A PATIENT'S GUIDE TO HERNIA REPAIR

This brochure is intended to provide basic information about hernia repair and to assist you in making an informed decision about your treatment options. If you have any questions or concerns about the diagnosis or treatment of your medical condition, please talk to your doctor.

GORE

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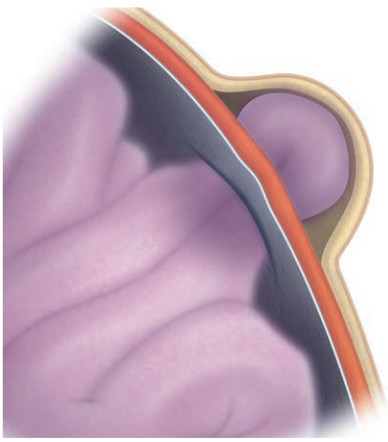
What is a hernia?

A hernia is defined as a bulge of an organ or a part of an organ through the wall of the cavity that normally contains it.



What causes a hernia?

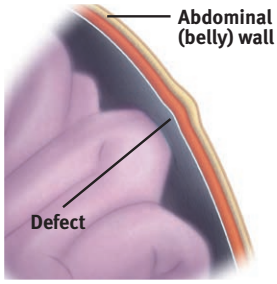
Most hernias develop in the abdominal (belly) wall, which runs from just below your breastbone down into your groin. This wall is similar to the rubber on a tire: it surrounds and protects your organs the same way a tire surrounds and protects the air-filled tube inside of it.

Hernias develop when a section of the abdominal wall wears down or tears. There are several possible reasons for this:

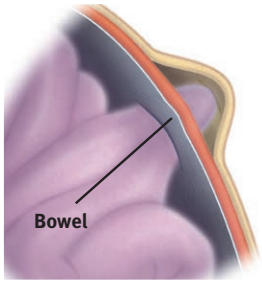
- An area of your abdominal wall is weak at birth.
- An area of your abdominal wall weakens over time due to physical stress, injury, pregnancy, aging, smoking and obesity.
- A weakness or tear develops at the site of a previous surgical incision.

Hernias generally grow larger due to pressure applied on them, such as a loop of your bowel or fatty tissue pushing into the weak abdominal tissue or tear. No matter what the cause is, it is important to see a doctor for a medical evaluation because hernias do not get better over time or go away on their own. In fact, they usually grow larger and get worse.

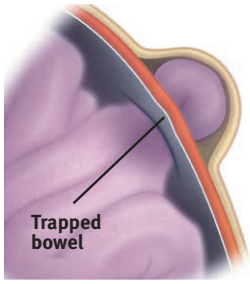
How a hernia develops



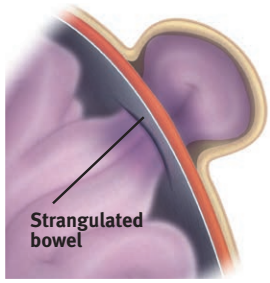
Wall weakens or tears
The abdominal lining bulges out through a weak area and begins to form a hernia sac. The sac may contain fat, bowel or other tissues. At this point the hernia may or may not cause a visible bulge.



Bowel pushes into the sac
As the bowel pushes further into the sac, it forms a visible bulge. The bulge may flatten when you lie down or push against it. This is called a reducible hernia and does not cause any immediate danger.

