

Hospital ID:

Name:

# Consent Form for Endoscopy Procedure

(Including small polyp removal)

**SMC**

SAMSUNG MEDICAL CENTER

## Participating Physician

Attending Physician Name : \_\_\_\_\_ (Signature)

Participating Physicians

Name : \_\_\_\_\_  Specialist (Specialty : \_\_\_\_\_ )  
 General Practitioner (Department: \_\_\_\_\_ )

Name : \_\_\_\_\_  Specialist (Specialty: \_\_\_\_\_ )  
 General Practitioner (Department: \_\_\_\_\_ )

Name : \_\_\_\_\_  Specialist (Specialty: \_\_\_\_\_ )  
 General Practitioner (Department: \_\_\_\_\_ )

## Patient's Condition

- Diagnosis:
- Name of operation/procedure/test :
  - Conscious Sedation Endoscopy
  - Gastroscopy
  - Sigmoidoscopy/Colonoscopy and Polypectomy/Endoscopic submucosal dissection (Scheduled date : \_\_\_\_\_)
- Past history of Endoscopy :  None
  - Conscious Sedation Endoscopy     Gastroscopy
  - Sigmoidoscopy/Colonoscopy and Polypectomy/Endoscopic submucosal dissection
- Present Medical Condition :  None
  - Allergy  Hypertension  Diabetes  Heart Disease
  - Glaucoma  Side effects from medication ( \_\_\_\_\_ )
  - Thrombocytopenia  BPH  Asthma
  - Cerebrovascular Disease  Abdominal Operation
  - Other Medical Condition: ( \_\_\_\_\_ )
- Current Medication :  Warfarin and Anticoagulant ( \_\_\_\_\_ )
  - Aspirin and Antiplatelet ( \_\_\_\_\_ )
  - Other ( \_\_\_\_\_ )
- Additional information:  Dental Conditions ( \_\_\_\_\_ )
  - Bowel Preparation( \_\_\_\_\_ )

## Explanation of the intended medical practice

### Conscious Sedation Endoscopy

- Purpose and Effects
 

Allows the patient to be sedated when conducting an endoscopy. Sedation is different from general anesthesia yet the patient might still feel hazy. However, the patient will still be able to understand the medical team's instructions as this procedure is not intended for deep sleep.
- Examination/Procedure Steps and Method
  - Distribute sedation and analgesic (painkiller) with an intravenous injection and achieve sedation.

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② Occasionally, even with sufficient amounts of sedation, it might not be able to induce sedation. Larger dosage of sedation can't be administered as there are many side effects including respiratory inhibition.

③ After the procedure, the patient will recover in a recovery room. When leaving the hospital, the patient must be accompanied by a guardian for patient's safety. Do not drive on the day of sedated endoscopy.

### 3. Other Treatment Methods and Limitations

It is possible to undergo the endoscopy without administering sedation; however, most people feel uncomfortable during the procedure.

### 4. Possible dangers/complications during the examination/procedure or recovery.

① Difficulty breathing, decrease in blood pressure, coughing, a case of hiccups, etc. may occur during sedated endoscopy but often they are only temporary. It is highly unlikely, but respiratory arrest, cardiac arrest, and allergic reaction can occur. Emergency treatment will be given if needed.

② It is widely known that these side effects frequently occur to the elderly with low blood pressure or lung function impairment or for patients with cardiac or kidney problems.

### 5. Results when the planned medical treatment isn't followed.

It is possible to undergo the endoscopy without administering sedation; however, most people feel uncomfortable during the procedure.

### 6. Other

① Understand that the sedation might be administered additionally and drugs, such as antagonist, can be additionally administered which will require additional payment.

② If the patient is not sedated even after all the sedation has been administered, refund will not be given

### 7. Fall Prevention Education

① Request for assistance when moving.

② Refrain from getting up from the bed.

③ Refrain from going over the side rails of the beds.

④ When leaving, the patient must be accompanied by a guardian.

⑤ Before recovering, urination and excretion should take place resting from the bed.

## © Gastroscopy

### 1. Purpose and Application

Directly examines the esophagus, stomach, and the mucous membrane from part of the duodenum and will enable the diagnosis of esophagitis, esophageal cancer, esophageal varix, gastritis, gastric ulcer, gastric cancer, duodenal ulcer, duodenal cancer, etc.

### 2. Examination/Procedure Steps and Method

① Before the examination, the patient will drink defoaming agent and will be injected with a movement restrainer. For the patients with a history of glaucoma or prostatism, please inform the medical team before the examination.

② Insert the endoscope through the patient's mouth and the esophagus, stomach, and parts of the duodenum will be examined. If needed, forceps might be inserted with the endoscope in order to retrieve small amounts of tissue for a biopsy. The retrieved tissue will be sent to the Department of Pathology for further evaluation.

