

Informed Consent - PDO (Polydioxanon) Suture Threads for Lifting

POSSIBLE RISKS and SIDE EFFECTS ASSOCIATED PDO SUTURES

1. **DISCOMFORT:** Some discomfort may be experienced during treatment despite the use of appropriate anesthesia.
2. **SCARRING:** Threads are inserted via a small acupuncture type needle, although rare it may take a few days to heal or may form permanent scar.
3. **BRUISING, SWELLING, INFECTION:** With any minimally invasive procedure, bruising of the treated area may occur. Additionally, there may be swelling noted. Finally, skin infection is rare, but a possibility with any injection or incision into the skin.
4. **BLEEDING:** It is possible, though extremely unusual, to experience a bleeding episode during or after the procedure. Should bleeding occur, it may require treatment to drain accumulated blood (Hematoma). Do not take any aspirin for 7 days or anti-inflammatory medications (Advil, Motrin, Ibuprofen) for 2 days before procedure, as this may contribute to a greater risk of bleeding.
5. **DAMAGE TO DEEPER STRUCTURES:** Deeper structures such as nerves, blood vessels and muscles may be damaged during the course of procedure. The potential for this to occur varies according to the location on the body the procedure is being performed. Injury to deeper structures may be temporary or permanent.
6. **ALLERGIC REACTIONS:** In very rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions, which are more serious, may result from drugs used during procedure and prescription medicines. Allergic reactions may require additional treatment.
7. **ANESTHESIA:** Local Topical anesthesia may be used and can involve risk of allergic reaction and rash.
8. **PIGMENT CHANGES (SKIN COLOR) (hyper or hypo-pigmentation):** There is a remote possibility of the treatment area either becoming lighter or darker in color than the surrounding skin. This is usually temporary, but on rare occasions, may be permanent. Appropriate sun protection is very important.
9. **PARTIAL LAXITY CORRECTION:** Although PDO Threads will give some improvement in laxity, but may not correct all your facial laxity.
10. **DELAY HEALING:** Complications may ensue as a result of smoking, drinking liquids through a straw, or similar motions. Because of this, smoking and similar actions are **STRONGLY** discouraged.
11. **CONTRAINDICATIONS:** Any known allergy or foreign body sensitivities to plastic biomaterials.
12. **OTHER:** Slight asymmetry, redness, visible thread(s) may require additional treatment and or the removal of the threads.

ADDITIONAL PROCEDURES MAY BE NECESSARY

- In some situations, it may not be possible to achieve optimal results with a single procedure and other procedures may be necessary. The practice of medicine is not an exact science. Although good results are expected, there cannot be any guarantee or warranty expressed or implied on

the results that may be obtained. I understand that my cheeks or jowls may not achieve the desired improvement in shape that was anticipated.

- I understand that sutures may extrude, and may have to be trimmed or removed in the future.
- I understand that the results may relax over time and additional procedures may be required.

FINANCIAL RESPONSIBILITIES

- The cost of the procedure may involve several charges for the services provided. The total may include fees charged by your doctor/practitioner, the cost of supplies, or laboratory tests if needed. Additional costs may occur should complications develop from the procedure. Results are not guaranteed, there is no warranty for this medical treatment and there will be no refunds offered.
- I realize that, as in all medical treatment, complications or delay in recovery may occur which could lead to the need for additional treatment, and could also result in economic loss to me because of my inability to return to activity as soon as anticipated.

CONSENT

Your consent and authorization for this procedure is strictly voluntary. By signing this informed consent form, you hereby grant authority to your physician/practitioner to perform insertion of PDO Suture Threads for lifting and rejuvenation purposes and/or to administer any related treatment as may be deemed necessary or advisable in the diagnosis and treatment of your condition.

The nature and purpose of this procedure and the complications and side effects have been fully explained to me. Alternative treatments and their risks and benefits have been explained to me and I understand that I have a right to refuse treatment. I agree to adhere to all safety precautions and instructions after the treatment. I have been instructed in and understand post treatment instructions and have been given a written copy of them.

I understand that no refunds will be given for treatments received. No guarantee has been given by anyone as to the results that may be obtained by this treatment.

I have read this informed consent and certify that I understand its contents in full. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. I have had enough time to consider the information given to me by my practitioner and feel that I am sufficiently advised to consent to this procedure. I accept the risks and complications of the procedure. I hereby give my voluntary consent to this procedure and release my practitioner, the facility, medical staff, and specific technicians from liability associated with the procedure. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

Name: _____

Signature: _____

Date: _____

Witness: _____