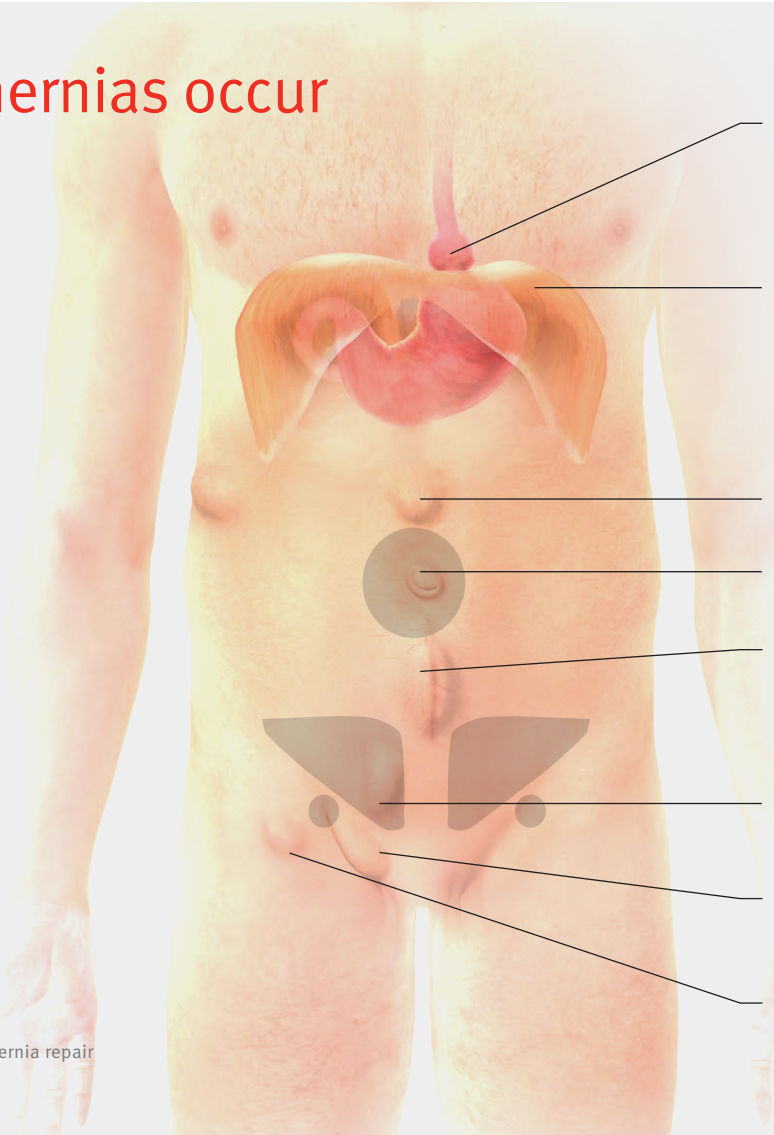


Bowel may become trapped
The sac containing the bowel may become trapped (incarcerated). If this happens, you won't be able to flatten the bulge. You may also have pain. Prompt treatment may be needed.



Bowel may be strangulated
If the bowel is tightly trapped, it becomes strangulated, or cut off and the area loses blood supply and may die. This can cause severe pain and block the bowel. Emergency surgery is needed to relieve the blockage.

Where hernias occur



Diaphragmatic hernias

Hiatal / Paresophageal hernias occur when the esophagus or part of the stomach move upward through the hiatus (a hole in the diaphragm) into the chest area.

Diaphragmatic hernias occur when one or more abdominal organs move upward into your chest through a defect (opening) in the diaphragm.

Ventral hernias

Epigastric hernias occur in the upper abdomen at the midline.

Umbilical hernias occur at the navel.

Incisional hernias occur at the site of a previous surgical incision.

Inguinal hernias

Direct inguinal hernias occur in the groin near the opening of the inguinal canal.

Indirect inguinal hernias occur in the groin at the opening of the inguinal canal.

Femoral hernias occur in the femoral canal.

Types of hernias

There are three main categories of hernias, named according to where they occur on the body. Within each of these categories, there are different types of hernias (Not an exhaustive list of all hernias. More rare hernias not pictured).

Diaphragmatic hernias

Diaphragmatic hernia – Occur when one or more abdominal organs move upward into your chest through a defect (opening) in the diaphragm.

Hiatal / Paresophageal hernia – Occur when the esophagus or part of the stomach move upward through the hiatus (a hole in the diaphragm) into the chest area.

Ventral hernias (also called abdominal hernias)

Incisional hernia – With abdominal surgery comes the risk of an incisional hernia. This type of hernia bulges through the scar from a past surgery, and can occur anywhere on the abdomen months or years after surgery.

