BRONSON

Affix Patient Label	
Patient Name:	Date of Birth:

Informed Consent: Endoscopic Ultrasound of the Esophagus, Stomach, and Duodenum with possible Fine Needle Aspiration

This information is given to you so that you can make an informed decision about having **Endoscopic Ultrasound of the Esophagus, Stomach, and Duodenum with possible Fine Needle Aspiration.** This procedure is sometimes referred to as an **EUS**. This procedure is most often done with moderate sedation or anesthesia.

Reason and Purpose of this Procedure:

EUS is a procedure in which your doctor places a tube in your esophagus (the tube connecting your mouth and stomach). The esophagus, stomach, and upper duodenum (the beginning of your small intestine) can be viewed. Ultrasound is used to create images and guide needle placement for biopsies if needed. A pathologist is onsite to examine the samples.

This test is used to help your doctor diagnose and treat your problem.

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.

- Samples of tissue can be taken and examined.
- Staging of cancers.
- Imaging of area and lesion.
- Ability to get images and biopsies at one time.
- Minimally invasive.

General Risks of Procedures:

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.

- **Bleeding.** This may need further treatment or repair.
- **Injury to your teeth, lips or throat.** This is rare.
- **Infection.** You may need antibiotics.
- **A tear in the stomach, duodenum, esophagus or bile ducts.** This may require surgery to repair.
- **Pancreatitis or inflammation of the pancreas.**
- **Reaction to the anesthetic may occur.** The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

Risks of this Procedure:

- Small abnormalities may not be seen and may be missed.

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.

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Risks Specific to You:

_____

_____

_____

_____

Alternative Treatments:

Other choices:

- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- We may be unable to diagnose your problem.

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 Ultrasound of the Esophagus, Stomach and Duodenum with possible Fine Needle Aspiration** _____
- 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: _____