



Adhesix™ Mesh

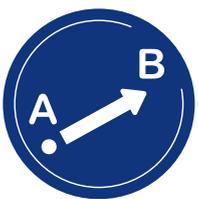
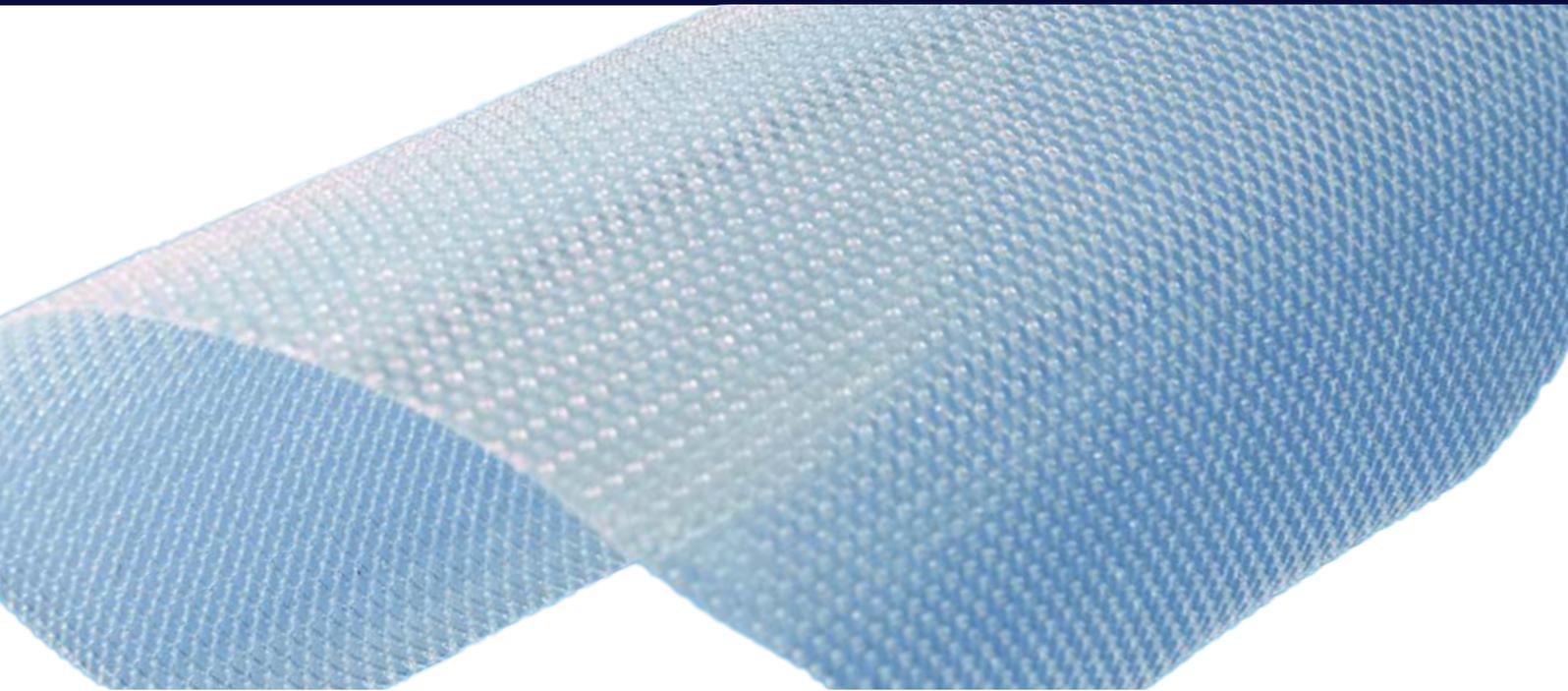
Self-Adhering Reinforcement Implant



1st Atraumatic self-adhering mesh

Adhesix™ Mesh is a unique hernia repair prosthetic constructed of lightweight polypropylene monofilament surrounded by a gel-coating of polyvinylpyrrolidone (PVP) and polyethylene glycol (PEG). Upon implantation, the self-adhering gel con-forms to the human anatomy, providing a flexible, long-term repair. The self-adhering coating provides

for an atraumatic repair that may minimise the amount of required fixation, potentially lowering both patient discomfort and overall operative time. Adhesix™ Mesh is available in numerous sizes and configurations for Lichtenstein, Laparoscopic Inguinal, and Open Ventral Hernia repair.



