



**Amir Malik, MD**  
*Director of Peripheral Interventions*  
Plaza Medical Center  
Fort Worth, TX

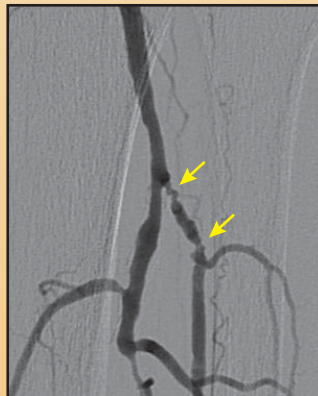
*Dr. Amir Malik is an Interventional Cardiologist who trained at SUNY– Stonybrook in Long Island, New York. He has been in private practice in Fort Worth, Texas since 1998 and is the Director of the Peripheral Interventions program at Plaza Medical Center of Fort Worth. Dr. Malik is the principal investigator on the majority of the cardiovascular research performed at Plaza Medical Center.*

#### **PATIENT HISTORY:**

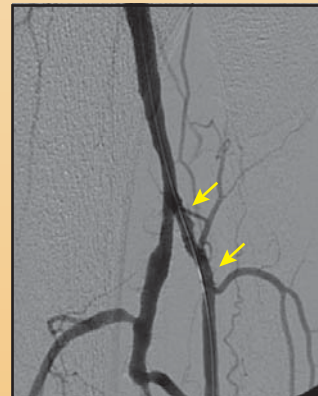
The patient is a 94 year old male with a history of bilateral non-healing leg ulcers. He underwent prior intervention to the right lower extremity two months prior to this admission. Wounds on his right leg showed signs of healing following intervention; however, the ulcer on his left heel increased in size. The patient has a focal 70% stenosis in the left popliteal artery, occlusion of the left posterior tibial and peroneal arteries, a 90% irregular stenosis in the ostium of the left anterior tibial artery, and a 90% stenosis more distally in the left anterior tibial artery (Figure 1), resulting in single vessel runoff to the left foot.

#### **PROCEDURE:**

A 6F femoral arterial sheath was placed in antegrade fashion using the modified Seldinger technique. A 2.5 x 20 mm AngioSculpt Scoring Balloon Catheter was advanced to the left anterior tibial artery over a 0.014" Choice PT Extra Support guide wire (Boston Scientific Corporation). The AngioSculpt Scoring Balloon Catheter was inflated several times in the distal and proximal portions of the anterior tibial artery to a maximum of 8 atm. The 2.5 x 20 mm AngioSculpt was then exchanged for a 3.5 x 20 mm AngioSculpt, which was used to treat the left popliteal artery and inflated to a maximum of 12 atm.



*Figure 1. Pre-procedure angiogram demonstrating 90% stenosis at the ostium of the left anterior tibial artery. Another 90% stenosis is seen more distally.*



*Figure 2. Post-procedure angiogram demonstrating a residual diameter stenosis of <20% in both treated lesions without any dissections or plaque shift into the tibio-peroneal trunk.*

#### **RESULTS:**

Following treatment with AngioSculpt, an optimal angiographic result was achieved in the popliteal and anterior tibial arteries (Figure 2). No other devices were needed to treat the lesions and there were no complications. The total fluoroscopic time was 18 minutes.

## SAFETY SUMMARY

### INDICATIONS

The AngioSculpt PTA Scoring Balloon Catheter is intended for balloon dilatation of lesions in infrapopliteal arteries. Not for use in the coronary or neuro-vasculature.

### CONTRAINDICATIONS

None known for Percutaneous Transluminal Angioplasty (PTA) procedures.

### WARNINGS

This device is intended for single (one) use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

The inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis, in order to reduce potential vessel damage.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation.

Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Balloon pressure should not exceed the rated burst pressure (RBP). Refer to product label for device specific information. The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence level) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Proceed cautiously when using the AngioSculpt catheter in a freshly deployed bare metal or drug eluting stent. The AngioSculpt catheter has not been tested for post-dilation of stents or in lesions distal to freshly deployed stents in clinical studies. Bench testing has shown no additional risk when inserting or withdrawing the AngioSculpt catheter through stents (no interference with stent struts, no retention of or damage to the AngioSculpt catheter).

Use the catheter prior to the "Use Before" (expiration) date specified on the package.

### PRECAUTIONS

A thorough understanding of the principles, clinical applications and risks associated with PTA is necessary before using this product. Any use for procedures other than those indicated in these instructions is not recommended. The device is not recommended for use in lesions which may require inflation pressures higher than those recommended for this catheter.

Do not use if package is opened or damaged.

Prior to angioplasty, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used.

During and after the procedure, appropriate anti-coagulants, anti-platelet agents and vasodilators should be administered to the patient according to institutional practice for peripheral angioplasty of similar arteries.

Only pass the AngioSculpt catheter through a  $\geq 6F$  guiding catheter or  $\geq 5F$  introducer sheath.

### POSSIBLE ADVERSE EFFECTS

Total occlusion of the treated artery, arterial dissection or perforation, arterial spasm, pseudo-aneurysm, restenosis of the dilated artery, embolism, thrombus, retained device components, hemorrhage or hematoma, arteriovenous fistula.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.



5055 Brandin Court ■ Fremont, CA 94538 ■ Customer Service 877-264-4692  
Fax 510-933-7993 ■ [orders@angioscore.com](mailto:orders@angioscore.com) ■ [www.angioscore.com](http://www.angioscore.com)