INSTRUCTIONS FOR USE

Caution: Federal law restricts this device to sale by or on the order of a physician.

e-IFU is available online at www.angiosafe.com/label.

NOTICE TO USER: In the event a serious incident has occurred in relation to the use of this device and/or a device deficiency occurs, please notify your local representative and/or manufacturer as soon as possible via email to complaints@angiosafe.com. Refer to the Return of Devices section of the IFU.

Contents
One (1) Santreva™-ATK Endovascular Revascularization Catheter, **REF: AS-1963-01**

Indications for Use
The Santreva™-ATK Endovascular Revascularization Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including Chronic Total Occlusions (CTOs), in the femoropopliteal (arterial) peripheral vasculature.

Device Description
The Santreva™-ATK Endovascular Revascularization Catheter (**Figure 1** and **Figure 2**) is intended for intraluminal peripheral CTO crossing and designed for simultaneous plaque compression and recanalization of Chronic Total Occlusions (CTOs) to prepare the vessels for further imaging and final treatment in one step. The flexural and axial properties of Santreva-ATK are designed for optimal peripheral vessel access, delivery to, and crossing of CTO disease locations to facilitate placement of a guidewire into the true vessel lumen.

Santreva-ATK consists of an outer catheter shaft, handle with integrated wheel and luer fitting for guidewire insertion, and inner torque cable tube with guidewire lumen. The distal catheter has a rotating tip with an integrated cutting loop designed to puncture, displace, and compress the plaque as the mechanism of CTO crossing in combination with a centering system component to maintain luminal position. The centering system component has three collapsible wings and in combination with the distal tip advances into the open lumen of the vasculature and within the CTO, which may facilitate formation of an intraplaque and angiographically visible channel. These collapsible centering system wings are sloped in each direction to present a tapered interface to both the CTO body plaque and to accessories such as guide catheters or guiding sheaths during advancement and retraction of the catheter.

After delivery of the Santreva-ATK distal catheter tip to the CTO lesion through support accessories and the peripheral vasculature, the operator grasps the outer catheter shaft to advance the catheter tip in the distal direction while rotating the handle wheel such that the tip and cutting loop combination punctures the entrance cap to the CTO body plaque. As the operator continues to advance the catheter shaft and rotate the handle wheel, the rotation of the tip and cutting loop combination punctures the CTO plaque with simultaneous radial displacement and compression. As the operator advances the device through the CTO body, the plaque is further compressed laterally by the centering system wings, thereby crossing and recanalizing the CTO intraluminally in a controlled manner. Once the tip and cutting loop of the catheter is advanced to and punctures the exit cap of the CTO body, the operator is now able to advance a guidewire into the distal lumen beyond the CTO lesion. The Santreva-ATK catheter is then retracted from support accessories and the peripheral vasculature. The immediate result is a lumen gain and blood flow restoration through a channel formed by Santreva-ATK, revascularizing the previously ischemic distal zone, and allowing for a guidewire to be placed through this channel into the distal true lumen for further imaging and treatment.

Santreva-ATK has a working length of 135 cm and maximum crossing profile of 7.2 Fr (2.4 mm) with the centering system expanded.

Santreva-ATK catheter shaft has a 3.4 Fr distal segment of 95 cm length and 4.8 Fr proximal segment of 40 cm length.

Santreva-ATK is compatible with 0.014 inch guidewires.

Santreva-ATK is compatible with 6 Fr (of 0.070 inch Minimum ID) or larger guide catheters, which are recommended for maximum support.

Santreva-ATK is also compatible with 5 Fr (of 0.070 inch Minimum ID) or larger guiding sheaths when not using a guide catheter.

