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## **New Deep Vein Thrombosis (DVT) Registry Data Show Clot Quickly Removed, Blood Flow Restored in Large Patient Registry**

### ***Interventional Radiology DVT Treatment Should Become a Standard of Care***

Washington, D.C. (March 17, 2008)—Registry data for more than 500 patients presented today at the Society of Interventional Radiology’s 33rd Annual Scientific Meeting show deep vein thrombosis (DVT) treatment with the Trellis device breaks up a blood clot in most patients much quicker than using a drug alone. Using imaging, the device is guided directly to the clot via a catheter in the vein. DVT occurs when the blood clot either partially or completely blocks the flow of blood in the vein. The Trellis device removes the blood clot and restores blood flow much quicker than the current catheter-directed thrombolysis (CDT) technique, which uses a drug alone and can take as long as two to three days to be effective with the patient in an intensive care unit.

“It gets the clot out right away, restoring blood flow in the vein while the patient’s blood becomes sufficiently thinned by anticoagulation medication to prevent blood clots in the future. Patients experience dramatic relief of pain, swelling and skin discoloration in just a few hours,” says Gerard J. O’Sullivan, M.D., interventional radiologist. Presently, this is the largest commercial data registry by a manufacturer to assess the effectiveness and safety of this type of treatment for DVT.

“This is a very significant advance in DVT treatment, which hasn’t changed in more than 40 years,” added O’Sullivan. “The procedure is now so commonplace where I work that the ER, oncology and general medicine doctors all refer patients directly to me for this procedure because it works so well and is so safe. With the aid of the Trellis device, this interventional radiology procedure could really change the way DVT patients are treated and should become a standard of care,” he said.

The Trellis device combines the use of clot-busting drugs with a drug dispersion device to break up the clot, providing interventional radiologists with physical assistance to break up the clot faster. Because the device disperses the drug throughout the clot, it allows the clot-dissolving drug to work much more quickly—and often less drug is used, which may lead to a decrease in the risk of bleeding.

Currently, most patients are put on anticoagulation medication (blood thinners), which prevents future clots but does not break up the existing clot.

DVT can lead to serious consequences, including pulmonary embolism (PE) or post-thrombotic syndrome (PTS). Approximately 200,000 individuals die annually as a result of pulmonary embolism. The standard initial treatment with blood thinners is important to prevent a life-threatening pulmonary embolism, but does not treat the existing clot.

Removing these clots is important because about 50 percent of the time, untreated clots will cause PTS, a condition characterized by chronic leg pain, swelling and ulcers. The clot may eventually dissolve on its own, but in the meantime the veins are permanently damaged. PTS is caused by a combination of vein valve damage and blocked blood flow in the vein from residual thrombus (clot).

“My Trellis patients not only felt better right away, but they continued to feel good months later. With anticoagulation alone, it may take days to months for patients to feel better, and some never feel better,” said O’Sullivan. Some larger clots do not break up on their own. This leaves the patient with an underlying obstruction or lesion that should be corrected to prevent a future clot. PTS—while not life threatening—limits a person’s ability to walk or stand for a period of time and can be disabling.

There is growing awareness in the medical community about the need to aggressively treat DVT. Increased focus and awareness of DVT is being brought by new initiatives and standards from a variety of organizations including the Office of the U.S. Surgeon General, the Joint Commission and the American College of Chest Physicians.

“All acute DVT patients should be sent to the interventional radiology department for a consult. We can help their physicians determine the best course of action. If the vein is completely or severely blocked, immediate treatment is needed. Not all partial clots will require treatment, but if the area is still swollen after five to seven days, patients should ask for an appointment with an interventional physician at the hospital,” said O’Sullivan. Interventional radiologists are widely available across the United States in most hospital radiology departments.

Abstract 4: “*An Endovascular Approach to Deep Venous Thrombosis Utilizing Isolated Thrombolysis and Adjunctive Measures*,” can be found at [www.SIRmeeting.org](http://www.SIRmeeting.org).

### **About the Study**

There were 565 limbs treated in 532 patients. The vein was reopened in all cases, and the treatment worked on acute or chronic clots, which is important because acute, fresh clots are more easily treated. Sixty-eight percent of the patients’ thrombi were in the iliac vein (large thigh vein), 19 percent in the smaller femoropopliteal veins (in the leg area), and 13 percent in the subclavian vein (arm and neck area).

Thrombus is generally classified by how long it has been present in the body; SIR’s Reporting Standards define acute as 14 days or fewer, subacute as 15 to 28 days and chronic as more than 28 days.

Thrombus was acute in 28 percent, acute on chronic in 44 percent, 11 percent subacute, 12 percent subacute on chronic and chronic in 6 percent, per the SIR clot-age

classification guidelines. Combined Grades II and III lysis (> 50 to 100 percent thrombus removal) were established in 96.8 percent of acute onset of symptoms, 93.6 percent in acute on chronic, 96.7 percent in subacute, 89.2 percent in subacute on chronic and 90.9 percent with chronic onset of symptoms, with venous patency achieved in all cases. No adverse events were reported in the acute procedural follow-up period. Venous angioplasty, and/or stenting, were also used in the study in conjunction with the Trellis procedure to treat underlying problems depending on individual patient needs, such as a narrow area in the vein that would make a person susceptible to future clots.

### **About The Trellis<sup>®</sup>-8 Infusion System**

The Trellis<sup>®</sup>-8 Infusion System is positioned at the site of the clot and a balloon is inflated on both sides of the clot to prevent pieces of the clot from traveling to other parts of the body and to isolate the treatment zone, so that there is less chance the infused drug will cause bleeding. Then a “dispersion wire” is fed through the catheter of the system. The wire begins to rotate, mixing the clot-busting drug within the clot; the clot pieces are aspirated into the catheter and removed from the body.

The Trellis is approved by the Food and Drug Administration (FDA) as a drug-infusion catheter for peripheral vascular clots. The drug and device have been used for years to remove blood clots from arteries and veins. The data are specific to DVT, showing that it works and is safe.

### **About the Society of Interventional Radiology**

Interventional radiologists are physicians who specialize in minimally invasive, targeted treatments. They offer the most in-depth knowledge of the least invasive treatments available coupled with diagnostic and clinical experience across all specialties. They use X-ray, MRI and other imaging to advance a catheter in the body, usually in an artery, to treat at the source of the disease internally. As the inventors of angioplasty and the catheter-delivered stent, which were first used in the legs to treat peripheral arterial disease, interventional radiologists pioneered minimally invasive modern medicine.

Today many conditions that once required surgery can be treated less invasively by interventional radiologists. Interventional radiology treatments offer less risk, less pain and less recovery time compared to open surgery. Visit [www.SIRweb.org](http://www.SIRweb.org).

***Local interviews, medical illustrations and broadcast-quality video footage are available by contacting SIR's communications department at [mverrillo@SIRweb.org](mailto:mverrillo@SIRweb.org).***

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