③ It will take approximately 10 minutes to examine the stomach, and it might take longer depending on the condition of the stomach and the purpose of the examination. In the case of sedated endoscopy, it will take approximately 1 hour including the recovery phase.

④ If the endoscope irritates the throat area during the examination, the patient might feel nauseous. If the patient experiences severe nausea, the stomach membrane might be damaged and after the examination, pain in the throat area might become more severe.

During the examination, relaxing the neck and shoulders and inhaling through the nostrils and exhaling through the mouth will be helpful for the patient.

### 3. Other Treatment Methods and Limitations

It is possible to perform an upper gastrointestography instead of an upper gastrointestinal tract endoscopy. An upper gastrointestography has its positives as the patient will not have to experience the side effects from an upper gastrointestinal tract endoscopy such as: feeling nausea, feeling uncomfortable in the throat area, and experiencing pain. However, it will be impossible to perform a biopsy, and it will be difficult to notice the classifications of stomach cancer in its early stages.

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4. Dangers/Complications that might develop during the examination/procedure or recovery.

- ① This is a fairly safe examination, but it could rarely result with a complication such as bleeding, perforation, infection, breathing disorder, an abrupt change in blood pressure, etc.
- ② Rarely, these aforementioned complications might be too severe to the extent that an emergency operation or cardiopulmonary resuscitation (CPR) might be necessary. It is extremely rare, but if the patient does not respond to the proper treatment, it may lead to death.
- ③ If there is food remaining in the stomach, examination will be impossible and the endoscopy will be scheduled for another day.
- ④ If a lesion is found during the examination, a biopsy will be performed if needed. Rarely, a patient might experience the complication of continuous bleeding, and if this complication becomes much more severe, either an emergency operation or hospitalization might be needed. If the patient is taking an antiplatelet drug or an anticoagulant drug, then a biopsy might be impossible as it is much more dangerous. Therefore, the patient must inform the medical staff what medications he or she is taking.
- ⑤ Biting the mouthpiece aggressively during the examination or the existing teeth being weak or the teeth being temporarily stuck together is dangerous for the teeth. The patient should either get checked before the endoscopy or the patient should discuss this matter with the medical staff. We do not take on any responsibility for the damage on the teeth during the examination.
- ⑥ Abdominal distension may occur due to the air that flowed in during the examination. Small amounts of blood might be found with the saliva or pain in the throat area might be experienced due to the irritation by the endoscope apparatus.

5. Results when the planned medical treatment isn't followed.

It will be difficult to diagnose a lesion and to decide on the treatment course for a lesion.

## © Sigmoidoscopy / Colonoscopy and Polypectomy / Endoscopic Submucosal Dissection

1. Purpose and Application

Sigmoidoscopy/Colonoscopy examinations consist of inserting the endoscope through the anus in order to diagnose various infections including polyp and colorectal cancer. If needed during the examination, the surgical procedures such as the polypectomy/ Endoscopic submucosal dissection with the endoscope or endoscopic decompression can be performed.

2. Examination/Procedure Steps and Method

- ① Before the examination/operation, a drug (painkiller) will be injected to inhibit movement in the gastrointestinal tract and relieve abdominal pain. If a patient is diagnosed with glaucoma, prostate hypertrophy, or cardiopulmonary disorder, the gastrointestinal tract movement inhibitor will temporarily worsen the symptoms. Please inform the medial staff of the patient's medical history before the examination.
- ② The examination/surgical procedure usually lasts 15~30 minutes; however, it might take longer for some patients depending on the existence of a polyp/lesion, etc.
- ③ During the examination/ surgical method, air will be inserted into the colon in order for a close examination. As a result, abdominal tenderness, distension, intermittent abdominal pain, etc. might occur; however, these symptoms will naturally disappear after the examination.
- ④ If a small polyp is found during the examination/surgical procedure, polypectomy/ Endoscopic submucosal dissection can be performed.



Colonoscopy



polypectomy



Endoscopic submucosal dissection

3. Other Treatment Methods and Limitations

Radiographic Colonography, CT Colonography, etc are different methods to perform a colon examination. Compared with the Colonoscopy,

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there is a lower chance of experiencing a perforation and bleeding. However, biopsy/polypectomy can't be performed and these methods are less precise.

