

**INFORMED CONSENT FOR BILIOPANCREATIC  
DIVERSION WITH DOUDENAL SWITCH (BPD-DS)**

It is very important to Midtown Surgical Specialists that you understand and consent to the treatment your doctor is rendering and any procedure your doctor may perform. You should be involved in any and all decisions concerning surgical procedures your doctor has recommended. Sign this form only after you understand the procedure, the anticipated benefits, the risks, the alternatives, the risks associated with the alternatives and all of your questions have been answered. Please initial and date directly below this paragraph indicating your understanding of this paragraph.

\_\_\_\_\_  
Patient's Initials or Authorized Representative

\_\_\_\_\_  
Date

I, \_\_\_\_\_, hereby authorize Dr. Blaney \_\_\_\_\_ and any associates or assistants the doctor deems appropriate, to perform biliopancreatic diversion with doudenal switch (BPD-DS)surgery.

To the extent that another healthcare provider other than Dr. Blaney \_\_\_\_\_ wil  
I

perform any important part of the procedure, I understand that Dr. Blaney, MD (name and title) will perform the following:

**biliopancreatic diversion with doudenal switch (BPD-DS) surgery with appendectomy and cholecystectomy. (some or all parts of the operation may not be able to be completed in the judgment of the surgeon due to unforeseen circumstances.**

The doctor has explained to me the risks of obesity and the benefits of biliopancreatic diversion with doudenal switch (BPD-DS)surgery vs the other available surgical and nonsurgical options for weight loss. However, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure. I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, well being and safety.

**Condition.** I recognize that I am severely overweight with a weight of \_\_\_\_\_ lbs. at \_\_\_\_\_ ft. \_\_\_\_\_ inches tall. My surgeon or surgeons have clearly explained to me that this level of obesity has been shown to be unhealthy and that many scientific studies show that persons of this level of obesity are at increased risks of respiratory disease, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, clotting problems, cancer and death as well as other serious and less serious medical illnesses.

**Commitment.** I am committed to long-term follow-up with my surgeon or surgeons and to make every effort to follow his/her directions to protect myself from these and other problems associated with biliopancreatic diversion with doudenal switch (BPD-DS) surgery. I understand that

to be effective, I need to make a life-long commitment to lifestyle changes, which may include, but not be limited to, dietary changes, an exercise program, and counseling. I understand that I will need to maintain proper nutrition, eat a balanced diet, and take vitamin and mineral supplements for the rest of my life. I will also be required to maintain follow-up medical care for my lifetime. Laboratory work will be required at least annually, and perhaps more often, as directed by a physician.

**Pre-operative Requirements.** I have completed the Physician-Supervised Multidisciplinary Program, which included Dietary Therapy, Physical Activity, and Behavior Therapy and Support. And have also engaged in a preop liquid diet as prescribed by my physician.

**Post-operative Requirements.** I agree to participate in a post-surgical multidisciplinary program that includes diet, physical activity, and behavior modification.

**Proposed Procedure.** I understand that the procedure that my surgeon or surgeons have recommended for the treatment of my obesity is the Laparoscopic Biliopancreatic diversion with doudenal switch (BPD-DS). My surgeon or surgeons have provided a detailed explanation of the medical history of the development of the surgical treatment of obesity, the biliopancreatic diversion with doudenal switch (BPD-DS) surgery is a treatment of obesity, the development of laparoscopic (minimally invasive) surgery and the biliopancreatic diversion with doudenal switch (BPD-DS) surgery. I have been strongly encouraged to make every effort to investigate and understand the details of the operation.

I understand the nature of a biliopancreatic diversion with doudenal switch (BPD-DS) which will be done laparoscopically. I understand that performing this procedure laparoscopically entails the use of a fiberoptic endoscope along with special endoscopic instruments and staplers to facilitate in completing the procedure with smaller incisions than in an open approach. It has been further explained to me that the laparoscopic approach to biliopancreatic diversion with doudenal switch (BPD-DS) surgery to treat morbid obesity is new. I understand that since it is a new procedure, the incidence of risks of the surgery along with its effectiveness will not be known for some time.

