CONSENT FOR TREATMENT with PDO (Polydioxanone) Suture Threads

- **INSTRUCTIONS:** This is an informed consent document that has been prepared to help inform you concerning PDO Thread Lift Procedure, its risks, and alternative treatments. It is important that you read this information carefully and completely. Please initial each section, indicating that you have read the page and sign the consent for the procedure proposed by your practitioner. *

- **INTRODUCTION:** Thread Lift, is effective in most cases; no guarantees can be made that a specific patient will benefit from this procedure. Additionally, the nature of cosmetic procedure may require a patient to return for numerous visits in order to achieve the desired results or to determine whether Thread Lift may not be completely effective at treating the particular condition. Therefore, this permission for care will be effective for (1) year from the date of execution with respect to the above outlined procedure(s). *

- **INDICATIONS OF USE:** ON or OFF LABEL USE only concerns marketing & promotional material for a product. Physicians are free to use any medical device for any purpose, even a use that the FDA has not approved. PDO threads are to be used in soft tissue approximation where the use of absorbable sutures is appropriate.

- **ALTERNATIVE TREATMENTS:** Alternative forms of non-surgical and surgical management consist of facelift, Nd:YAG Laser, full-face CO2 Laser, dermal fillers, or chemical peels. Risks and potential complications are associated with alternative forms of treatment. Every procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo a procedure is based on the comparison of the risk to the potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your practitioner to make sure you understand the risks, potential complications, and consequences. *

Patient initials: _____

POSSIBLE RISKS and SIDE EFFECTS ASSOCIATED PDO SUTURES

- **1. DISCOMFORT:** Some discomfort may be experienced during treatment. I give permission for the administration of the anesthesia when deemed appropriate. *

- **2. SCARRING:** PDO Thread Lift for Mid-Face. Threads are inserted via a small acupuncture type needle; although rare it may take a few days to heal. Scar at entry point is extremely rare but must always be considered a possibility when entering the skin*

- **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 or anti-inflammatory medications (Advil, Motrin, Ibuprofens) for ten (10) days before surgery, 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 know 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. *

Patient initials: _____

- **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.

- **FINANCIAL RESPONSIBILTIES.** The cost of 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.

- **DISCLAIMER:** Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process to define principles of risk disclosure should generally meet the needs of patients in most circumstances. However, Informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your practitioner may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge. Informed-consent document are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and subject to change as science knowledge and technology advance and as practice patterns evolve. It is important that you read the above information carefully and have all of your questions answered before signing the consent that follows. *

- I understand that no warranty or guarantee has been made to me as to result or cure. 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. *

- I understand that my practitioner may discover other or different conditions, which require additional or different procedures than those planned. I authorize the practitioner and such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment. *

- 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. *

Patient initials: _____

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 & purpose of this procedure and the potential complications & side effects have been fully explained to me. Alternative treatments and their risks and benefits have been explained to me as well 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 me by my physician/practitioner and feel that I am sufficiently advised to consent to this procedure. I accept the risks and complications of the procedure. I certify if any changes occur in my medical history I will notify the office.

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. I certify that I am a competent adult of at least 18 years of age and am not under the influence of alcohol or drugs. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

Should I have any questions or concerns regarding my treatment / results, I will notify this office at _____ immediately so that timely follow-up and intervention can be provided.

_____ _____ _____

Patient Name (please print name) Patient Signature Date

_____ _____ _____

Witness Name (please print name) Witness Signature Date