



Hernia Repair and Treatment Failures— A Legal Guide

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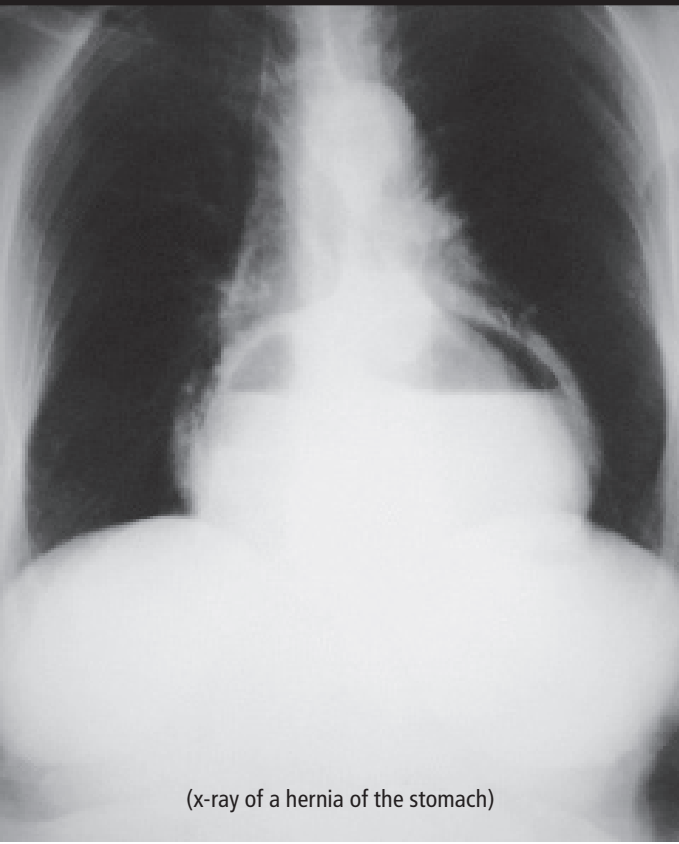
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(x-ray of normal stomach)



(x-ray of a hernia of the stomach)

ABOUT HERNIAS

The more you know and understand about hernias, the better your chances of getting the best repair.

Hernia repair requires two basic steps:

- Push back the protruding bulge, return the intestine to where it belongs, inside the peritoneal cavity.
- Close the window through which it came out in the first place.

A hernia occurs when part of an internal organ bulges through a weak area of muscle. Most hernias occur in the abdomen. Hernias are common medical problems affecting men, women, and children. Untreated hernias can cause pain and health problems.

The usual treatment for a hernia is surgery to repair the opening in the muscle wall. There are, several ways of doing this and results vary widely.



WHAT CAUSES HERNIAS?

The abdomen wall provides strong support to the internal organs which exert significant outward pressure.

The opening of a gap in the tissue can occur of its own accord at a point of natural weakness, or by over-stretching a part of the tissue. Overexertion may cause the gap, so can a simple cough or sneeze.

The gap in the abdominal wall is not the problem. Almost every movement puts more pressure on internal tissues which push out through the opening a bit more each time. This also enlarges the opening itself. If unchecked, this process can continue even to the extent of allowing much of the intestine to hang down through the hernia.

- chronic constipation, which causes a person to push too hard during a bowel movement
- chronic cough
- cystic fibrosis
- enlarged prostate and pushing to urinate
- overweight
- heavy lifting
- un-descended testicles

A combination of muscle weakness and straining, such as heavy lifting, might contribute to hernia or people born with weak abdominal muscles may be more likely to get a hernia.



WHAT ARE THE DIFFERENT TYPES OF HERNIAS?

- **Most common/inguinal or groin:** Groin pain is a frequent disability commonly seen in by football players, golfers and other sportsmen, and athletes. In certain muscle strains and tears, the sequence is acute groin pain which, at first, can be completely crippling, then gradually subsiding with chronic, repetitive, sharp pain and aching groin.
- **Umbilical/around the belly button:** Umbilical hernias are especially common in infants of African descent, and occur more in boys than girls. They involve protrusion of intra-abdominal contents through a weakness at the site of passage of the umbilical cord through the abdominal wall. These hernias often resolve spontaneously. Umbilical hernias in adults are largely acquired, and are more frequent in obese or pregnant women.
- **Incisional, through a scar:** An incisional hernia occurs when the defect is the result of an incompletely healed surgical wound. When these occur in median laparotomy incisions in the linea alba, they are termed **ventral hernias**. These can be the most frustrating and difficult to treat, as the repair utilizes already attenuated tissue.
- **Hiatal:** Hiatal is a small opening in the diaphragm that allows the upper part of the stomach to move up into the chest. Causes vary per individual—improper heavy weight lifting, hard coughing, and sharp blows to the abdomen, tight clothing, bad posture, obesity, bowel strain, urine strain, and chronic lung disease. Less likely but still plausible—weakened muscles caused by poor nutrition, smoking, and overexertion.
- **Femoral:** Women have a preponderance of femoral hernias which occur just below the inguinal ligament, when abdominal contents pass into the weak area at the posterior wall of the femoral canal. The incidence of strangulation in femoral hernias is high. Repair techniques are similar to inguinal hernia.
- **Diaphragmatic hernia:** Higher in the abdomen, an internal diaphragmatic hernia results when part of the stomach or intestine protrudes into the chest cavity through a defect in the diaphragm.
- **Congenital diaphragmatic:** This is a birth defect occurring in 1 in 2,000 births and requires pediatric surgery.

