

# ThreadLift™ & Barbed Suture Informed Consent

## **INSTRUCTIONS**

This is an informed-consent document that has been prepared by Dr. Hudson his staff to help inform you about the Threadlift ® procedure and Barbed Sutures, the risks, benefits and alternatives. During your consultation, we will review with you the potential benefits of the ThreadLift® procedure and Barbed Sutures, the alternatives and the few risks that are associated. You may ask any questions about the ThreadLift® and Barbed Sutures and we will provide you with answers to these questions to the best of our ability. It is important that you read the information contained in this booklet carefully and completely. Only when you have no questions or concerns do you initial each page, indicating that you have read and fully understood all the items it discusses. When you arrive at the end of the booklet, please sign the consent for the procedure. If you have any remaining questions about the alternatives, proposed benefits or risks involved with the ThreadLift™ procedure, do not initial or sign the consent without speaking with the or physician, or by calling 505 242 0070.

## **INTRODUCTION**

Deep supporting sutures, using monofilament Prolene sutures have been used in surgery for decades. Cardiac heart surgery sutures the vessel graft on the heart using small prolene sutures that stay for the rest of your life in the heart tissue. These permanent prolene sutures are prevalent in all surgeries in the body including surgery in the abdomen, lung, brain or skin. Prolene sutures are frequently used in open facelift like procedures to suspend, lift and tighten deep muscle and structures of the face and/or neck.

A special prolene suture, or thread, called the APTOS suture has been developed. This prolene suture has numerous "barbs" or "cogs" on them that will hold onto the tissue in the lifted position.

The Threadlift™ and Barbed Sutures are most commonly performed in the office under local freezing anesthetic only. The ThreadLift™ does not require an general or IV sedation anesthetic. The procedure involves freezing the patients areas of concern and then passing a tiny trocar under the manually elevated brow, cheek, pre-jowl and neck. The small Aptos suture is gently and expertly passed under the droopy soft tissue. The "barbs" adhere to the lifted fat and hold its position.

Each ThreadLift™ and Barbed Suture takes approximately 60 minutes to complete and you may go home following the procedure. There is often a minor to moderate degree of swelling and bruising of the skin that may last 4-10 days and some tingling discomfort that usually disappears in 2-3 hours. You may apply makeup immediately and return to work or regular activities. The best candidates for the ThreadLift™ and Barbed Sutures procedure have some degree of droopiness or laxity.

Although experience has proven these treatments to be very safe, there are some uncommon risks that you must consider before proceeding with treatment. You should balance these rare risks with proven benefits of less discolored and blemished-reduced skin.

## **BENEFITS OF THE THREADLIFT™ PROCEDURE**

The most obvious potential benefits are an improvement in the appearance and elevation of the droopy elements of the face.

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## **ALTERNATIVES**

The easiest and safest alternative is to leave your cosmetic skin concerns alone and camouflage them with make-up. Laser resurfacing, chemical peels, injectable collagen, hyaluronic acid, fat etc. and cosmetic surgery are all alternative therapies to the ThreadLift™ procedure.

## **RISKS OF THE THREADLIFT™ TREATMENTS**

Every cosmetic skin procedure involves a very small degree of risk and, although uncommon, it is important you understand and accept the rare risks involved with the ThreadLift™ procedure. An individual's informed decision to undergo any cosmetic procedure is based upon a comparison of the risks to potential benefits, alternatives and costs. Although the vast majority of ThreadLift™ patients do not ever experience any of these complications, you will have discussed each of them with Dr. Hudson and his nurse coordinator to ensure you fully understand the alternatives, risks, potential complications and average outcomes of these procedures.

**Discomfort** – The ThreadLift™ is a comfortable procedure when preformed under local anesthetic (freezing in the region of the thread placement) and most patients find the treatments to be a very tolerable experience. When the local freezing wears off, 2 hours or so after the procedure, there is only a minor degree of discomfort.

**Long Term Pain** -With any procedure, the healing potential with patients is quite variable, as is the reactions of various sensory nerves to procedures. It is possible to have longterm intermittent, or persistent pain which can be vague and ill-defined or sharp and focused. This outcome is very uncommon with non-surgical procedures like the ThreadLift™, but possible. The management with this rare complication can be variable and unsuccessful.

**Skin Wound** - It is exceedingly rare for the ThreadLift™ procedure to cause any mark, blister or skin wound. If a blister or skin wound develops it may take 5-10 days to heal, and, in extremely rare instances, may leave a noticeable whitening or darkening or lightening of the skin or, even more rarely, a scar.

**Scarring** - Occurs less than 0.1%. If you are unlucky enough to develop a wound and a scar, the scar may end up being flat and white (hypotrophic), large and red (hypertrophic) or even be large and extend beyond the margins of the injury (keloid). Subsequent treatment or surgery may be required to improve the appearance of the scar. The scar may be a permanent, visually displeasing skin deformity.

**Pigment Change** – The ThreadLift™ should not cause a pigment change in your skin. Unlike many laser procedures, you may undergo either the procedure when your skin is tanned. With any needle based treatment, like the ThreadLift™, there is a small risk (<1%) of post-inflammatory hyperpigmentation (increased pigment or brown discoloration) or hypopigmentation (whitening of the skin). Usually these pigment effects are temporary and resolve over several weeks or months. Permanent hyperpigmentation or hypopigmentation is very rare and may occur in far less than 1 % of cases. Should these rare pigmentation complications arise, then long term skin care such as bleaching may be required.

**Skin Mark, Indentation or Blemish** – There is a rare risk of a small noticeable skin mark where the needle is inserted or exits the skin. The mark may be dark, or light and/or indented and is usually small and round and the size of the needle itself. These marks may disappear with skin care creams, but may be permanent.

