

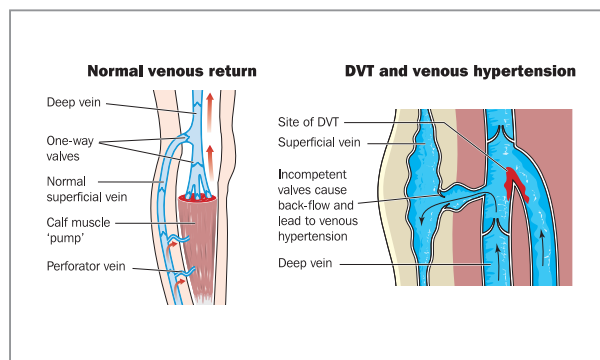
## Deep Vein Thrombosis

Deep vein thrombosis (DVT) is a bigger problem than generally acknowledged. The lack of appropriate intervention in patients with DVT can create major problems for these patients in the future. While DVT affects more than 2 million people a year in the United States, only 600,000 are diagnosed per year (WebMD). Even more troubling, most of these patients are sent home with simple anticoagulants.

**While effective at helping to prevent future clots, anticoagulants are ineffective at breaking down the existing acute thrombus.**<sup>4</sup> This can lead to a dangerous condition called post thrombotic syndrome (PTS). While some people who have had a DVT or blood clots in the leg recover completely, others may be left with symptoms and physical signs in the affected limb that are collectively known as the PTS<sup>†</sup>. Venous hypertension is the main cause of PTS and occurs when a clot in the vein damages the valves and creates outflow obstruction.

Without dissolving the clot already present in the venous system, patients can develop PTS,<sup>1</sup> which affects 60-70 percent of iliofemoral DVT patients (SIR). **In fact, several studies have shown that 50-82% of patients with iliofemoral DVT who were treated with anticoagulant alone went on to suffer from PTS.**<sup>2</sup> PTS occurs when a clot forms in a vein, damaging the valves inside the vein. According to the Venous Disease Coalition, “The damaged valves can permit back-sliding of the blood into the lower leg, and the residual clot can block the return of blood from the leg veins back to the heart. This results in increased venous pressures (venous hypertension) in the leg.” PTS results in a high level of chronic pain

and disability, with patients experiencing leg pain, aching, heaviness or tiredness, swelling, discoloration, cramping and itching. Some patients can develop ulcers. Permanent damage can often result due to the toll PTS takes on the venous system. It is calculated that as high as 40% of the total costs of treating DVT is spent on PTS.<sup>1</sup> **Therefore, it is important to treat the DVT by removing the clot as early and as effectively as possible.**



Conventional standard of care is to prescribe anticoagulants such as Low Molecular Weight Heparin (LMWH) and Coumadin. However, “such a regimen does not promote lysis to reduce the thrombus load, nor does it contribute to restoration of venous valve function. **Anticoagulation alone does not protect the limb from PTS, which can occur months to years**

**after the acute thrombotic event**<sup>3</sup>.” Therefore, organizations such as the American Venous Forum and the Society for Interventional Radiology have been outspoken about the need to take invasive action when DVT is diagnosed. DVT is a growing problem and current standards of care have not proven sufficient.

There are a variety of treatment options typically offered by an Interventional Radiologist or Vascular Surgeon. These methods range from a catheter that delivers lytic directly to the site of the clot (catheter directed thrombolysis) to more advanced mechanical options that isolate the clot and disperse lytic through a mixing wire of sorts. It is important that patients diagnosed with DVT be seen by a thrombus management expert in the hospital to determine the best course of care for each patient.

<sup>†</sup><http://www.venousdiseasecoalition.org/diseaseinfo/pts/>

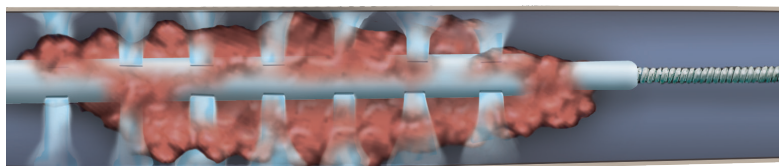
Footnote: numbers are based on the population of the United States.

# Uni-Fuse

## INFUSION CATHETER

AngioDynamics has paved the way as the market leader for catheter directed thrombolysis catheters with patented slit technology to infuse in a consistent, even distribution of lytic agent to an area of clot. The Uni-Fuse\* catheter uses a patented, time-tested technology to provide faster and more effective treatment for clots, and its sturdier construction makes it more versatile.

- Patented time-tested technology
- Even distribution results in faster treatment of clot
- Sturdier construction allows for more versatility



1. Baldwin Z, et al. Catheter-Directed Thrombolysis for Deep Venous Thrombosis. *Vascular and Endovascular Surgery* 2004; 28,1:1-9.
2. Elsharaway M, Elzayat E. Early Results of Thrombolysis vs Anticoagulation in Iliofemoral Venous Thrombosis. A Randomised Clinical Trial. *E Journal of Endovascular Surgery* 2002; 24.
3. Mewissen M, et al. Catheter-Directed Thrombolysis for Lower Extremity Deep Venous Thrombosis: Report of a National Multicenter Registry. *Radiology* 1999; April:39-49.
4. Razavi M, Charles Semba. The Changing Role of Thrombolytic Therapy in the Management of Acute Deep Vein Thrombosis. *Therapy* 2005; 2,1:57-59.

### IMPORTANT RISK INFORMATION

**INDICATION FOR USE:** AngioDynamics UNI-FUSE Infusion System is intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral vasculature. **CAUTION:** Federal (USA) law restricts the sale of these devices by or on the order of a physician.

**CONTRAINDICATIONS:** The UNI-FUSE Infusion System is contraindicated for use in the coronary vasculature and is not for the infusion of blood or blood products.

**WARNINGS AND PRECAUTIONS:** The UNI-FUSE Infusion System is sterile and intended for single patient use and use only by fully trained physicians in angiography and percutaneous interventional procedures. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Do not inject contrast medium with a pressure injector if the occluding ball wire is in place. Use an introducer sheath if the puncture is through a synthetic graft. Failure to

use an introducer sheath may result in damage to the catheter.

**POTENTIAL COMPLICATIONS:** Adverse reactions may include, but are not limited to: vessel perforation, dissection, hematoma, stroke, hemorrhage, contrast extravasation, embolism/thrombus, vaso spasm, drug reaction, neurological deficits, and pain and tenderness.

Indications, contraindications, warnings and instructions for use can be found in the instructions for use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.



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