Easy

- Self-adhering gel coating allows mesh to be atraumatically implanted, positioned and secured
- Self-adhering gel coating conforms to tissue planes, providing a secure repair



Reliable

- Lightweight polypropylene mesh provides a permanent tension-free repair



Effective

- Available in multiple configurations and sizes for Lichtenstein, Laparoscopic Inguinal and Open Ventral hernia repair
- Published animal and human data

Easy

Unique self-adhering gel coating allows for atraumatic implantation

- Smooth adhesive side conforms to tissue in the presence of heat and moisture.
- Designed for easy handling and positioning.
- All in one design is more convenient than fibrin glue.

Reliable

Lightweight Polypropylene for an optimal repair

- Lightweight polypropylene delivers a fast fibrotic response resulting in strong tissue incorporation into the abdominal wall.
- Conforms readily to the anatomy.
- True tension-free repair.



Effective

Suitable for both inguinal and ventral hernia repair

- Wide array of sizes specifically designed for Lichtenstein repair.
- Laparoscopic inguinal configuration with protective sheet allows for easy insertion and positioning.
- Larger sizes suitable for open ventral hernia repair.



Adhesix™ – Smooth Mesh profile for atraumatic implantation; competitive Mesh – Mesh strands that may limit the ability to reposition

Two peer reviewed published articles on effectiveness of Adhesix™ Mesh

Champault G., et al., Hernia (2009)*

Simulated Lichtenstein repair in a porcine model w/results at T=0, 1, 7 and 28 days

- Significantly lower operative time vs. fixation group.
- Good macroscopic and microscopic integration with no shrinkage or migration.

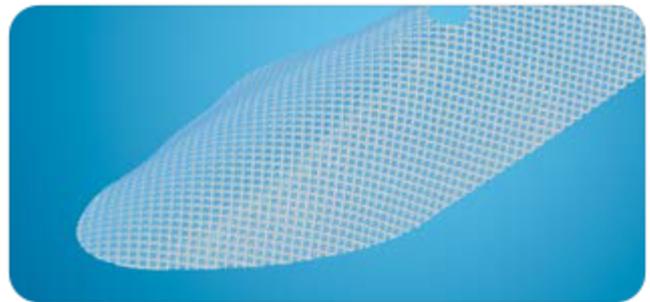
Champault G., et al. Hernia (2011)**

Multicenter, prospective and non-comparative study Completed 132 patients with visits at T=7, 30, and 90 days

- No hernia recurrences were reported at 3 months.
- Chronic pain was well below the figures encountered in literature.†
- Significant improvement in Quality of Life.

2011 Study conclusion

“Adhesix™ self-adhering mesh for prosthetic reinforcement following inguinal hernia repair is atraumatic and associated with infrequent post-surgical complications or pain, a rapid recovery rate, and a high patient reported QoL.”



Patient comfort

Lightweight polypropylene mesh combined with minimal fixation for less pain and discomfort

- Mesh weight is <math><40\text{ g/m}^2</math> after resorption of the gel coating.
- PVP/PEG self-adhering gel coating allows mesh to be positioned and secured in an atraumatic fashion.
- Adhesix™ Mesh is a macroporous lightweight mesh.
- Avoids aggressive fixation and is more convenient than using fibrin glues.

“At 3-months post-surgery, 97.7% of patients reported that they were very satisfied with the procedure and would choose the same operation again.”**

* G. Champault, C. Polliand, F. Dufour, M. Zioli, L. Behr. A “self-adhering” prosthesis for hernia repair: experimental study. Hernia. 2009 February; Volume 13, Issue 1:49-52

** G. Champault, A. Torcivia, L. Paolino, W. Chaddad, F. Lacaine, C. Barrat. A self-adhering mesh for inguinal hernia repair: preliminary results of a prospective, multicenter study. Hernia. 2011 December; Volume 15, Issue 6: 635-41

† Reduction in chronic pain is solely the finding of the author. Pain reduction is not a claim covered in the IFU.