Figure 1: Santreva™-ATK Endovascular Revascularization Catheter Components

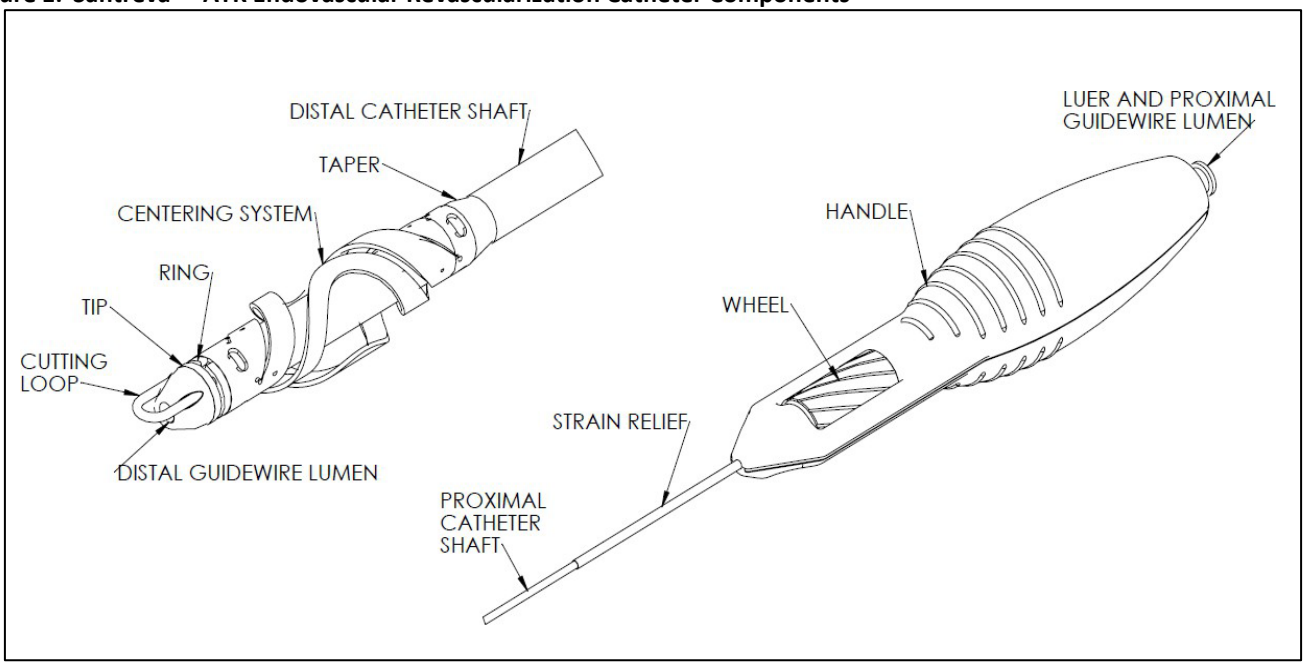
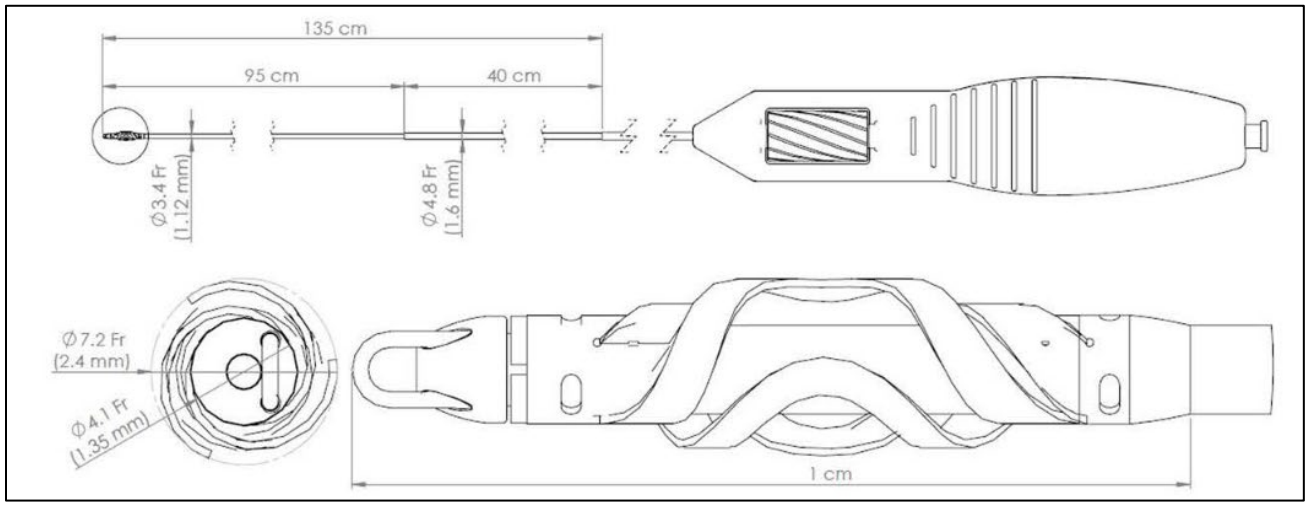


Figure 2: Santreva™-ATK Endovascular Revascularization Catheter Dimensions



Contraindications

- The device is not intended for use in the renal, mesenteric, cerebral, or coronary vasculature.
- Contraindicated for use in patients with known hypersensitivity to nickel or titanium.
- Contraindicated for use in patients who cannot tolerate anticoagulant or anti-platelet therapy.
- Contraindicated for use in patients with unresolved bleeding disorders.

