



Patient Label

### **Procedures and Possible Complications**

- Colonoscopy**  
Possible complications may include but are not limited to: Bleeding, perforation, splenic injury, missed lesion and any additional risks that may be discussed with me by my physician.
- Esophagogastroduodenoscopy**  
Possible complications may include but are not limited to bleeding, perforation, damage to teeth or dental work, missed lesion and any additional risks that may be discussed with me by my physician.
- Esophageal Dilation**  
Possible complications of the procedure may include but are not limited to the following: Bleeding, perforation, difficulty swallowing, damage to teeth or dental work and any additional risks that may be discussed with me by my physician.
- Flexible Sigmoidoscopy**  
Possible complications may include but are not limited to bleeding, perforation, missed lesion and any additional risks that may be discussed with me and my physician.
- Hemorrhoid Banding**  
Possible risks of the procedure may include but are not limited to the following: rectal bleeding, infection and/or shock secondary to rectal bleeding, infection, missed lesion and any additional risks that may be discussed with me by my physician.
- PEG change/placement**  
Possible risks of the procedure may include but are not limited to the following: infection, redness to the stoma and any additional risks that may be discussed with me by my physician.
- ReShape Procedure (Intragastric balloon placement for weight loss intention)**  
This balloon has been studied exclusively in clinical trials upon individuals with a BMI ranging from 30 to 40. It has not been studied in a controlled setting on patients with a BMI greater than 40. Patients with a BMI of greater than 40 have undergone this procedure without any case reports of complications separate from or in a greater percentage than the study patients in the BMI of 30 - 40. However, due to the lack of controlled clinical data regarding the ReShape Balloon in patients greater than BMI 40, this procedure is technically "Off-Label" for patients with a BMI greater than 40. No guarantees may be made to you regarding the safety of efficacy of this product. Possible risks of the procedure may include but are not limited to the following: Gastric bleeding, Gastric perforation, and Aspiration.

### **Anesthesia Types and Complications**

- Deep Sedation**  
Including an unconscious or semi-conscious state with some degree of arousal, occasional purposeful movement. The use of a breathing tube in the windpipe and other airway devices is unlikely. Intravenous medications will provide most of the anesthesia. Risks include mouth or throat pain, hoarseness, injury to mouth or teeth, awareness of intraoperative events, injury to blood vessels, aspiration, and pneumonia.
- Monitored Anesthesia Care (MAC)**  
Semi-conscious state with some degree of arousal, occasional purposeful movement. The use of a breathing tube in the windpipe and other airway devices is unlikely.  
Some of the more common complications of sedation include: increase or decrease in heart rate and blood pressure, difficulty breathing, allergic reaction (rash, itching) to medication and/or nerve damage/phlebitis at the IV site. Although rare, unexpected severe complications may occur including difficulties breathing, cardiac arrest and death.

- Moderate Sedation\_\_\_\_\_ RN \_\_\_\_\_ CRNA**

**Moderate Sedation/Analgesia (“Conscious Sedation”)**

A drug-induced depression of consciousness during which patients respond purposefully\*\* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained

- Local/Topical Anesthesia**

Some of the more common complications of sedation include: toxicity from injected medication, injury from the needle used to inject the local anesthetic, hematoma at the injection site, nerve damage/phlebitis at the IV site and discomfort during the procedure. Until the effects (numbness) wears off patient should be careful not to injure the numbed area. Although rare, unexpected severe complications may occur including difficulties breathing, cardiac arrest and death.

I authorize the diagnostic procedure(s) and such other therapeutic procedure(s) which may be necessary, including, anesthesia care and pathology. I understand and agree that the persons administering anesthesia or performing other professional services, such as pathology and the like, are independent contractors and may not be employees or agents of the attending physician or the facility. I acknowledge and understand that the following procedure which has been described to me is to be performed at Gulf Comprehensive Surgery Center (the “Facility”):

(A) Understanding of the Procedure: I understand the nature of the procedure, the expected benefits or effects of such procedure, the medically acceptable alternative procedures or treatments. I have a general understanding of the procedure to be performed on me. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees or promises have been made to me as to the results of the care and treatment which I have hereby authorized.

(B) Possible Risks of The Procedure(s): I understand and consent to the possible complication of the scheduled procedure as they have been explained to me.

