INFORMED CONSENT FOR ADJUSTABLE GASTRIC BANDING SURGERY

This informed-consent document that has been prepared to help inform you about Adjustable Gastric Band Surgery including the risks and benefits, as well as alternative treatments. This procedure is also known as “Lap-Band surgery”.

It is important that you read this information carefully and understand it completely. Please ask your surgeon or the staff any questions you may have. Initial each page, indicating that you have read and understand the information on that page. You should also carefully review the pamphlet(s) given to you after your first consultation.

These forms must then be returned to the office 3 weeks before surgery. These forms will be kept in your chart. We would be pleased to provide you with a photocopy if you wish.

INTRODUCTION

I affirm that I am overweight and have attempted non-surgical weight loss programs without permanent success. I recognize that the preponderance of medical literature states that obesity increases the risk of multiple medical problems including diabetes, hypertension, cardiac disease and even premature death. I understand that Adjustable Gastric Band Surgery is a surgical aid in weight reduction and can improve or induce remission in a number of these conditions, if they are present. Weight reduction may prevent the onset of these conditions. However there are no specific guarantees that any of these conditions will improve in a given patient, including myself.

I understand that Adjustable Gastric Band Surgery is a surgical procedure where a silastic band (Lap-Band) is placed around the stomach to restrict caloric intake by inducing a sense of satiety with a smaller portion of food. Therefore, I understand that Adjustable Gastric Band Surgery is a surgical treatment for being overweight.

ALTERNATIVE TREATMENTS

I am aware that there are non-surgical alternatives to Adjustable Gastric Band Surgery to achieve weight loss and that these options generally consist of diet and exercise programs, as well as prescribed weight loss medications. I acknowledge that these may serve as a valuable and necessary adjunctive therapy in the overall reduction of excess weight.

RISKS AND COMPLICATIONS OF ADJUSTABLE GASTRIC BAND SURGERY

I acknowledge that it has been explained to me that surgery can result in unpredictable events and unpredictable complications can occur. I acknowledge and understand that while many patients never have a complication, every surgical procedure involves a certain amount of risk. It has been explained to me that it is important that I understand the risks involved with Adjustable Gastric Band Surgery. My choice to undergo any surgical procedure is based upon my assessment of the risks relative to the potential benefits. I acknowledge
that I have had the opportunity to discuss with my surgeon each of the complications referred to below, and that I understand all of the material consequences of Adjustable Gastric Band Surgery. I am aware that if I have further questions about my surgery or any possible complication, I should discuss them with my surgeon prior to surgery.

Each of the following potential complications has been explained to me and I understand and accept the risk of each of them. I have had the opportunity to ask questions and have my questions answered. Where the potential complication could give rise to the requirement for unanticipated but necessary treatment during surgery, as described below, I consent to such treatment.

**Bleeding:** It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it might require emergency treatment to stop the bleeding which may involve making a larger incision in the abdomen (open procedure) or blood transfusion.

**Conversion to Open Surgery at Surgeon’s Discretion:** It may be necessary to complete the Adjustable Gastric Band Surgery by making a larger incision in the abdomen. Experience shows that this occurs in less than 0.5% of procedures. This may occur if anatomical or other considerations preclude the safe conclusion of my operation using the laparoscopic approach. Other possible conditions that may lead to conversion to open surgery include bleeding, extremely large liver size and extreme amounts of fat around the stomach or equipment malfunction. It is also possible that anatomical or other considerations preclude the placement of the Adjustable Gastric Band under any condition. In this rare situation, other options will be discussed with the patient post-operatively.

**Possible Unexpected Medically Necessary Procedures:** Other procedures may be necessary at the discretion of the surgeon during the Adjustable Gastric Band Surgery. These may include, but are not limited to, liver biopsy if an abnormal or abnormally enlarged liver is identified. The least intrusive measures will be undertaken in these circumstances until express patient consent can be obtained.

**Admission to hospital:** If there are unanticipated difficulties with the surgical procedure, anaesthesia or post-operative recovery, it may be necessary that I be admitted to the hospital. If this becomes necessary it will be arranged by the surgeon who will manage then in-hospital care.

**Death:** The death rate with Adjustable Gastric Band Surgery worldwide is approximately 1 in 5000 procedures. Although Adjustable Gastric Band Surgery is considered to be a minimally invasive surgical procedure, complications are still possible which may, in very rare cases, be fatal.

**Band Slippage/Band Erosion:** Band Slippage or pouch dilatation can occur in approximately 2-3% of patients undergoing Adjustable Gastric Band Surgery. Erosion of the gastric band is very unusual and occurs in approximately 1 of 1000 patients. Modification of surgical technique and band design has reduced the risk of these complications, but they are still possible. If these problems occur, the patient will likely require further surgery to reposition or remove the band. Normally these can be dealt with laparoscopically, but they may require open surgery.
**Esophageal or Stomach Injury:** These are rare complications. Injury to the esophagus or stomach can be a very serious complication. It may require prolonged hospital stay, further surgery including possible removal of the gastric band, antibiotics and very rarely death.