Ordering information

Lichtenstein

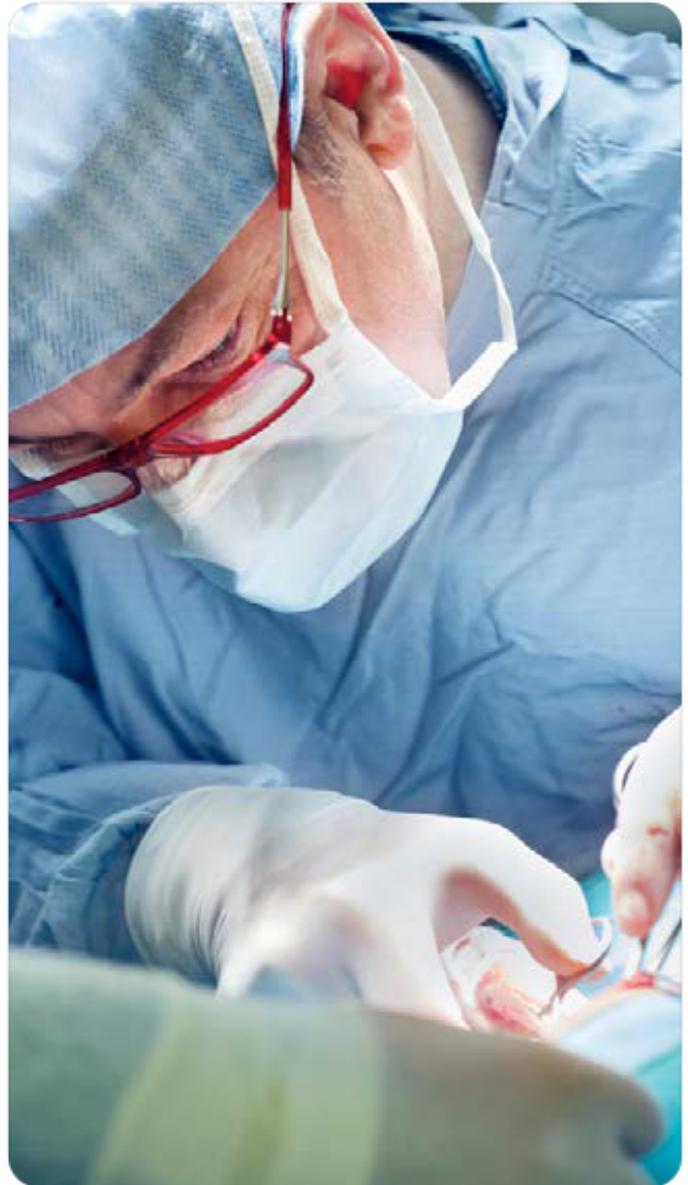
Product code	Qty.	Description	Dimensions	
0119310	1/cs.	Pre-cut onlay mesh	4 x 10 cm	■
0119330	1/cs.	Pre-cut onlay mesh	6 x 13.5 cm	□
0119350R	1/cs.	Right, Pre-cut onlay mesh	7.5 x 15.5 cm	■
0119320L	1/cs.	Left, Pre-cut onlay mesh	7.5 x 15.5 cm	□
0119340	1/cs.	Pre-cut onlay mesh	8.5 x 12.5 cm	■

Laparoscopic Inguinal

Product code	Qty.	Description	Dimensions	
0114310	1/cs.	Pre-cut mesh + protection film	10 x 15 cm	□
0114320	1/cs.	Pre-cut mesh + protection film	12 x 15 cm	■

Open Ventral

Product code	Qty.	Description	Dimensions	
0113310	1/cs.	Mesh	15 x 20 cm	■
0113420	1/cs.	Mesh	20 x 25 cm	□
0113530	1/cs.	Mesh	30 x 30 cm	■



Adhesix™ Mesh

Indications Parietal repair and reinforcement of inguinal, umbilical, linea alba, and ventral hernias. **Uses.** Adhesix™ meshes can be used in laparoscopic surgery or in open surgery and are designed for extraperitoneal implantation. Adhesix™ meshes are coated with a resorbable adhesive hydrogel and are biocompatible. These devices promote reactionary fibrosis. They can be easily cut to fit any hernia size. Adhesix™ meshes are also very flexible and allow good tissue ingrowth as well as rapid and optimum tissue colonization. **Contraindications.** Do not implant in the following cases: • Allergy to one of the components • Infected site • Anticoagulant therapy • Pregnant woman • Growing child (<18 years) **Adverse Side Effects.** As with any implantable medical device, Adhesix™ Mesh may induce adverse side effects such as: • Recurrence • Inflammation • Adhesions • Pain • Infection • Allergic reaction • Seroma • Cutaneous dehiscence • Cutaneous necrosis • Migration • Discomfort • Extrusion • Hematomas • Fistula formation • Erosion • Foreign Body Reaction • Obstruction • Lymphocele • Deformation of the mesh and irritation of nearby organs. **Precautions.** for Use The device must be implanted only by a qualified surgeon with knowledge of anatomy and visceral surgery, proper expertise of the device, its intended use and the surgical technique. Adhesix™ meshes are delivered sterile; verify the integrity of the packaging (do not use if the labels and/or blister packs/peeled pouches are damaged). Do not use if the device is damaged or has expired. **General Recommendations** Keep the mesh dry (away from any type of liquids) until placement in the abdomen during surgery. The adhesive hydrogel does not affect hemostasis; the area of dissection and the fascia on which the Adhesix™ implant is placed must be clean and dry. If necessary, use a surgical gauze to ensure the surgical field is dry. The adhesive hydrogel is activated by heat and moisture. Once the implant is in place, it must not be repositioned by the surgeon. **Specific Recommendations for Lichtenstein Surgical Technique.** The adhesive side of the implant (smooth side) must be placed on the fascia. The implant should first be slid onto the pubis, then the arms wrap around the spermatic cord. **Specific Recommendations for Preperitoneal Implantation for Ventral Hernias.** Adhesix™ Mesh is indicated for preperitoneal placement. It is recommended that the adhesive hydrogel side should be implanted deeply. The size of the implant must fit the size of the defect. It is recommended to place an abdominal strap around the patient's abdomen for several days following surgery in order to reinforce the abdominal wall. **IMPORTANT: DO NOT REUSE - DO NOT RESTERILIZE** As stipulated on the product's label, Adhesix™ Mesh is a single-use device. Under no circumstances should it be reused and/or resterilized (potential risks include, but are not limited to: loss of product sterility, risk of infection, loss of product efficacy, and recurrence). **Storage Precautions.** Store in a dry place, away from light, and in its original packaging. For any additional information on the use of this product, please contact your C. R. Bard, Inc. representative or distributor.

