

# MEDICAL DEVICE MANUAL FOR EUROTHREADS

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EuroThreads is a medical device indicated for the subcutaneous dermal implantation of surgical sutures. EuroThreads provides hands-on training for FDA approved PDO and PLLA suture (thread) technology. We provide the highest and most comprehensive hands-on training for every level of thread lifting,



EuroThreads offers individualized, hands-on training to medical professionals. Our classes range from beginning to advanced and are lead by the top experts in the thread lifting industry. Trainees gain confidence and understanding of each technique with regards to each treatment area of the body.

**SAFETY**

**CONSIDERATIONS**

# PACKAGING

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EuroThreads should not be used in patients with any known allergy or foreign body sensitivities to polydioxanone or poly-L-lactic sutures or in situations where internal fixation is otherwise contraindicated. The device should also, not be used in patients appearing to have very thin or soft tissue in which implant may become visible. Implantation of foreign materials into tissue can result in histological reactions. Do not use in patients that are allergic to EuroThreads.



## INSTRUCTIONS

Instructions of Use: Consult instructions for use. See product Training Protocols, Medical Device Manual and other available educational material.



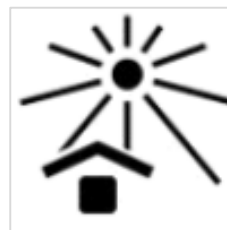
## STERILE

The contents of each package have been sterilized by Ethylene Oxide. Product is non-toxic and non-pyrogenic meaning product is non-flammable.



## STORAGE CAUTION

Use caution when storing this product. Consult accompanying documents. Do not store opened, resealed bags for more than eight weeks.



## DIRECT LIGHT

Keep package out of direct sunlight. The outer re-sealable foil bag protects from direct light and humidity. Store bag in dry area out of direct sun.



## SINGLE USE

This product is for single Use Only. Please discard immediately after opening. Do not use if package is open or damaged as sterility may be compromised.



## MOISTURE

Store bag in a temperature controlled room. Product is sensitive to moisture so if bag is not properly sealed, product viability will be compromised.



## MANUFACTURER

The product is distributed by EuroThreads LLC, a registered Wyoming company. Please visit website provided on back label for additional information.



## LOT NUMBER

Each package contains a lot number, manufacturing date and product expiration date. Information is located on bottom of the back label.

EuroThreads LLC is a medical device company known for its aesthetic enhancement technology. Providing innovative technology that enables physicians all around the world to meet their patients' needs for safe and effective aesthetics solutions, EuroThreads is committed to support medical professionals with excellent customer service and high-quality training programs.

**Important EuroThreads Safety Considerations** EuroThreads is a FDA approved medical device indicated for soft tissue approximation where the implantation of sutures is appropriate. Physicians should be familiar with recommended techniques involving EuroThread's devices, as well as proper patient selection and suture placement.

EuroThreads should not be used in patients with any known allergy or foreign body sensitivities to polydioxanone or poly-L-lactic acid sutures or in situations where internal fixation is otherwise contraindicated, (e.g. infection.) The device should also, not be used in patients appearing to have very thin or soft tissue in which the implant may become visible.

After placement patients may experience a minimal acute inflammatory tissue reaction. Symptoms may include minor pain, swelling and bruising.

Material sensitivity / allergic reactions should be reported to EuroThreads LLC.

Implantation of foreign materials into tissue can result in histological reactions.

Other potential side effects include sensory nerve injury, asymmetry or banding.

Individual results may vary.

EuroThreads medical device is available only through a licensed practitioner. Complete product and safety information is available from [www.EuroThreadLift.com](http://www.EuroThreadLift.com) or Call +1 612 800 7155 1621 Central Avenue, Cheyenne, WY 82001, USA

**STERILE**

Sterilized by Ethylene Oxide.  
Non-toxic, Non-pyrogenic



**Instructions of Use:**  
Consult instructions for use. See product Training Manual & educational material.



**Single Use.** Please discard immediately after use.

Do not use if package is open or damaged as sterility may be compromised. Keep away from sunlight.



**Storage: Caution!**  
Consult accompanying documents.

The outer re-sealable foil bag protects sutures from light and humidity. The inner pouches are for sterility. You can store unopened pouches in re-sealable foil bag. Opened pouches should be used the same day, otherwise discard immediately.

When resealing foil bag, expel all air as seal is being closed. Store bag in a temperature controlled room, away from direct sunlight.

We do not recommend storing opened, resealed foil bag and its contents for more than 8 weeks.

Distributed by: EuroThreads LLC

# EuroThreads



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# IMPORTANT CONTRAINDICATIONS

# CONTRAINDICATIONS

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Conditions which make a treatment or procedure potentially inadvisable, the contraindications listed below highlight the balance of risk versus the benefit of performing a thread lift treatment.

1

## Active Acne

Active acne, cystic acne and vulgaris acne.

2

## Auto-Immune

Diseases such as scleroderma, sarcoidosis, amyloidosis.

3

## Keloid Predisposition

If patient has a predisposition to Keloid scarring

4

## Adverse Medication

Patient cannot be on Anti-coagulants, Coumarin, Heparin.

5

## Pregnancy

Pregnancy or In Vitro fertilization and breastfeeding.

6

## Blood Diseases

Not suitable for patients with Hepatitis B and C, HIV.

7

## Malignancies

Malignant cancer or any treatments for cancer.

8

## Body Dysmorphia

Excessive preoccupation with a minor defect of face or body.

9

## Allergic Reactions

Severe allergies of any kind or hypersensitivity to sutures.

10

## Porphyria

A group of rare inherited blood disorders that effect hemoglobin.

11

## Skin Infections

Skin irritations or rashes should be closely observed.

12

## Clotting Disorder

Patients with Hemophilia should not be treated with threads.

13

## Inflammation

Caused by open sores, rashes, infections or breakouts.

14

## Systemic Diseases

Diseases like diabetes and tuberculosis.

# PROCEDURES & TRAINING PROTOCOLS

EUROTHREADS

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# Policy and Procedure Protocols

Version 3

April 20, 2018

Presented by:  
EuroThreads LLC

## Policy and Procedures

This document features EuroThreads Medical Device Policy and Training Protocols

Upon the completion of EuroThreads Training the physician and approved injectors per state law participating will have a better understanding of the following:

Protocols
Purpose
Scope
Settings
Qualifications
Administration
Patient Assessment
Indications
Contraindications, Warnings and Precautions
Pre-Treatment
Risk Exposure and Complications
Injection Technology
Injection Techniques

## EuroThreads Policy and Procedure Protocols

### **Disclaimer**

Please read the enclosed information carefully.

#### ▲ **Company Disclaimer**

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The user acknowledges state laws vary on whom can provide the medical aesthetic treatments identified in these documents and further acknowledges and accepts full responsibility to follow their state laws without exception.

EuroThreads LLC 612.800.7155

[www.eurothreadlift.com](http://www.eurothreadlift.com)

## EuroThreads Policy and Procedure Protocols

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## EuroThreads Policy and Procedure Protocols

### **Purpose**

The purpose of this Policy and Procedure Protocol is to ensure the safe and effective treatment of patients undergoing injection of surgical sutures, PDO & PLLA threads, for the augmentation of the soft tissues approximation.

### **Scope**

The protocol applies to all Aesthetic Health Care Providers injecting PDO & PLLA threads.

### **Settings**

Injections of PDO & PLLA threads should be performed in an appropriate facility under the direction of a physician/provider in accordance with local state statutes.

### **Qualifications**

Licensed and Registered Physicians, Physician Assistants, Nurse Practitioners and Nurses with appropriate education, training and privileges are eligible to perform these treatments in accordance with this protocol (check state guidelines for scope of practice). The treating Aesthetic Health Care Provider should be familiar with the manufacturer's package insert for each thread type, which is included as an appendix to the manual. PDO & PLLA threads have been classified as a medical device and the performance of such treatments is the practice of medicine.

### **Administration**

PDO & PLLA threads may be injected by any properly credentialed individual(s) under the direction of this protocol and/or a licensed physician/provider.

### **Patient Assessment**

Patients should be properly consulted and assessed for appropriate indications and contraindications for treatment, and a record of that assessment should be documented in the patient's medical record. INFORMED VERBAL AND WRITTEN CONSENTS SHOULD BE OBTAINED PRIOR TO PROCEEDING WITH THE TREATMENT. Patients will be consulted regarding any common adverse reactions to the medical device, treatment procedures, post treatment care and expectations following the procedure. Patients should also be informed regarding possible side effects and complications associated with treatment.

## EuroThreads Policy and Procedure Protocols

Compliance with the Health Insurance Portability and Accountability Act ("HIPAA") should be followed in relation to patient care.

### **Indications**

Injection with PDO & PLLA is indicated for soft tissue augmentation where the insertion of surgical sutures is appropriate. Injection of PDO / PLLA threads is indicated for subcutaneous (intra dermal and hypodermal) implantation. In addition, it is used off label for the augmentation of the volume of the soft tissues in locations such as the lips, malar regions, brows, earlobes, and tear troughs. It is also used off label for the temporary treatment of facial lines, scars, creases, and other depressed contour irregularities not amenable to other treatments. For the purposes of this protocol, the only areas authorized for treatment under the direction of the delegating/supervising physician or licensed provider should be those areas in which the physician/provider has determined the Aesthetic Health Care Provider has demonstrated appropriate skill, knowledge, and judgement in the use PDO & PLLA threads.

### **Contraindications, Warnings and Precautions**

A review of the patient's medical history including, but not limited to, medical problems, allergies, history of previous treatments, and procedures at the site of the treatment area should be conducted during the patient's assessment. Upon review of the assessment, the following protocols related to indications, contraindications and exclusions should be observed (see package labeling for individual product information).

The injection of PDO & PLLA threads is contraindicated in the following conditions (see manufacturer's manual for product information and individual treatment recommendations):

- Pregnancy and breast feeding
- The presence of infection or any other inflammatory condition at the proposed treatment site
- A history of hypersensitivity or allergic reaction to previous injection with PDO or PLLA sutures
- A history of repeated unsuccessful treatments with PDO or PLLA threads
- A history of hypersensitivity or allergic reaction to surgical sutures
- A history of anaphylaxis or anaphylactoid reaction to injected products
- A history of non-compliance with post-injection instructions

## EuroThreads Policy and Procedure Protocols

- Intoxication or influence of illicit drugs
- Immunodeficiency such as active viral infection
- Poorly controlled diabetes (\*)
- Use of chronic anticoagulation drugs (\*)
- Use with caution in patients on immunosuppressive therapy
- Use with caution in patients with various acute infectious diseases (SARS, influenza, etc.)
- Do not use in patients with a non-absorbable implant (Silicone) in zone of desired treatment area
- Do Not use in Oncology Patients
- Do not use in patients with Keloid scarring tendencies
- Use with caution in patients with bleeding tendencies
- Do not use in patients with neurotic or psychological disorders

\*Patients with any of the above conditions should be excluded from treatment until the condition is controlled or resolved.

\* Patients taking chronic anticoagulation drugs should provide approval for treatment from their primary care physician/provider.

### **Pre-Treatment**

For the prevention of herpes outbreak, standing orders for antiviral medications are on file (see standing drug order).

## Complications of EuroThreads

### Risk Exposure and Potential Complications

▲ *This table describes possible complications and risk exposure associated with thread insertion.*

The specific risks and complications of PDO & PLLA thread insertion are listed below within associated risk categories. The expected rate of each risk/complication is listed when treatment is performed by an experienced injector. Additional comments are provided when appropriate.

COMMON (70%)	
Bruising	Most bruising typically resolves within 7–10 days
Swelling	Visible swelling typically resolves within 7–10 days. When present residual swelling typically resolves completely within 30 days
RARE (<5%)	
Palpable Thread	May be removed / replaced if problem persists
Thread Breakage	Suspension typically not affected. May be replaced if necessary
Asymmetry	Correction of symmetry is possible with tightening of existing threads or placement of additional threads
VERY RARE (1%)	
Hair Loss	Loss of 4–8 hair follicles in the insertion hair. Usually hidden
Scarring	Scarring from insertion of needles or cannulas is rare

## EuroThreads Policy and Procedure Protocols

Early Support Loss	Additional threads can be replaced enhanced support
UNEXPECTED (<1%)	
Dimpling of Skin	Easily corrected early with treatment. Additional treatment may be necessary
Contour Irregularity	Typically resolves spontaneously or is correctable
Visible Thread	Visible threads should be removed / replaced
Infection	May require drainage or antibiotics. Remove thread(s)
Bleeding	May require drainage
Nerve Injury	Resolution may occur over time

## EuroThreads Policy and Procedure Protocols

### Injection Technology and Instructions

1. EuroThreads is a medical device distributed by EuroThreads LLC. They are packaged in sterile, disposable syringes with sterile needles/cannulas to be used for injection. They should be stored in accordance with the manufacturers' packaged guidelines. They should not be stored or used past the expiration date printed on the package.
2. Once the area to be treated is defined, and an appropriate examination is completed, the patient is seated. If topical anesthetic is to be used, it is applied liberally to the treatment areas and should be allowed to work for at least 15 minutes prior to injection.
3. The appropriate thread packages required for the treatment area are opened and removed from the package. The thread is attached in accordance with the manufacturer's instructions. Proper use of the product(s) should minimize the chances of dislodging or breaking while injecting the PDO or PLLA thread. Both the thread and the needle or cannula should be carefully inspected, and if it is not in tack and is lacking appropriate structure (specific to thread type, gauge size and length\*), it should not be used, and it should be returned to the manufacturer for a refund. A different package of threads should then be selected for this treatment. Once selected, the adhesive patient record label from the envelope or foil packaging should be removed and placed in the appropriate location on the treatment record in the patient's chart or transferred to the electronic record (keep consistent with clinical charting).
4. The treatment area should be prepped by cleansing and removing the topical anesthetic and/or makeup.
5. Correct injection technique is critical to the success of the treatment in achieving the desired results. The needle or cannula should be inserted into the treatment site with the tip ending up at an appropriate depth within the skin. The thread should then be released using a slow, steady withdrawal of the needle/cannula. OVERCORRECTION (more threads than suggested or required) IS GENERALLY NOT NEEDED AND IS TO BE AVOIDED.
6. Once the first thread is appropriately inserted, another thread is inserted into the next adjacent location, and the process is repeated. Care should be taken to adequately assess the entire area to be treated with the correct number of threads to ensure even and symmetrical distribution of the product.

