

Venous Thromboembolism (VTE) is a serious and potentially life threatening condition that includes both Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE). DVT occurs when a blood clot forms in one of the deep veins in your body, limiting blood flow. It usually occurs in your leg or pelvis, but it can also occur in your arm or chest.

There are several reasons to seek immediate treatment for DVT. There is a risk that a portion of the clot could break off and travel to your lungs, blocking the blood flow and damaging your heart and lungs. This condition, called Pulmonary Embolism, can be fatal within a few hours.

There are also long-term consequences of upper leg DVT. If the clot isn't dissolved within a few weeks, it becomes a Chronic Deep Vein Thrombosis. The old blood clot can permanently damage the valves in your veins creating a

condition called Post-Thrombotic Syndrome (PTS). An estimated 50 percent of patients with chronic DVT in the upper leg area may develop PTS, which can cause disability and negatively impact your quality of life.^{1,2,3}

Symptoms Of DVT

Symptoms include:

- Redness or skin discoloration
- Calf or leg pain or tenderness, especially when walking or standing
- Swelling of the affected body part
- Sensation of warmth
- Leg fatigue

1. Kahn, S et al. Relationship between Deep Venous Thrombosis and the Post-Thrombotic Syndrome. Arch Intern Med 2004; 164:17-26.
2. Ashrani AA, Heit JA. Incidence and cost burden of post-thrombotic syndrome. J Thromb Thrombolysis. 2009;28::465-476.
3. Kahn, S. et al. Determinants and Time Course of the Post-thrombotic Syndrome After Acute Deep Venous Thrombosis. Annals of Internal Medicine, 149, 2008, 698-707.

Indications and Safety Information

FDA CLEARED INDICATIONS: The EkoSonic® Endovascular System is indicated for the ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism; the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature; and the infusion of solutions into the pulmonary arteries. Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician.

Potential Adverse Events - Potential adverse events (in alphabetical order) which may be associated with use of the system are similar to those associated with other interventional procedures and include but are not limited to the following: air embolism, allergic reaction to contrast medium, amputation, arteriovenous fistula, bleeding from access site, death, dissection, distal embolization of blood clots, drug reaction, hematoma, hemolysis, hemorrhage requiring transfusion, hypotension/hypertension, infection at access site, pain and tenderness, perforation, pseudo aneurysm, total occlusion of treated vessel, vascular spasm, vascular thrombosis, vessel wall or valve damage.

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A Patient's Guide To Advanced, Minimally-Invasive Treatment Of Venous Thromboembolism (VTE)

How Ultrasonic Sound Waves Can Help Safely Dissolve Blood Clots



Dissolving The Clot At An Early Stage May Reduce The Risk Of Complications

When a person develops a Deep Vein Thrombosis (DVT), there is a window of opportunity in which the clot can be dissolved and normal blood flow restored. Dissolving the clot reduces the short-term risk of a pulmonary embolism (from a piece of clot breaking off and traveling to the lungs). It also reduces the long-term risk of developing Post-Thrombotic Syndrome. A minimally invasive system for dissolving thrombus using ultrasonic technology is now available.

Until recently, the routine treatment for DVT was anticoagulation therapy (blood thinning drugs). These drugs are used to prevent a clot from getting bigger and to lessen the possibility that a piece of the clot will break off, causing a pulmonary embolism. They are also used to reduce the risk of future clots.

However, anticoagulants do not actively dissolve the clot,

nor can they restore blood flow to the vein. So while they reduce the risk of pulmonary embolism, they can't eliminate it.

Frequently the clot will harden, potentially damaging both the vein and the valves that regulate blood flow. When this happens, the patient may develop the chronic complications associated with Post-Thrombotic Syndrome.

Minimally-Invasive Treatment Can Dissolve Clots And Restore Function

Acoustic Pulse Thrombolysis™ treatment uses ultrasonic waves in combination with clot-dissolving drugs to dissolve a clot, reducing the risk of both pulmonary embolism and long-term side effects. The biochemistry involved is similar to that of the human body's actual process in dissolving clot.

The procedure, which is usually done in a hospital, is minimally invasive and does not require general anesthesia. A special catheter (long, flexible tube) is inserted into a vein. Using image-guided technology, the doctor gently threads the catheter to the clot. (Because there are no nerve cells in blood vessels, there is no sensation of the catheter moving.)

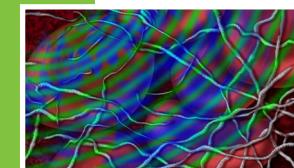
Inside the specialized catheter are low-power micro-transducers. Once the catheter is in place, the system will transmit low power, high-frequency sound waves into the clot.

The ultrasonic energy loosens the tightly bound clot and, at the same time, forces clot-dissolving drugs deep inside the clot. The combination of the sound waves and the drugs gently dissolves the clot without breaking it apart.

Like a tightly wound ball of string, a clot can be difficult to penetrate. Ultrasonic sound waves gently loosen the fibers that hold the clot together and push clot-dissolving drugs inside. The clot quickly and gently dissolves away.



Tightly bound fibrin



Loosened fibrin

What You Should Know Before Choosing Acoustic Pulse Thrombolysis™ Treatment

This treatment for DVT is most effective when the clot is relatively new, usually when you have had symptoms for less than 30 days.

Because this treatment uses clot-dissolving drugs, there is a risk of bleeding. So if you have a history of bleeding or blood disorders, it may not be appropriate for you. You should also not have this procedure if you have high blood pressure that is difficult to control or have sensitivities to contrast agents used in imaging studies.

Afterwards, you may still need to take blood thinners to assure another clot does not form. You may also need additional treatment to address the underlying causes of the clot. Your doctor will talk with you about other risks associated with this procedure.

What is Post-Thrombotic Syndrome?

When a clot remains in the leg, it can cause irreversible damage to the veins and its valves. The damaged valves don't open and close properly, allowing the blood to pool in the legs. The condition, known as Post-Thrombotic Syndrome (PTS), is often debilitating with patients experiencing:

- Chronic pain
- Swelling
- Skin ulcerations
- Varicose Veins

The pooled blood also makes the patient more prone to develop another DVT and increases their risk for pulmonary embolism.

September 2008 U.S. Surgeon General's "Call to Action"

The Surgeon General has announced a Call To Action to Prevent Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE). The goal is to create greater awareness and the development of evidence based practices through education of the consumer and healthcare providers on the screening, symptoms, prevention, diagnosis and treatment of DVT and PE.

www.ncbi.nlm.nih.gov/books/NBK44178/