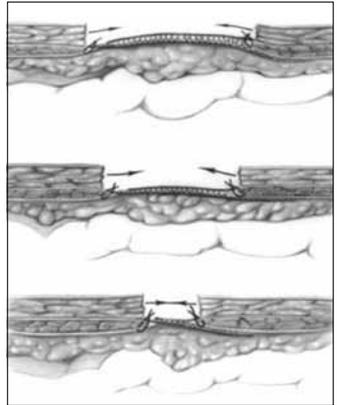


Figure 3 Re-approximation of the fascial edge