## EuroThreads Policy and Procedure Protocols

7. Once the injection is completed, the treated areas should be gently massaged, setting the threads per instruction. More vigorous massage may result in additional swelling, bruising or dispersement of the filler material.

8. The patient should be informed that the treated area may remain swollen, irregular in shape, and bruised for several days. Ice or a cold compress can be applied intermittently the first 48–72 hours post treatment.

9. The patient should be advised to allow healing for at least two weeks before any assessment is made of final volume and contour. If the outcome is satisfactory, no further treatment is indicated. If the outcome is unsatisfactory, the appropriate Aesthetic Health Care Provider should be contacted to arrange for an evaluation of the patient. If the patient desires further correction the procedure may be repeated. (See Post-Treatment Sheet)

### **Mandatory Supplies**

The following list of mandatory supplies is required during EuroThreads training and to be used during all post training treatments:

1. Product Manual & Training Protocols
2. Antibacterial Solution
3. Phlebectomy Hook
4. Needle large Gauge
5. Latex Gloves
6. Surgical Scissors
7. Wax Pencil
8. EuroThreads (marked for training)
9. Patient Release Forms & Post Treatment Instruction sheet

### **Additional Supplies**

Additional supplies such as cold packs, arnica cream and distraction devices have proved to be very useful during trainings.

## Techniques for Thread Injection

### ▲ Injection Techniques

*This table describes several injection techniques for thread insertion.*

Technique	Instructions
Linear Technique	This technique involves the injection of threads <b>intradermally</b> , <b>hypodermally</b> and <b>intramuscularly</b> depending on treatment. Thread injection runs parallel to the surface of the skin in the identified direction
Meshing Technique	This technique involves the injection of threads <b>intradermally</b> , <b>hypodermally</b> and <b>intramuscularly</b> depending on treatment. The threads run parallel to the surface of the skin and are inserted in a cross-stitch pattern to form a web pattern
Meridian Technique	This technique involves the injection of threads <b>intradermally</b> and <b>hypodermally</b> depending on treatment. Threads are injected from same injection site into varying directions
Compression Technique	This technique involves the injection of threads <b>intradermally</b> and <b>hypodermally</b> depending on treatment. Threads injected parallel to the surface of the skin from one injection point and in the same direction. Threads are inserted into multiple layers of the dermis
Lifting Technique	This technique involves the injection of threads <b>intradermally</b> and <b>hypodermally</b> depending on treatment. Threads are injected parallel to the surface of the skin in the direction resulting in desired lift

## **Facilitate a Successful Outcome / Patient Selection**

### **Patient Selection**

#### ▲ ***Important Steps to Insure Optimum Treatment Outcome***

There are several steps that the injector can take that are essential for the best outcome. Selecting the correct patient type for each treatment and setting realistic expectations are critical.

### **Insure a Successful Training**

#### ***Pre-Training Logistics***

Five to seven days before the training day **INJECTOR** should:

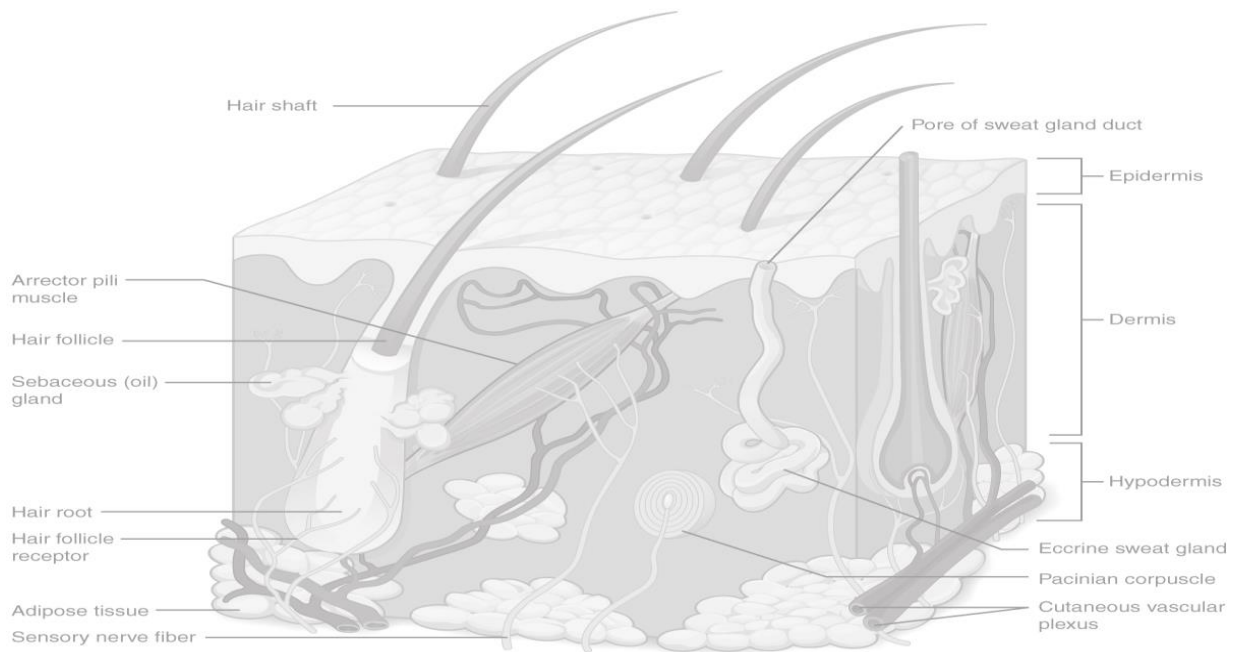
- a. Review the EuroThreads Product Manual thoroughly
- b. Review label Specifications on Thread packages sent for training
- c. Do not open any of the thread packages prior to training
- d. Review Training Protocols provided by EuroThreads
- e. Study all Contraindications outlined in Training Protocols
- f. Review ideal qualifications for Training-Demo patients
- g. Ensure that Training-Demo patient "Consent Forms" have been carefully read and signed.
- h. Confirm that all participants have signed the Photo / Video Release form
- i. Review all Complications outlined in Training Protocols

#### ***Patient Selection for Training***

- Patient should be familiar with Aesthetic and minimally invasive Injections
- Models for training will be receiving more threads inserted than a normal client would compared to a single treatment. Non-training patients will have a treatment of smooths first followed by barbed threads 3 to 4 weeks afterwards. However, for training it is likely both treatments will be done at same time.
- Consult with your sales representative regarding "ideal" patient type.

# INJECTING INTO THE DERMIS

# SUPERFICIAL DERMIS

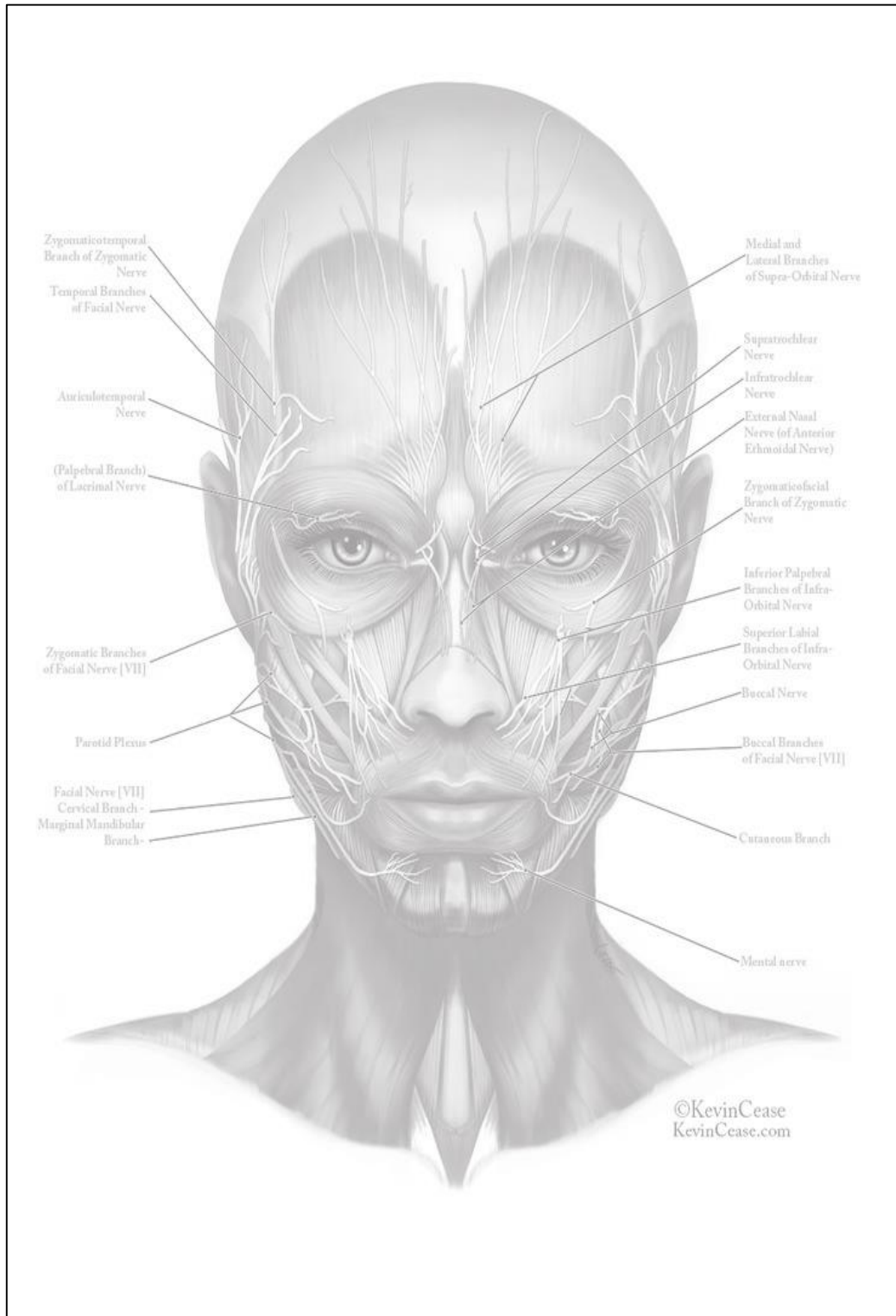


Threading targets the dermis and subcutaneous tissue. The plane of insertion for barbed threads is the superficial musculaponeurotic system, commonly referred to as SMAS. Remaining in this plane diminishes tissue distortion, bruising and discomfort. Most importantly, this area is risk adverse to facial artery and vein damage.

# FACIAL ANATOMY

## WITH REGARDS TO THREAD INJECTION

An intimate knowledge of facial anatomy is critical when avoiding damage during any facial procedure. Injury to the frontal and marginal mandibular branches of the facial nerve in particular can lead to obvious clinical issues. Prior to any thread insertion, it is essential to have complete knowledge of large vessel location in an effort to minimize facial bruising. Navigating the underlying anatomical structures with complete certainty will facilitate a much safer treatment.



# INJECTION MAPPING & OVERVIEW

# INJECTING EUROTHREAD'S PDO THREADS

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This section illustrates in detail both the technology and techniques used for treating different areas with different threads. FDA indications for PDO sutures allow for soft tissue approximation that provide numerous aesthetic benefits. Clinicians can improve the appearance of cheeks, brows, jawline and nasolabial folds through soft tissue manipulation.

# INJECTION SUMMARY

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The eight steps detailed below provide a general overview for a thread lift procedure. In addition, several other items are needed during this process and our listed in this manual's appendix.

1

## Patient Physiognomy

Study in detail the characteristics and physiognomy of each patient. Analyze tension lines and vectors to be used.

2

## Thread Selection

For optimal results carefully choose the correct thread, gauge size and length for each area to be treated.

3

## Mapping

After treatment identification and thread selection, mark the surface of the skin to illustrate the vector lines that the threads will follow.

4

## Apply Anesthetic

Depending on the pain tolerance of your patient choose the proper anesthetic required. This could be topical or injectable.

5

## Needle Insertion

Insert the needle or cannula at the marked injection points. The threads are inserted into the subdermal or subcutaneous layer of the skin.

6

## Thread Insertion

Begin with the areas that require more tension and larger gauge needles. Then insert the shorter threads to create a network.

7

## Needle Removal

When removing the needle or cannula it is important to hold the area around the tip. This is essential to ensure maximum results.

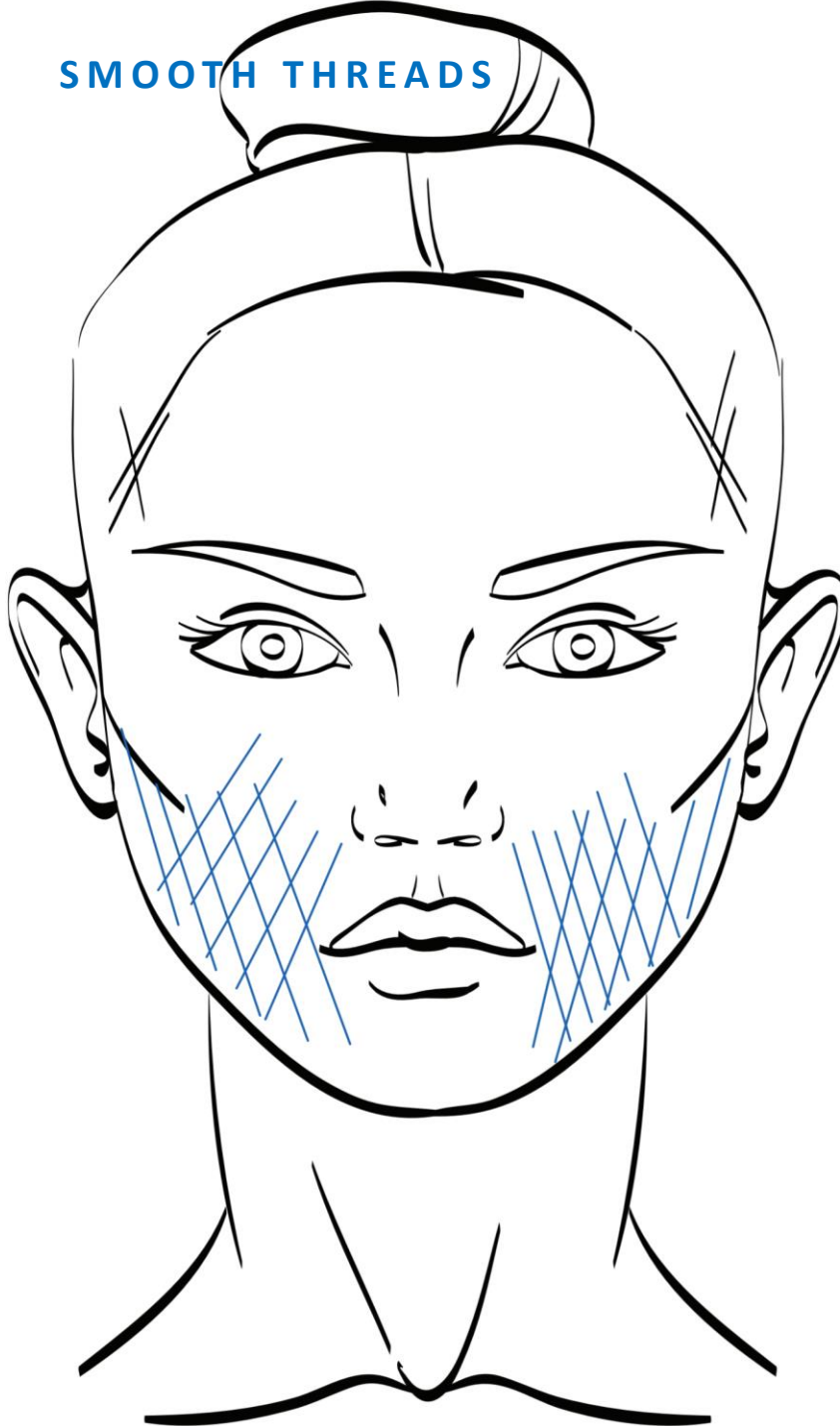
8

## Pressure Application

After removing the needle or cannula, apply pressure to on the injection site for a few minutes. This can be done with a finger(s) wrapped in a latex glove.