Warnings

- The device should be used in peripheral vessels with target lesion reference diameter(s) of ≥ 3.0 mm and ≤ 10 mm by visual estimate.
- Do not use the Santreva-ATK catheter with hydrophilic coated guidewires.
- Do not use in a target lesion located in a bypass graft or stent (i.e., in-stent restenosis).
- Before the insertion of the device, administer appropriate anti-coagulant.
- The device is intended for single patient use only. Do not re-sterilize or reuse, as this can result in compromised device performance.
- Do not use if the package is opened or damaged.
- Do not use after the "Use By" date on the product label.
- After use, dispose of product and packaging in accordance with hospital, administrative, and/or government policy.

Precautions

- Do not use without completely reading and understanding this document.
- Santreva-ATK catheter is designed for use by physicians trained in and familiar with percutaneous interventional techniques in a fully equipped catheterization laboratory or vascular surgery suite.
- Store Santreva-ATK catheters at ambient conditions in a catheterization laboratory or storage room.
- Do not expose the Santreva-ATK catheter to organic solvents (e.g., alcohol).
- The outer box is not a sterile barrier. The pouch contained within the outer box is the sterile barrier. Only the contents of the inner pouch are sterile. The outside surface of the inner pouch is not sterile. Do not remove the contents of the pouch until immediately prior to the use of device.
- Excessive bending or kinking of the catheter may affect performance.
- Torquing the catheter excessively may cause damage to the product.
- If the catheter is believed to become kinked, unintentionally damaged, and/or structural integrity of the device is thought to be impacted, withdraw the catheter and replace with a new unit to continue with the procedure.
- If strong resistance is felt during manipulation, determine the cause of the resistance before proceeding further. If the cause cannot be determined, withdraw the catheter.
- If the device is withdrawn during the CTO crossing procedure, inspect the device tip and catheter shaft for damage prior to reinsertion into the patient.

Summary of Clinical Safety and Performance

The RESTOR-1 study titled "Safety and Effectiveness Study of the AngioSafe Santreva™-ATK Endovascular Revascularization Catheter (RESTOR-1)," was a prospective, single-arm, multi-center, pivotal clinical study designed to enroll subjects with a prior diagnosis of Peripheral Arterial Disease (PAD) and peripheral Chronic Total Occlusion (CTO) in the peripheral arteries of lower limbs.

The RESTOR-1 study enrolled a total of 179 subjects in the pre-screening portion of the study at a total of 14 investigational sites, all of which were located in the United States (U.S.). A total of 132 subjects were eligible for the Baseline Visit Screen, and of these, 91 subjects were eligible for the study procedure. A sample size of 79 subjects had post-procedure data reviewed by the Core Laboratory (Full Analysis Set, FAS); this 79-subject population was used for safety analyses (Initial FAS and Safety Set n=79). Five (5) subjects were removed from the FAS due to protocol changes resulting in a final FAS population of 74 subjects (FAS n=74) used for effectiveness analyses. Four (4) additional subjects were removed from the FAS for major protocol violations resulting in a PP analysis set of 70 subjects (PP n=70).

RESTOR-1 Study Endpoints	
Primary Effectiveness Endpoint	Clinical success, defined as the ability to facilitate placement of a guidewire into the distal true lumen of a femoropopliteal artery with CTO in the absence of device-related MAEs through discharge or 24-hours post-procedure, whichever occurred sooner.
Secondary Endpoints	1. Technical success, defined as the ability of the study device to facilitate placement of a guidewire into the distal lumen. 2. Procedural success, defined as Technical Success without a procedural complication within 30 days after the procedure. 3. Evaluation of intraluminal CTO crossing (as assessed by intravascular ultrasound, IVUS). 4. Primary endpoint in the subgroup stratified by the degree of calcification.
Safety Endpoints	1. Frequency of device-related MAEs through discharge or 24-hours following the procedure, whichever occurred sooner. 2. Frequency of MAEs through Day-30. MAEs were defined as: all-cause death, adverse events leading to unplanned amputation of the treated extremity or unplanned endovascular and/or surgical revascularization of the treated extremity, and distal embolization requiring additional treatment after crossing the lesion with the Santreva-ATK device.

