EUROTHREADS

Training Policies & Protocols

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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:

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Disclaimer

Please read the enclosed information carefully.

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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

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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.

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 (intradermal 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

-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 us 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

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

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.

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 **intradermally**, **hypodermally** and **intramuscularly** 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 **intradermally**, **hypodermally** and **intramuscularly** 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 **intradermally** and **hypodermally** depending on treatment. Threads are injected from same injection site into varying directions
Compression Technique	This technique involves the injection of threads **intradermally** and **hypodermally** 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 **intradermally** and **hypodermally** 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 that 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.

Notes during Training

Treatment	Threads Inserted

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