

Potential Breakthrough Cancer Treatment Now Available from Vascular Designs

The Company Announces FDA 510(k) Marketing Clearance for IsoFlow™ Infusion Catheter, Making Possible the Direct Delivery of Chemotherapy to Cancerous Tumors

San Jose, Calif. – September 2, 2009 – [Vascular Designs](#), a medical device company, today announced that its [IsoFlow™](#) infusion catheter has secured 510(k) marketing clearance by the U.S. Food and Drug Administration (FDA) for the direct delivery of medications into highly targeted areas. An important application of IsoFlow may be in the treatment of cancer.

The IsoFlow Infusion catheter enables sideways perfusion, which allows physicians to precisely target and isolate areas within the body where the infused drugs are delivered. With IsoFlow's unique design, medications can be delivered into areas that could not previously be treated directly, for instance, a cancerous tumor. According to numerous studies, this approach lets physicians increase drug concentrations at targeted sites while reducing systemic exposure, thereby improving efficacy and patient outcomes when treating illnesses such as cancer with chemotherapy.*

“In select clinical situations, the benefits of delivering a local endovascular drug dose without systemic exposure can reduce complications, improve results, and benefit patients,” said Dr. Michael Dake, former chief of interventional radiology and current professor of cardiothoracic surgery at Stanford University School of Medicine. “The IsoFlow catheter facilitates the use of regional infusion therapies, especially in cases of challenging arterial anatomy where it helps achieve these promises of targeted delivery. IsoFlow is a valuable addition to our treatment arsenal.”

IsoFlow is a dual balloon catheter designed to isolate a specific treatment region within the body from blood flow. It allows the infusion of fluids into the region and the perfusion of blood past the region to keep the blood flow intact during treatment. One of the many unique features of the IsoFlow infusion catheter is the ability to deliver medications sideways while using pressure to push the medication into the targeted area. The IsoFlow catheter is inserted over a guide wire for precise positioning within a patient's body. Once in place, medication is infused and isolated when both of the catheter's balloons are simultaneously inflated using fluid via a single inflation lumen. To view an animation detailing this process, please visit www.vasculardesigns.com.

“We are thrilled to receive FDA 510(k) marketing clearance after working on the IsoFlow catheter for more than seven years,” said Robert Goldman, CEO and founder of Vascular Designs. “But what is most important is that individuals battling life-threatening illnesses will have a breakthrough treatment option to pursue with highly targeted drug delivery.”

“IsoFlow could have a huge impact on the way many of today's deadliest illnesses such as cancer are treated. This method of local delivery may cause tumors that were previously unresponsive to systemic chemotherapy to respond. Additionally, the IsoFlow catheter may be able to provide treatment for a number of other medical conditions for which local delivery would be an ideal option,” continued Goldman. “The potential applications of IsoFlow are exciting. We are looking forward to seeing how physicians will leverage this breakthrough catheter medical device into practice and the impact that it will surely make on the prognosis of so many patients.”

The IsoFlow infusion catheter is now available. For more information on Vascular Designs or to purchase IsoFlow, please visit www.vasculardesigns.com or call (408) 484-9010.

About Vascular Designs

Vascular Designs, Inc. is a medical device company located in San Jose, California. Founder Robert Goldman developed the idea behind Vascular Designs and its innovative IsoFlow™ infusion catheter. His personal experience of watching loved ones suffer from and succumb to cancer had a profound influence on the creation of IsoFlow.

Vascular Designs has received FDA 510(k) marketing clearance for IsoFlow, which enables the direct delivery of medications into targeted areas. An important application for the IsoFlow catheter may be in the treatment of cancer. IsoFlow enables sideways perfusion, which allows physicians to precisely target and isolate areas within the body where the infused drugs are delivered. With the IsoFlow catheter's unique design, medications can be pushed into areas that could not previously be treated directly. According to numerous studies, this type of approach to delivery can increase drug concentrations at targeted sites while reducing systemic exposure, potentially improving treatment outcomes.

For more information on Vascular Designs or to purchase IsoFlow, please visit www.vascular designs.com or call (408) 484-9010.

*Chrysos, E., et al. Treatment of Unresectable Malignant Abdominal, Pelvic and Thoracic Tumors Using Abdominal Pelvic and Thoracic Stop-flow Chemotherapy. *Anticancer Research*, Sept.-Oct. 2001. 21(5):3669-3675.

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