# SMOOTH MAPPING

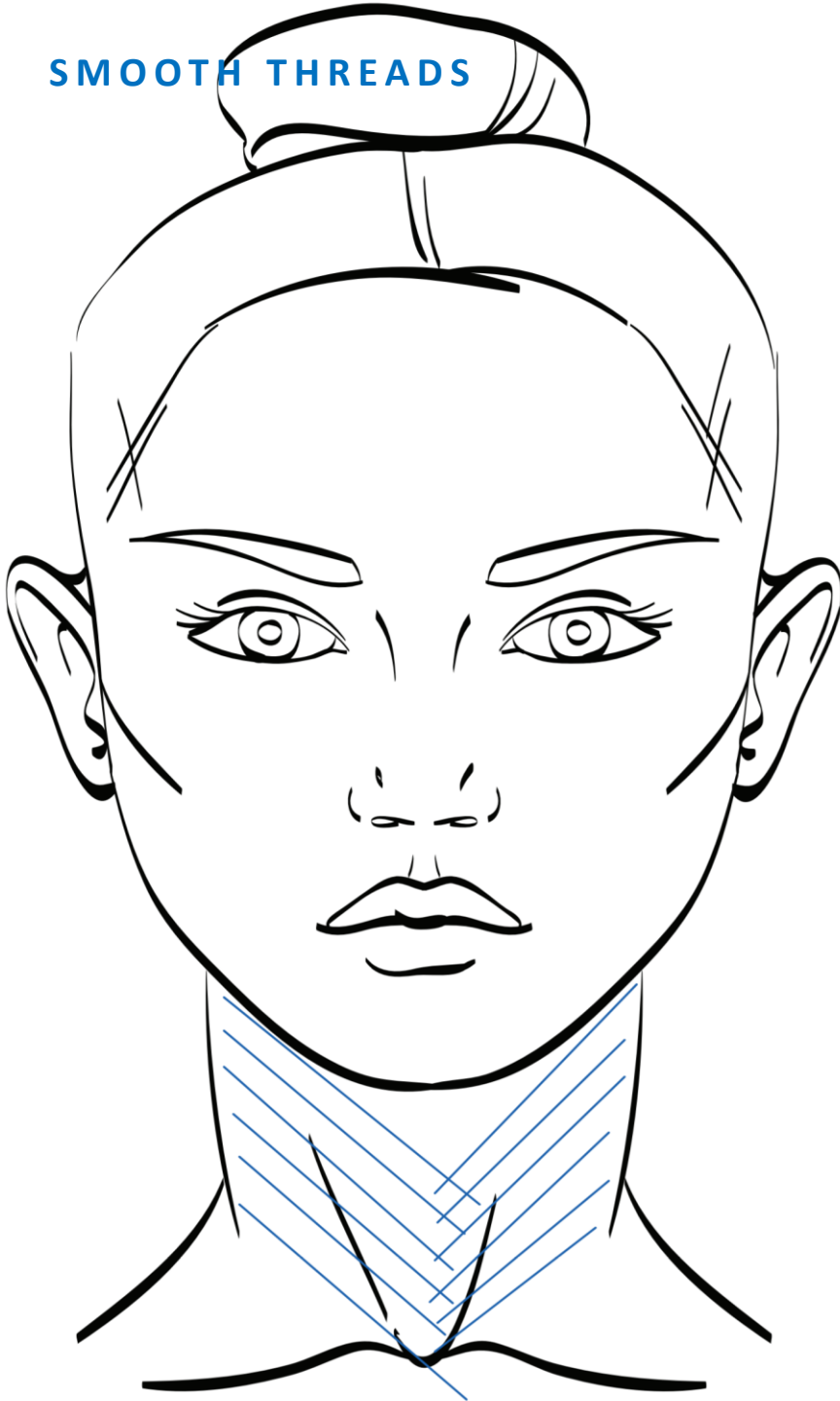
## SMOOTH THREADS



**SUGGESTED 27g 70MM**



## SMOOTH THREADS

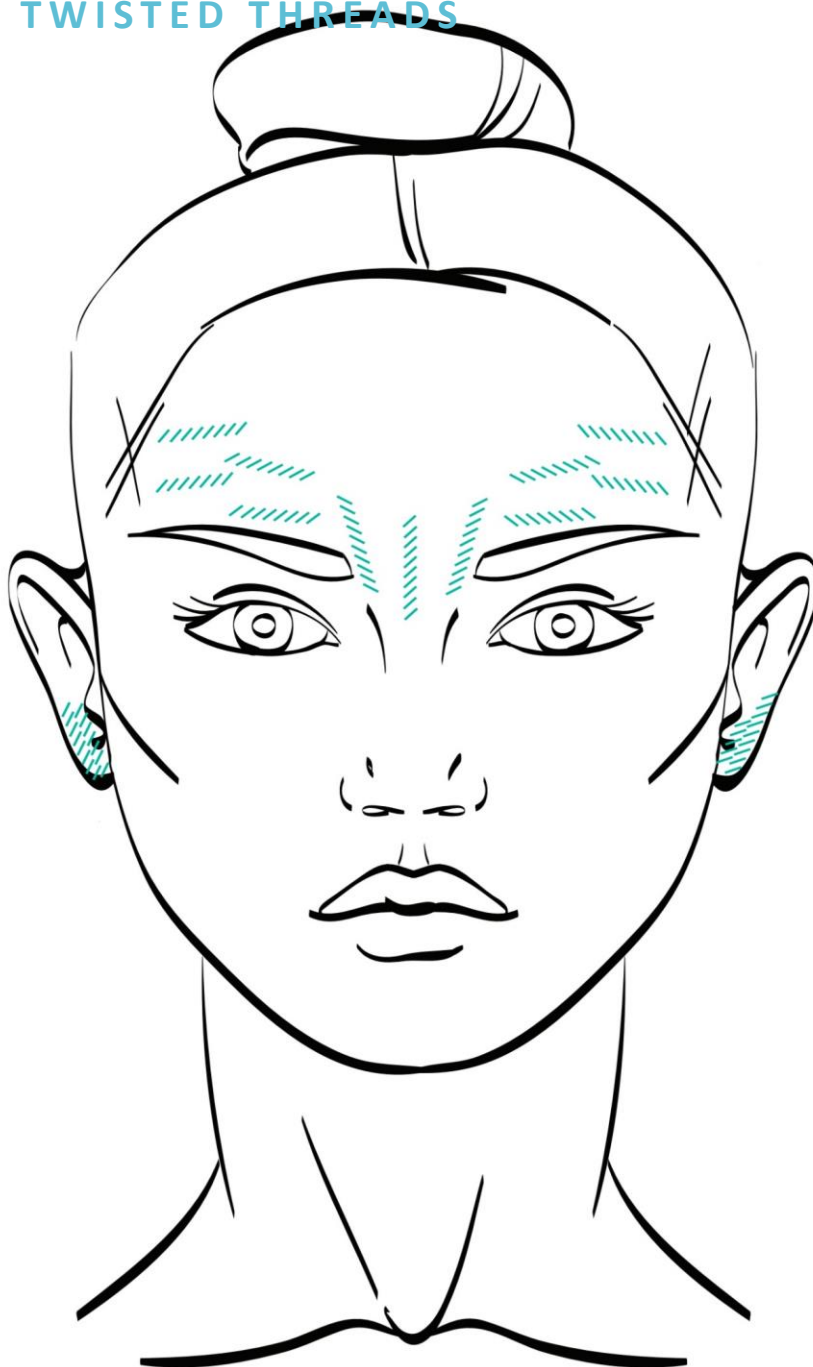


**SUGGESTED 27g 70MM**



# TWISTED MAPPING

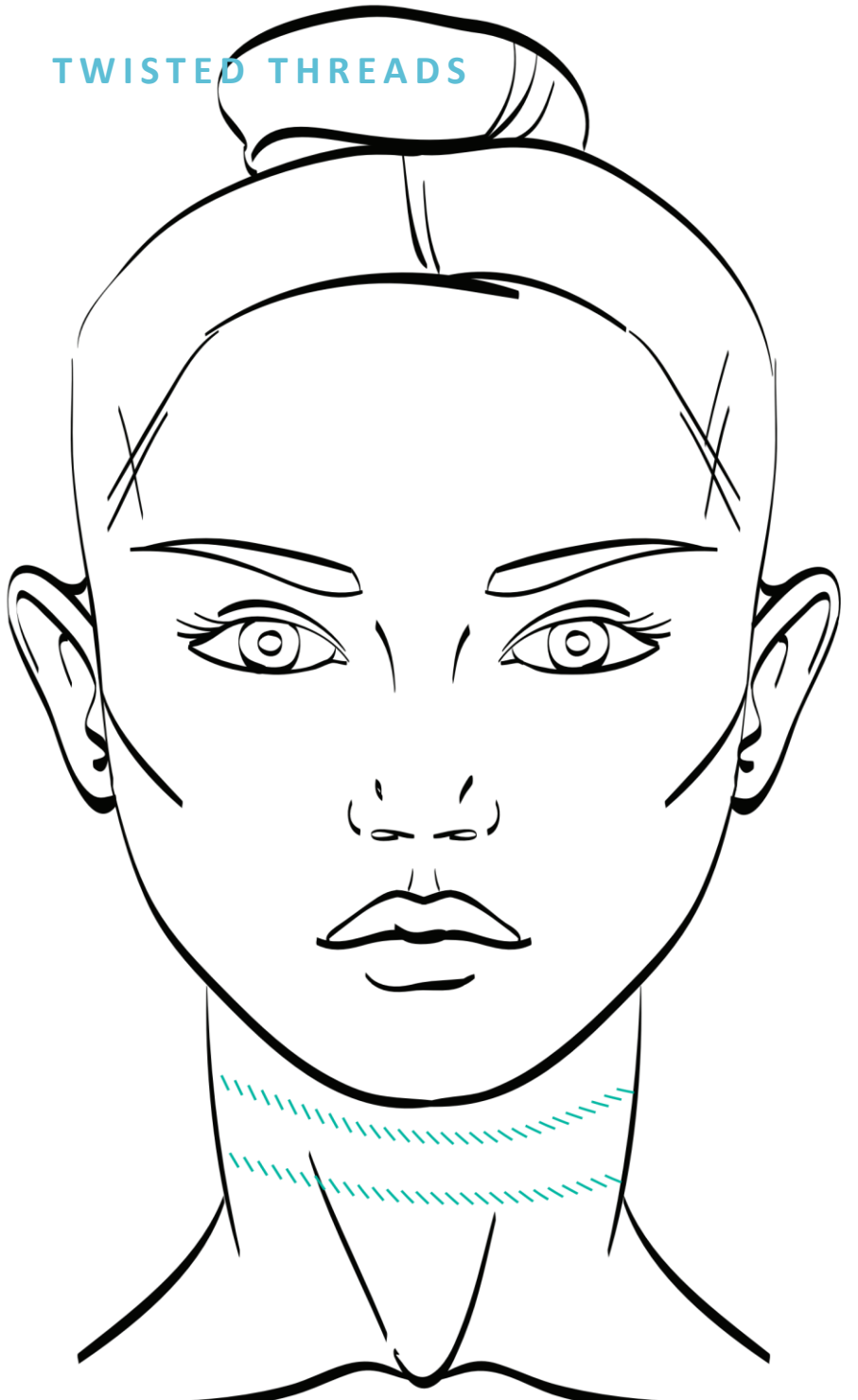
## TWISTED THREADS



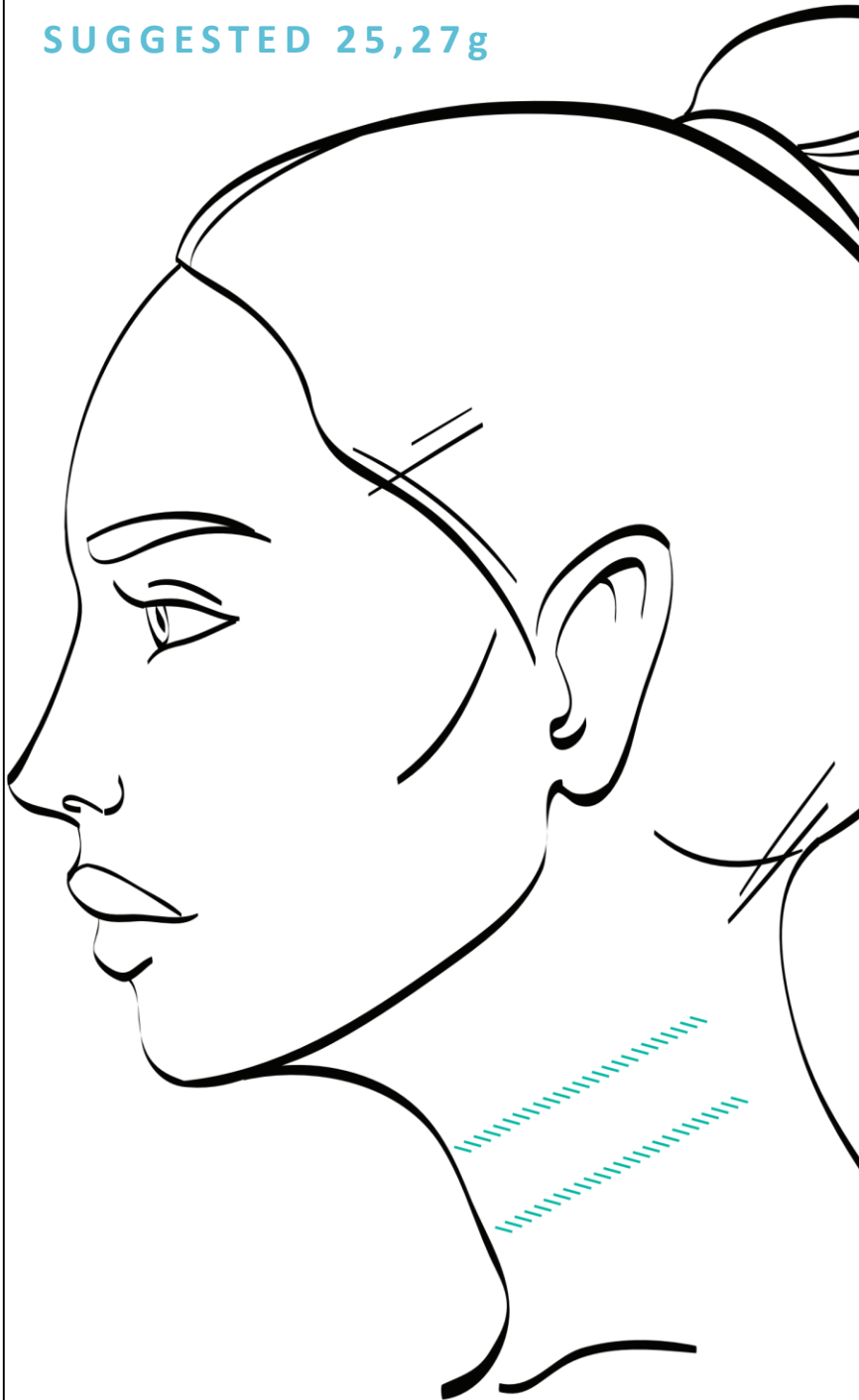
**SUGGESTED 27,29,30g**



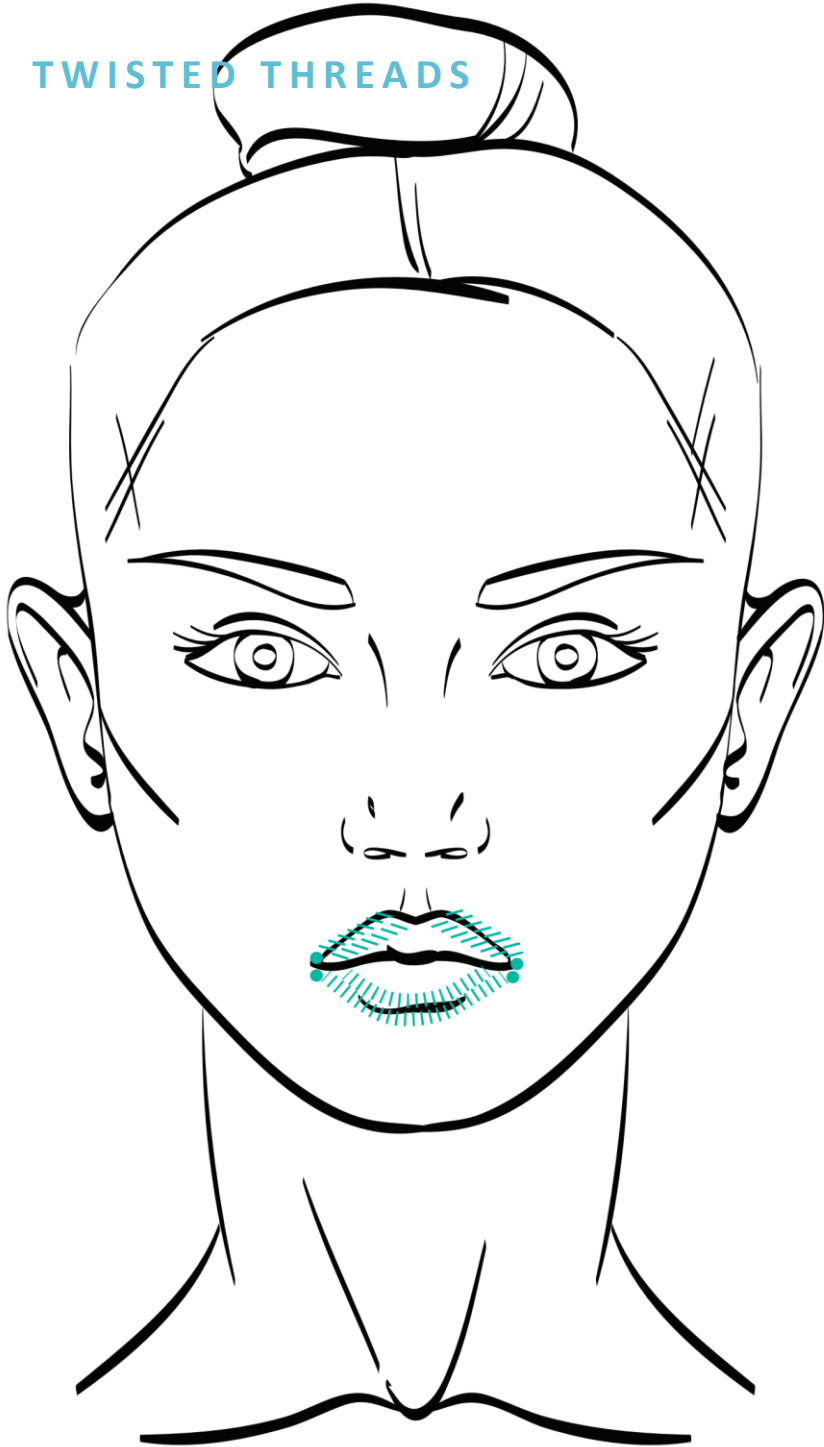
## TWISTED THREADS



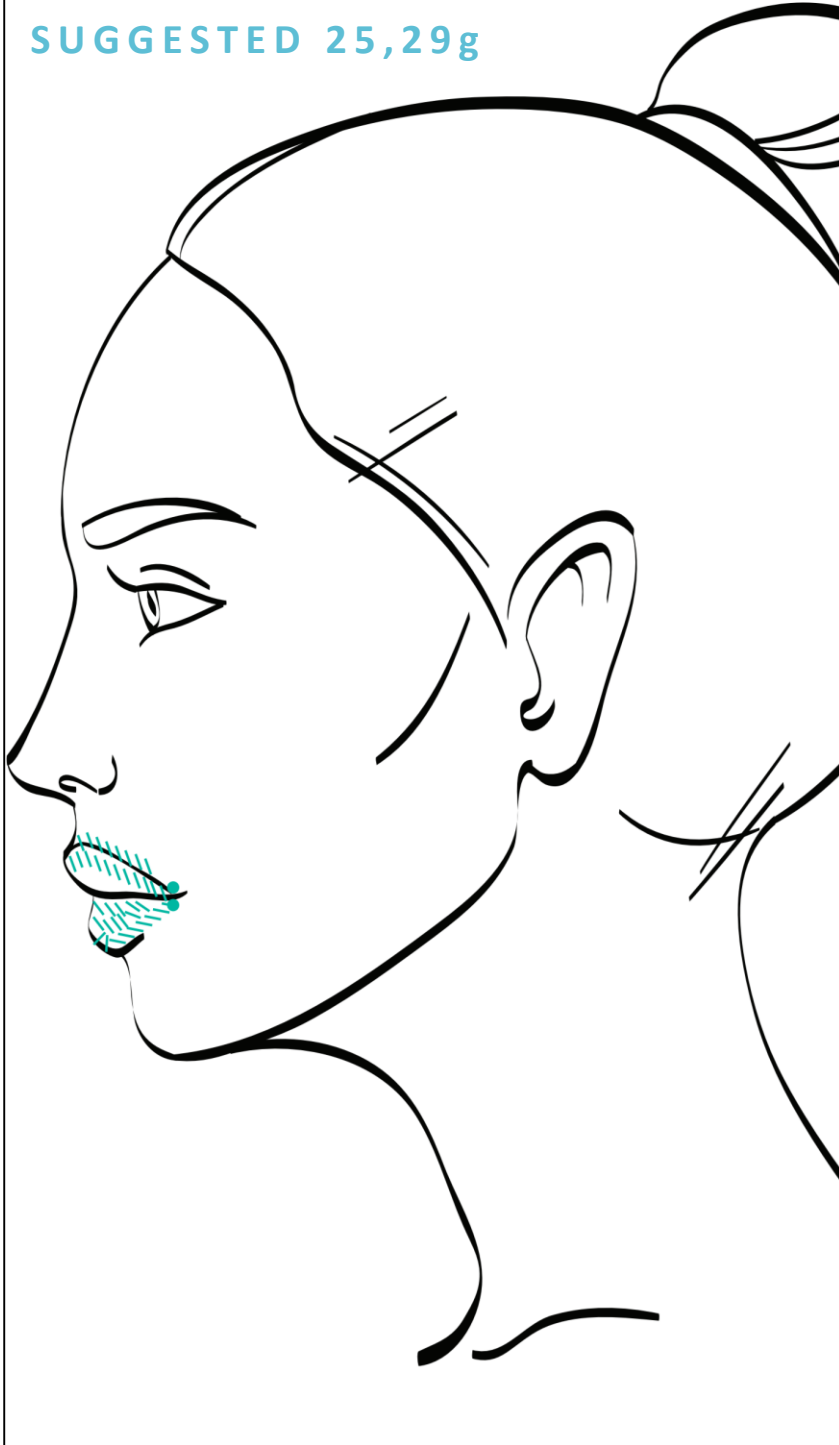
SUGGESTED 25,27g



## TWISTED THREADS

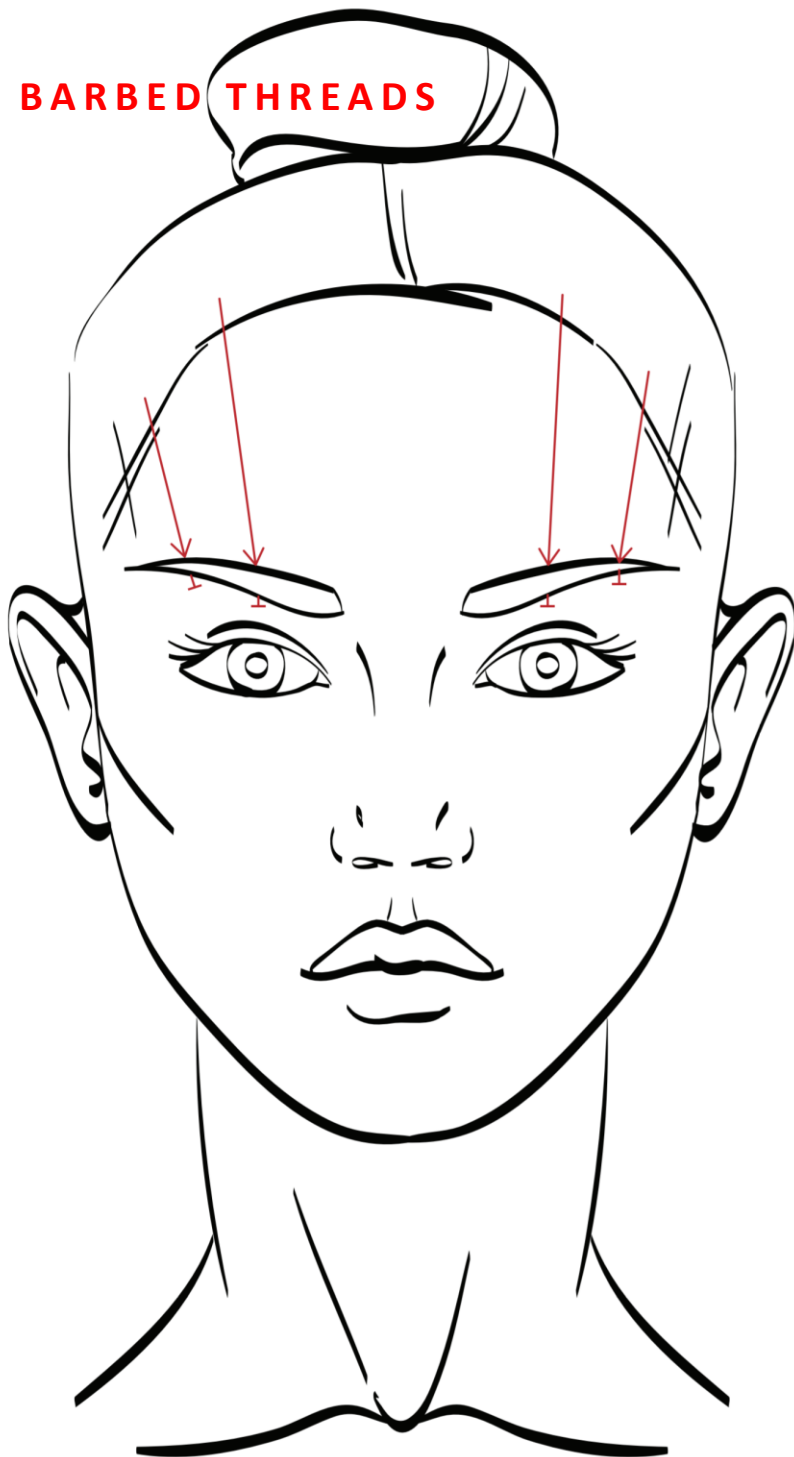


SUGGESTED 25,29g



# BARBED MAPPING

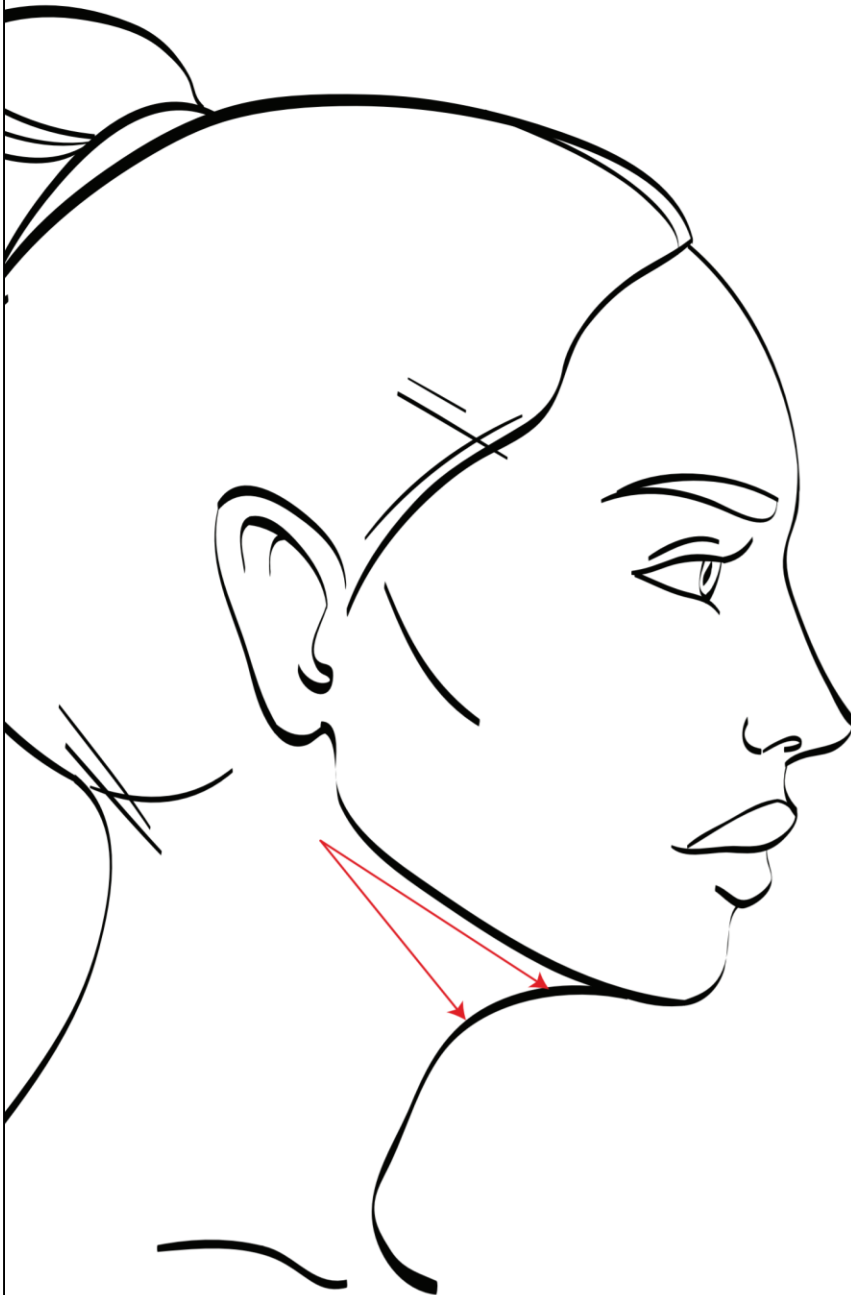
## BARBED THREADS



**SUGGESTED 19,21,23g**



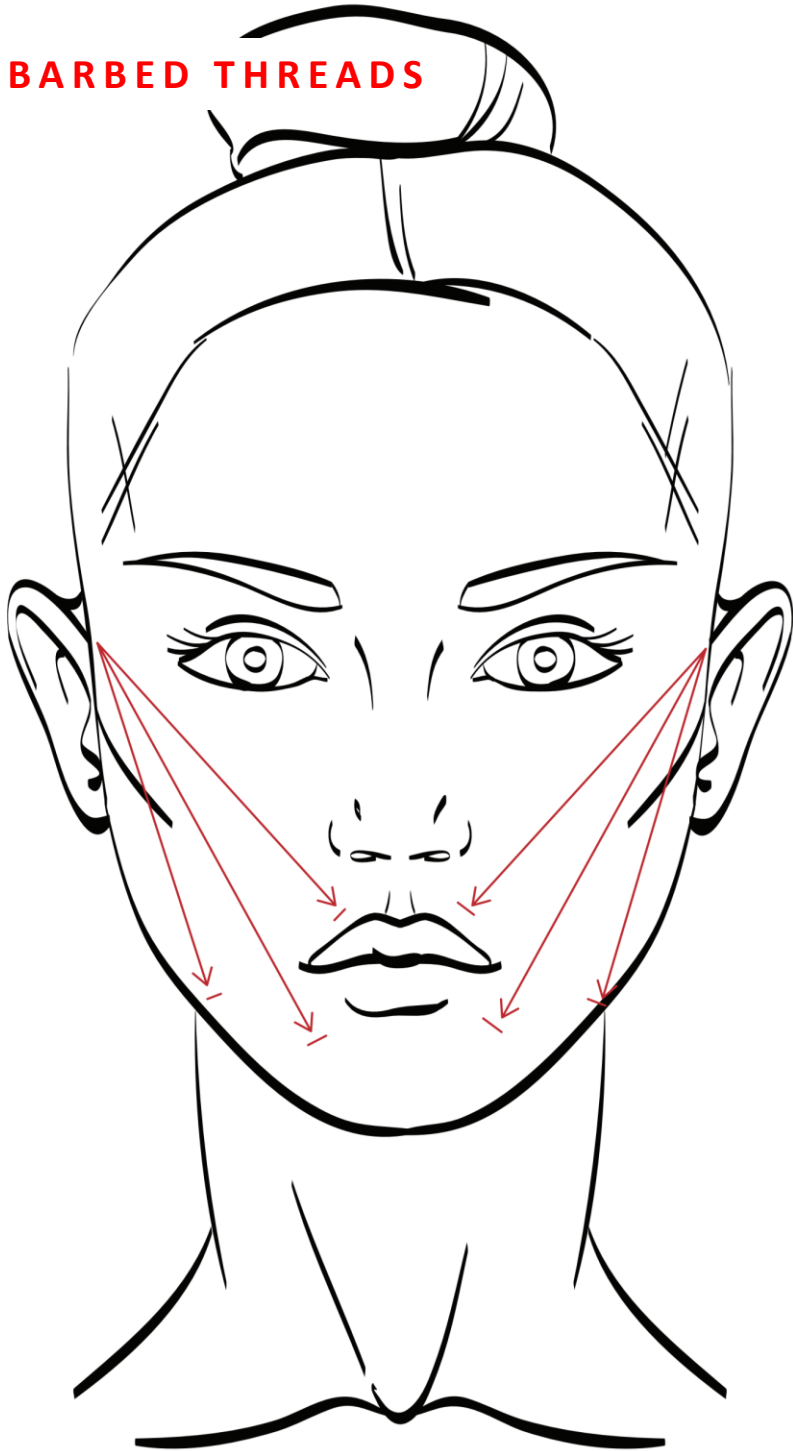
## BARBED THREADS



**SUGGESTED 18,19,21g**



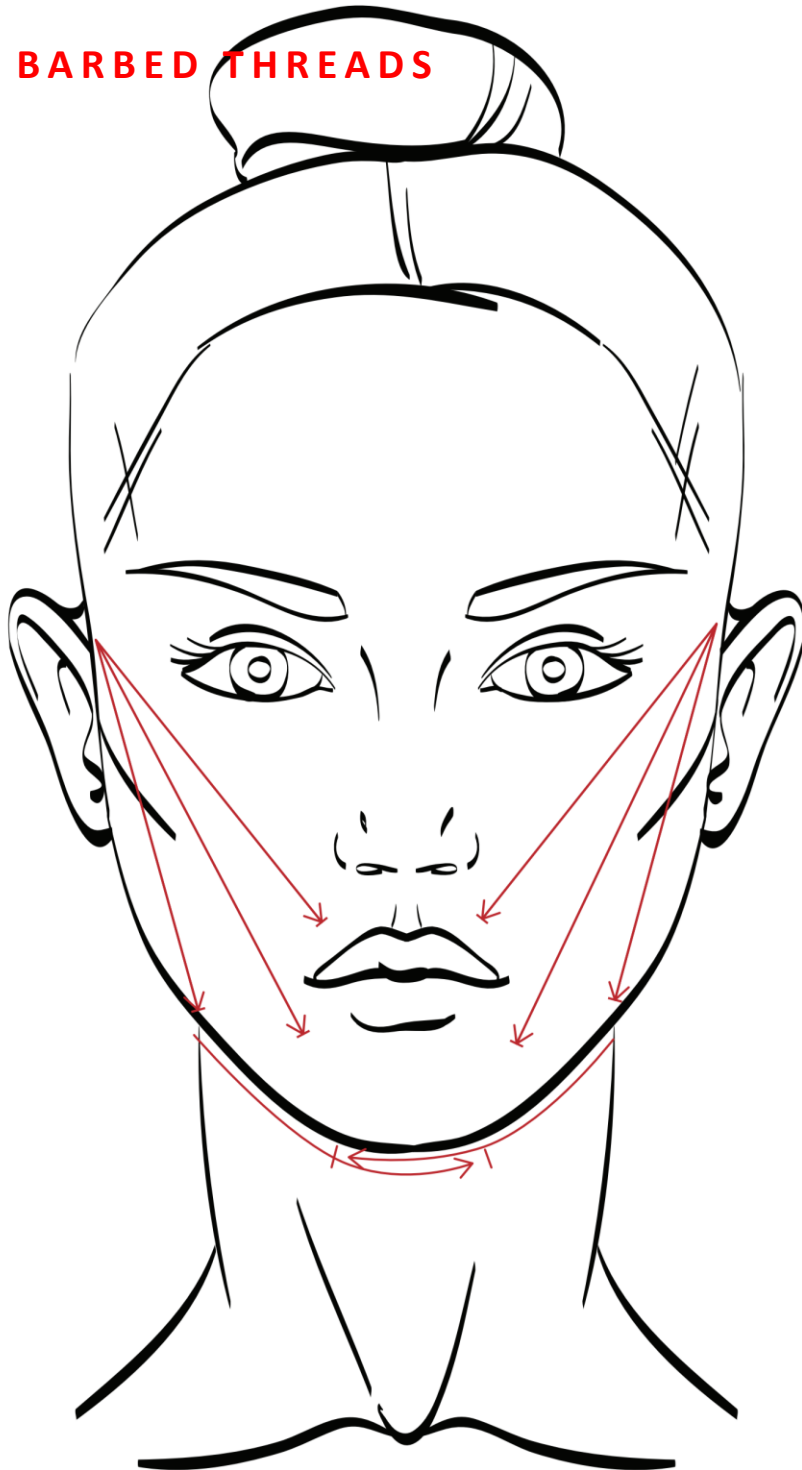
## BARBED THREADS



**SUGGESTED 18,19,21g**



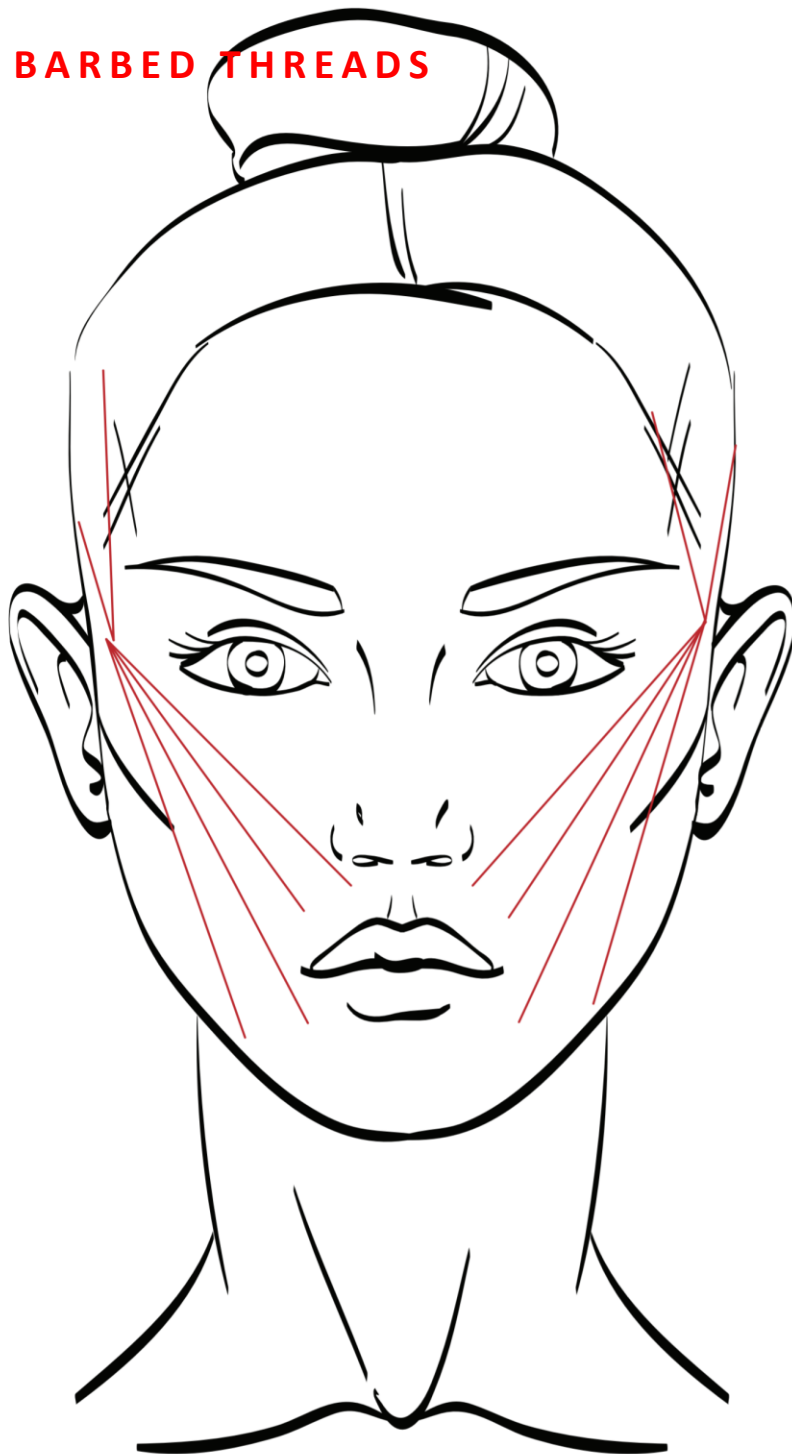
## BARBED THREADS



**SUGGESTED 18,19g**



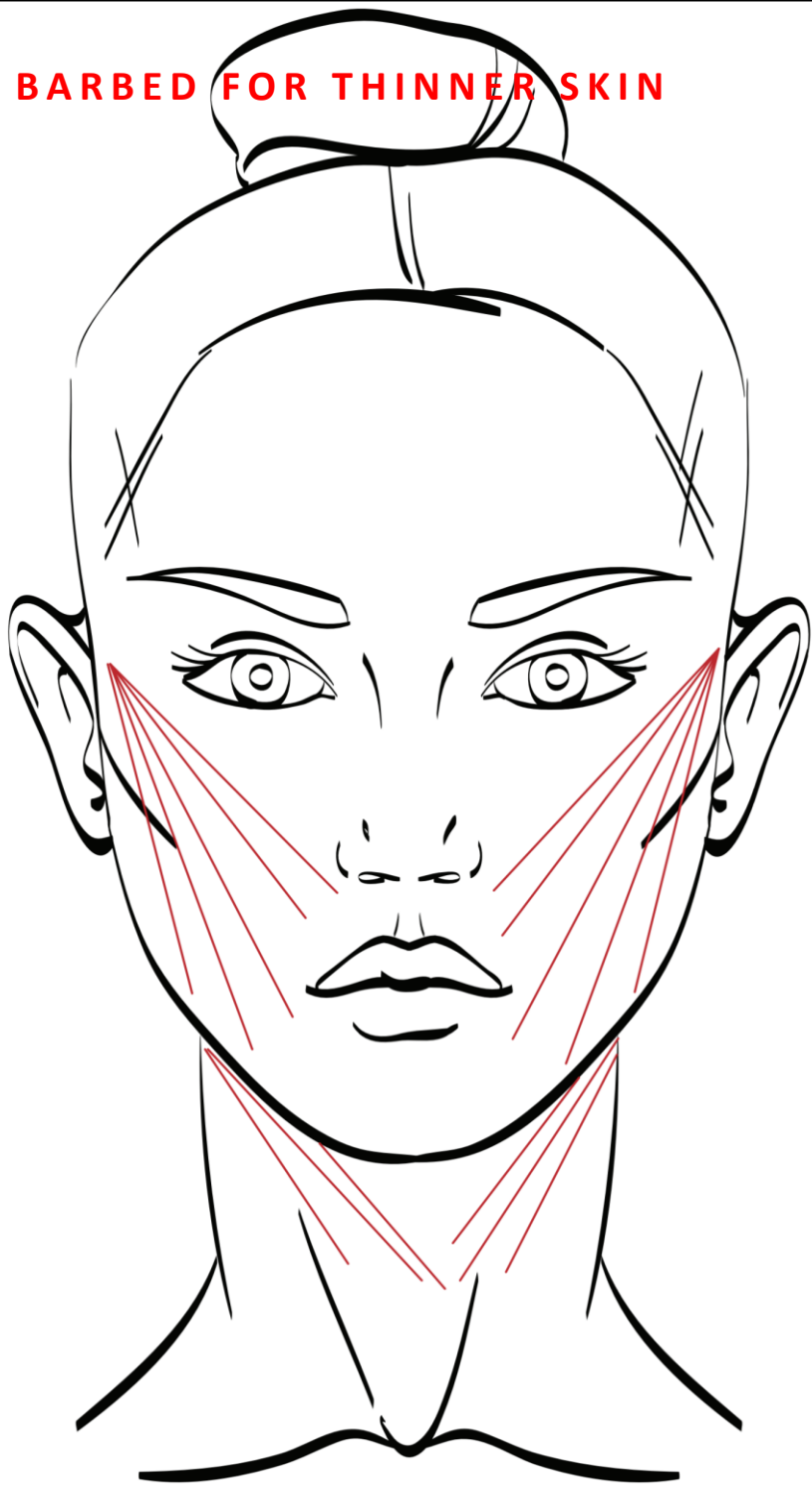
## BARBED THREADS



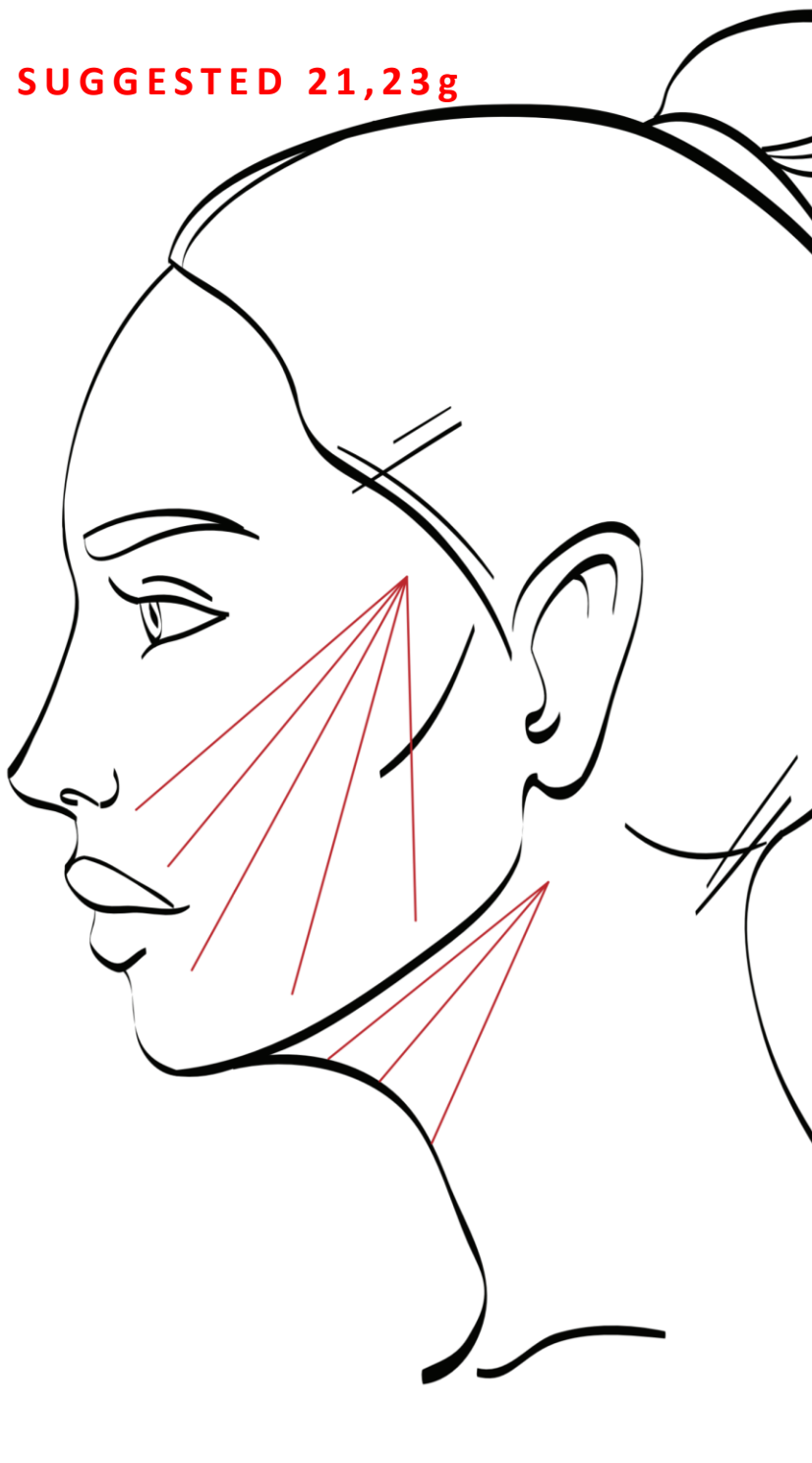
**SUGGESTED 18,19g**



**BARBED FOR THINNER SKIN**

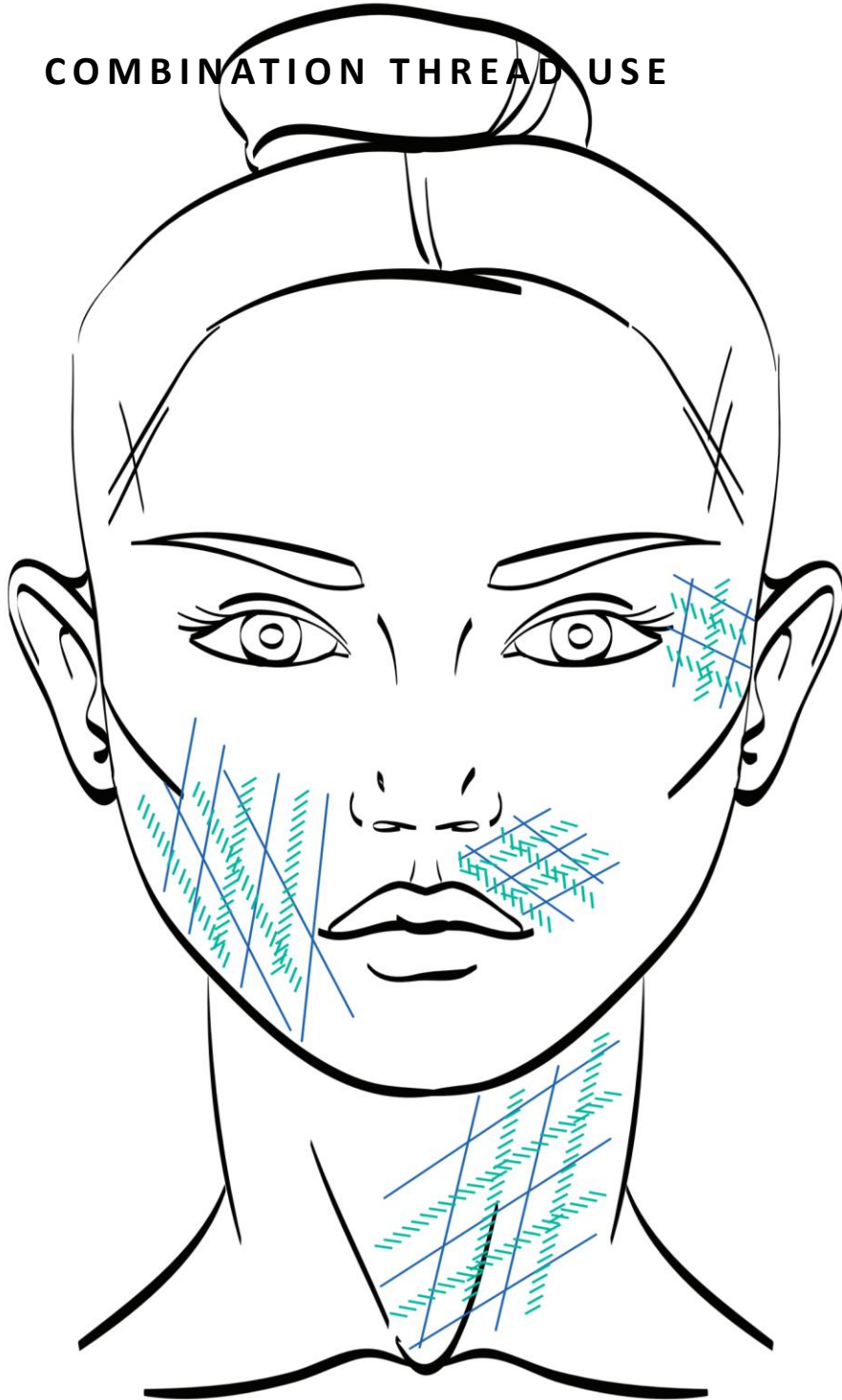


**SUGGESTED 21,23g**

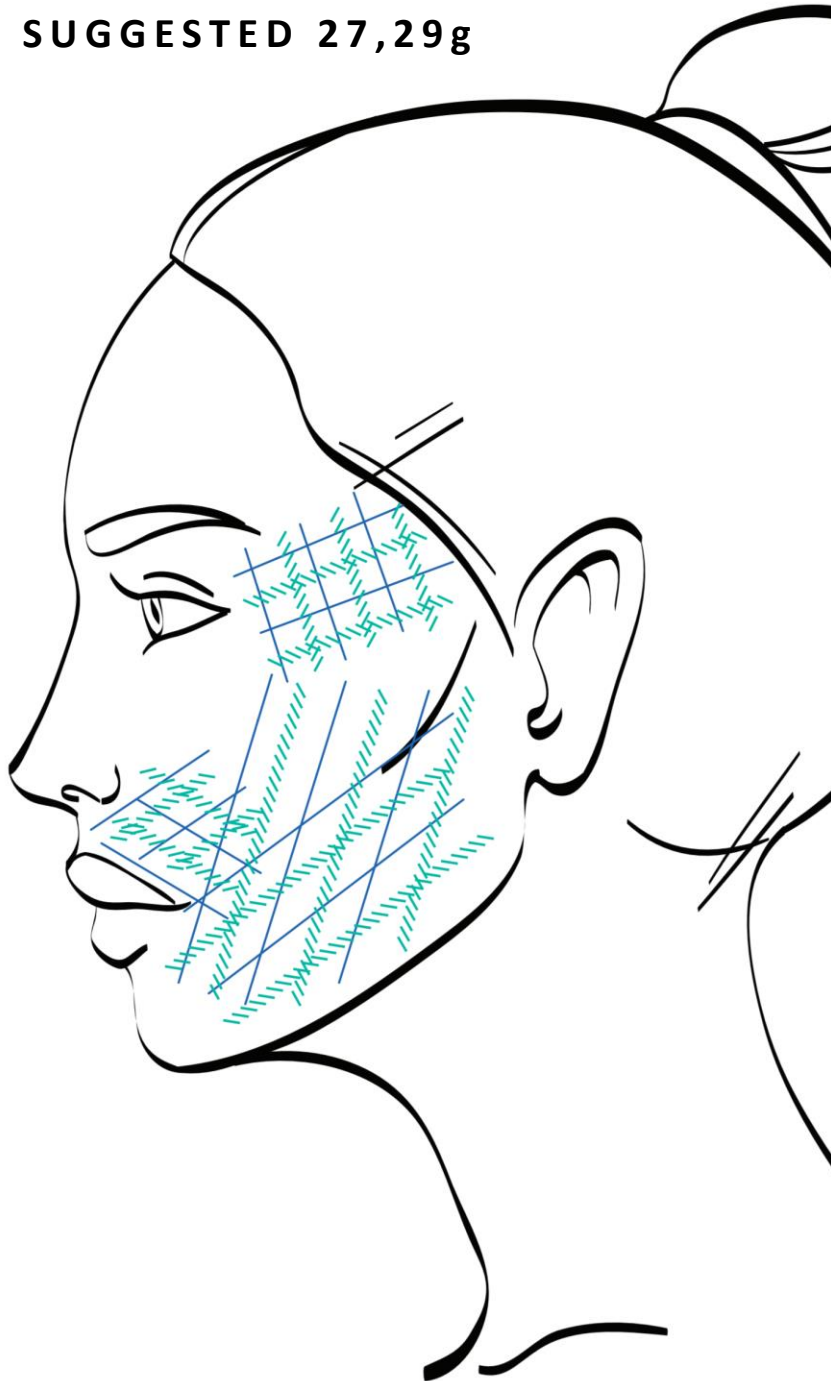


# THREAD COMBINATIONS

## COMBINATION THREAD USE

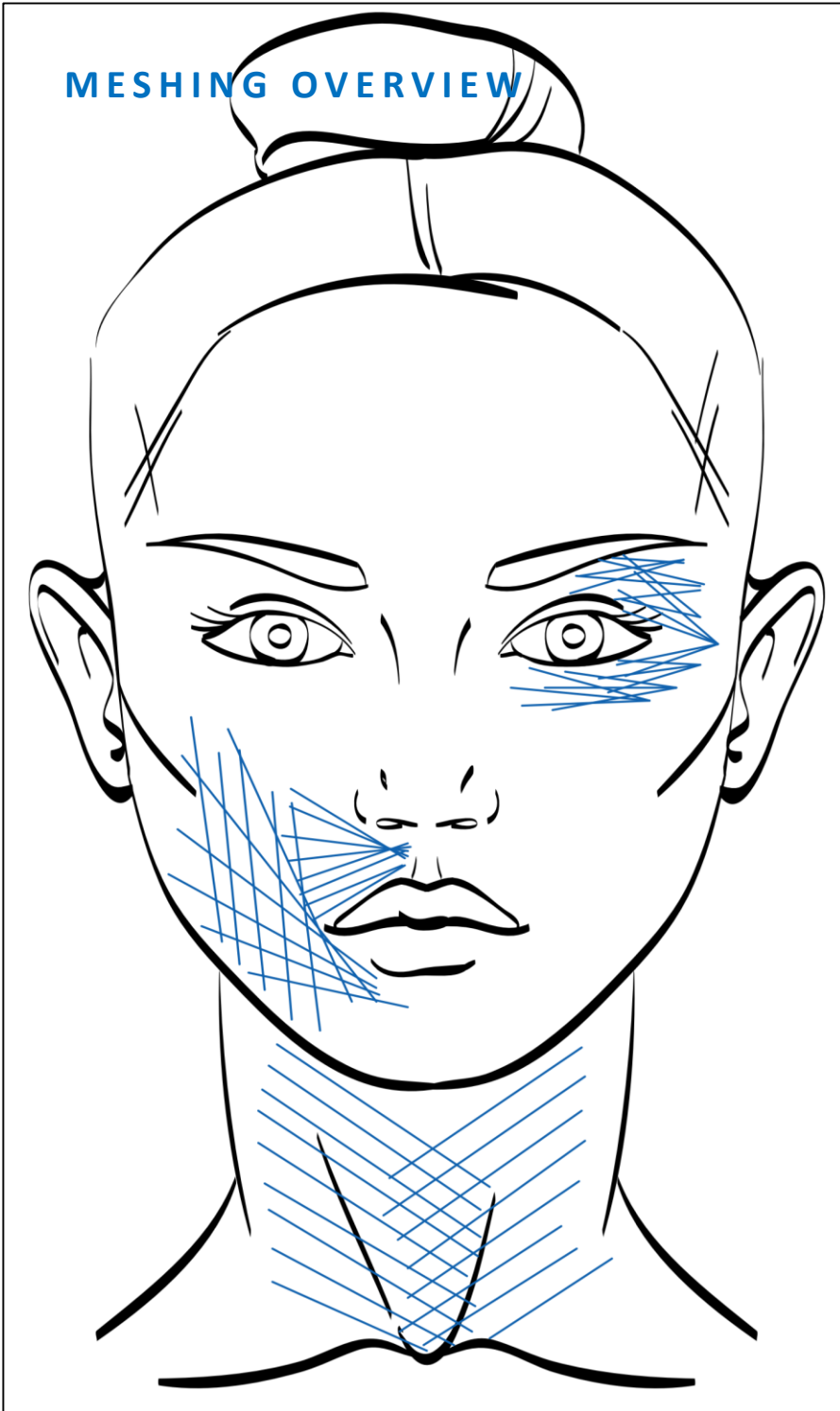


**SUGGESTED 27,29g**

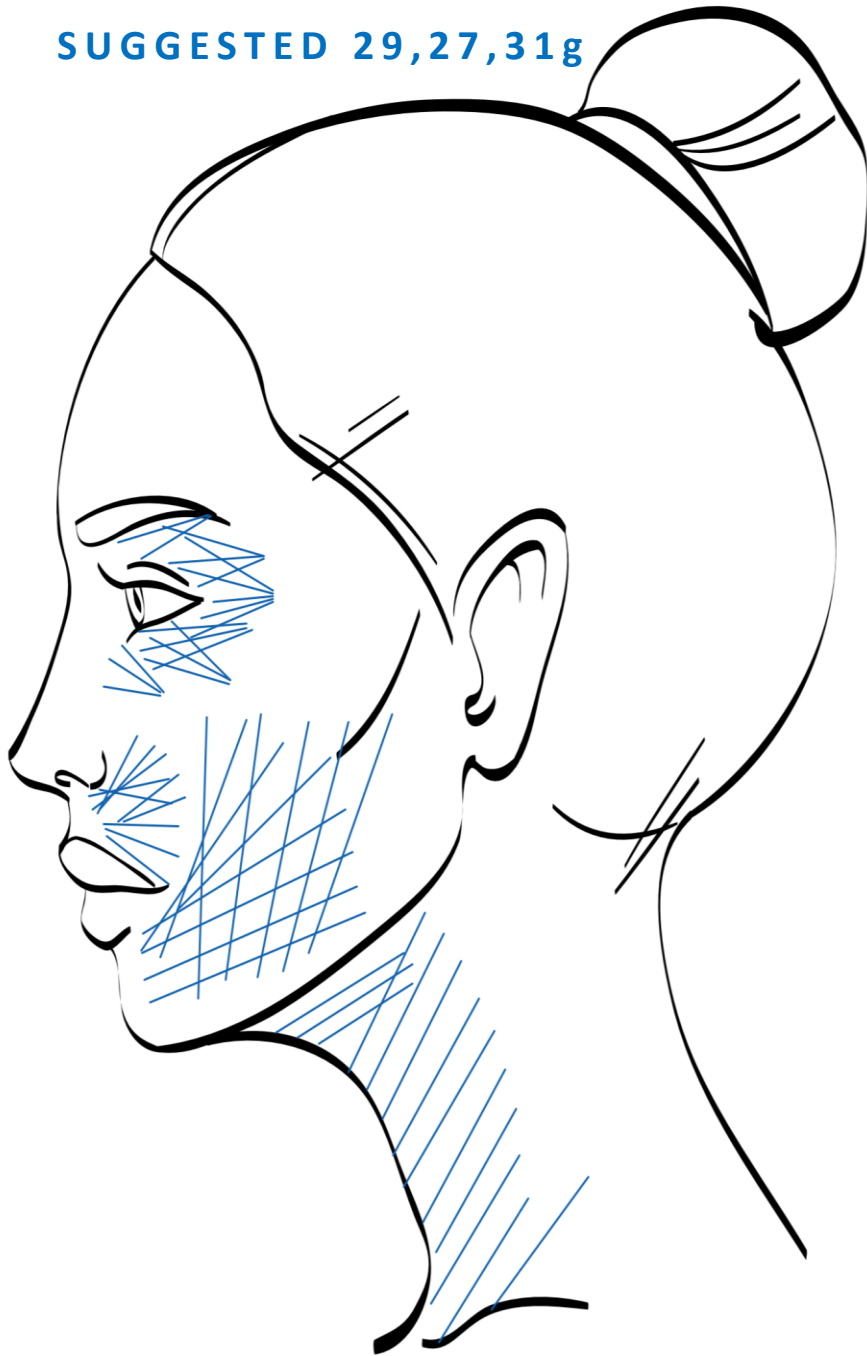


# INJECTION TECHNIQUES

## MESHING OVERVIEW

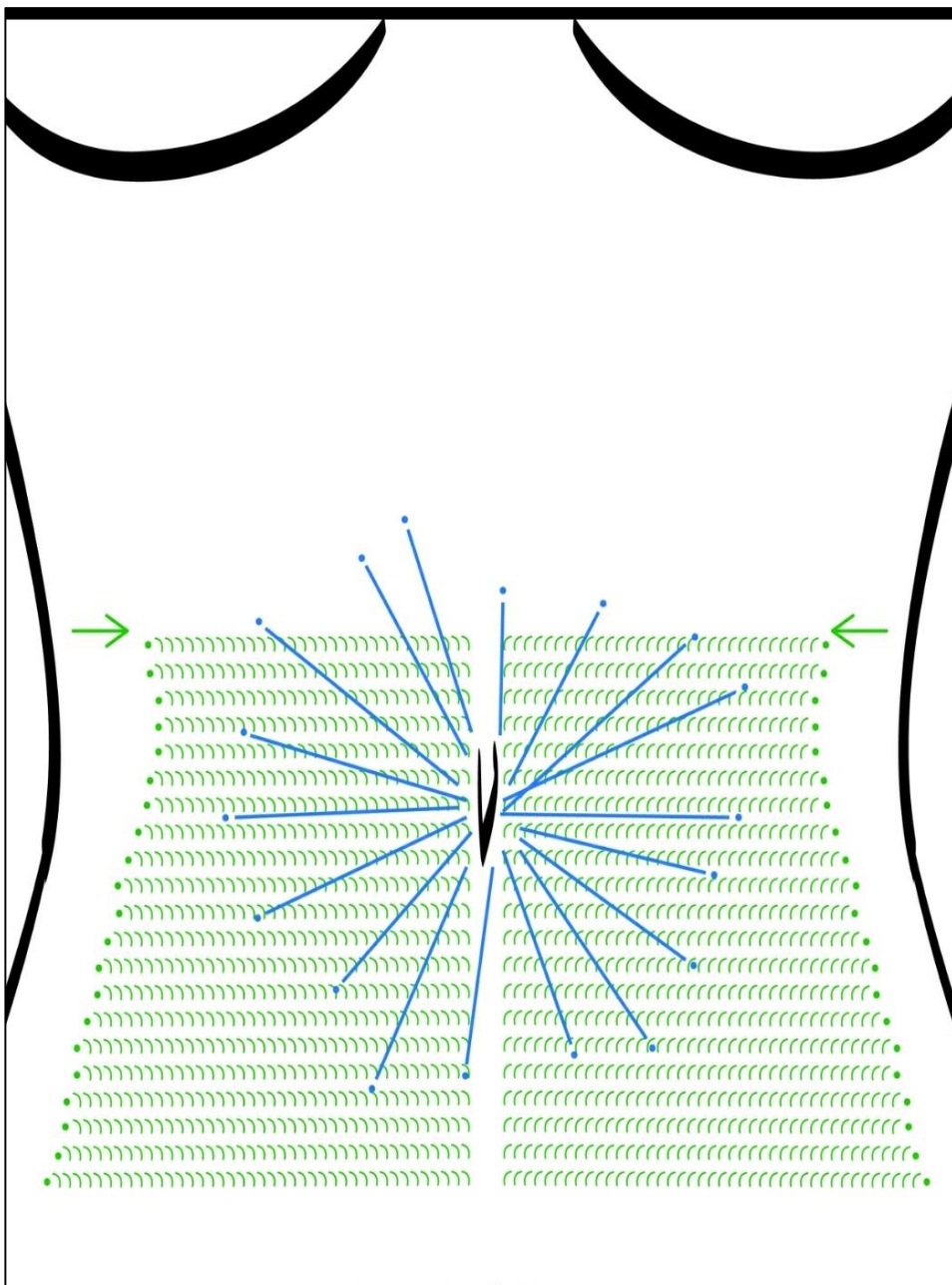


**SUGGESTED 29,27,31g**

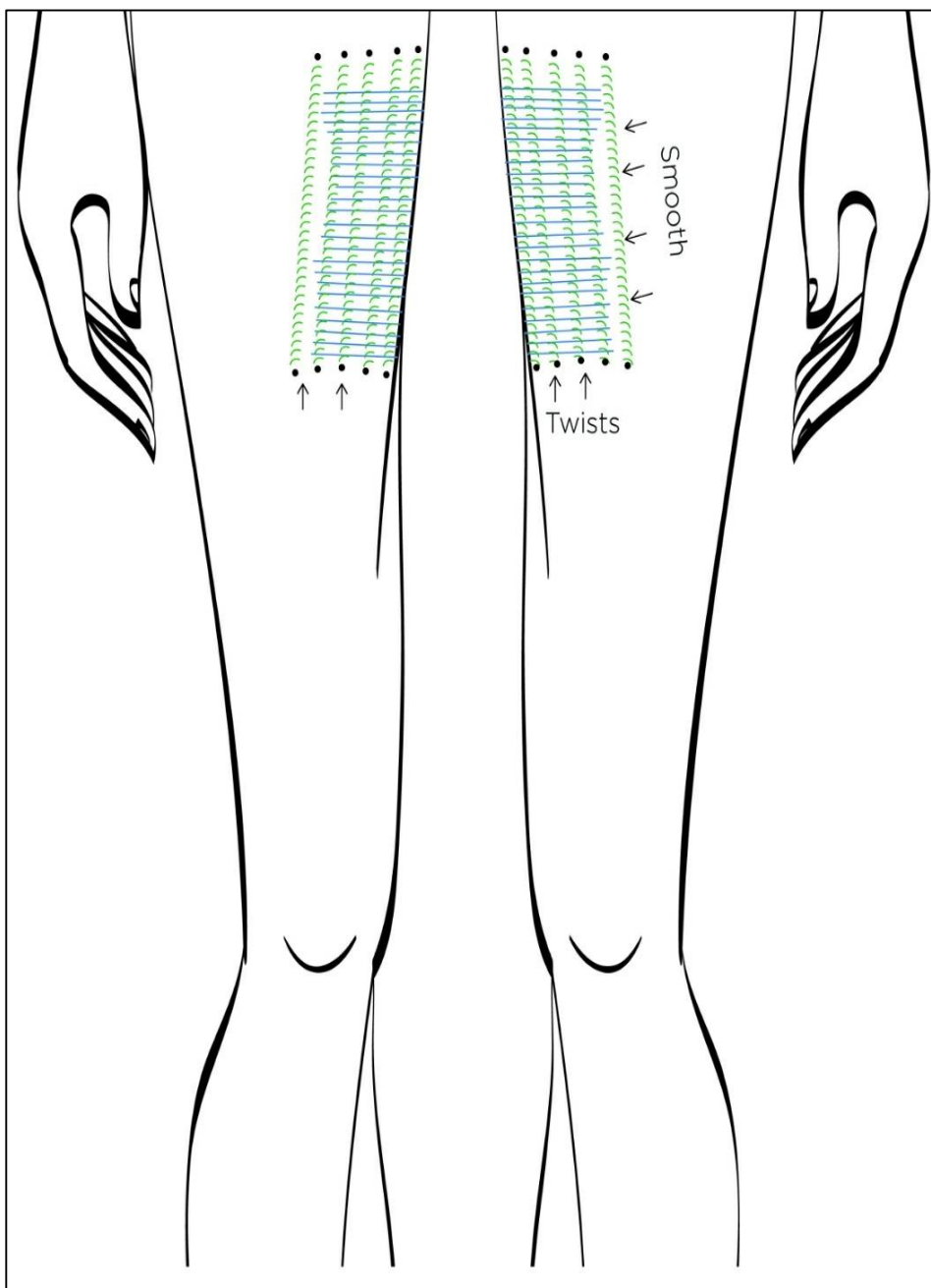


# BODY MAPPING

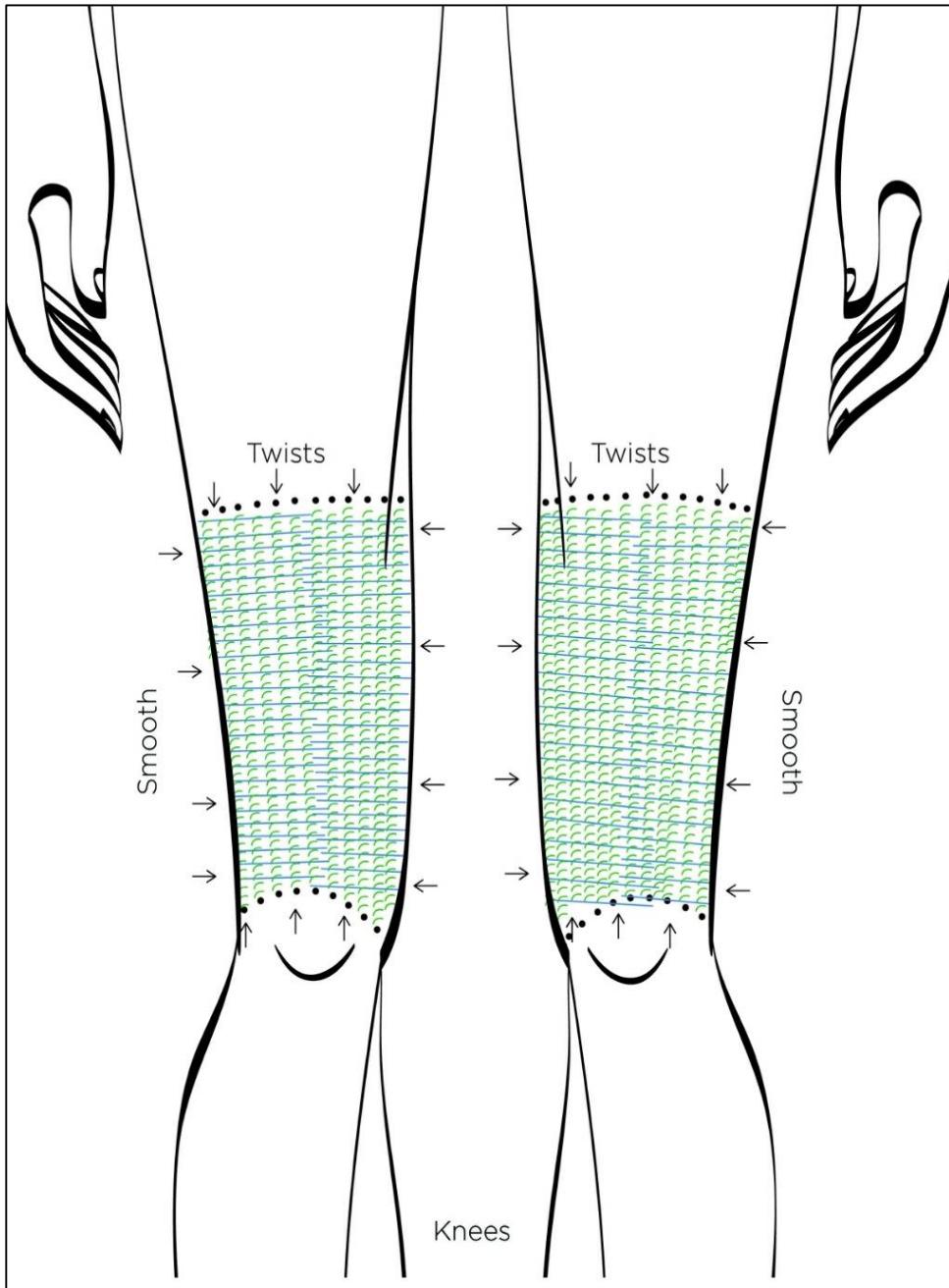
## SMOOTH & TWIST STOMACH SUGGESTED



## SMOOTH & TWIST INNER THIGH SUGGESTED



## SMOOTH & TWIST KNEES SUGGESTED





## TRAINING TOOLS & RESOURCES

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All of our training is  