#### 4. Dangers/Complications that might develop during the examination/procedure or recovery.

- ① This is a fairly safe examination, but it rarely results with a complication such as bleeding, perforation, infection, breathing disorder, an abrupt change in blood pressure, etc.
- ② Due to the diathesis of a patient, allergic reactions from the drugs including fall in blood pressure, difficulty in breathing, angioedema, etc can occur. In this case, emergency cardiopulmonary resuscitation (CPR) can be performed.
- ③ Depending on the situations a complication occurs, an emergency operation can be performed. It is extremely rare, but if the patient does not respond to the proper treatment, the patient might pass away.
- ④ It is rare, but for some patients, intestinal adhesion or intestinal mobility might occur due to their abdominal operation history, peritonitis, etc. In this situation, it is impossible to examine the colon and the fee for the examination will not be refunded.
- ⑤ Inadequate cleanliness of the colon will make it impossible for an examination; the examination can be postponed.
- ⑥ If a polyp/lesion is found during the examination, a biopsy can be performed if deemed necessary. Furthermore, with the consent from the patient or the guardian, polypectomy can be performed immediately. When polypectomy is performed, additional drugs can be used and equipment can be replaced accordingly with the number of polyps, size, location, etc. In this case, an additional fee will be requested.
- ⑦ If a large polyp is found, the occurrence of complications including bleeding and perforation is increased; therefore, the patient will be hospitalized and the polyp will be removed later on.

**\*If a removable polyp is found during the observation/procedure, I request to get it removed right away if possible. (    )**

#### 5. Results when the planned medical treatment isn't followed.

- ① It will be difficult to diagnose a polyp/lesion and to decide on the treatment course for a polyp/lesion.
- ② If a polyp is not removed, the size of the polyp and the number of the polyps can increase. In the case of adenoma, there is a possibility that it will turn malignant.

#### 6. Possible modifications or extension of the operation/test/procedure

During the operation (surgical procedure/examination), the operation (surgical procedure/examination) method can be changed inevitably or extensions can be made to the operation range depending on the condition of the patient. In this case, if additional explanations have to be made to the patient or the guardian, the medical staff will explain the modified operation (surgical procedure/ examination) method and will earn his or her consent.

However, during the operation, if the situation is too urgent due to the condition of the patient to explain in advance and earn his or her consent, the modified operation (surgical procedure/examination) will be performed or an extension to the operation range will be made. After the operation, the medical staff will inform the patient or the representative of the modifications or the results of the operation without delay.

#### 7. Possibility of changing the operating surgeon

The surgeon or the attending physician may inevitable change in the course of operation/test/procedure due to the patient's condition or to the surgeon/physician's circumstances (emergencies, personal reasons such as being ill or childbirth, other reasons: \_\_\_\_\_).

In such cases, there will be further explanations made to the patient of the guardian and consent obtained prior to the operation (test/procedure).

However, in cases where there is no time for an informed consent to change the surgeon due to the urgency of the situation, the operation/test/procedure will be carried out with an alternative participating surgeon/physician, and the patient of guardian will be notified of the detailed reasons for the change and the results of the operation/test/procedure without delay.

#### 8. Other

- ① The patient (or guardian) may request for a copy of this consent form and the attached documents, and it should be issued with no delay. Additional charges may incur upon request.
- ② Following the operation/test/procedure, an additional specialized exam(s) may be performed for a more accurate diagnosis and additional charges may incur in such cases.

#### ■ Patient's Right to Self-Determination

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**I confirmed the following and agree.**

1. I confirm that I have been informed by the medical staff of the purpose, effect, process, expected complications, and aftereffects of the operation(procedure, test, anesthesia, conscious sedation) on me(or the patient)
2. I confirm that I understood from above 1 explanation that by this operation(procedure, test, anesthesia, conscious sedation), complications caused by force majeure or unusual nature of the patient may cause unexpected accidents
3. I agree to cooperate with this operation(procedure, test, anesthesia, conscious sedation) and I pledge to sincerely notify the current patient status of this consent form and agree to this operation(procedure, test, anesthesia, conscious sedation) by delegating medical treatment to the judgment of participating medical staff.
4. I confirm that possibility of changing the operation(procedure, test, anesthesia, conscious sedation) method or additional site of the operation was informed by the medical staff before the operation.
5. I confirm that possibility of change in the participating medical staff and explanation of the reason was informed by the medical staff before the operation.

I have been informed

**Explained by**

Explaining medical staff Name: \_\_\_\_\_ (Signature) \_\_\_\_\_

**The consentee**

Date : \_\_\_\_\_ Time : \_\_\_\_\_  AM  PM

Patient Name : \_\_\_\_\_ (Signature) \_\_\_\_\_

Legal representative (Relationship to Patient : \_\_\_\_\_ ) Name : \_\_\_\_\_ (Signature) \_\_\_\_\_

Date of Birth : \_\_\_\_\_ Home phone : \_\_\_\_\_

**Reason for signature by legal representative**

- Patient is unable to fully understand the content of this form due to patient's physical or psychological disability.
- Patient is unable to fully understand the content of this form due to being underage.
- It is apparent that explaining the content will adversely affect the patient's health.
- Patient has authorized the right regarding the consent to a designated person(in this case, a separate contract should be attached).
- others

**ATTN : President & CEO**