Umbilical hernia – This hernia is seen in children and adults of both sexes in the umbilical ring that surrounds the navel. It may be caused by a defect that is present at birth or may occur over time due to obesity, excessive coughing or pregnancy.

Epigastric hernia – An epigastric hernia pushes through the abdominal wall between your lower breastbone and navel. Both men and women can get this type of hernia, which is usually the result of a weakness present at birth combined with intra-abdominal pressure along the midline.

Inguinal hernias (also called groin hernias)

Direct inguinal hernia – This type of hernia occurs in the weak muscle next to the opening of the inguinal canal in the groin area. Direct hernias typically occur in men over 40 and may result from aging or injury.

Indirect inguinal hernia – As the most common type of hernia in men, an indirect hernia occurs when a loop of bowel and / or fat presses into or through the inguinal canal in the groin area. This area may be weak at birth, allowing hernias to form later in life. Both men and women can get this type of hernia.

Femoral hernia – This hernia is more common in women, who may get it as a result of a weakness in the femoral canal area of the groin.

There are three main categories of hernias, named according to where they occur on the body. Within each of these categories, there are different types of hernias.

Your treatment options

The most typical sign of a hernia is a bulge under your skin in the groin or abdomen. You may also feel pain when you lift, cough or strain. This common condition affects men, women and children of all ages.

The good news is hernias are highly treatable with surgery and innovative hernia repair products.

Non-surgical options

Watchful waiting – Your surgeon will watch the hernia and make sure it is not getting bigger or causing problems. Watchful waiting is an option for people who do not have complications or symptoms with their hernias, and if recommended by their surgeon.

Surgical options

Open repair – The surgeon makes an incision (cut) near the hernia and the weak area is repaired. Open repair can be done with or without surgical mesh.

Laparoscopic repair – Laparoscopic procedures are minimally invasive, meaning they make only small incisions, and offer the benefits of less pain and shorter recovery. The surgeon makes several small incisions in the abdomen that allow surgical tools into the openings to repair the hernia. Laparoscopic surgery can be performed with or without surgical mesh.

Robotic repair – Robotically-assisted procedures also are minimally invasive, meaning they make only small incisions and offer the benefits of less pain and shorter recovery. The surgeon makes several small incisions in the abdomen that allow robotic surgical tools into the openings to repair the hernia. Robotic surgery can be performed with or without surgical mesh.

What is surgical mesh?

Surgical mesh is a medical device that is used to provide additional support to weakened or damaged tissue. It is often used in open, laparoscopic and robotic hernia repairs.

Hernias have a high rate of recurrence, meaning they may happen again and surgeons often use surgical mesh to strengthen the hernia repair and reduce the rate of recurrence.

To address the risk of recurrence after suture (stitches) repair, surgeons also can perform abdominal wall reconstruction and hernia repair with mesh reinforcement of the defect. With the exception of small first-time (primary) hernias, mesh repair is generally recommended for all other ventral hernias.[1] In cases with complicated or large hernias, the rate of mesh use may approach 90 percent depending on the specific hernia type or patient population.[2,3]

The use of surgical mesh may also improve patient outcomes through decreased operative time and minimized recovery time. However, recovery time depends on the type of hernia, the surgical approach and the patient's condition both before and after surgery.

Surgical mesh can be constructed from synthetic (man-made) materials or materials of human or animal origin.

Synthetic mesh can be divided into three different types based on the needs of the patient and the case.

Permanent mesh, such as GORE® DUALMESH® Biomaterial, is used to provide permanent reinforcement to the repaired hernia. Absorbable mesh, such as GORE® BIO-A® Tissue Reinforcement and GORE® ENFORM Biomaterial, is meant to be fully absorbed after a specific time period. Hybrid meshes, such as GORE® SYNECOR Biomaterials, are the newest innovation that use both permanent and absorbable features to deliver benefits of both.

Animal-derived (biologic) mesh is made of human or animal tissue, such as bowel or skin, that has been processed and disinfected to be suitable for use as an implanted device. The majority of tissue used to produce these mesh implants are from a pig (porcine) or cow (bovine) source.