guaranteed “hands on”  
training.

# RECOMMENDED TOOLS

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**EUROTHREADS**  
PREFERRED

Several threads are available in the current market but we use EuroThreads due to both quality and their advanced technology. EuroThreads offers the largest selection of thread sizes.



**MAPPING TOOL**  
REQUIRED

A wax pencil or surgical marker is used to draw vector lines on the skin surrounding the treatment area(s). Lines outline the path that the thread follows after thread insertion.



**CLEANSER**  
FDA REQUIRED

Anti-bacterial cleanser should be used to disinfect each injection site prior to needle or cannula insertion. Iodine or betadine can also be used in place of anti-bacterial cleanse.



**LATEX GLOVES**  
FDA REQUIRED

As with any cosmetic treatment, it is important and a legal requirement that the medical professional maintain a sterile environment. Latex gloves play a primary role in sterilization.



**SUTURE SCISSORS**  
REQUIRED

Any pair of scissors will work but suture scissors are most effective. Suture scissors are used for clipping the remaining thread that is left outside of the skin after thread insertion.



**TWEEZERS**  
REQUIRED

Surgical tweezers with a smooth or barbed tip are necessary for thread removal. In the event a thread disengages or extrudes from entrance site removal will be required.

# ADDITIONAL TOOLS



## PHLEBECTOMY HOOK REMOVAL

Phlebectomy hooks are the preferred tool used to remove a thread that has been inserted incorrectly or is causing the patient discomfort. They are available in disposable form.



