



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent: Endoscopic Retrograde Cholangiopancreatography

This information is given to you so that you can make an informed decision about having an **ERCP, or endoscopic retrograde cholangiopancreatography procedure**. This procedure is most often done with moderate sedation or anesthesia.

Reason and Purpose of this Procedure:

An ERCP is done to look for stones, tumors or narrowing of the biliary and pancreatic ducts. You will be given some medicine to help you relax as well as pain medicine during the procedure. This usually controls any discomfort.

A scope with a camera on the end is passed down your esophagus (the tube that connects your mouth and stomach) to your stomach, and into your duodenum (the beginning of your small intestines). Dye is injected through the endoscope into the common bile duct and will show up on x-ray. The x-rays will show any blockages.

If there is a gall stone in the common bile duct, the doctor can perform a sphincterotomy. This is when the doctor makes a small cut to make the opening of the common bile duct bigger. This will let the stones pass through.

If a tumor is blocking the common bile duct, a plastic or metal tube (stent) can be placed into the common bile duct to hold it open. This allows bile to flow through.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Your doctor may be able to diagnose and treat a specific condition.
- Relief of stones blocking the common bile duct.
- Diagnosis of a tumor.

Risks of this Procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- **Pancreatitis (inflammation of the pancreas).** This may require hospitalization.
- **A hole or tear in the small intestine.** This may require surgery to repair.
- **Bleeding at an incision site.** You may need further treatment.
- **Complications from sedation medicine.** These include low blood pressure and breathing problems including breathing and aspiration (choking on vomit). A reaction to the medication can cause throat spasms, and excessive sweating. You will be watched by a nurse and given oxygen to breathe.
- **Difficulty swallowing and sore throat.** This is from the tube placement. This is usually temporary.
- **Injury to your teeth or jaw joints, lips, or throat.** This is rare.
- **Infection.** This may require antibiotics.

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to You:

Alternative Treatments:

Other choices:

- Your physician can discuss any other treatments for your particular symptoms.
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- Your abdominal symptoms may not be properly diagnosed or treated.
- If you have bleeding, cancer, or any other undiagnosed problem, it may lead to death.

Information on Moderate Sedation:

You will be given medicine in an IV to relax you. This medicine will also make you more comfortable. This is called “moderate sedation”. You will feel sleepy. You may even sleep through parts of your procedure. We will monitor your heart rate and your blood pressure. We will also monitor your oxygen level.

If your heart rate, blood pressure or oxygen levels fall outside the normal range, we may give medications to reverse the sedation. We may be unable to reverse the sedation. We may need to support your breathing.

Even if you have a NO CODE status:

- You may need intubation to support your breathing.
- You may need medications to support your blood pressure.

We will re-evaluate your medical treatment plan and your NO CODE status when sedation has cleared your body.

Benefits of Moderate Sedation:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Less pain during the procedure.
- Less anxiety or worry.
- Decreasing your memory of the procedure.

Risks of Moderate Sedation:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect. The list includes:

- Decreased breathing during the procedure and dropping oxygen levels. To help you breathe, a tube may be placed into the mouth or nose and into the trachea to help you breathe.
- Allergic reactions: nausea & vomiting, swelling, rash.
- Vomit material getting into the lungs.
- A drop in blood pressure. This needs fluids or medicine to increase blood pressure.

- Heart rhythm changes that may require medicines to treat.
- Not enough sedation or analgesia resulting in pain or discomfort.

Your physical and mental ability may not be back to normal right away. You should not drive or make important decisions for at least 24 hours after the procedure.

General Information:

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical salespeople, and other staff may be present during the procedure. My doctor will supervise them.



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By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
 - I understand its contents.
 - I have had time to speak with the doctor. My questions have been answered.
 - I want to have this procedure: **Endoscopic Retrograde Cholangiopancreatography** _____
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- I understand that my doctor may ask a partner to do the procedure.
 - I understand that other doctors, including medical residents or other staff may help with the procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to procedure. If so, please obtain consent for blood/products.

Patient Signature: _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian/POA Healthcare

Reason patient is unable to sign: _____ Telephone Consent Obtained

First Witness Signature: _____ Second Witness Signature: _____ Date: _____ Time: _____
(One witness signature MUST be from a registered nurse (RN) or provider)

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: _____ ID #: _____ Date: _____ Time: _____

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back:

Patient shows understanding by stating in his or her own words:

_____ Reason(s) for the treatment/procedure: _____

_____ Area(s) of the body that will be affected: _____

_____ Benefit(s) of the procedure: _____

_____ Risk(s) of the procedure: _____

_____ Alternative(s) to the procedure: _____

OR

_____ Patient elects not to proceed: _____ Date: _____ Time: _____
(Patient signature)

Validated/Witness: _____ Date: _____ Time: _____