Potential surgical repair and mesh risks

There are risks associated with any surgical procedure. The most common adverse events for all surgical repair of hernias with or without mesh are pain, reflux, difficulty swallowing (dysphagia), irritation or inflammation, infection, hernia recurrence, scar-like tissue that sticks tissues together (adhesion), blockage of the large or small bowel (obstruction), bleeding, abnormal connection between organs, vessels, or bowels (fistula), fluid build-up at the surgical site (seroma), blood and fluid build-up at the surgical site (hematoma), wound re-opening or not healing (dehiscence), fever, an additional surgical procedure and a hole in neighboring tissues or organs (perforation). Some other potential adverse events that can occur following hernia repair with mesh are mesh migration and mesh shrinkage (contraction). The risks of medical procedures are different for each patient. Talk to your doctor to discuss the risks further.

Treatment considerations

While some hernia defects can disappear if they are pressed, this does not permanently resolve the hernia. In addition, because hernias typically worsen over time, the patient should consult a surgeon after a hernia has been identified. Surgical hernia repair is considered a standard of care for this pathology and is one of the most common surgical procedures across U.S. By repairing hernia with mesh (compared to suture alone), the recurrence rate of the hernia is dramatically reduced.

Keep in mind, some hernias can cause serious health complications, so if you think you may have one, it is important to see your doctor for a complete medical evaluation.

Gore's general surgical products are designed to work with your body's own tissues, helping to reduce complications from hernias following surgery.

Where can i get more information?

FDA website: Hernia Surgical Mesh Implants
http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/herniasurgicalmesh/default.htm

Gore conditions website: Hernia
https://www.goremedical.com/hernia

Abdominal Core Health Quality Collaborative (ACHQC): Patient Information
https://www.achqc.org/patients

This patient guide is not intended to be a substitute for professional medical advice. Patients should consult with their own physicians for information on the risks associated with the referenced device(s) or procedure(s). Only the patient's physician is qualified to diagnose and treat his or her hernia. The purpose of this Patient Guide is to provide the patient with generalized information about hernias and Gore's medical devices used to treat hernias in lay terms to facilitate a discussion with the patient's physician.

Gore products for hernia repair

We make multiple products for hernia repair. These products are developed in partnership with hernia-specialist surgeons for different types of surgery and different patient needs. You can read about the different hernia repair products we offer and the risks and warnings for those products online at **www.goremedical.com/hernia**. However, this information is meant only to support a discussion with your doctor and is not meant to provide you with detailed risk and warning information about Gore's products.

It is important to discuss with your doctor which type of surgery and which hernia repair product is right for you, including the benefits, contraindications, risks and warnings of the types of surgeries and the hernia repair products. Only your doctor can diagnose and treat your hernia.

Gore Bioabsorbable Technology

20 year history of effective clinical use

Minimizing complications. Maximizing outcomes.

Proven leader in reducing risks and raising the standard for hernia surgery

Currently there are questions about hernia device implants and the potential for long term complications.

At Gore, our devices for hernia repair and abdominal wall reconstruction are designed with differentiated, innovative materials that support quality outcomes for patients.

We offer innovative, proven materials with 20 years of clinical data that supports your surgeon in delivering a strong repair with the least possible amount of material left in the body. If your surgeon is concerned about your risk for complications, they may recommend a product containing Gore's fully absorbable technology.

Our Gore bioabsorbable technology is a unique three dimensional (3D) material with a web structure that acts as a tissue building scaffold to support your repair during the critical wound healing cycle.

The unique 3D material and web structure:

- Helps your body generate quality tissue fast during the natural healing process.
- Is fully absorbed within six to seven months.
- Leaves behind your body's own quality tissue supporting a strong repair.
- Supported by the most extensive body of positive clinical results over 10 years of hernia repairs.
- The 3D tissue-building scaffold fully absorbs to leaves no permanent material behind, just healthy tissue.