## GAUZE REQUIRED

Any type of gauze can be used for thread lifting purposes. However, gauze allowing for maximum absorption is preferable in the event that a vein is accidentally nicked.



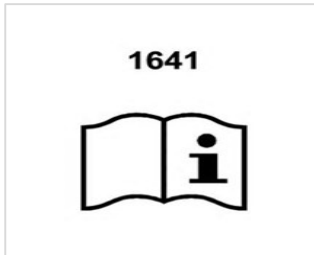
## LARGE NEEDLE REQUIRED

Ideally an eighteen (18) gauge needle should be used for pre-injection purposes.. The needle is inserted into the injection site creating a port for the cannula to then be inserted.



## LIDOCAINE PER PATIENT

The use of either a topical or injectable antiseptic is completely dependent on each patient's tolerance to pain and left to the discretion of the injector.



## TRAINING MANUAL FDA REQUIREMENT

As with any medical device requiring FDA approval, it is important to consult the product manual. Also, pay close attention to any and all declarations on the product's label.



## AUTOCLAVE OPTIONAL

The use of an autoclave is recommended but optional. Many of the tools required are available for purchase in a sterilized, single use disposable form.

# TRAINING RESOURCES

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EuroThreads offers multiple online resources for thread lift training and continued education. Additionally, we work with several qualified aesthetic training companies and qualified trainers throughout the country.



# MANUAL APPENDIX

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The appendix includes additional resources for your reference. As with any procedure, both the patient consent form and after care instructions are essential. Included is a “sample” of both for further edit by your legal representative.

