

CONSENT FOR UPPER GASTROINTESTINAL ENDOSCOPY

This document helps us inform you about this procedure. Please read it carefully and address any questions or concerns you may have personally with the doctor prior to signing it.

Dr. Patrick D. Gerstenberger, Dr. Steven R. Christensen, Dr. Stuart B. Saslow or Dr. Paula M. Dionisio and his or her assistants are authorized to perform:

Upper Gastrointestinal Endoscopy - Examination of the esophagus, stomach and duodenum with a flexible tube passed through the mouth.

Biopsy - Remove small pieces of tissue for analysis.

Polypectomy - Remove small growths with special instruments.

Dilation - Enlarge a narrowed area.

Cautery/injection/sclerotherapy/band ligation/clip application - Use specialized instruments to apply heat, medication, small rubber bands or metal clips applied internally to stop or prevent bleeding.

Removal of foreign body

Placement of tubes or stents

Sedation and analgesia (moderate-deep procedural sedation with propofol) - Administer medication into a vein, under the doctor's direction, prior to and during the procedure, to make the procedure comfortable by relieving anxiety, discomfort, and pain.

Upper gastrointestinal endoscopy is frequently performed for: evaluation of symptoms (such as heartburn, swallowing problems, abdominal pain, bleeding, diarrhea and weight loss), screening for and follow-up of Barrett's esophagus, treatment of a narrowing (stricture), follow-up of gastric ulcer, evaluation of anemia, placement of tubes or stents and removal of foreign bodies.

ALTERNATIVES: Imaging tests ("upper GI series," CT scan, MRI, ultrasound, nuclear scans) are sometimes recommended as alternatives. Imaging tests are less likely to cause a complication, but are less accurate for diagnosis of some conditions, and do not allow treatment, such as dilation of a narrowing. No test at all is an alternative, but no testing carries risks of failing to diagnose a problem at an early and more treatable stage. In most cases we perform upper endoscopy using moderate-deep propofol-based procedural sedation, under the endoscopy doctor's supervision. It is possible to perform this procedure in some cases without sedation. Anesthesia administered by an anesthesiologist is indicated in some cases, and is an alternative available at Mercy Regional Medical Center.

RISKS: These procedures involve some risks. Major complications include: **perforation** (<1/3000), **bleeding** requiring blood transfusion or surgery (<1/3000), **heart or lung problems** (major problems are rare), infection (rare), allergic reactions (rare), nerve injury (rare) and death (rare). Minor complications (needle site irritation, dental injury, internal burns or bruises, minor medication reactions, temporary bowel distention or prolonged sleepiness) occur infrequently. Complications occur more frequently when polyps are removed, bleeding is treated, or foreign bodies are removed. These are highly accurate procedures, but with any medical test there is a small chance of missing something.

Complications may occur even when a procedure is properly performed. Treatment of major complications may require hospitalization, surgery, and blood transfusion.

SEDATION: Sedation involves a risk of heart or lung problems (<1/200), which rarely can be fatal (<1/160,000). Sedation (moderate-deep propofol procedural sedation) at this facility is administered and monitored by trained registered nurses under the continuous direction of the physician performing your procedure. While gastroenterology and endoscopy organizations in the U.S. support the use of propofol by gastroenterologists in the manner now employed at this facility for over 3 years, propofol sedation by gastroenterologists is not FDA approved. Anesthesia care provided by an anesthesiologist may be preferred to moderate-deep procedural sedation in some situations. Anesthesiologist services are not available at the Southwest Endoscopy Center but are available at Mercy Regional Medical Center and can be arranged at the request of either the patient or the physician performing your procedure, at an additional cost.

MEDICATIONS THAT AFFECT BLOOD CLOTTING: In most cases these drugs (such as Coumadin, Plavix, Effient, aspirin, nonsteroidal anti-inflammatory agents and others) are discontinued before endoscopy to reduce possible bleeding risk. Stopping and restarting these drugs carries some risk of blood clot related problems, including stroke and heart attack. In some cases we may advise you to continue these medications, in the belief that possible bleeding is less of a risk to your health than the risk of heart attack or stroke.

RECUPERATION: Recuperation from endoscopy is generally complete within a few hours following the procedure. Most individuals can return to typical activities and diet at that time. Because the effects of sedation on memory, coordination and judgment may linger however, activities such as driving, operation of machinery, vigorous physical exertion or activities requiring full mental attention, coordination or recall should not be resumed until the following day. **Increasing throat, chest or abdominal pain, bleeding, fever, chills or other signs of illness could be signs of complication of endoscopy or of your sedation, and should be reported promptly to the on call Digestive Health physician.** You will be provided with written instructions on discharge telling you how to contact us in the event of a problem after the procedure.

TRANSFUSION: Blood transfusions are not administered at the Southwest Endoscopy Center. Transfusions are occasionally administered at Mercy Medical Center during endoscopy if a patient has lost a large amount of blood prior to the procedure. A separate written consent prior to transfusion is obtained if transfusion is needed.

SUCCESS: Complete examination of the upper gastrointestinal tract is nearly always achieved. Most areas of narrowing (strictures) we detect are dilated at the time of the examination. Some strictures may require additional endoscopy procedures or surgery to allow complete dilation. Most swallowed foreign bodies can be removed successfully, though surgery may occasionally be necessary.

ASSISTANTS: Registered nurses and/or technicians who are employees of the facility providing your procedure will assist the physician. Students, industry representatives or other observers will not be permitted to be present without your written permission. Other physicians or assistants are rarely necessary during endoscopy, though occasionally the physician may request an opinion regarding a finding or technique from another physician during a procedure.

PATIENT CONSENT

I have had sufficient opportunity to discuss my condition and treatment with my physicians and/or their associates, and all of my questions have been answered to my satisfaction. I believe that I have adequate knowledge upon which to base an informed consent to the proposed procedure.

I have read and fully understand this form and I voluntarily authorize and consent to this procedure. I understand that I should not sign this form until all my questions have been answered to my satisfaction and until I understand all the words or terms on this form.

I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results of the procedure. I have been advised that the proposed procedure may not improve my condition and may, in fact, worsen it.

X _____ Date: _____ Time: _____
Signature of Patient or Authorized Agent

_____ Date: _____ Time: _____
Signature of Witness to Above Signature
**Must be the physician, provider or an assistant who observed the patient or authorized agent sign above.*

PHYSICIAN/PROVIDER DECLARATION

I have explained the contents of this document to the patient and have answered all the patient's questions, and to the best of my knowledge, I feel the patient has been adequately informed and has consented.

_____ Date: _____ Time: _____
Physician Assistant (if applicable)

_____ Date: _____ Time: _____
Physician performing procedure