

BOICE-WILLIS CLINIC, PA

Patient Name: _____ DOB: _____ MRN: _____



Informed Consent

Labiaplasty

Patient Name: _____ DOB: _____ MRN: _____

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about labiaplasty surgery, its risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page, and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

Labiaplasty is offered to women with excessive, redundant labia who suffer from unsightly contour lines and physical discomfort. Such women report pinching or chafing when sitting or walking, hindrance during intercourse, and difficulty maintaining hygiene during menses or after defecation.

The term labiaplasty refers to the reduction in size of the labia minora. The labia minora are the bands of tissue on either side of the vagina that are directly inside the labia majora. These two flaps of skin extend down from the clitoris. Hormonal changes in the body brought on by pregnancy, puberty, menopause, and age, enlarge and darken the color of these tissues. Many women find these changes particularly disturbing as they may be obvious to them and their sexual partners. In some cases, the labia minora can become so large that they will interfere with sexual intercourse.

Labiaplasty is one of the most common genital rejuvenation procedures performed. The procedure involves cutting away the excess tissue and closing the incision. The aim of the surgery is to reduce the labia minora and not to totally remove them.

ALTERNATIVE TREATMENTS

Alternative forms of treatment consist of not reducing the labia surgically.

INHERENT RISKS OF LABIAPLASTY SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand all the possible consequences of labiaplasty.

SPECIFIC RISKS OF LABIAPLASTY SURGERY

Scarring:

All surgeries leave scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of a different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is a possibility of visible marks in the skin from sutures. Scarring in this area may result in painful intercourse, other sexual dysfunction, or changes to the urinary stream; in some cases, it may require surgical revision or treatment.

Pain:

You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue (neuroma) or due to tissue stretching. Scarring in this area may result in painful intercourse, and in some cases may require surgical revision or treatment. This may lead to functional problems with sexual intercourse or urination/defecation.

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Skin Contour Irregularities:

Contour and shape irregularities may occur. Visible and palpable wrinkling of skin may occur. Residual skin irregularities at the ends of the incisions or “dog ears” are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

Delayed Healing:

Wound disruption or delayed wound healing is possible. Some areas of skin may die or slough. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have a decreased blood supply to tissue from a past surgery or radiation therapy may be at increased risk for wound healing and poor surgical outcome. Smokers have a greater risk of skin loss and wound healing complications.

Skin Discoloration/Swelling:

Bruising and swelling normally occurs following surgery. The skin in or near the surgical site can appear either lighter or darker than the surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

Change in Sensation:

It is common to experience diminished (or loss of) skin sensation in areas that have had surgery. It is rare to experience permanent changes in sensation, but is possible. Diminished (or complete loss of) skin sensation may not totally resolve after surgery.

GENERAL RISKS OF SURGERY**Healing Issues:**

Certain medical conditions, dietary supplements, and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes, resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery due to the length of surgery and anesthesia. Patients with significant skin laxity will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become involved with healing scars from surgery. While there may not be a major nerve injury, the small nerve endings may become too active during the healing period, thus producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

Bleeding:

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require an emergency treatment to drain the accumulated blood or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to an increased chance of bleeding and additional surgery. It is important to follow post-operative instructions and to limit exercise and strenuous activity for the instructed time. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Hematomas can occur at any time, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Your surgeon may provide medications after your surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

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Infection:

Infection, although uncommon, can occur after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to tell your surgeon of any other infections, such as a history of methicillin-resistant Staphylococcus aureus (MRSA) infections, an open wound, recent upper respiratory infection/pneumonia, ingrown toenail, insect bite, tooth abscess, or urinary tract infection. Infections in other parts of the body may lead to an infection in the operated area. Post-operative infections often result in more extensive scarring and predispose to revision surgery.

Scarring:

All surgeries leave scars, some more visible than others. Although good wound healing after a surgical procedure is expected, this surgery will result in long, prominent scars that are permanent. Abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of a different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is a possibility of visible marks in the skin from sutures. These scars may become raised, red, or discolored in the first few weeks/months, but usually settle down over time. However, some patients are prone to “hypertrophic” or “keloid” scars, i.e., prominent, raised, red scars that do not settle. Further treatments with medications and/or surgery may be required.

Firmness:

Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment, including surgery, may be necessary.

Skin Sensitivity:

Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations, it may be chronic.

Major Wound Separation:

Wounds may separate after surgery. Should this occur, additional treatment, including surgery, may be necessary.

Sutures:

Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible, or produce irritation that requires suture removal.

Damage to Deeper Structures:

There is the possibility for injury to deeper structures including nerves, blood vessels, lymphatics, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

Fat Necrosis:

Fatty tissue found deep in the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is a possibility of contour irregularities in the skin that may result from fat necrosis.

Seroma:

Infrequently, fluid may accumulate between the skin and the underlying tissues following surgery, trauma, or vigorous exercise. Should this problem occur, it may require additional procedures for drainage of fluid.

Surgical Anesthesia:

Both local and general anesthesia involve risks. There is a possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

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Shock:

In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Pain:

You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. If you are a chronic pain patient followed by a Pain Therapy Practitioner, you may be asked to see this practitioner pre-operatively to assist you in the management of your pain disorder in the post-operative period. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

There are nerve endings that may become involved with healing scars from surgery. While there may not be a major nerve injury, the small nerve endings may become too active during the healing period, thus producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early non-surgical intervention resolve this. It is important to discuss post-surgical pain with your surgeon.

