



**CHOLECYSTECTOMY CONSENT FORM**

I, \_\_\_\_\_ have been asked to carefully read all of the  
(name of patient or substitute decision-maker)  
information contained in this consent form and to consent to the procedure described below on behalf of  
\_\_\_\_\_. I have been told that I should ask questions  
(name of patient)  
about anything that I do not understand. (If the decision-maker signing this form is not the patient, references to  
“I,” “my” or “me” should be read as if referring to “the patient,” when applicable).

I understand that the information about the procedure described in this consent form, in addition to discussions with my physicians and any other written materials they may provide, is intended to help me make an informed decision whether to voluntarily undergo the proposed treatment.

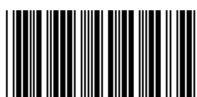
I understand that after evaluation including, but not necessarily limited to an interview, physical examination and a review of diagnostic studies, such as blood tests and x-rays, my physician(s) have recommended that I have my gallbladder removed. I understand that surgical removal of my gallbladder, also known as a cholecystectomy, has been recommended because my gallbladder may be causing symptoms such as pain after eating, nausea, excessive belching or vomiting. My gallbladder may also contain an abnormality for which removal may be advisable. The abnormality (ies) of my gallbladder that are suspected to be present and/or the cause of my symptoms are:

- Stones or sludge in the gallbladder
- Inflammation of the gallbladder
- Abnormal contraction of the gallbladder (biliary dyskinesia)
- A mass of the gallbladder
- Abnormal calcifications (hardened areas) of the gall bladder
- Other: \_\_\_\_\_

I understand that the gallbladder stores fluid produced by my liver. In response to eating food, the gallbladder contracts and empties its fluid into the intestine where the fluid mixes with food. I also understand that the gallbladder connects to passageways coming out of my liver known as bile ducts. One or more blood vessels travel to my gallbladder from the blood vessels that supply my liver. I understand that to remove my gallbladder, my physician(s) must identify and cut the connection of my gallbladder to the bile duct(s) and the blood vessels traveling to the gallbladder. My gallbladder must also be separated from my liver and other structures to which it may be attached.

**Description of the Surgery:** After I have been identified I will be anesthetized. This will usually mean I will be put to sleep under general anesthesia. The type of anesthesia and the risks of anesthesia will be explained to me by a representative of the Anesthesia Department and I must sign a separate consent. After I am put to sleep other medications such as antibiotics or blood thinners may be given to me before or during the surgery. Other devices may be placed to monitor my condition or help the operation be completed safely. These devices may include a catheter placed into my bladder to empty it of urine and to measure urine output during the surgery and a tube passed through a nostril or my mouth to empty my stomach.

I will be positioned lying on my back with my arms either at my sides or extended outward. My abdomen will then be cleansed and if necessary will be shaven.



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The surgical team will then perform the operation to remove my gallbladder. This may be performed either using an incision large enough to allow the gallbladder to be directly seen and to allow instruments or hands to be placed into my abdomen (“open cholecystectomy”) or using several small incisions through which instruments and a long camera called a laparoscope are inserted into my abdomen (“laparoscopic cholecystectomy”). The surgical team will visualize my gallbladder directly or using the laparoscope and will then divide the attachments of my gallbladder and remove it using hands and/or instruments passed through the incision(s) into my abdomen. The bile ducts exiting my liver and connecting to my gallbladder may be evaluated for abnormalities by injecting dye into the ducts and taking x-ray pictures (“cholangiogram”), by examining the bile ducts using sound waves, or by exploring the ducts using instruments. If abnormalities are found, my surgeon may decide that additional treatment of my bile duct is necessary by surgical or other means. The entire operation usually requires between one (1) and five (5) hours to complete, but may be shorter or longer. Once the operative procedure has been finished and after carefully inspecting for any signs of bleeding or other abnormalities, the incision(s) will then be closed.

