

# Oncology

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## NEW REGIONAL CHEMOTHERAPY DELIVERY DEVICE

## Vascular Designs' IsoFlow™ Infusion Catheter: Enabling Regional Chemotherapy Delivery

**ONG:** Can you describe the IsoFlow infusion catheter (its rationale, how it works, etc)?

**Vascular Designs:** Vascular Designs has secured 510(k) marketing clearance by the US Food and Drug Administration (FDA) for its IsoFlow™ catheter device, which enables the direct delivery of medications in a highly targeted and concentrated fashion. The IsoFlow catheter enables sideways perfusion, which gives physicians the ability to push specified fluids both into side branch and angiogenically formed vessels. With IsoFlow's unique design, fluids can reach areas that previously could not be treated directly.

IsoFlow is inserted with a guidewire and catheter for precise positioning within a patient's body. Once in place, both of IsoFlow's balloons are simultaneously inflated using radiopaque fluid via a single inflation lumen. Physician-specified fluid is introduced through the infusion lumen or the guidewire lumen via the one-way stopcock connection. The mixture of infusion and radiopaque agents is then delivered to the target region between the two balloons. For sideways infusion, the guidewire is retracted to allow blood to bypass the isolated target region via holes in the catheter's exterior. Complete removal of the guidewire allows fluid delivery from the distal tip. Animation detailing this process can be found at [www.vasculardesigns.com/V2/video.html](http://www.vasculardesigns.com/V2/video.html).

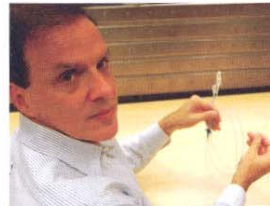
**ONG:** What are the benefits of using the IsoFlow catheter?

**Vascular Designs:** As indicated by numerous studies, a direct delivery approach can help physicians increase drug concentrations at targeted sites, thereby reducing systemic exposure and side effects while improving efficacy and patient outcomes. With the IsoFlow catheter's unique design, fluids can be pushed into areas physicians were previously unable to treat directly. IsoFlow's dual balloon catheter isolates 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.

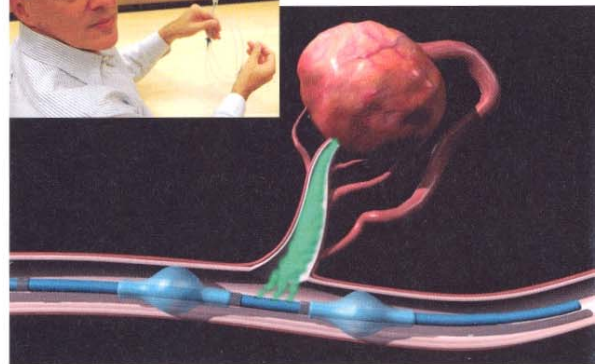
**ONG:** Which cancers has the device been used for and what are its potential applications?

**Vascular Designs:** Potential applications include late-stage cancer treatment, pre-surgical treatment of cancer, direct treatment of disease, and stroke intervention. For example, one potential use is for the treatment of solid cancerous tumors with defined vasculature that have comprised a solid organ with vascular access. IsoFlow can provide an additional treatment option for patients who are not surgical candidates or who have already exhausted the treatment possibilities of radiofrequency ablation, chemoembolization, radiation, and systemic chemotherapy.

Having recently secured 510(k) marketing clearance by the FDA, the IsoFlow device is in the early stages of introduction into the cancer treatment arsenal. To date, one T8 spinal tumor procedure has been performed by Dr Osama Zaidat at the Froedtert and Medical College of Wisconsin in Milwaukee. The IsoFlow catheter was successful in shrinking the T8 tumor, resulting in a dramatic reduction in pain for the patient as well as increased mobility.



LEFT: Robert Goldman, CEO and founder of Vascular Designs, holding the IsoFlow catheter. BOTTOM: Artistic representation showing the IsoFlow catheter delivering chemotherapy to a tumor.



**ONG:** How did this device come to be?

**Vascular Designs:** Robert Goldman, founder and CEO, developed the idea behind Vascular Designs and its innovative IsoFlow infusion catheter. After watching three close family members suffer from and eventually succumb to cancer, he set out to find a new way to battle the disease and others like it. Motivated by a 2002 study, "Stop-flow Technique for the Loco-regional Delivery of Antitubercular Agents,"\* Goldman embarked on a 7-year mission to advance the local delivery of cancer treatment. With help from collaborators at Stanford University and other institutions, he has led the development of the company's breakthrough IsoFlow infusion catheter.

**ONG:** How may oncologists have already adopted this device?

**Vascular Designs:** Vascular Designs is currently scheduling meetings with leading interventional radiologists and oncologists throughout the country. As more physicians are being introduced to the usefulness and potential applications of the IsoFlow catheter, multiple devices are either being tested or considered for immediate treatment use. Oncologists who want to request a meeting with Vascular Designs or wish to secure more information about the IsoFlow catheter can visit [www.vasculardesigns.com](http://www.vasculardesigns.com).

#### REFERENCE

\*Pilati P, Mocellin S, Miotto D, et al. Stop-flow technique for loco-regional delivery of antitubercular agents: Literature review and personal experience. *Eur J Surg Oncol.* 2002;28(5):544-553. Abstract available at: <http://tinyurl.com/yj8kcr>.