

**Supplementary file 2.** Endoscopic Sedation Informed Consent Form

## 1. What is an endoscopic sedation?

Sedation (sleep) endoscopy refers to a procedure that is performed after placing the patient under a certain level of sedation by injection of sedative(s) (midazolam, propofol).

## 2. Purpose and necessity of sedation

The purpose of sedation is to enable the procedure or examination to be performed adequately and smoothly by reducing the level of anxiety and minimize the pain the patient may feel during the procedure. The procedure is performed with the patient placed under a state of sedation that would allow certain degree of cooperation and not under anesthesia. However, depending on each individual, an adequate level of sedation may not be reached or excessive sedative effect may cause the procedure to become difficult despite using ideal amount of sedative.

## 3. Endoscopic sedation processes and methods

Prior to endoscopic sedation, the medical history of the patient is checked and the physical status of the patient is assessed according to the physical status classification by the American Society of Anesthesiologists (ASA).

**ASA Physical Status Classification**

ASA Class	Description
ASA I	A normal healthy fit patient
ASA II	A patient with mild systemic disease
ASA III	A patient with severe systemic disease
ASA IV	A patient with severe systemic disease that is a constant threat to life
ASA V	A moribund patient who is not expected to survive without the operation
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes

After the patient has been moved to the examination room, various monitoring equipment are attached to the patient to assess the patient's systemic condition, including level of consciousness, while the patient's blood pressure (BP), heart rate, respiratory rate, and oxygen saturation are checked prior to sedative injection. After this step has been completed, the physician or nurse administers the sedative by intravenous injection, during which time, some patients may feel slight pain in the injection site. Sedation begins approximately one minute later. During sedation, the physician or nurse adjusts the sedation depth to make sure the patient remains stable, while BP, heart rate, respiratory rate, and oxygen saturation are monitored regularly. For high-risk patients, electrocardiogram (ECG) monitoring may be performed during endoscopic sedation, when necessary. Upon completion of the procedure, the patient is moved to the recovery room, where the patient's BP, heart rate, respiratory rate, and oxygen saturation are monitored regularly to assure safe recovery from sedation. The duration of stay in the recovery room may vary depending on the patient's condition, but in most cases, the duration of stay is less than one hour. If the vital signs, such as BP and heart rate, are normal, the patient is discharged once he/she regains complete consciousness and is in stable condition.

## 4. Problems that may occur during endoscopic sedation

Adverse effects that patients may experience include slight dizziness, nausea, vomiting, hypotension, and temporary memory loss. Typically, most patients recover without any specific treatment. Although not common, some patients may also experience phlebitis, hypersensitivity to drugs, convulsions, respiratory adverse events (AEs) such as hypoxia due to respiratory depression, and cardiovascular AEs such as hypotension. In extremely rare cases, emergency measures may be required due to life-threatening cardiopulmonary arrest. The likelihood of such AEs is known to be high among elderly or obese patients and patients with chronic respiratory, heart, liver, or kidney disease. Although sedation (sleep) endoscopy is not impossible for these patients, they do require special attention.

## 5. Post-sedation discharge criteria chart

After recovering from sedation, the patients are discharged if their Aldrete Score based on the discharge criteria chart is  $\geq 9$  points or if they have recovered to their pre-procedure status.

**Aldrete Score**

Adult post-procedure/Post-sedation recovery score (Aldrete Score)		Score
Activity level	Able to move all extremities voluntarily or on command	2
	Able to moves 2 extremities voluntarily or on command	1
	Cannot move extremities voluntarily or on command	0
Respiration	Able to take deep breath and cough	2
	Dyspnea/shallow breathing	1
	Apnea	0
Circulation	BP within 20% of pre-anesthesia/sedation level	2
	BP within 20%–50% of pre-anesthesia/sedation level	1
	BP >50% of pre-anesthesia/sedation level	0
Consciousness	Fully awake	2
	Arousable on calling	1
	Not responding	0
Oxygen saturation	Maintains >92% on room air	2
	Maintains >90% with supplemental oxygen	1
	Oxygen saturation <90% even with supplemental oxygen	0

6. AEs and sequelae that may occur after endoscopic sedation

The patient needs rest to completely recover after endoscopic sedation. Driving or important work should be avoided on the day of the procedure. To prevent fall accident due to dizziness, the patient must be accompanied by a guardian.

7. Other available treatment methods besides endoscopic sedation

In cases with increased likelihood of AEs after endoscopic sedation due to underlying respiratory or heart disease or requiring cooperation from the patient, the endoscopy examination could be performed without sedation.

8. Prognosis without endoscopic sedation

Without endoscopic sedation, poor cooperation from the patient due to increased discomfort may cause inaccurate examination or treatment. In particular, the risk of bleeding or perforation may increase, and depending on the person, the treatment or examination may be terminated. In some cases, such anxiety and pain may lead to hypertension or cardiac abnormalities, and in severe cases, serious AEs, such as arrhythmia, myocardial infarction, and cerebral hemorrhage, or post-traumatic stress syndrome due to emotional shock may appear.

I, the patient (or representative), have received sufficient explanation from the medical staff about the need for endoscopic sedation and AEs associated with the procedure and understand the contents. I also fully understand the processes involved in the procedure and am aware that BP, heart rate, respiratory rate, and oxygen saturation will be measured regularly to assess the physical status before, during, and after the procedure, and if needed, ECG monitoring may be performed as well. I also fully understand the pre- and post-procedure instructions, unavoidable AEs that may occur, and the possibility of spontaneous accidents based on prior explanation. I choose of my own free will to receive the endoscopic sedation and other relevant treatments and hereby request such examination/treatment from your hospital.

Date: (YYYY/MM/DD)

Primary physician (physician providing the explanation): (signed)

Patient: (signed)

Relationship to the patient: Guardian (legal representative): (signed)

<Reason for document being signed by a representative> [Evidence: Fair Trade Commission, standard terms and conditions for surgery consent form]

- The patient is incapable of understanding the terms and conditions due to physical and/or mental impairment.
- The patient is a minor (<19 years old) and cannot fully understand the contents of this consent form.
- Explaining the contents of this consent form would clearly have a detrimental effect on the physical and mental well-being of the patient.
- The patient has signed a power of attorney (in such case, a copy of the power of attorney agreement must be attached to this consent form)

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