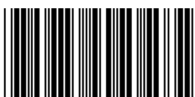
My surgeon will discuss with me whether my cholecystectomy is planned as an open or laparoscopic procedure. I understand, however, that although my surgery may be planned as a laparoscopic cholecystectomy, it may not be possible to complete in this manner and it may be necessary to change to an open cholecystectomy. During the course of the operation my surgeon will determine if it is necessary to change to an open cholecystectomy.

**Post-Surgical Recovery, Care and Conditions:** At the completion of my surgery, I will be taken from the operating room to the recovery room where my recovery from anesthesia will be monitored. When I have recovered sufficiently, I will be discharged from the recovery room to either an inpatient unit or to the Same Day Surgery unit.

If I require more extended or closer monitoring, I may be taken from the operating room to an Intensive Care Unit. If this occurs, when I have progressed sufficiently, I will be transferred from the Intensive Care Unit to an inpatient unit.

My physician(s) will determine when I can be discharged from the hospital. If I undergo a laparoscopic cholecystectomy, I may be discharged as early as the day of surgery. If I undergo an open cholecystectomy, it is likely that I will be hospitalized longer than if I had undergone a laparoscopic cholecystectomy. I understand that I may have some restrictions and limitations after the surgery. These may include restrictions or limitations on my diet and physical activities, including but not limited to driving and exercise. I acknowledge that these restrictions and limitations have been thoroughly discussed with me, and I agree to adhere to these restrictions and limitations.

After the surgery, I will most probably have pain whether my cholecystectomy is performed in a laparoscopic or an open manner. I may be given pain medications, antibiotics or other drugs as needed. I understand that it is important for my physician(s) to know all details of my medical history and all drugs that I am currently taking in order to avoid any unwanted and harmful drug interactions. I agree that prior to the surgery I will inform my physicians about my medical history and all medications, drugs, herbs and supplements I am taking.

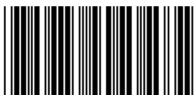


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I understand that I will develop scar tissue at the site of the incision (s). I also understand that I may have diarrhea and cramping temporarily. This usually resolves with time, but in some instances may persist. If this should occur, further evaluations and treatments may be advised, and may or may not be successful in resolving or treating these changes.

**Risks of Surgery:** I understand that there are inherent risks in the performance of the recommended procedure. These include:

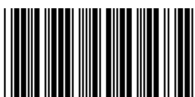
1. Injury to the gallbladder during its removal. This could result in the spillage of bile or stones that may result in infection, complications affecting the intestine, or other problems, and may require additional medical or surgical treatment.
2. Pain should normally resolve in a few days but could persist chronically. I may also have temporary or permanent numbness related to the incision.
3. Injury to the intestine that may require additional medical or surgical treatment.
4. Infection. This includes infection of the wound, within the abdomen or under the liver (subhepatic).
5. Bile duct complications
  - a. Injury to the bile ducts inside or outside of the liver. The cystic duct leads to the gall bladder and is normally cut to permit removal of the gall bladder. Other ducts connecting to the liver, intestine or pancreas may be transected (divided), cut, nicked, clipped, cauterized, or in some other manner injured. This may result in bile obstruction, bile leak, biliary stricture (narrowing), pain, infection, peritonitis, sepsis, or liver failure. Injury to the bile ducts might also require repair by another surgical procedure. A major bile duct injury occurs in the range of 1/200 cases to 1/300 cases. Repair of a bile duct injury usually requires a large, open procedure. The surgeon may not recognize that a bile duct injury occurred at the time of surgery. If a bile duct injury is recognized at the time of my cholecystectomy, the surgeon may attempt to repair it by placing a tube or stent into the bile duct, by suturing the bile duct, by re-connecting it to the intestine, or by some other means, or the surgeon may decide to defer repair of the bile duct to a future date. The surgeon may also call for assistance by another surgeon to repair the bile duct. Tests may need to be performed post-operatively to determine if a bile leak or bile duct injury has occurred.
  - b. Bile leak. Bile is a secretion of the liver that aids in digestion. Bile leak may occur from the duct to the gallbladder (cystic duct stump), from an accessory bile duct that is not seen or identified at surgery, or from another cause. The incidence of a post-operative bile leak is less than 5%, but it may occur. If a bile leak occurs, often a tube or catheter needs to be placed through the skin to drain the bile collection. A gastroenterologist may need to perform an endoscopic procedure in which a flexible telescope is passed from my mouth to the stomach and then to the beginning of my intestine to promote healing of the bile leak. In some cases, surgery is necessary to correct the bile leak. A surgical drain may be placed at the time of surgery (and brought out through the skin) if the surgeon believes it is indicated.
  - c. Biliary strictures (narrowing or constrictions of the ducts conveying the bile from the liver) can also occur. This may not be evident immediately after surgery. If a stricture occurs, treatment by means of endoscopic, radiologic, or surgical means may be necessary.