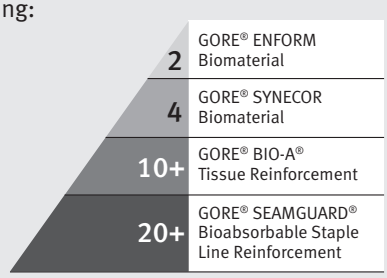
Surgical mesh devices that utilize Gore Bioabsorbable Technology are:

- GORE® BIO-A® Tissue Reinforcement: A 3D scaffold for hernia repair.
- GORE® ENFORM Biomaterial: A 3D tissue matrix for abdominal wall reconstruction, plastic surgery and reconstructive procedures.
- GORE® SYNECOR Biomaterial: A hybrid device featuring Gore 3D bioabsorbable technology and our Gore PTFE knit for a durable repair supported by permanent strength.

Our bioabsorbable technology is proven and trusted. It is backed by more than 20 years of research and clinical use with a record of reliability in numerous parts of the body including:

- Groin
- Abdominal wall
- Colon
- Stomach
- Lungs
- Liver
- Pancreas
- Spleen

Many of the competitive products for complex hernia repair are called "biologics" since they are made from human or animal tissue. As our Gore bioabsorbable material is synthetic or man made, it alleviates concern with people who have religious beliefs or cultural practices regarding the use of certain animals or their body parts.[4]



Years supporting patient quality of life

GORE® BIO-A® Tissue Reinforcement*

Is what we call "biosynthetic." It is made of synthetic polymers that are very biocompatible, meaning that they interact well in the body. It is beneficial in complex open hernia repair where there may be complications due to having diabetes, smoking or other health factors that you discuss with your doctor.

A unique feature of this product is that it is absorbed completely by the body over six to seven months so that there is no permanent foreign material left behind in the body. This device will be replaced with your own quality tissue fast during the critical healing period after surgery.

Over 10 years of data
For hernia repairs, more than 150,000 GORE® BIO-A® Devices have been sold. In addition, clinical studies cites more than 1,700 repairs that show GORE® BIO-A® Tissue Reinforcement is an excellent choice in soft tissue repair.

- Paraesophageal / hiatal hernia repair
- Ventral hernia repair
- Suture line reinforcement

GORE® BIO-A® Tissue Reinforcement
Fully bioabsorbable option. Leaves no permanent material behind.

Over **10 years** of positive clinical reults.

GORE® ENFORM Biomaterial*

Optimized conformability

This is our latest fully bioabsorbable innovation that works with the body during the critical healing phase and leaves behind only your healthy tissue.

- Unprecedented flexibility of a synthetic soft tissue reinforcement.
- Conforms to match anatomy and better accommodate the surgeon's choice of technique to support your repair.
- Abdominal wall reconstruction.
- Plastic and reconstructive surgery.
- Complex ventral, incisional hernia repairs.
- Complex hiatal and paraesophageal repairs.

GORE® ENFORM Biomaterial
Our latest fully bioabsorbable innovation is strong, soft and pliable to support your comfort during the healing process.

* Discuss the risks associated with surgical repair of hernias and risks related to the referenced products with your physician.

GORE® DUALMESH® Biomaterial*

GORE® DUALMESH® Biomaterial is the first dual-surface material for repair of hernia, soft tissue and fascial reconstruction, including congenital defects and chest wall reconstruction.

The clinical reputation of GORE® DUALMESH® Biomaterial products for the repair and reconstruction of hernias and soft tissue deficiencies is well known, exceeding 450 peer-reviewed scientific articles published since 1996.

When a strong, durable repair is needed, GORE® DUALMESH® Biomaterial has the **proven performance**.

Our **innovative, expanded polytetrafluoroethylene (ePTFE) based products** have demonstrated superior biocompatibility and inertness in a wide range of applications including: Cardiothoracic, vascular and endovascular surgery, neurosurgery, hernia repair and thoracic reconstruction.

GORE® DUALMESH® Biomaterial

Over **20 years** of clinical use and data for this product line.