These are by no means all the hernias. Rather, the above list is the most common.



WHAT ARE HERNIA SYMPTOMS?

Symptoms and signs vary depending on the type of hernia. In the case of reducible hernias, you can often see and feel a bulge in the groin or in another abdominal area. When standing the bulge becomes more obvious.

Besides the bulge, other symptoms including groin pain may also include a heavy or dragging sensation. For men, there is sometimes pain and swelling in the scrotum around the testicles area.

Irreducible hernias may be painful, but their most relevant symptom is not being able to return to the abdominal cavity when pushed in. They may be chronic, although painless, and can lead to strangulation.

Nausea, vomiting, or fever may occur in cases due to bowel obstruction.

Also, the hernia bulge may turn red, purple or dark.



WHAT IS THE 'R' WORD IN TREATMENT FAILURE?

A treatment failure would be when a hernia repair operation breaks down as in a recurrent hernia. Further repair operations are more difficult than the first and, to make matters worse, the chances of success actually diminish with each successive attempt at repair.

Not only are the tissues in the abdominal wall more scarred and therefore potentially harder to work on, but recurrent repair operations suffer a significant failure rate.

The same is true of the breakdown of the scar in the abdominal wall from an incision for a previous operation for some other problem. This is called an incisional hernia. Both the recurrent hernia and the incisional hernia are very similar, including the difficulties in affecting a reliable repair.

There are also cases of multiple hernias and of combinations of all the above, such as multiple, recurrent hernias. Recurring and multiple hernias pose many difficulties to most doctors and are, frequently, not successfully repaired with a 50 percent or more chance of treatment failure.

In the case of the male patient, the front approach of recurrent hernia repair carries the risk of damage to the blood supply to the testicle when cutting through scar tissue in that area, which can lead to losing a testicle.

WHAT ARE THE COMPLICATIONS RELATED TO SURGICAL HERNIA REPAIRS?

Infection, chronic pain, hernia recurrence, repeated surgeries (expenses/loss of work/quality of life), death.





WHAT QUESTIONS TO ASK YOUR DOCTOR PRIOR TO HERNIA REPAIR SURGERY?

- What are the pros and cons of using surgical mesh for my condition?
- If surgical mesh will be used, is there special patient information that comes with the product, and may I have a copy?
- If surgical mesh will be used, what's your experience with this particular product and with treating potential mesh complications?
- Can my repair be successfully performed without using mesh?
- What's your experience in dealing with complications if they occur?
- What can I expect to feel after surgery and for how long?
- Are there any specific side effects I should let you know about after the surgery?
- What are the chances of recurrence?

Also, remember to inform the doctor if you've had a past reaction to materials used in surgical mesh or sutures, such as polypropylene.



WHAT IS THE PROBLEM WITH ALLODERM FOR HERNIA REPAIR?

In a recent study comparing two different kinds of hernia repair medical devices, it was determined that Alloderm used in abdominal wall reconstruction had a significant impact on recurrence rates.

37 patients with abdominal wall repairs using Alloderm were identified from January 2004 and December 2005. Eleven patients underwent bridged fascial repair; 26 patients had reinforced fascial repair.

In the bridged group, one patient died on postoperative day 20. Of the remaining 10 patients, eight patients developed recurrences. Seven patients required reoperation, but one patient refused repair. In the reinforced group, four patients were lost to follow-up and two patients died. Four of the remaining 20 patients developed recurrences that required repair; this was significantly different from the recurrence rate in the bridged group.

Also, the expense of Alloderm demands careful evaluation to justify widespread use.

WHAT IS THE PROBLEM WITH THE KUGEL MESH HERNIA PATCH?

From December 2005 through January 2006, Davol, Inc., makers of [Kugel Mesh Hernia Patch](#) issued expanded recalls due to memory recoil ring breaks that have been the cause of bowel perforation problems, bowel obstruction, and death. In January 10, 2007, Kugel Mesh Patch recall was extended as hernia damage complications multiplied. The recall included large-sized patches due to additional reports of memory recoil ring breakage.

Symptoms included unexplained or persistent abdominal pain, fever, tenderness at the implant site; bowel perforation symptoms such as severe abdominal pain intensified by movement, nausea and vomiting, fever and chills; bowel obstruction symptoms include abdominal pain and distention, vomiting, fecal vomiting, and constipation; or other unusual symptoms.

Davol, Inc. knew that there was a possibility of failure in the Kugel Mesh Patch but did not properly warn the public. Davol also blamed the doctors initially for bad performance.



HOW CAN I REPORT HERNIA REPAIR COMPLICATIONS?

In order to help FDA learn more about possible [problems with hernia repair](#) devices, it's important that both doctors and patients report complications.

Start by reporting problems to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by FAX.

- Online : [MedWatch Online Voluntary Reporting Form \(3500\)](#)
- Regular Mail : use postage-paid FDA form 3500 available at: [MedWatch Forms](#)
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- FAX: 1-800-FDA-0178

You should also contact [Anapol Schwartz](#) personal injury law firm. With offices in Pennsylvania, New Jersey, and West Virginia, we have the expertise in handling harmful medical device lawsuits.

CAN I AFFORD A HERNIA REPAIR INJURY LAWSUIT? HOW MUCH DOES A LAWSUIT COST?

Yes, you can afford a [hernia repair injury lawsuit](#) because there is no cost to you. If Anapol Schwartz agrees to be retained, we take your case on a percentage contingency basis. If you don't win your medical device product negligence lawsuit, we don't get paid.

Please [contact us](#) for a free no-obligation consultation.