**Infection:** Infection is rare after this type of surgery. Should infection occur, treatment, including antibiotics or additional surgery, may be necessary.

**Skin scarring:** Excessive scarring is uncommon, but all surgery leaves permanent scars. Adjustable Gastric Band Surgery leaves a small number of scars on the abdominal wall. In rare cases, abnormal scarring may occur.

**Anaesthesia:** General anaesthesia involves risks. Patients who have any specific concerns about the risk of general anaesthesia should contact the clinic or the surgeon to discuss these concerns with the assistance of an anaesthesia specialist. However, there is the possibility of complications, injury, and even death from all forms of surgical anaesthesia.

**Smokers:** Smokers have a greater risk of wound healing complications.

**Allergic reactions:** In rare cases, local allergies to tape, suture materials, or topical preparations have been reported. Systemic reactions, which are more serious, may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment, including possible hospitalization. Allergic reactions to the gastric band device have not been reported.

**Deep Venous Thrombosis / Pulmonary (lung) complications:** Pulmonary complications (pulmonary emboli) may occur, secondary to both blood clots (deep venous thrombosis) and partial collapse of the lungs after general anesthesia. Should either of these complications occur, hospitalization and additional treatment might be required. Pulmonary emboli are rare, but can be life threatening or fatal in some circumstances.

**Pain:** Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue after Adjustable Gastric Band Surgery.

**Complications:** I acknowledge that it is not possible to list every complication possible during and after this procedure. By signing this consent, I agree that I have been informed of the risks and complications associated with the treatment that are significant in making a decision as to whether or not I should proceed with the surgery. I have also been informed of more serious risks, even if they are less likely to occur. I acknowledge and agree that I have been given the opportunity to ask questions regarding potential complications and other questions of concern to me and/or to my family relating to the surgery and my questions have been answered to my satisfaction.

**DISCLAIMER**

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition, along with the disclosure of risks and alternative forms of treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most individuals.
patients in most circumstances. However, informed consent documents should not be considered all inclusive. Your surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge and this should be considered as part of the “informed consent process”.

**PATIENT ACKNOWLEDGMENT & CONSENT TO SURGERY/PROCEDURE OR TREATMENT**

1. I hereby authorize Dr. __________________________ and such assistants as may be selected to perform the following procedure or treatment: ADJUSTABLE GASTRIC BAND SURGERY

2. I have received and carefully reviewed the information which has provided to me with information on Adjustable Gastric Band Surgery, alternative treatments available; risks and complications, possible need for additional surgery, the expected results and all material information. I have also had an opportunity to ask questions about the procedure and all my questions have been satisfactorily answered.

3. I understand as part of the consultation process at the SmartShape Weight Loss Centre, I am required to watch a consultation video, prior to the consultation with my surgeon, to provide me with essential information on the Lap-Band program so that I may make an informed decision. The information contained in this video is not to be relied upon as medical advice and is not intended to replace a consultation with the surgeon. I agree that I have watched the consultation video and that I understood the risks and benefits of the Lap-Band procedure that was presented. I agree that I have had an opportunity to ask my surgeon any and all questions prior to signing this consent.

4. After carefully reviewing all information and discussing the procedure with my surgeon, I have decided that Adjustable Gastric Band Surgery is the best option for me.

5. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those described. I therefore authorize the above physician and assistants or designee to perform such other procedures that are, in the exercise of his or her professional judgment, necessary and desirable. The authority granted under this paragraph shall include all conditions that require immediate treatment and are not known to my physician at the time the procedure is commenced.

6. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and there is a possibility of complications and injury, including heart failure, stroke or even death, for example.

7. I acknowledge that no guarantee has been given by anyone as to the results of surgery that may be obtained.

8. I consent to the photographing or video-taping of the operation to be performed, including appropriate portions of my body, for medical or educational purposes, provided my identity is not revealed in the pictures or videos.

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9. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.

10. I consent to the disposal of any tissue, medical devices or body parts which may be removed.

11. I have arranged for a responsible adult, who knows what I am having done, to pick me up and to stay and watch over me for 24 hours following surgery.

12. OVERALL, IT HAS BEEN EXPLAINED TO ME (IN A WAY THAT I UNDERSTAND):
   a. The above treatment or procedure to be undertaken;
   b. That there may be alternative procedures or methods of treatment, which I have declined;
   c. There are risks and complications to the procedure or treatment proposed.

I consent to the treatment or procedure described in this document and agree with the 12 items listed above and I am, therefore, agreeing to proceed with Adjustable Gastric Band Surgery.

__________________________________________  ________________________________
Patient Signature                                               Witness Signature

__________________________________________  ________________________________
Patient Name (print)                                               Witness Name (print)

Date__________________________________________
PRIVACY POLICY

The SmartShape Weight Loss Centre complies with all Provincial Personal Health Information Privacy Policies.

Protecting personal information is not a new concept and we at the SmartShape Weight Loss Centre make it a priority. We maintain a high level of confidentiality by restricting access to all personal information, providing locked facilities, alarm systems, password protection, and technological “fire walls” in order to maintain appropriate security for this information. In order to provide you with quality healthcare, however, it is important that you understand that we need to gather, keep, and communicate your personal health information within and between various individuals in your healthcare team.

