**ITHACA MEDICAL AESTHETICS**

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**INFORMATION SHEET AND INFORMED CONSENT**

**for PDO (Polydiaxanone) Suture Threads for Lifting – MINT THREADS**

**It is important that you read this information carefully and completely.**

To the patient:

Being fully informed about your condition and treatment will help you make the decision whether or not to undergo PDO Thread treatment. This disclosure is not to alarm you but to better inform you so that you may withhold your consent for this treatment.

**Consent for PDO (Polydiaxanone) Suture Threads for Lifting – MINT THREADS**

**Instructions:**This is an Informed Consent document that has been prepared to help inform you concerning the PDO Mint Threads procedure, its risks, and alternative treatments. It is important that you read this information carefully and completely.

**Treatment:**Mint Threads are hypodermic needles preloaded with a synthetic PDO absorbable barbed sutures.  Both entry and exit points are determined depending on the area you wish to lift and in each entry point, a hole is made using an 18-G needle.  A canula is inserted with the thread and is advanced through the subcutaneous layer between the entry points.  Following the removal of the cannula, any remaining thread that protrudes outside of the entry site is cut and removed.  Your skin should fully absorb the Mint Thread within 4 to 6 months, but it could sometimes take longer.   You should see immediate tightening results and overtime the sutures also create a selective inflammatory response to produce collagen.   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 Mint Threads may not be completely effective at treating the particular condition.

**Alternative Treatments:**Alternative nonsurgical and surgical management consist in the form of facelift, laser, dermal fillers, and 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. 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.

**Possible Risks and Side Effects Associated With PDO Sutures**

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

**Scarring**. Mint Threads are inserted via a canula. 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.

**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.

**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, ibuprofen) for ten (10) days before surgery, as this may contribute to a greater risk of bleeding.

**Damage to deeper structures**. Deeper structures, such as nerves, blood vessels, and muscles, may be damaged during the course of the procedure. The potential for this to occur varies depending upon which location on the body the procedure is being performed.

**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 the procedure and prescription medications. Allergic reactions may require additional treatment.

**Eating hard foods or chewing may be difficult for the first week after the procedure**.  You must avoid opening your mouth widely in order to prevent movement of the thread.

**Anesthesia**. Local topical anesthesia may be used and can involve risk of allergic reaction and rash.

**Changes in skin color (hypo or hyper pigmentation).** There is a remote possibility that the treatment area may become lighter or darker in color than the surrounding skin. This is usually temporary, but on rare occasions it may be permanent. Appropriate sun protection is very important.

**Partial laxity correction**. Although PDO threads will give some improvement in laxity, they may not correct all your facial laxity.

**Delayed 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.

**Contraindications**. This procedure is contraindicated in any individual with a known allergy or foreign body sensitivities to plastic biomaterials.

**Other.** Slight asymmetry, redness, and/or visible thread(s) may require additional treatment or the removal of the threads.  DO NOT TRY TO REMOVE ANY PROTRUDING THREAD ON YOUR OWN.

**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.

Pregnancy and Nursing Mothers: Animal reproduction studies have not been performed to determine if PDO threads could produce fetal harm.  It is not recommended that pregnant women or nursing mothers receive PDO treatments.

**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 treatments. 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 to be all-inclusive in defining other methods of care and risks encountered.

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 may require additional or different procedures than those planned. I authorize the practitioner and such associates, technical assistants, and other healthcare providers to perform me of such other procedures as are advisable in their professional judgment.

I understand that my cheeks or jowls may not achieve the desired improvement in the laxity or 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.

I will follow all aftercare instructions as it is crucial for healing.​​​​​

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 Mint Threads sutures 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.

**Further Information can be obtained from the manufacturer, Hans Biomed Co. Ltd.**

**Patient Certification**

By signing below, I state that I am 18 years of age or older, or otherwise authorized to consent. I have read or have had explained to me the contents and risks outlined in this form regarding **PDO (Polydiaxanone) Suture Threads for Lifting**. I understand the information on this form and give my consent to what is described above and to what has been explained to me. If I have any questions or problems after treatment I will callDr. Dana Gabriela Negoi, PLLC. I have been provided with their contact information.

**All services and products are non-refundable.** I have read the above and understand it. My questions have been answered satisfactorily by Dr. Dana Gabriela Negoi, PLLC. I accept the risks and complications of the procedure. I understand that I can withdraw my consent at any time.

Patient Name (Print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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