Lip Augmentation with Silicone Lip Implant

I hereby request Dr. Scott M. Gayner and his operating room team to perform upon me a surgical operation known as a lip augmentation with a solid silicone implant. We use a shaped soft silicone implant for augmentation of the lips. The implant is FDA approved for the face, but we plan to use it for your lip (lips) i.e. an "off label" use. Off label use permits a physician to use a material that is FDA approved for purposes that is not specifically FDA approved.

1. This procedure has been explained to me, and I completely understand the nature and consequences of the procedure. The following points have been particularly stressed to me:

   The purpose is to increase the fullness of the lip (s) by making a small incision in each corner of the mouth; the surgeon makes a tunnel through the lip (s), extending from side to side to the other, into which the implant is inserted. The implant is a soft, flexible, sterile, medical-grade silicone that is custom shaped to fit each patient's lip (s).

   Although unfavorable results are uncommon from this type of operation, they do rarely occur. It is possible the operation will not improve any appearance. It is even possible that the appearance will be less pleasing after the operation than it is now. Because of these facts, we can make no guarantee as to the result that might be obtained from this operation, which could require additional surgery. However, in the vast majority of patients, the result desired from the surgery is achieved.

   There will be swelling for an indeterminate period. Much of such swelling will normally disappear in 2-3 weeks and the remainder may require several months.

   Bruising may persist for 1-2 weeks.

   There may be areas of numbness over the lip(s) following surgery, which may persist for an indefinite period of time. In rare occasions, permanent areas of numbness may persist.

   Some of the possible complications of surgery are: Infection; bleeding; hematoma (abnormal collections of blood underneath skin resulting in visible lumps); abnormal contour of the lip (s); nerve damage causing a change of feeling in the lip (s); extrusion (implant breaks through sutures); Restriction of lip function; tightness; difficulty using a straw, visible edge of implant of one lip; shifting of implant to one side; personality or mental difficulties following surgery, sometimes occurring even when the operation has been a cosmetic success, allergic or other unfavorable reactions to one or more of the substances used in the operation.
Smoking: I have been advised to stop smoking 1 week prior to surgery and 2 weeks post-surgery due to possible complications; circulation; compromise tissue loss (necrosis); poor scarring; delayed healing; decreased longevity of results.

No guarantees can be made as to results or outcome of surgery.

DVT- Deep vein thrombosis can be a post-surgical complication following any surgical procedure. This condition is serious and can be fatal. It is a formation of a blood clot in a deep vein of the legs. Symptoms: muscle tenderness in the lower legs; cramping in the calf; temperature; swelling in the calf; pain or warmth in the lower legs; redness. This complication is much lower with procedures done under local anesthesia.

Some of the complications of this operation can result in the need for further surgery. Some of the complications can cause prolonged illness, poor healing wounds (tissue necrosis), unattractive scarring, and permanent disability; allergic reactions have even been known to cause death. Furthermore, there may be alternatives to this operation available to me, which carry their own risk of complications and varying degree of success.

I AM AWARE THAT THE PRACTICE OF MEDICINE AND SURGERY IS NOT AN EXACT SCIENCE< AND I ACKNOWLEDGE THAT NO GUARANTEES HAVE BEEN MADE TO ME AS TO THE RESULTS OF THE OPERATION.

1. I am not known to be allergic to anything except: (please list)

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2. I agree to keep Dr. Gayner informed of any changes of addresses in order to be notified of any late findings, and I agree to cooperate with my care after surgery until completely discharged.
I CERTIFY: I have read or had read to me the contents of this form; I understand the risks and alternatives involved in this procedure; I have had the opportunity to ask any question which I had and all of my questions have been answered.