



Statement to the  
Food and Drug Administration's  
Circulatory System Devices Panel Meeting

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By

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Good afternoon members of the panel, FDA staff and guests:

My name is Dr. Bruce Gray. I am the Director of Endovascular Services at the Greenville Hospital System, Greenville, South Carolina and the Chairman of the Peripheral Vascular Disease Committee of the Society for Cardiovascular Angiography and Interventions.

It is my privilege to represent the Society for Cardiovascular Angiography and Intervention (SCAI), a non-profit professional association representing over 4,000 invasive and interventional cardiologists. SCAI's mission is to optimize patient care, patient safety and outcomes by promoting excellence in cardiac catheterization, angiography and interventional cardiology. SCAI is committed to quality care for patients with peripheral arterial disease and has developed programs to provide education and training for its members to better understand and treat this debilitating systemic problem.

I am an interventional vascular specialist and have been involved in caring of PAD patients for 22 years. I have participated in many studies and trials over the years including the Zilver PTX trial, the results of which are before you today.

Physicians seek expanded treatment options for our patients with claudication and critical limb ischemia to improve their quality of life and to reduce limb loss. We believe that the soon-to-be published results of the Zilver PTX trial support the use of drug-eluting stents for patients with symptomatic PAD.

We want to emphasize to the Committee the significance of PAD on functional limitation, and disability. Our current standard of care endovascular treatment options are challenged by high recurrence rates that exceed our patients' expectations and needs. We need to provide better non-surgical therapies.

SCAI believes that the Zilver study was rigorous and methodologically sound. Considering the limited time available, I will try to put this technology into perspective with other randomized trial data available.

Slide 1:

Cover Slide (Slide numbers are in red at the bottom right hand sided of each page.)

Slide 2:

The goals of revascularization are to preserve life and limb, avoid morbidity and to improve function and quality of life. It is very clear that the persistent presence of claudication symptoms leads to progressive functional decline. This decline escalates mortality and carries a not insignificant risk of limb loss with continued neglect.

Slide 3:

The best predictor of mortality is evidence in the patient's performance on a 6-minute walk test. The patient is asked to simply walk for 6 minutes in the office and the distance is quantified. Those who perform poorly on the test carry the highest risk of cardiovascular events and death. This is a stronger predictor than the absolute ankle: brachial index, presence of diabetes or even CAD.

Slide 4:

Clearly the results of Zilver PTX demonstrate that stents are better than stand-alone angioplasty and that the drug-elution offers added advantage over stenting with bare metal stents.

## CONCLUSION

We believe that the new technology offered by the Zilver PTX will further enhance non-surgical endovascular care for patients limited by PAD. Our patients should have access to this new technology to improve their quality of life and outcomes. We will be grateful to offer our patients this therapy and thank you for your time and consideration.