# APPENDIX A

# PATIENT CONSENT FORM

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**Patient Name** \_\_\_\_\_

**Treatment Areas** \_\_\_\_\_

I duly authorize \_\_\_\_\_ to perform EuroThreads thread lifting procedure and any other treatments using PDO / PLLA threads which in their opinion may be necessary.

I understand that clinical results may vary according to my skin type. I also understand that there is a possibility of short-term effects such as reddening, mild discomfort, bruising and swelling at injection site, bleeding and in very rare cases allergic reaction. Further, I understand that in extremely rare cases slight asymmetry, thread visibility and pigment changes may require additional treatments. All side effects have been fully explained to me.

## Clinical Results.

I fully understand that clinical results may vary depending on individual factors, including patient's medical history, skin type, patient compliance with both pre / post treatment instructions and individual response to treatment. I also understand that treatment with EuroThreads involves a series of treatments and the fee structure has been fully explained

## Patient Consent.

I certify that I have been fully informed of the nature and purpose of this procedure, expected results and possible complications, and I understand that no guarantee can be given as to the final results obtained. I am fully aware that my condition is of cosmetic concern and that the decision to proceed is based solely on my expressed desire and consent to do so. Additionally, the use of thread lifting may not be completely effective at treating a particular condition, therefore, my permission for consent will remain effective for 1 year from the date of execution with respect to the procedures outlined herein.

