Cook Medical Study of Tibiopedal Access for Crossing of Infrainguinal Artery Occlusions Exceeds 50% Enrollment

The Associated Press

BLOOMINGTON, Ind.--(BUSINESS WIRE)--Feb 5, 2013--With more than 100 patients enrolled, Cook Medical has exceeded 50 percent enrollment in the Tibiopedal Access for Crossing of Infrainguinal Artery Occlusions trial. The first-of-its-kind, prospective, multicenter study is evaluating the retrograde tibiopedal vascular access technique for treating critical limb ischemia (CLI), a manifestation of peripheral arterial disease (PAD).

According to trial's global principal investigator, Craig Walker, M.D., the founder, president and medical director of the Cardiovascular Institute of the South in Louisiana, up to 200 patients with totally occluded lower-limb arteries will be enrolled in the study. Physicians will assess the technical success rates of the new procedure both for gaining vascular access via the foot and for crossing the lesion. Patient follow-up will consist of a telephone interview approximately 30 days after the procedure.

Using the below-the-knee, retrograde tibiopedal approach, a physician gains vascular access below the knee and advances wire guides and catheters up the leg to reach and cross arterial blockages so that the blockages may be opened. Individuals 1 and single centers 1 have reported initial success with the technique, which is often tried after a traditional antegrade vascular approach from above the knee fails.

The trial is open at seven trial sites across the United States: Terrebonne Medical Center in Houma, La., First Coast Cardiovascular Institute in Jacksonville, Fla., Metro Heart and Vascular in Wyoming, Mich., and Rex Hospital, Inc. in Raleigh, N.C., Washington Hospital Center, D.C., West Virginia University, W.V., and Mount Sinai Medical Center, Miami, Fla. Patients also are being enrolled at several sites in the European Union.

CLI is a severe obstruction of the arteries that decreases blood flow to the extremities, producing pain and skin ulcers or sores. The condition, which affects up to 300,000 people a year in the U.S., 2 is the end stage of lower-extremity PAD and poses a significant risk of limb loss. Currently, 25 percent of CLI patients undergo amputation as a primary treatment. 4 Within two years of treatment, 25 percent of these patients die and another 30 percent experience additional lower-limb amputation. 3 The mortality rate at five years after amputation can be as high as 68 percent. 4 Dr. Walker is compensated by Cook Medical for educational lectures he presents to physicians on the tibiopedal access procedure. About Cook Medical A global pioneer in medical breakthroughs, Cook Medical is committed to creating effective solutions that benefit millions of patients worldwide. Today, we combine

medical devices, drugs, biologic grafts and cell therapies across more than 16,000 products serving more than 40 medical specialties. Founded in 1963 by a visionary who put patient needs and ethical business practices first, Cook is a family-owned company that has created more than 10,000 jobs worldwide. For more information, visit www.cookmedical.com. Follow Cook Medical on Twitter and LinkedIn.

1 Montero-Baker M, Schmidt A, Bräunlich S, et al. Retrograde approach for complex popliteal and tibioperoneal occlusions. J Endovasc Ther. 2008;15(5):594-604.

2 Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). Eur J Vasc Endovasc Surg. 2007;33(suppl 1):S1-S75.

3 Ibid.

4 Reiber GE, Boyko EJ, Smith DG. Lower extremity foot ulcers and amputations in diabetes. In: Harris MI, Cowie CC, Stern MP, et al., eds. Diabetes in America. 2nd ed. Washington, DC: National Institute of Diabetes and Digestive and Kidney Diseases; 1995:409-428.

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