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*Dr. R. Stefan Kiesz is a highly respected Interventional Cardiologist who has personally performed over 10,000 coronary interventions and thousands of leg and renal interventions. He is the co-founder of American Heart of Poland, one of Europe's most reputable heart centers and a world-renowned research institute. Dr. Kiesz serves on the faculty for some of the most prestigious interventional meetings in the world. He continues to make significant contributions to interventional medicine.*

**PATIENT HISTORY:**

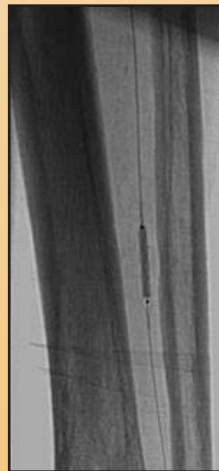
The patient is an 81 year old male with a history of severe end-stage peripheral arterial disease, coronary artery disease, chronic kidney disease, hypertension, hypercholesterolemia, and diabetes. The patient recently developed a cold lower left extremity. Angiography showed a proximally occluded left peroneal artery with reconstitution above the ankle and total occlusions of the left anterior and posterior tibial arteries.

**PROCEDURE:**

A 6F femoral arterial sheath was placed in antegrade fashion using the modified Seldinger technique. Following prolonged manipulation, a 0.014" Whisper wire (Abbott Vascular/Guidant Corporation) was successfully positioned across the total occlusion in the left peroneal artery. A 2.5 x 20 mm AngioSculpt Scoring Balloon Catheter (AngioScore, Inc., Fremont, CA) was then advanced over the wire to the left peroneal artery. Multiple overlapping inflations were performed from the ostium to the distal portion of the artery (Figures 1-3) at a maximum of 10 atm.



*Figure 1. Pre-procedure angiogram demonstrating occlusion of all three tibio-peroneal vessels (yellow arrows).*



*Figure 2. AngioSculpt Scoring Balloon Catheter (2.5 x 20 mm) inflated in the left peroneal artery.*



*Figure 3. Post-procedure angiogram demonstrating a widely patent left peroneal artery with < 10% residual stenosis (yellow arrows).*

**RESULTS:**

The post procedure angiogram demonstrated a widely patent left peroneal artery with excellent flow to the foot. The foot was noted to be warm immediately following the procedure.

## 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.



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