GORE® SYNECOR Biomaterial*

GORE® SYNECOR Biomaterial products are the unique hybrid mesh solution to deliver rapid vascularity with permanent strength in a hernia repair or abdominal wall reconstruction.

It is an easy-to-use solution for your surgeon in open, laparoscopic and robotic cases.

The hybrid design has key features combined to support an effective, permanent repair with quality outcomes:

- Features our unique Gore bioabsorbable web scaffold to support rapid vascularity and tissue ingrowth to support the critical healing cycle.
- Minimal permanent material in the body but offering durable strength for a single-stage repair.

For you as a patient, these products offer and support a single surgery with faster recovery and fewer complications versus a staged repair requiring multiple surgeries.

GORE® SYNECOR Biomaterials
Latest innovation high-strength hybrid solution for a durable repair.

Our latest innovation, when long term, permanent strength is needed:

Your surgeon will consider GORE® SYNECOR Biomaterial for hernia repair and abdominal wall reconstructions when permanent strength is needed and has been observed to help provide value for patients with complex repair needs or other risk factors such as high BMIs, obesity, smoking, diabetes, etc.

The permanent, synthetic, large pore knit of dense fibers in our GORE® SYNECOR Biomaterial is unique in that it is:

- Chemically inert to help avoid risk for long term inflammation in your body.
- Provides permanent strength for a durable repair, with a minimal amount of inert material in the body.

* Discuss the risks associated with surgical repair of hernias and risks related to the referenced products with your physician.

Glossary of hernia terms

Abdominal (belly) wall – The layers of muscle and fatty tissue that surround your abdomen.

Biomaterial – A natural or synthetic material, such as GORE® SYNECOR Biomaterial, that can be used in the human body, often as part of a medical device.

Congenital – A condition that is present at birth.

Diaphragmatic hernia – Occur when one or more abdominal organs move upward into your chest through a defect (opening) in the diaphragm.

Epigastric hernia – A hernia that occurs at the midline of the abdomen, between the breastbone and the navel.

Femoral canal – The opening between the leg and abdomen where large blood vessels and nerves run.

Hernia – A hernia is the bulge of an organ or part of an organ through the wall of the cavity that normally contains it.

Hiatal hernia – a condition in which the upper part of your stomach bulges through an opening in your diaphragm. Your diaphragm is the thin muscle that separates your chest from your abdomen. Your diaphragm helps keep acid from coming up into your esophagus. When you have a hiatal hernia, it is easier for the acid to come up.

Indirect inguinal hernia – The most common type of inguinal hernia, occurring at the opening of the inguinal canal in the groin area.

Inguinal canal – A naturally occurring "tunnel" in the groin area, through which hernias may form.

Inguinal hernia – A hernia that occurs in the groin area at or near the opening to the inguinal canal.

Intra-abdominal – Inside the abdomen.

Laparoscopic surgery – A surgical procedure that involves making small incisions through the skin and inserting instruments into the body to perform a repair. Sometimes a same-day procedure performed under general anesthesia.

Open surgery – A surgical procedure that involves making an incision in the abdomen, and repairing the hernia either by sewing the tissues back together with sutures or covering the hernia with a patch or mesh. The incision is closed with stitches, staples, surgical tape or special glue.

Recurrent hernia – A hernia that occurs at the same location as a previous hernia.

Reducible hernia – A hernia that can be flattened out either by applying pressure or by lying down.

Robotic surgery – A method to perform surgery using very small tools attached to a robotic arm. The surgeon controls the robotic arm with a computer.

Strangulated – An emergency situation, in which a loop of bowel or fatty tissue becomes tightly trapped and loses its blood supply, which can result in an obstruction of intestinal flow and / or gangrene.

Ventral hernia – Hernia that occurs in the abdominal wall, but not the groin area.

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Consult Instructions for Use
eifu.goremedical.com

Physicians should refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004

+65 67332882 (Asia Pacific)
1 800 680 424 (Australia / New Zealand)
00800 6334 4673 (Europe)
800 437 8181 (United States)
928 779 2771 (United States)

goremedical.com