Santreva™ ATK

Endovascular Revascularization Catheter

Dependable Solutions for Complex Cases

RESTOR-1 Pivotal Clinical Study

Study Design

Safety and Effectiveness of the AngioSafe Peripheral CTO Crossing System

Design	Prospective, single-arm, multi-center pivotal study
Patients/Sites	74 patients / 14 clinical sites
Primary Endpoint	Clinical Success of the AngioSafe Peripheral CTO Crossing System to facilitate placement of a guidewire into the distal true lumen of a femoropopliteal artery CTO, in the absence of device-related major adverse events through discharge or 24 hours post-procedure, whichever is sooner.
Safety Endpoints	Frequency of device-related MAEs through discharge or 24 hours following the procedure, whichever is sooner. Frequency of MAEs at 30 days.
Secondary Endpoints	Technical Success of the AngioSafe Peripheral CTO Crossing System, defined as the ability of the catheter to facilitate placement of a guidewire into the distal lumen. Procedural Success of the AngioSafe Peripheral CTO Crossing System, defined as Technical Success without a procedural complication within 30 days after the procedure. – Procedural complication is defined as the need for open or repeat endovascular surgical repair in the treated limb, or a major bleeding event as defined by Bleeding Academic Research Consortium (BARC) criteria 3 - 5. Evaluation of intraluminal CTO crossing facilitated by the AngioSafe Peripheral CTO Crossing System, as assessed by IVUS. The primary endpoint in the subgroup of the degree of calcification (none/focal/mild/moderate, severe).

Introducing AngioSafe's Santreva™-ATK Endovascular Revascularization Catheter designed to enable efficient and wire-free crossing of complex CTOs. This Atheroplasty™ based platform is backed by rigorous clinical evaluation.

Baseline Characteristics

Characteristics	Results (n=74)
Male (%)	64.9
Age (years)	69.4
Current Smoke (%)	45.9
Previous Smoke (%)	36.5
Hypertension (%)	90.5
Hyperlipidemia (%)	93.2
DMII (%)	44.6
Prior MI (%)	23.0
CKD* Stage 2 adn 3 (%)	70.3

*Calculated GFR using CKD-EPI formula N Engl J Med. 2021;385:1737-1749

Target Lesion Characteristics	Results (n=74)
Chronic Total Occlusion (%)	100
Target Lesion Length (mm)	131.6
Target Lesion Diameter (mm)	5.7
Severe Calcification (%)	34.1
Moderate Calcification (%)	37.5

Consistent with the typical PAD population with significant calcification

Santreva-ATK delivers core-lab adjudicated, compelling results where it matters most

Achieved Primary Endpoint

Clinical Success	Full Analysis Set (n=74)	Per Protocol Set (n=70)
Overall	87.8%	90.0%

Clinical success separated by calcification		
None to mild calcification	90.4%	94.7%
Moderate to severe calcification	86.7%	88.2%

Safety

0
Device Related MAEs

0
Embolization

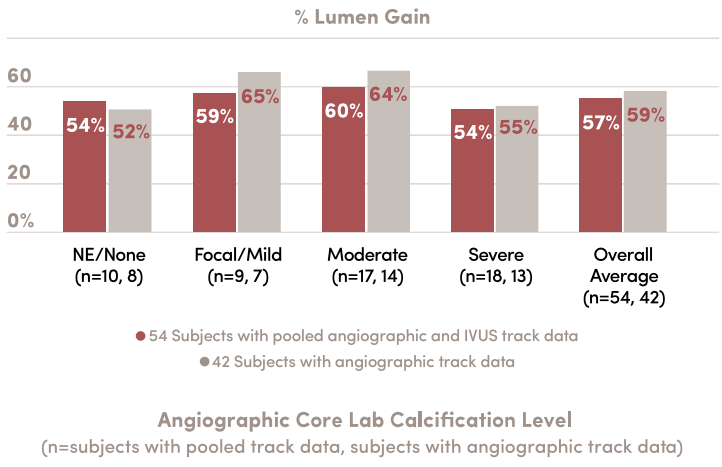
0
Major Perforations

0
Flow Limiting Dissections

0
Bailout Stenting

Breakthrough performance that goes beyond crossing

Vessel Opening Confirmed by Pooled Angiographic and IVUS Data by Calcification Severity



Angiographic Core Lab Calcification Level
(n=subjects with pooled track data, subjects with angiographic track data)

>80%
Of successful case crossings completed fully intraluminally

95%
Of successful cases were crossed antegrade only

9 min
Rapid crossing time (median) with a mean crossing time of 25 min

>55%
Lumen gain post Santreva-ATK crossing

Read the full publication here: Safety and Effectiveness of the Santreva™-ATK Endovascular Revascularization Catheter in the RESTOR-1 Peripheral CTO Crossing Pivotal Study

References

Banerjee, S. et al. Safety and effectiveness of the Santreva™-ATK Endovascular Revascularization Catheter in the RESTOR-1 Peripheral CTO Crossing Pivotal Study. American Journal of Cardiology. 2026. *online ahead of print*

Santreva™-ATK is an endovascular revascularization catheter intended to facilitate placement of a guidewire in the true lumen of peripheral vessels (e.g., femoropopliteal arteries) after crossing CTOs in patients with Peripheral Arterial Disease (PAD) and to prepare the peripheral vessel for further treatment with other interventional devices per the physician's discretion.

Refer to Instructions for Use (IFU) for complete Indications for Use, Contraindications, Warnings, Precautions, and Expected Clinical Benefits.

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