(C) Consent for the Administration of Anesthesia: In addition to the foregoing, I consent to the administration of Anesthesia as required for the procedure. I understand and acknowledge that all forms of anesthesia involve some risks and the facility can make no guarantees or promises concerning the results or outcome of the anesthesia plan of care. I acknowledge that I have made arrangements to have a responsible person to drive me home after the administration of anesthesia. I acknowledge that impairment of full mental alertness may persist for several hours following the administration of anesthesia, and I will avoid making decisions or taking in activities, which depend upon full concentration or judgment during this period. If you have ever had a severe allergic reaction to ANY substance or environment (including latex or a bee sting) you must tell your physician and the anesthesia provider before we give you medication or other substances. I understand the possible complication of the planned anesthesia care as they have been explained to me.

(D) Pregnancy Testing: I request and consent to the Facility performing a urine pregnancy test, as part of the Facility’s routine pre-operative lab work due to the possible risks of anesthesia and certain medications to a fetus, including birth defects and miscarriage. I understand a urine pregnancy test is generally accurate, but no pregnancy test is 100% reliable, and there is a possibility this test could miss an early pregnancy or have a false positive result. *If the Patient you believe that you might be pregnant, it is your responsibility to notify the attending physician and anesthesia provider before any medication or anesthesia is given.*

(E) Human Immunodeficiency Virus (HIV) and Hepatitis Testing: I understand that in the event a health care worker sustains a significant exposure to my blood or body fluids, I may be asked to undergo testing for HIV, (the virus that causes AIDS), and hepatitis. The results of any test will be confidential and will be treated in accordance with Florida law. I understand that, in accordance with Florida law, a positive HIV test result will be reported to the county health department with sufficient information to identify me. Furthermore, I hereby authorize the Gulf Comprehensive Surgery Center and my physician to disclose such HIV test results to any third party payor, as appropriate for processing and payment.

(F) If a Physician Has Signed and Issued DNR (Do Not Resuscitate) Order For You: If I have consented to a do not resuscitate order ("DNR"), I understand and acknowledge that my consent to a DNR order is temporarily SUSPENDED while I undergo any procedure performed at this Facility. It is the policy of this center that, regardless of the contents of any advance directives/living will or instruction from a health care surrogate, patient representative, or attorney, the Center will always attempt to resuscitate and transfer you to an acute health care facility in the event of deterioration.

(G) Use/Disposal of Tissue: I hereby authorize the Facility to retain, photograph, preserve, dispose and submit for scientific or teaching purposes, or dispose of at its convenience any specimens or tissues taken from my body during my procedure or treatment. Specimens or tissues removed may be sent to a laboratory for further testing or examination by a pathologist.

(H) Consent for Transfer: I understand that the surgical and/or diagnostic procedure to be performed on me at the facility will be done on an outpatient basis and that the facility does not provide 24 hour patient care. If my attending physician or any other duly qualified physician in his/her absence, shall find it necessary or advisable to transfer me from the facility to a hospital, then, I consent and authorize the employees of the facility to arrange the transfer. In an event of a hospital transfer, I consent to the surgery center obtaining a copy of my discharge summary from the hospital.

(I) Observation Consent: For medical, scientific or educational purposes, I consent to the admittance of approved observers to the procedure room and release of Gulf Comprehensive Surgery Center and the attending physician from any liability that may arise from their presence in the procedure room.

(J) Photographs: I consent to the taking and publication of any-photographs in the course of this operation for the purpose of treatment and/or medical education.

(K) Certification and Signatures: I certify that I understand the information regarding my procedure and the administration of anesthesia (if necessary) and that I have been fully informed of the risks and possible complications thereof, as well as, medically acceptable alternatives to my procedure. I have been given ample opportunity to ask questions, and any questions I have asked have been answered or explained in a satisfactory manner. I hereby authorize and permit the physician and whomever he/she may designate as his/her assistants to perform upon me the named procedure(s).

If any unforeseen condition arises during the procedure calling in his/her judgment for additional procedures or medications, I further request and authorize him/her to do whatever he/she deems advisable.

I certify that I have been informed that I may receive a sedative for this procedure. I understand that I should not drive, operate machinery, make critical decisions, or drink any alcohol until the day after my procedure. I have signed this form prior to receiving sedation.

Have you ever had a Hysterectomy or sterilization procedure? YES, NO, N/A

I understand that certain procedures and/or drugs may be harmful to me and my unborn child. YES, NO, N/A

I voluntarily assume the risk of any injury or damage to me and my unborn child if I am pregnant. YES, NO, N/A

I decline the facility urine pregnancy test. YES, NO, N/A

**Patient Signature** \_\_\_\_\_ **Date** \_\_\_\_\_ **Time** \_\_\_\_\_

**Witness Signature** \_\_\_\_\_ **Date** \_\_\_\_\_ **Time** \_\_\_\_\_

**Physician Signature** \_\_\_\_\_ **Date** \_\_\_\_\_ **Time** \_\_\_\_\_