Primary inclusion criteria were peripheral artery disease (PAD), with Rutherford Clinical Classification 2 – 5 ("moderate claudication" to "minor tissue loss") with a Chronic Total Occlusion (CTO) in the peripheral arteries of the lower limbs. Confirmation of stenosis was completed by angiography or Duplex ultrasound. Subjects who presented with Acute Limb Ischemia (ALI), previous major amputation above the ankle in the extremity that was to be treated were excluded from the study. Subjects were assessed at pre-treatment, treatment, and hospital discharge. Follow-up visits were scheduled for Day-30. The RESTOR-1 study utilized an independent angiographic Core Laboratory, as well as a Clinical Events Committee (CEC), to assess the outcomes data and adjudicate adverse events.

The null hypothesis was that the AngioSafe Santreva-ATK Endovascular Revascularization Catheter would perform better than 0.70 - the lower bound of the 95% Confidence Interval (CI) of the technical success rate. The primary effectiveness endpoint of this study, the clinical success of the Santreva-ATK Endovascular Revascularization Catheter, was met and was achieved in 87.8% of the study participants (65 of 74 subjects) in the FAS population, with a 0.78 lower bound of the 95% CI, with over 70% of the subjects having CTOs with moderate to severely calcified plaques. In the PP population, the success rate was 90.0% (63 of 70 subjects), with a 0.80 lower bound of the 95% CI with the same level (over 70%) of moderate to severely calcified plaques.

The secondary endpoints of technical and procedural success were achieved at the same rate as the primary endpoint of clinical success since procedural success was defined in this study as technical success without a procedural complication within 30 days after the procedure and there were no procedural complications within 30 days after any of the procedures. Clinical success of the primary endpoint was stratified by levels of calcification, which included two groups: none to mild calcification and moderate to severe calcification. Results are consistent across all levels of calcification. The success rate for none to mild calcification was 90.4%, and for the moderate to severe calcification 86.7%. Average treated CTO length was 131.6 mm, average target lesion diameter was 5.7 mm, target lesion severe calcification mean was 34.1%, median crossing time was approximately 9 minutes, and mean crossing time was approximately 25 minutes.

There were no device-related Major Adverse Events (MAEs) through discharge or 24-hours following the procedure, whichever was sooner. There was one (1) MAE within the 30 days following the procedure, which was neither procedure-related nor device-related.

Potential Complications

The use of this product carries the risks associated with peripheral vascular angioplasty, including thrombosis, vascular complications, and/or bleeding events. The risks associated with standard percutaneous transluminal angioplasty (PTA) procedures are reported in the published literature and include the following:

- Access site pain
- Allergic reaction to contrast medium, anticoagulant, antithrombotic therapy, or device materials
- Aneurysm
- Arrhythmias
- Arterial dissection
- Arterial perforation
- Arterial rupture
- Arterial spasm
- Arteriovenous fistula
- Bleeding complications
- Concomitant medication complications (drug reactions, bleeding from antiplatelet/anti-coagulation agents)
- Death
- Emboli (air, tissue, thrombus or atherosclerotic emboli)
- Emergency or non-emergency arterial bypass surgery
- Entry site complications
- Fever
- Fracture of the guidewire or any component of the device that may or may not lead to device embolism, serious injury or surgical intervention
- Hematoma
- Hemorrhage at the vascular access site
- Hemolysis
- Hypertension
- Hypotension
- Infection
- Ischemia
- Myocardial infarction
- Pseudoaneurysm
- Renal failure
- Restenosis of the treated segment
- Sepsis
- Shock/pulmonary edema
- Thrombosis
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair (conversion to open surgery)

Guidewire and Support Accessory Compatibility

- 0.014 inch / 0.36 mm Nominal OD Guidewire (Note: Do not use the Santreva-ATK catheter with hydrophilic coated guidewires)
- Minimum size of 5 Fr (0.070 inch / 1.78 mm Minimum ID) or greater Introducer or Guiding Sheath **without a Guide Catheter**
- Minimum size of 6 Fr (0.070 inch / 1.78 mm Minimum ID) or greater Guide Catheter **with 6 Fr or greater Introducer or Guiding Sheath**

  Note: Use of a 6 Fr or greater size Guide Catheter is recommended for maximum support.

Device Preparation

1. Use sterile technique to carefully remove the device from the packaging. Inspect to ensure the device exhibits no signs of damage.
2. Flush the Santreva-ATK catheter lumen with heparinized saline using the proximal luer of the handle.
3. If desired, pre-load a 0.014" guidewire into the proximal insertion luer of the handle and advance the guidewire until it is approximately 1 cm proximal to the distal tip of the Santreva-ATK catheter.