## Medical Release.

I confirm that I am not pregnant at this time and have not taken any aspirin or anti-inflammatory medications within the last 10 days. I have also completed a medical history checklist and been fully informed about what I "must do" and "not do" before, during and after this treatment. Further, I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

**Patient:** \_\_\_\_\_

**Business:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Witness** \_\_\_\_\_

**Witness:** \_\_\_\_\_

**Photography & Videography Release. I understand that by giving my release that these materials may appear in print and online and the public may have access to them. (Additional Signature here grants release)**

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# POST TREATMENT INFO

## Post Treatment Instructions for EuroThread's PDO / PLLA Sutures

**Patient Name:** \_\_\_\_\_

**Treatment Areas:** \_\_\_\_\_

**Name of Injector:** \_\_\_\_\_

Congratulations on your EuroThreads treatment. To ensure optimal treatment results it is important that you read this information carefully. Please sign form below indicating that you have read these instructions in their entirety and that you fully understand the need to notify our office immediately if you are experiencing any adverse effects or abnormalities not listed below.

### Treatment Results

1. It may take a minimum of two plus weeks for treatment results to become noticeable.
2. Minor bruising and swelling is normal and to be expected.
3. Lumps and/or bumps may temporarily occur at or along treatment site(s). These will resolve with time and are seldom a cause for concern.