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Adhesix™ Mesh (Laparoscopic)

Indications. Parietal repair and reinforcement of inguinal, umbilical, linea alba, and ventral hernias. **Uses.** Adhesix™ meshes can be used in laparoscopic surgery or in open surgery and are designed for extraperitoneal implantation. Adhesix™ meshes are coated with a resorbable adhesive hydrogel and are biocompatible. These devices promote reactional fibrosis. They can be easily cut to fit any hernia size. Adhesix™ meshes are also very flexible and allow good tissue ingrowth as well as rapid and optimum tissue colonization. **Contraindications.** Do not implant in the following cases: • Allergy to one of the components • Infected site • Anticoagulant therapy • Pregnant woman • Growing child (<18 years) **Adverse Side Effects** As with any implantable medical device, Adhesix™ Mesh may induce adverse side effects such as: • Recurrence • Inflammation • Adhesions • Pain • Infection • Allergic reaction • Seroma • Cutaneous dehiscence • Cutaneous necrosis • Migration • Discomfort • Extrusion • Hematomas • Fistula formation • Erosion • Foreign Body Reaction • Obstruction • Lymphocele • Deformation of the mesh and irritation of nearby organs. **Precautions for Use.** The device must be implanted only by a qualified surgeon with knowledge of anatomy and visceral surgery, proper expertise of the device, its intended use and the surgical technique. Adhesix™ meshes are delivered sterile; verify the integrity of the packaging (do not use if the labels and/or blister packs/peeled pouches are damaged). Do not use if the device is damaged or has expired. **General Recommendations.** Keep the mesh dry (away from any type of liquids) until placement in the abdomen during surgery. The adhesive hydrogel is activated by heat and moisture. Once the implant is in place, it must not be repositioned by the surgeon. **Specific Recommendations for Laparoscopy.** Following standard dissection, the Adhesix™ Mesh and its protective film are rolled horizontally. The protective film is rolled towards the inner side of the mesh. Both the mesh and the protective film must be inserted in a 12 mm trocar. The implant is unrolled from top to bottom or from bottom to top. It must completely cover the weakened area. The nonadhesive side of the implant (rough side) must be placed on the fascia. The protective film must be removed. **IMPORTANT: DO NOT REUSE - DO NOT RESTERILIZE** As stipulated on the product's label, Adhesix™ Mesh is a single-use device. Under no circumstances should it be reused and/or resterilized (potential risks include, but are not limited to: loss of product sterility, risk of infection, loss of product efficacy, and recurrence). **Storage Precautions.** Store in a dry place, away from light, and in its original packaging. For any additional information on the use of this product, please contact your C. R. Bard, Inc. representative or distributor.

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Not all products, services, claims or features of products and services may be available or valid in your local area. Please check with your local BD Representative

Disclaimer: Please consult product labels and instruction for use for indications, contraindications, hazards, warnings, and precautions

ADHESIX is a class III medical device manufactured by COUSIN BIOTECH S.A.S. The CE conformity has been carried out by the notified body SGS Belgium NV (CE1639). The management system of COUSIN BIOTECH S.A.S is certified for compliance with ISO 13485 standard.

Cousin Biotech is the legal manufacturer of the ADHESIX medical device.

Manufacturer: COUSIN BIOTECH

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