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- d. If a bile duct complication occurs, treatment to correct the complication may be unsuccessful.
6. If a cholangiogram is performed, I may develop an allergic reaction to the X-ray dye. The allergic reaction may be minor (such as hives, itching, or redness), or may be severe and life threatening with low blood pressure, swelling of the throat and airways requiring emergency treatment including assistance with breathing.
  7. Injury to one of the arteries or veins around the liver may occur leading to bleeding, liver damage, liver abscess, or liver failure. This may require another operation to repair the damage.
  8. Bleeding from the cystic or hepatic artery, liver, stomach, intestine or other blood vessels in the abdomen or abdominal wall can occur. If needed, blood and/or blood products have the following general risks: reactions resulting in itching, rash, fever, headache or shock; respiratory distress (shortness of breath); kidney damage; systemic infection; exposure to blood borne viruses including hepatitis (an inflammatory disease affecting the liver) and Human Immunodeficiency Virus (HIV, the virus that causes AIDS); and death. Alternatives to transfusion include the use of devices that filter and return blood lost in surgery to me or by providing medications that boost my blood count prior to an elective procedure. Bleeding and/or severe anemia could put my life in danger or cause permanent brain damage. I understand that substitutes for blood or plasma might not work well enough. Blood and/or blood products might offer the only chance to preserve my life.
 

I refuse the transfusion of blood and/or blood products and understand that I will be asked to sign a separate form entitled, Release from Liability for Refusal of Blood Transfusion.
  9. Gallstones may be left in place in the main bile duct or hepatic ducts. This may lead to post-operative problems such as infection, obstruction, or pancreatitis, and may require an ERCP procedure or additional surgical procedure to remove them.
  10. Pancreatitis. My pancreas, an organ involved in digestion of food and regulation of my blood sugar, may become inflamed or damaged in some other way. Although inflammation of the pancreas is usually mild, at times it can be very severe and life threatening. Treatment with medications or surgery may be necessary.
  11. The surgical incisions can separate, delaying healing.
  12. A hernia could occur that may require additional medical or surgical treatment.
  13. Postoperative abdominal adhesions (scar tissue inside the abdomen) can occur that may require further treatment including surgery.
  14. Blockage and inability of food, fluids, gas or waste to pass and be eliminated from the body (intestinal obstruction) due to adhesions (scar tissue), lack of proper motion of the intestines and other causes. Blockage can cause severe pain and require additional medical and/or surgical treatment.
  15. Blood clots. These clots usually develop in the legs and can break free and move through the heart to the lungs (pulmonary embolus). In the lungs, they can cause serious interference with breathing, which can lead to death. Blood clots are treated with blood-thinning drugs that may need to be taken for an extended period of time.



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16. Damage to nerves from pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or pain. In most cases these symptoms are temporary, but in rare cases they can last for extended periods or even become permanent. If an open procedure is performed, a retractor may be used for exposure that can cause rib bruising, damage, or fracture.
17. Air or gas embolus from the pneumoperitoneum (insertion of gas into the abdomen) may occur causing cardiac arrest, stroke, pulmonary embolus, or heart attack
18. Burns caused by use of electrical equipment that may be needed to stop bleeding or by other equipment.
19. As with all surgeries, there is a risk of heart attack, stroke, or death, even in healthy patients.
20. Post-operative pneumonia, urinary tract infection, or catheter infection may occur.
21. Other unforeseen risks or complications may occur.