Your healthcare information which is shared within the various individuals in your healthcare team, includes but is not limited to: summary of medical history, medication history, relevant investigation reports, consult notes and immunization history and maybe communicated between one another and with you via various mediums including but not limited phone, fax, e-mail and Skype.

By your signature on this notice, you are indicating your awareness and your consent that there are always potential risks when health information is discussed via these technological mediums and that you have voluntarily accepted the necessity for these types of communications and the minimal risks involved.

SIGNED
in the presence of

Witness

Witness Name (print)

Patient Signature

Date

I have read and understood the information on this page

Patient Initials ______

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NOTICE TO PATIENT

REMOVAL OF THE ADJUSTABLE GASTRIC BAND
I acknowledge that I am aware that removal of the Gastric Band may be medically necessary as a result of complications, or as a result of other unrelated medical issues, which may arise. As well, I am fully aware that I may choose to have the Gastric Band removed for reasons of preference rather than medical reasons or medical issues that have arisen. If the Gastric Band is removed for personal or non-medically necessary reasons, I acknowledge that I have been informed and I fully accept that I will not be entitled to a refund of the fees paid for the services. I acknowledge that if the Gastric Band is removed for reasons that do not involve medical necessity, that there may be additional fees charged.

FOLLOW-UP PROGRAM AT SMARTSHAPE WEIGHT LOSS CENTRE
I understand that the follow-up program at SmartShape Weight Loss Centre includes counseling, band adjustments and all visits with the staff employed by the SmartShape Weight Loss Centre. These services are included in the program for a period of five (5) years from the date of surgery. Currently, the cost of any acute complications of the gastric band procedure are covered by provincial health insurance plans and there is no further cost to the patient if urgent care is necessary for complications or adverse events.

After the five (5) year anniversary of the date of your Gastric Banding surgery, non-urgent care including band adjustments, band or port replacement, band repositioning or band removal may be subject to further charges. These charges may apply if care is provided at a SmartShape Weight Loss Centre facility, or by an affiliate. The current schedule of fees for these procedures is available on request, but is subject to change without notice.

ADJUSTMENTS PERFORMED AT AFFILIATE CENTRES
The SmartShape Weight Loss Centre has trained nurses and physicians ("Affiliates") to perform band adjustments under the direction of our nursing and physician staff. The staff at the clinic will provide you with the name and contact information for the Affiliate in your area at your request. The staff at the SmartShape Weight Loss Centre must direct all adjustments performed by affiliates. Affiliates are not trained to determine the timing or amount of band adjustments and consultation with the SmartShape Weight Loss Centre is essential prior to accessing Affiliates for adjustments.

RESULTS OF ADJUSTABLE GASTRIC BAND SURGERY
I acknowledge that I have been advised that a critical element in the success of Adjustable Gastric Band Surgery is my compliance in modifying both lifestyle and eating patterns. I accept that if a patient is not willing to comply with the recommended dietary and exercise recommendations, it is likely that the results will be disappointing and weight loss will be lower than anticipated. The potential results for my particular situation have been discussed with me during the consultation. I have, however, been advised that exact results are not predictable. I have had the opportunity to discuss any specific concerns or questions I have about the anticipated results with my surgeon prior to my surgery and I have had my questions satisfactorily answered. I understand and accept that the practice of medicine and surgery is not an exact science. There is no guarantee or warranty expressed or implied, on the results that may be obtained and I have voluntarily accepted these conditions.
CONSENT FOR ACCESS PERSONAL HEALTH INFORMATION FOR CLINICAL & MARKETING RESEARCH

From time to time, physicians within the SmartShape Weight Loss Centre (SWLC) become involved with clinical research projects and marketing initiatives which allow them to analyze the services, successes and results of the various treatments offered at the clinic. These projects may include clinical trials which may be submitted for publication to medical journals, as well as marketing and market research projects which are not published, but may help the Centre and/or its affiliated business partners, to continuously improve the service offerings and products extended to their patients.

In order to conduct these initiatives, the physicians, members of their staff, or a representative from an outside agency who has specifically been authorized by your physician, may require access to information in your medical charts and/or permission to contact you for additional follow-up information, as it relates to your treatment. Your personal information will not be released or be made public in any way.

Your consent or your refusal to participate in these initiatives and to grant your consent for us to use your personal health information, will not affect or influence your ongoing treatment through the SmartShape Weight Loss Centre.

If you have any questions concerning this research, please feel free to contact the SmartShape Weight Loss Centre at any time.

☐ I hereby authorize the SmartShape Weight Loss Centre, or external parties who have been expressly authorized access by the physicians employed by the SmartShape Weight Loss Centre, to access information in my medical charts and use the data for clinical research and/or marketing purposes, as required, and as described and consented above.

☐ I do not wish to give consent to access my personal health information in connection with clinical and/or marketing research as outlined above.

SIGNED
in the presence of

Witness

Patient Signature

Witness Name (print)

Date

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I have read and understood the information on this page

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