Cardiac and Pulmonary Complications:

Pulmonary complications may occur subsequent to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life threatening or fatal in some circumstances. Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heartbeats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Venous Thrombosis (Clot) and Sequelae:

Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites, and usually resolve without medical or surgical treatment. It is important to discuss with your surgeon any birth control pills you are taking. Certain high estrogen pills may increase your risk of thrombosed veins, personal history of bleeding and clotting problems may also increase your risk of thrombosed veins.

Allergic Reactions:

In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations, or injected agents have been reported. Serious systemic reactions, including shock (anaphylaxis), may occur in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment. It is important to notify your physician of any previous allergic reactions.

Drug Reactions:

Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over-the-counter, as well as medications you regularly take. Provide your surgeon with a list of medications and supplements you are currently taking.

Asymmetry:

Symmetrical body appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to normal asymmetry in body features. Most patients have differences between the right and left side of their bodies before any surgery is performed. Additional surgery may be necessary to attempt to diminish asymmetry.

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Surgical Wetting Solutions:

There is a possibility that large volumes of fluid containing dilute local anesthetic drugs and epinephrine that is injected into fatty deposits during surgery may contribute to fluid overload or systemic reaction to these medications. Additional treatment, including hospitalization, may be necessary.

Fat/Air Embolism:

In rare cases, fat particles or air can enter the vascular system and travel to the heart, lungs, or brain. This can result in significant complications including death.

Persistent Swelling (Lymphedema):

Persistent swelling can occur following surgery.

Unsatisfactory Result:

Although good results are expected, there is no guarantee or warranty, expressed or implied, on the results that may be obtained. The body is not symmetric and almost everyone has some degree of unevenness that may not be recognized in advance. One side of the face may be slightly larger or one side of the face droopier. The breast and trunk area exhibit the same possibilities. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations are to the results, the better your results will appear to you. Some patients never achieve their desired goals or results, at no fault of the surgeon or surgery. You may be disappointed with the results of surgery. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

ADDITIONAL ADVISORIES**Medications and Herbal Dietary Supplements:**

There are potential adverse reactions that occur as a result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with the forming of blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting such as Plavix®, Coumadin®, Xarelto®, Effient®, or Pradaxa®, discuss management of these medications around the time of surgery with your plastic surgeon. Your plastic surgeon may sometimes coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop them without discussing it first with your plastic surgeon. Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with medications that you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room.

When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Sun Exposure – Direct or Tanning Salon:

The effects of the sun are damaging to the skin. Exposing the treated areas to the sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use of sun block or clothing coverage.

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Travel Plans:

Any surgery holds the risk of complications that may delay healing and your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame. Allow at least 10-14 days to travel via airplane. Medications may be required should you have a long flight/trip to prevent DVT/PE in the immediate post-operative period.

Long-Term Results:

Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your surgery.

Body-Piercing:

Individuals who currently wear body-piercing jewelry in the surgical region are advised that an infection could develop from this activity. Body-piercing jewelry should be removed prior to your surgical procedure.

Nails:

To determine your vitals status during surgery, your anesthesia provider may require access to your fingernails for monitoring. Make sure to have at least two fingernails free of nail polish or acrylic nails on the date of your surgery.

Jewelry:

Jewelry should not be brought with you at the time of your surgical procedure. Items such as earrings, wedding rings, and necklaces, should be removed and placed in a safe place.

Future Pregnancy and Breastfeeding:

This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and offset the results of surgery. You may have more difficulty breastfeeding after this operation.

Female Patient Information:

It is important to inform your plastic surgeon if you use birth control pills or estrogen replacement, or if you suspect you may be pregnant. Many medications, including antibiotics, may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

Intimate Relations After Surgery:

Surgery involves coagulating of blood vessels, and increased activity of any kind may open these vessels leading to a bleed or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need to return to surgery to control bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

Mental Health Disorders and Elective Surgery:

It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery, and are often stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

ADDITIONAL SURGERY NECESSARY (Re-Operations)

There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of body structures. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur

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infrequently, the risks cited are associated with this surgery. Other complications and risks can occur but are less common. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty, expressed or implied, on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the options available should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology, and lab testing.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for a successful outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activities need to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation, and the need to return to surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

ATTESTATIONS

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):

Patients who are currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin loss, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complications. Please indicate your current status regarding these items below:

I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications.

I am a smoker or use tobacco/nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

I have smoked and stopped approximately _____ ago. I understand I may still have the effects and, therefore, risks from smoking in my system, if not enough time has lapsed.

I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations, and alternatives to my surgery if I continue smoking.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this time frame, and understand that for my safety, the surgery, if possible, may be delayed.

Smoking may have such a negative effect on your surgery that a urine or blood test may be done just before surgery, which will prove the presence of nicotine. If positive, your surgery may be cancelled and your surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon.

COMMUNICATION ACKNOWLEDGEMENT – CONSENT

There are many ways to communicate with you. It is important to keep appointments and let us know if problems or issues arise. Methods of communicating are by telephone, text, pager, answering service (if available), email, and regular mail. If an emergency arises, keep us alerted of your progress so we may aid in any necessary treatments. Please do not leave a message after hours or on weekends on the office answering machine if any urgent or emergent situation exists, as there is a delay in retrieving such



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CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Karen Szymanski, DO, MPT and such assistants as may be selected to perform **Labiaplasty**.
I have received the following information sheet: **Labiaplasty**.
2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those stated above. I therefore authorize the above physician and assistants or designees 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 treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific, about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices, or body parts that may be removed.
8. I am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by my surgeon and/or his/her appointees.
9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option. I opt out of having this procedure _____.
12. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12).
I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date/Time _____ Witness _____