**Alternatives.** I understand that I have the choice NOT to undergo the recommended procedure or any procedure. If I do not undergo the procedure, the condition for which I am being treated may get worse. I acknowledge that my physician(s) have discussed other alternative procedures or treatment(s) for my particular condition, if any.

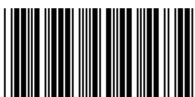
If my procedure is to be performed in an Ambulatory Surgical Facility (ASF), the comparative risks, benefits and alternatives associated with performing the procedure in the ASF instead of a hospital have been fully explained to me.

I understand the hospital may require that all jewelry and/or body piercing hardware be removed prior to surgery.

**Teaching Facility:** I understand that the facility is a teaching facility. The health care team may include residents, fellows, students, and skilled healthcare professionals. These team members may perform all or parts of my procedure under the supervision and guidance of my physician(s). I understand my physician(s) will perform or be present for the key portions of the surgery. Representatives of medical device companies may be present to provide devices, and observe and advise on their use. Who will participate and in what manner will be decided at the time of the procedure and will depend on the availability of individuals with the necessary expertise and on my medical condition.

I understand that the physician(s) or others may choose to photograph, televise, film or otherwise record all or any portion of my procedure for medical, scientific or educational purposes. I consent to the photographing, televising, filming or other forms of recording of the procedure(s) to be performed, including appropriate portions of my body, body functions or sounds, provided my identity is not revealed. I understand and agree that 1) any photographs, films, or other audio or visual recordings created will be the sole property of the facility; and 2) the facility or any appropriate staff member may edit, preserve, or destroy all or any part of the photographs, films, or other audio or visual recordings. Such recordings are not part of the medical record and I understand I cannot obtain a copy.

I authorize the disposal or retention, preservation, testing, or use for scientific, educational or other purposes of all or any portion of specimens, tissues, body parts, or other things, including prostheses and medical/surgical appliances, that may be removed from my body.





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I understand that if any medical device, as defined by federal regulations, is implanted in a patient’s body, the facility is required by law to report to the manufacturer the name, address and social security number of the patient and the description and identity of the device.

**MY SIGNATURE BELOW ACKNOWLEDGES THAT:**

1. I have read (or had read to me), understand and agree to the statements set forth in this consent form.
2. A physician or physician’s representative has explained to me all information referred to in this consent form. I have had an opportunity to ask questions and my questions have been answered to my satisfaction.
3. All blanks or statements requiring completion were filled in before I signed.
4. No guarantees or assurances concerning the results of the procedure(s) have been made.
5. I am signing this consent voluntarily. I am not signing due to any coercion or other influence.
6. I understand that I can withdraw my consent at any time prior to the procedure.
7. I hereby consent and authorize Dr. \_\_\_\_\_ (my physician(s)) and/or those associates, assistants and other health care providers designated by my physician(s) to perform a cholecystectomy. I understand that during the course of the surgery, conditions may become apparent that require my physicians or their designees to take steps or perform additional procedures that they believe are medically necessary to achieve the desired benefits or for my well-being, including but not limited to, the administration of blood and/or blood products. I authorize and request my physician(s) or their designees to perform whatever medical acts or additional procedures they, in the exercise of their sole professional judgment, deem reasonable and necessary, and I waive any obligation on their part to stop or delay the continuation of my surgery in order to obtain additional consent.

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Signature of patient or person authorized to consent for patient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Relationship to patient if signer is not patient

I have explained to the patient signing above all of the information contained in this consent form. I have given no guarantee or assurance as to the results that may be obtained.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

\_\_\_\_\_  
Signature of Physician or Physician’s Representative