4. Minor pain at the injection site is normal and to be expected. Pain may last up to a week post treatment.
5. Asymmetry and irregularity of tissues treated is common post treatment and usually resolves itself.

### Due Diligence

1. Avoid exercise for 24 hours after treatment.
2. Diligently follow your practitioner's instructions with the use of antihistamines if you are prone to seasonal allergies.
3. If you experience severe weather or dramatic atmospheric pressure changes in your geographic location, you may experience greater than normal swelling or complications.
4. Avoid excessive chewing and hard foods for 3 days post treatment. Do not drink through a straw.
5. Avoid animated facial expressions for a week post treatment.
6. To avoid additional swelling, sleep with head elevated for 2-3 days post treatment.
7. Avoid massaging treatment area(s) excessively.
8. Avoid washing your face for 12 hours following treatment.
9. Don't not wear makeup or apply facial creams for 48 hours following treatment.

Contact us at \_\_\_\_\_ If you:

1. Experience increased redness, swelling or pain at the injection site.
2. Have one or more threads begin to extrude.
3. Have additional questions or concerns regarding your treatment / treatment follow-up.

**Patient Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

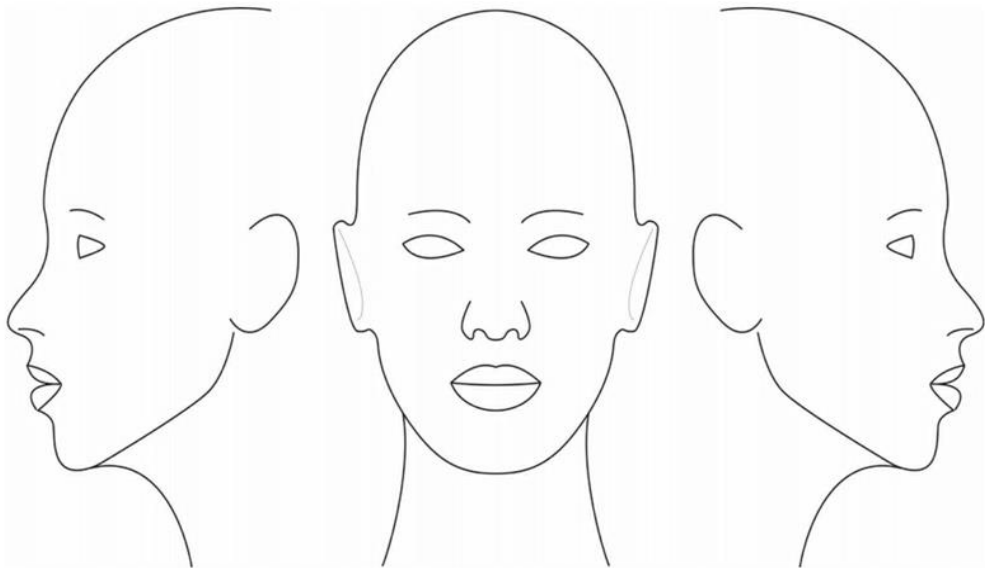
# INJECTION RECORD

## EUROTHREADS INJECTION SITE RECORD

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

Date of Treatment: \_\_\_\_\_

Area Treated & Threads Used:



Notes:

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# EURO THREADS

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