   Note: The guidewire may be backloaded into the device tip as necessary for over-the-wire technique during the procedure.
4. If desired, pre-load the Santreva-ATK catheter into the support accessory (selected sheath or guide catheter) prior to inserting into the vasculature by advancing the device tip until just proximal of the support accessory tip.

   Note: Rotate the Santreva-ATK catheter tip and centering system counterclockwise during insertion into the proximal hub of the support accessory to assist the folding and compression of the Santreva-ATK centering system.

Directions for Use

1. Prepare the insertion site using sterile technique.
2. Achieve vascular access and place an introducer or guiding sheath.
3. Inject a weight-based Unfractionated Heparin (UFH) bolus dose followed by as needed additional boluses to achieve and maintain an Activated Clotting Time (ACT) of 250-400 seconds.
4. Insert the Santreva-ATK catheter into the selected support accessory or a pre-loaded assembly of Santreva-ATK catheter/guidewire/support accessory into the selected introducer and/or guiding sheath.
5. Advance the selected support accessory tip as close as possible to the entry cap of the CTO for maximum support.
6. If not pre-loaded, insert a 0.014" / 0.36 mm guidewire into the proximal insertion luer of the Santreva-ATK handle and advance the guidewire until it is approximately 1 cm proximal of the distal tip of the Santreva-ATK catheter.
7. Advance the Santreva-ATK catheter tip out of the support accessory tip until the nitinol centering system has exited and expands.
8. With the guidewire remaining within the Santreva-ATK catheter proximal of the distal tip, advance the Santreva-ATK catheter tip to the entry cap of the CTO.
9. Advance the Santreva-ATK catheter shaft with the guidewire remaining in place with one hand to allow the distal tip to penetrate the entry cap of the CTO while simultaneously rotating the torque wheel on the handle with the other hand in either a clockwise or counterclockwise (or alternate directions) such that the cutting loop at the tip of the Santreva-ATK catheter facilitates CTO cap penetration.
10. Advance the Santreva-ATK catheter tip and centering system with the guidewire remaining in the Santreva-ATK catheter through the CTO by advancing the catheter shaft with one hand while continuing to rotate the torque wheel on the handle with the other hand in either a clockwise or counterclockwise direction (or alternate directions) until the distal tip is approximately 1 cm from the exit cap of the CTO.
11. Cautiously continue to advance the Santreva-ATK catheter and distal tip while rotating torque wheel up to the distal cap until the tip and cutting loop with the guidewire remaining in the Santreva-ATK catheter are through the exit cap.

    Note: Only the Santreva-ATK distal tip and cutting loop should cross the exit cap to minimize embolization risk.
12. Advance the 0.014" / 0.36 mm guidewire distally out of the Santreva-ATK catheter tip past the exit cap of the CTO into the distal vessel lumen.
13. While stabilizing the guidewire distal to the CTO, carefully withdraw the Santreva-ATK catheter from the CTO using over-the-wire technique, while confirming that the guidewire tip remains in the true vessel lumen beyond the CTO.
14. Retract the Santreva-ATK catheter tip and centering system into the tip of the support accessory using simultaneous axial pull and counterclockwise rotation of the Santreva-ATK catheter shaft.
15. Continue retracting the Santreva-ATK catheter from the support accessory to remove the catheter from the patient and proceed with further treatment, if required.

Return of Devices

1. If any portion of the AngioSafe Santreva-ATK catheter fails, is unintentionally damaged, and/or structural integrity of device is thought to be impacted prior to or during a procedure, immediately discontinue use of this device and notify the device manufacturer via email at complaints@angiosafe.com.
2. If any Adverse Event, including a serious injury, occurs in relation to the use of this device, notify the manufacturer via email at complaints@angiosafe.com.
3. In the event a suspected device-related death has occurred in relation to the use of this device, notify the manufacturer via email at complaints@angiosafe.com and notify FDA in accordance with your institution's procedures for reporting adverse events to the FDA.

Symbol Key

Symbol	Description	Symbol	Description
REF	Catalog number	LOT	Lot / Batch number
	Date of Manufacture		Use-by Date
	Packaging Unit	MD	Medical Device
angiosafe.com/label	Consult electronic instructions for use (IFU)		Do not use if packaging is damaged
	Caution		Non-Pyrogenic
	Keep dry		Do not re-use
	Do not resterilize		Single sterile barrier system with protective packaging outside
STERILE R	Sterilized using radiation		Manufacturer
UDI	Unique Device Identifier	Rx Only	Caution: Federal law restricts this device to sale by or on the order of a physician

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