**Risks/Possible Complications.** The doctor has explained to me that there are risks and possible undesirable consequences associated with a biliopancreatic diversion with doudenal switch (BPD-DS) including, *but not limited to:*

1. **Abscess**
2. **Adult Respiratory Distress Syndrome (ARDS)**
3. **Allergic reactions**
4. **Anesthetic complications**
5. **Atelectasis**
6. **Bleeding, blood transfusion, and associated risks**
7. **Blood clots, including pulmonary embolus (blood clots migrating to the heart and lungs) and deep vein thrombosis (blood clots in the legs and/or arms)**

8. **Bile leak**
9. **Bowel obstruction**
10. **Cardiac rhythm disturbances**
11. **Complications in subsequent pregnancy (no pregnancy should occur within the first year after surgery)**
12. **Congestive heart failure**
13. **Dehiscence or evisceration**
14. **Depression**
15. **Dumping syndrome**
16. **Death.**
17. **Encephalopathy**
18. **Esophageal, pouch or small bowel motility disorders**
19. **Gout**
20. **Hernias, incisional (including the port sites for laparoscopic access) and internal**
21. **Inadequate or excessive weight loss**
22. **Infections at the surgical site, either superficial or deep including port sites for laparoscopic access. These could lead to wound breakdowns and hernia formation.**
23. **Injury to the bowels, blood vessels, bile duct, and other organs**
24. **Injury to adjacent structures, including the spleen, liver, diaphragm, pancreas and colon**
25. **Intestinal leak, with increased risk since this is a conversion operation**
26. **Kidney failure**
27. **Kidney stones**
28. **Loss of bodily function (including from stroke, heart attack, or limb loss)**
29. **Myocardial infarction (heart attack)**
30. **Narrowing of the connection between the stomach and small bowel**
31. **Need for and side effects of drugs**
32. **Organ failure**

33. **Perforations (leaks) of the stomach or intestine causing peritonitis, subphrenic abscess or enteroenteric or enterocutaneous fistulas**
34. **Pleural effusions (fluid around the lungs)**
35. **Pneumonia**
36. **Possible removal of the spleen**
37. **Pressure sores**
38. **Pulmonary edema (fluid in the lungs)**
39. **Serious intra-abdominal infection such as sepsis or peritonitis**
40. **Skin breakdown**
41. **Small bowel obstructions**
42. **Staple line disruption**
43. **Stoma stenosis**
44. **Stroke**
45. **Systemic Inflammatory Response Syndrome (SIRS)**
46. **Ulcer formation (marginal ulcer or in the distal stomach)**
47. **Urinary tract infections**
48. **Wound infection**
49. **Need to convert to a gastric bypass to address a complication such as a leak**

a. Nutritional complications *include but are not limited to:*

1. **Protein malnutrition**
2. **Vitamin deficiencies, including B12, B1, B6, folate and fat soluble vitamins A,D,E,K**
3. **Mineral deficiencies, including calcium, magnesium, iron, zinc, copper, and other**
4. **Uncorrected deficiencies can lead to anemia, neuro-psychiatric disorders and nerve damage, that is, neuropathy**

b. Psychiatric complications *include but are not limited to:*

1. **Depression**
2. **Bulimia**
3. **Anorexia**
4. **Dysfunctional social problem** c. Other

complications include but are not limited to:

1. **Adverse outcomes may be precipitated by smoking**
2. **Constipation**
3. **Diarrhea**
4. **Bloating**
5. **Cramping**
6. **Development of gallstones**
7. **Intolerance of refined or simple sugars, dumping with nausea, sweating and weakness**
8. **Low blood sugar, especially with improper eating habits**
9. **Vomiting, inability to eat certain foods, especially with improper eating habits or poor dentition**
10. **Loose skin**
11. **Intertriginous dermatitis due to loose skin**
12. **Malodorous gas, especially with improper food habits**
13. **Hair loss (alopecia)**
14. **Anemia**
15. **Bone disease**
16. **Stretching of the pouch or stoma**
17. **Low blood pressure**
18. **Cold intolerance**
19. **Fatty liver disease or non-alcoholic liver disease (NALF)**
20. **Progression of pre-existing NALF or cirrhosis**
21. **Vitamin deficiencies some of which may already exist before surgery**

## 22. Diminished alcohol tolerance

d. Pregnancy complications were explained as follows:

1. **Pregnancy should be deferred for 12 to 18 months after surgery or until the weight loss is stabilized**
2. **Vitamin supplementation during the pregnancy should be continued**
3. **Extra folic acid should be taken for planned pregnancies**
4. **Obese mothers have children with a higher incidence of neural tube defects and congenital heart defects**
5. **Pregnancy should be discussed with an obstetrician**
6. **Special nutritional needs may be indicated or necessary**
7. **Secure forms of birth control should be used in the first year after surgery**
8. **Fertility may improve with weight loss**

Further, any of these risks or complications may require further surgical intervention during or after the procedure, which I expressly authorize.

I also understand that some or all of the complications listed on this form and also explained to me may exist whether the surgery is performed or not, in that biliopancreatic diversion with duodenal switch (BPD-DS) surgery is not the only cause of these complications.

**Alternative Procedures.** In permitting my doctor to perform this procedure, I understand that unforeseen conditions may necessitate change or extension of the original procedure(s), including completing the operation by way of the conventional open surgical approach, or a different procedure from what was explained to me. I therefore authorize and request that the above-named physician, his assistants or designees to perform such procedure(s) as may be necessary and desirable in the exercise of his/her professional judgment.

The reasonable alternative(s) to the procedure(s), as well as the risks to the alternatives, have been explained to me. These alternatives include, ***but are not limited to***, various diet exercise and drug treatments.

I hereby authorize the disposal of removed tissues resulting from the procedure(s) authorized above.

I consent to any photographing or videotaping of the procedure(s) that may be performed, provided my identity is not revealed by the pictures or by descriptive texts accompanying them, so that my physician may follow my therapy progression. I consent to the admittance of students or authorized equipment representatives to the procedure room for purposes of advancing medical education or obtaining important product information.

By signing below, I certify that I have had an opportunity to ask the doctor all my questions concerning anticipated benefits, material risks, alternative therapies, and risks of those alternatives, and all of my questions have been answered to my satisfaction.

\_\_\_\_ / \_\_\_\_ / \_\_\_\_\_  
Date    Time    Signature of Patient or Authorized Rep.                      Relationship of Authorized Rep.

- ~ The Patient/Authorized Representative has read this form or had it read to him/her
- ~ The Patient/Authorized Representative states that he/she understands this information ~
- The Patient/Authorized Representative has no further questions

\_\_\_\_\_  
Date                                      Time                                      Signature of Witness

**CERTIFICATION OF PHYSICIAN:**

I hereby certify that I have discussed with the individual granting consent, anticipated benefits, material risks, alternative therapies and the risks associated with the alternatives of the procedure(s).

\_\_\_\_\_  
Date                                      Time                                      Signature of Physician

**USE OF INTERPRETER OR SPECIAL ASSISTANCE**

An interpreter or special assistance was used to assist patient in completing this form as follows:

- \_\_\_\_\_ Foreign language (specify)
- \_\_\_\_\_ Sign language
- \_\_\_\_\_ Patient is blind, form read to patient
- \_\_\_\_\_ Other (specify) \_\_\_\_\_

Interpretation provided by

(Fill in name of Interpreter and Title or Relationship to Patient)

\_\_\_\_\_  
Signature (Individual Providing Assistance)                      Date                      Time