

TARGETED RENAL THERAPY DELIVERS THERAPEUTIC AGENTS DIRECTLY TO THE KIDNEYS

FlowMedica, Inc., has developed novel, proprietary, minimally invasive intravascular systems for implementing targeted renal therapy (TRT™)—the delivery of certain medications and other therapeutic agents directly to the kidneys via the renal arteries. TRT is an alternative to systemic intravenous (IV) infusion to address kidney dysfunction resulting from cardiovascular procedures such as angiography or angioplasty, diseases such as heart failure, and conditions that may develop in connection with a medical treatment or diagnostic procedures.

Numerous medical centers throughout the United States are investigating the premise that TRT can maximize the effectiveness of medicines and other therapeutic agents that favorably affect the kidneys while minimizing serious side effects associated with IV administration. A physician-sponsored study accepted for publication in an upcoming issue of the *American Journal of Cardiology* suggests that side effects may be minimized with TRT because the kidneys excrete most of the drug that is infused directly into the renal arteries, thus limiting the amount of medication reaching the rest of the body.

Contrast-Induced Nephropathy: An Under-Recognized Consequence of Radiographic Procedures

Contrast-induced nephropathy (CIN) affects approximately 20% to 30% of high-risk patients, such as those with impaired renal function, diabetes mellitus or heart failure,

that are exposed to contrast media during diagnostic and interventional procedures. CIN is the third-highest cause of acute renal failure among hospitalized patients (1).

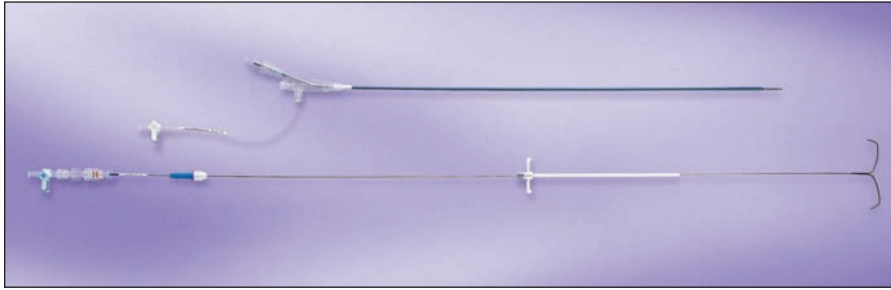
FlowMedica's **Benephit® CV Infusion System** and **Benephit® PV Infusion System** are FDA 510(k)-cleared and CE Marked, novel, proprietary, selective-infusion catheter systems that can simultaneously infuse medications and other therapeutic agents into both renal arteries using a single catheter. The **Benephit® CV Infusion System** is being used clinically as a means to deliver TRT in patients



undergoing interventional and diagnostic cardiovascular procedures. The **Benephit® PV Infusion System** provides TRT to patients undergoing interventional and diagnostic procedures to treat peripheral vascular disease or during endovascular procedures to address aortic aneurysms.

Benephit® HF Infusion System Studied in Heart Failure Patients with Cardiorenal Syndrome

FlowMedica's third platform, the **Benephit® HF Infusion System**, is being investigated in patients who may benefit from primary TRT procedures that extend beyond the catheterization laboratory, such as those with heart failure who develop cardiorenal syndrome (CS). There are no proven therapies for CS and, in the worst cases, the condition requires hemodialysis. The **Benephit HF system** features a reduced profile, increased flexibility, and a variety of lengths to allow access through sites that include the femoral,



brachial, and radial arteries, as well as greater patient mobility and ease in providing therapy once the patient leaves the interventional laboratory.

Clinical Experience with Targeted Renal Therapy

FlowMedica initiated the *Benephit* Renal Infusion Therapy (Be-RITe!) Registry to track the general commercial use of the *Benephit* Infusion Systems in a variety of clinical settings. One registry investigator, Giora Weisz, MD, an interventional cardiologist at the Center for Interventional and Vascular Therapy, Columbia University Medical Center and Cardiovascular Research Foundation, followed a subgroup of high-risk patients for 48 hours (those with diabetes and previous renal disease), and found that only 10% of patients experienced CIN.

“The estimated risk of developing CIN was reduced by 63.8%. This is very promising,” Dr. Weisz said. “From my experience with more than 30 patients in this study, this catheter is very easy to manipulate and to locate both renal arteries simultaneously. I had no

complications with this procedure and I'm very encouraged by the early results and the ease of use,” he added.

The latest results from the Be-RITe! Registry will be presented at this year's American College of Cardiology in Atlanta. Of the first 112 patients enrolled in the registry, 91% had chronic kidney disease, 48% had diabetes mellitus, and 32% had acute or chronic heart failure. A variety of agents were delivered through the *Benephit* systems. Fenoldopam was the most common agent infused (83%), followed by sodium bicarbonate (10%) and alprostadil (7%). While bilateral renal artery cannulation was accomplished in 88% of the patients overall, this rate increased to 95% in the most recent enrollees and can be attributed to device refinements and physician experience. Bilateral cannulation was accomplished in less than 2 minutes despite the investigators encountering a variety of renal artery anatomy and significant vascular disease.

In clinical settings, TRT may prove beneficial to interventional cardiologists, interventional radiologists,

and cardiovascular and vascular surgeons with interventional skills.

About FlowMedica

The company's initial solutions for TRT—the *Benephit* CV and the *Benephit* PV Infusion Systems—have received FDA 510(k) clearance for the infusion of physician-specified agents in the peripheral vasculature including, but not limited to, the renal arteries. The *Benephit* family of devices also has been cleared for use in the European Union. The company's products have not received FDA clearance to treat cardiorenal syndrome, contrast-induced nephropathy, acute renal failure, or any other condition.

For more information concerning FlowMedica's line of products, call at 1-510-252-9500; fax at 1-510-252-9515; e-mail to info@flowmedica.com; or visit the company's Web site at www.flowmedica.com.

Reference:

1. Allie DE, Weinstock BS, Teirstein P. Targeted renal therapy. *Endovascular Today* 2006; January: 38-42.

This article contains information about the Benephit Infusion Systems that has not been cleared or approved by the United States Food and Drug Administration.