

### **INSTRUCTIONS**

This is an informed-consent document that has been prepared to help your cosmetic surgeon inform you of the Silikon 1000 injection treatment, its risks as well as alternative treatments. It is important that you read this information carefully and completely. You will be asked to electronically sign this consent when checking in to our office on the day of your surgery. There is no need to print this document.

### **INTRODUCTION**

For many years, physicians and patients have sought a material that could be safely injected beneath the skin to fill out depressions, lines, and wrinkles. At the same time, considerable effort was being spent to develop a material that could be surgically implanted to correct larger defects. Silicone appears to be a material that is well-suited for both uses. Blocks of silicone carved into various shapes as well as silicone sacs containing a gel form of the material have been widely used as implant materials in all parts of the body. The liquid form of silicone is a medical grade of silicon oil, Silikon 1000, which was originally developed and used to correct retinal detachments and appeared to be a safe and simple way of augmenting tissue. It soon became apparent that this form of injection therapy frequently led to serious complications. As a result these, complications of injection therapy silicone were withdrawn from the market pending a study by a select group of investigators.

Since breast augmentation represented the major market for large amounts of injectable silicone, the Dow Corning Company, the major producer of injectable silicone, ultimately decided that the expense of the required government studies made it economically unfeasible to continue to produce silicone fluid intended for injection. This decision was not based on problems with the material. The investigators studying the problem actually found that silicone appeared to be a very safe material when used properly. There are now clinicians who have more than 20 years experience in the use of injectable silicone who claim that there have been no serious complications for its use. There has been no indication from research or clinical use that would indicate that there is any risk of the silicone-causing cancer. Similarly, there has been no indication that Silikon injection therapy is at all detrimental to patient's general health.

### **RISKS AND ADVANTAGES OF SILIKON INJECTION THERAPY**

Patients who choose to have Silikon injection therapy must understand that it is not approved by the FDA (Food and Drug Administration). This does not make the use of injectable silicone illegal. As in the case with any form of medical treatment, the decision as to whether or not a patient chooses to have the treatment depends on the patient's informed consent, understanding the potential advantages and risks of a given form of treatment.

When a patient undergoes Silikon injection therapy, no special preparation is required. The skin is cleaned and small amount of pure Silikon are injected in the desired location. It is unusual to achieve the desired result with one injection. More commonly, anywhere from a few to several injections will be required. Injecting the material in small amounts over a series of injections allows for accurate placement of the material with a minimum of risk of overfilling the area. Injections will always be separated by a period of several weeks to allow the surgeon and patient to observe and evaluate the effect of the previous injection treatment. After each injection, patients should massage the area as directed per surgeon for several hours after to allow an even disbursement of the Silikon.

Silikon 1000 injections can be used to fill in soft tissue defects in the face. These can be the result of growth abnormalities, injury, or aging. A frequent indication is to fill in the skin to smooth out wrinkles that occur with aging to improve the appearance of sagging skin, thinning lips, deep wrinkles and on frown lines.

When Silikon is injected beneath the skin, it becomes encapsulated when your body builds collagen around each droplet injection site, which means that the area is slowly filled as more body tissue forms. Asymmetry in the human face is normal with respect to structural anatomy and function before treatment. There can be a variation from one side to the other in terms of the response to Silikon injections to correct asymmetry or other defects. Therefore repeated injections may be necessary.

There is often a mild inflammatory pain response at the injection site, but this usually subsides quickly. It is possible, though unusual, to have slight bleeding from a Silikon injection. Bruising in soft tissues may occur after injection and last up to seven days after injection.



When injecting any biologic product into the human body, allergic and systemic anaphylactic reactions may occur. Allergic reactions may require additional treatment.

No medical or surgical procedure can be made entirely risk-free. Long-term experience by many clinicians has indicated that Silikon injection therapy has very high margin of safety. Complications can occur. The most commonly reported complications include lumpy or nodular appearance and the development of localized infections called granulomas. Nearly all of the complications reported have been related to injections of massive amounts into breast tissue. However, there have been reports of similar types of problems related to facial injections. Most experienced investigators feel that these problems are related to injections of too large of amounts of Silikon injected into areas too rapid.

**DISCLAIMER AND CONSENT FOR SILIKON INJECTION THERAPY**

I have read the above information and have asked any and all questions that I have concerning the use of Silikon injection therapy. Based on an understanding of the potential benefits and risks, I choose to avail myself of this form of treatment.

I understand that Dr. Erik Nuveen is not in a position where he can make any guarantees concerning the safety of the material other than the fact that, based on his knowledge and experience, he feels that this procedure can be employed safely and effectively in the treatment of my condition. I also understand that the FDA has not authorized the use of injectable Silikon for anything other than certain ophthalmic applications, but that the FDA's authorizing statutes does not enable it to regulate the practice of medicine.

It is important that you read the above information carefully and have all of your questions answered before signing the consent.



## CONSENT FOR SURGERY/ PROCEDURE

1. I hereby authorize Dr. Nuveen and such assistants as may be selected to perform the following procedure or treatment: **SILIKON 1000 INJECTION**

I have received the following information sheet: **SILIKON 1000 INJECTION CONSENT**

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those 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 acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

5. I consent to the photographing or televising of 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 which may be removed.

8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

9. The above information has been explained to me in a way I understand and as completely as possible, to my satisfaction.

a. I understand that there are options available to the proposed treatment including the option to do nothing.

b. I accept the well known, common, and uncommon risks of this procedure and I consent to the performance of the described procedure.

### **I CONSENT TO THE SILIKON 1000 INJECTION TREATMENT.**

Patient Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Date: \_\_\_\_\_ Witness: \_\_\_\_\_

**YOU WILL SIGN THIS DOCUMENT ELECTRONICALLY WHEN CHECKING IN TO OUR OFFICE ON THE DAY OF YOUR SURGERY.**

**THERE IS NO NEED TO PRINT THIS DOCUMENT.**