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**Bruising and Swelling** – It is very common to have a minor or moderate degree of skin bruising and swelling following the ThreadLift™ and Barbed Suture procedure. If bruising and swelling occurs, it can be camouflaged immediately and will usually resolve in 8-10 days. As the bruising fades, there may be a rust-brown discoloration of the skin (hyperpigmentation) that may take special creams to fade away. Rarely, the hyperpigmentation does not fade.

**Bleeding** - It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). **Do not** take any aspirin or anti-inflammatory medications 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 surgery. The potential for this to occur varies according to where on the body surgery is being performed. Injury to deeper structures may be temporary or permanent.

**Infection** - Because the ThreadLift™ procedure involves no actual cutting, surgery infection is exceedingly rare. However, because a needle is penetrating the skin and a facelift suture thread is being inserted, rare infections can arise. A prophylactic antibiotic is given at the time of surgery and then for 7 days following to reduce the risk of an infection. Occasionally, an infection becomes an abscess and must be drained. In these circumstances the thread must be removed.

**Excessive Redness and Swelling** - Rarely, a minor degree of redness and/or puffiness of the skin may follow treatment and usually lasts up to a week and is easily camouflaged with make-up. This may persist, in rare instances, for 1-2 days. A mild steroid cream will usually settle this.

**Fragile Skin** - The skin overlying the ThreadLift™ and Barbed Suture procedure area may become quite fragile. Although uncommon, the fragile skin can become reddened and the outer layer may peel off, much like a blister. This usually settles in 8-10 days.

**Noticeable Asymmetry** – A contour and lifting procedure involves a degree of subjective, artistic talent and knowledge of basic science. There may be some minor or noticeable asymmetry between one side of the face and its counterpart on the other side. The risk of asymmetry is much higher if there is facial asymmetry to begin with, as is most common with average faces. You may require additional treatment for any asymmetry and it may not ever be able to be corrected to your satisfaction.

**Additional Treatments and Revision Surgery** – Normal or complicated healing after your ThreadLift™ and Barbed Suture may require revision surgery. There will be some cost recovery of these revisionary procedures born by you, the patient and will not be offered free of charge.

**Lack of Satisfaction** – Despite an optimal result with the ThreadLift™ and Barbed Suture, you may not be happy with the ultimate lift effect, balance or symmetry. Your only option if you are truly dissatisfied is a more surgical facelift procedure.

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**Pregnancy** - Although no known adverse reactions upon a fetus are known to result from the ThreadLift™ and Barbed Suture during pregnancy, we do not recommend proceeding with treatment if you are known to be pregnant.

**Health Insurance** - Facial laxity is a cosmetic concern and poses no medical or health care threat. Most health insurance companies, exclude coverage for these treatments. Complications that may occur from the Threadlift™ and Barbed Suture procedure that require medical management **may** be considered a health care concern and are usually covered.

**Additional Surgery/Treatment Necessary** - There are many variable conditions in addition to risks and potential complications that may influence the short and long-term result from the ThreadLift™ and Barbed Suture treatment. Even though risks and complications

can occur infrequently, the risks cited in this booklet are particular for the ThreadLift™® and Barbed Suture treatment. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or treatment may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is not a guarantee or warranty expressed or implied as to the results that may be obtained. Infrequently, it is necessary to perform additional treatment to improve your results and you will have some financial responsibility and cost of this revisionary or enhancement procedure or surgery.

Financial Responsibilities - Depending on whether the cost of treatment is covered by an insurance plan, you will be responsible for necessary payments. Additional costs may occur should complications develop from treatment. There are no refunds once a treatment has been performed.

**Disclaimer** - Informed consent documents are used to communicate information about the proposed treatment of a condition along with disclosure of risk and alternative treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most cases.

What has discussed with you and included again in this booklet are the material risks both common and uncommon. The physician feels a reasonable person would want to know, understand, and consider these risks in trying to decide if the ThreadLift™® and Barbed Suture treatments are something with which they would like to proceed.

However, informed consent documents should not be considered all inclusive in defining other methods of care and risk encountered. Dr. Hudson 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 documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

**It is important that you read the above information contained on this and all preceding pages carefully and have all of your questions answered before signing the consent on the next page. Questions and concerns can be answered during consultation or by contacting the office at 505 242 0070.**

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## CONSENT FOR PROCEDURE AND/OR TREATMENT

I have received the following information/informed consent booklet for:

The ThreadLift™ and Barbed Suture procedure

I hereby authorize Dr. Hudson and/or such assistants as may be selected to perform ThreadLift™ and/or Barbed Suture procedure of (circle):

**brow**

**mid-face**

**neck**

I recognize that during the course of the procedure/treatment unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and/or 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.

I consent to the administration of such local, topical or general anaesthesia considered necessary or advisable. I understand that all forms of anaesthesia involve risk and the possibility of complications, allergic reaction and sometimes, in exceedingly rare cases, death.

My chart may be subject to a peer review for quality control.

I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

I consent to the photographing of appropriate portions of my body, for medical, scientific, or educational purposes, provided my name is not revealed by them. These photos may be presented by Dr. Hudson at medical meetings or to other patients considering surgery. A separate consent would be obtained for any marketing, internet or advertising.

For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.

I understand that the signature of the witness (if a non-physician) on this document indicates only that the signing of my name has been observed and not that the witness has necessarily provided information regarding the procedure.

### **IT HAS BEEN EXPLAINED TO ME BY MY PHYSICIAN AND/OR ASSISTANTS IN A WAY THAT I UNDERSTAND:**

THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN  
THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT  
THERE ARE RISKS TO THE PROCEDURE/TREATMENT PROPOSED  
ANY QUESTIONS I MAY HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION

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I consent to the Threadlift and/or Barbed Suture described above:

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NAME

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WITNESS

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DATE