

References: 1. Piedmont Heart Institute Hosts Chronic Total Occlusion Workshop. Piedmont Healthcare website. <http://www.piedmontphysicians.org/PHI/News/Piedmont-Heart-Institute-Hosts-Chronic-Total-Occlu-952.aspx>. Posted September 12, 2011. Accessed June 26, 2013. 2. Garratt, K. Chronic Total Occlusion of the Coronary Artery. Centers for Disease Control and Prevention, US Dept of Health and Human Services; 2006. 3. Christofferson RD, Lehmann KG, Martin GV, Every N, Caldwell JH, Kapadia SR. Effect of chronic total coronary occlusion on treatment strategy. *Am J Cardiol*. 2005;95:1088-1091. 4. Daniels D. Hybrid Strategies for Retrograde and Antegrade Lesion Crossing Based on Anatomy, the Hybrid Registry. Talk presented at the Chronic Total Occlusion and Left Main Summit; February 21-23, 2013; New York, NY. 5. Joyal D, Afilalo J, Rinfret S. Effectiveness of recanalization of chronic total occlusions: a systematic review and meta-analysis. *Am Heart J*. 2010;160(1):179-187. 6. Mehran R, Claessen BE, Godino C, et al. Long-term outcome of percutaneous coronary intervention for chronic total occlusions. *JACC Cardiovasc Interv*. 2011;4(9):952-961. 7. Total Coronary Occlusions. Cleveland Clinic website. <http://my.clevelandclinic.org/heart/disorders/cad/totalcoronaryocclusion.aspx>. Updated April 2010. Accessed June 12, 2013. 8. Brilakis ES, Grantham JA, Rinfret S, Wyman M, Burke MN, Karpaliotis D, et al. A percutaneous treatment algorithm for crossing coronary chronic total occlusions. *J Am Coll Cardiol Intv*. 2012;5(4):367-379. doi:10.1016/j.jcin.2012.02.006.

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

For CROSSBOSS and STINGRAY US prescriptive information, visit bostonscientific.com/Coronary-CTO.

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CROSSBOSS™ Catheter

Intended Use / Indications for Use: The CROSSBOSS Catheter is intended for use with a guidewire to access discrete regions of the coronary and peripheral vasculature. When used as part of the system consisting of the CROSSBOSS Catheter, STINGRAY™ Catheter, and STINGRAY Guidewire, the CROSSBOSS Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) prior to PTCA or stent intervention. **Contraindications:** • Do not use with guidewire extension systems with a coupling profile larger than 0.014 in (0.36 mm) diameter (i.e. wave pattern coupling mechanism). **Warnings:** • Only physicians thoroughly trained in interventional procedures should use the CROSSBOSS Catheter. • To reduce the potential for vessel damage, the CROSSBOSS Catheter should only be used in vessels that are ≥1 mm in diameter. • Always use the included torque device during catheter advancement and manipulation especially during device rotation. Failure to use the included torque device may result in catheter failure and may result in patient injury. **Precautions:** • In coronary applications, the CROSSBOSS Catheter should only be used in hospitals where emergency coronary bypass surgery can be immediately performed in the event of a potentially injurious or life threatening complication. • Before insertion of the CROSSBOSS Catheter, administer appropriate anticoagulant and vasodilator therapy. • The CROSSBOSS Catheter should be handled with care. Prior to use and during the procedure, inspect the packaging and catheter for bends, kinks, or other damage. Discontinue use if the catheter becomes damaged. • Do not expose to organic solvents. • The CROSSBOSS Catheter should only be manipulated under fluoroscopic observation. • Do not use a syringe smaller than 5 cc (ml) when flushing the catheter. • Do not use an inflation or power assist device when flushing the catheter. **Adverse Events:** Potential adverse events include, but are not limited to, the following: • Acute myocardial infarction • Vessel trauma requiring surgical repair or intervention • Hemorrhage or hematoma • Artery spasm • Embolism • Stroke • Neurological deficit • Drug reactions, allergic reaction to contrast media • Infection • Recurrence of angina • Chest discomfort • Bleeding from the catheter insertion point • Bruising at the catheter insertion point • Ischemia due to restenosis of the dilated segment • Ventricular failure • Dissection or thrombosis with vessel occlusion • Arterial Perforation (Surgery required) • Blood Toxicity • Toxicological response • Fever • Infection at skin puncture site • Deterioration of kidney function/kidney failure • Provocation of heart attack/stroke • Surgery to recover failed devices • Surgery to repair a failed procedure • Prolonged procedure time • Occlusion of a branch of coronary artery • Myocardial infarction with release of CK-MB into circulation • Death • When failures of PTCA occur, they are often treated using coronary artery bypass surgery. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. REVAB

STINGRAY™ Catheter

Intended Use / Indications for Use: The STINGRAY Catheter is indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions of the coronary and peripheral vasculature. When used as part of the System consisting of the CROSSBOSS™ Catheter, STINGRAY Catheter and STINGRAY Guidewire, the STINGRAY Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) prior to PTCA or stent intervention. **Contraindications:** • Not intended for use in the cerebral vasculature. **Warnings:** • Only physicians thoroughly trained in interventional procedures should use the STINGRAY Catheter. • To reduce the potential for vessel damage, the inflated balloon should only be used in vessels that are ≥2.5 mm in diameter as measured proximal and distal to the inflation site. • Balloon pressure should not exceed the rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization. • Use only the recommended balloon inflation medium. • Do not advance or retract the STINGRAY Catheter unless the balloon is fully deflated under vacuum. • Pay special attention when directing a guidewire out a side port. Never push, withdraw or torque components that meet resistance. Device kinking/breaking or vessel damage may occur. Fluoroscopy should always be used to aid device manipulation. **Precautions:** • In coronary applications, the STINGRAY Catheter should only be used in hospitals where emergency coronary bypass surgery can be immediately performed in the event of a potentially injurious or life threatening complication. • Before insertion of the catheter, administer appropriate anticoagulant and vasodilator therapy. • The STINGRAY Catheter should be handled with care. Prior to use and during the procedure, inspect the packaging and catheter for bends, kinks, or other damage. Discontinue use if the catheter becomes damaged. • Do not expose to organic solvents. • Always use wire support for advancement, manipulations, and withdrawal of the STINGRAY Catheter. • The STINGRAY Catheter should only be manipulated under fluoroscopic observation. **Adverse Events:** Potential adverse events include, but are not limited to, the following: • Acute myocardial infarction • Vessel trauma that may require further intervention or surgical repair • Hemorrhage or hematoma • Artery spasm • Embolism • Stroke • Neurological deficit • Drug reactions, allergic reaction to contrast media • Infection • Recurrence of angina • Chest discomfort • Bleeding from the catheter insertion point • Bruising at the catheter insertion point • Ischemia due to restenosis of the dilated segment • Ventricular failure • Dissection or thrombosis with vessel occlusion • Arterial Perforation (Surgery required) • Blood Toxicity • Toxicological response • Fever • Infection at skin puncture site • Deterioration of kidney function/kidney failure • Provocation of heart attack/stroke • Surgery to recover failed devices • Surgery to repair a failed procedure • Prolonged procedure time • Occlusion of a branch of coronary artery • Myocardial infarction with release of CK-MB into circulation • Death • When failures of PTCA occur, they are often treated using coronary artery bypass surgery. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. REVAB

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The Hybrid Approach to Treating CTOs



Treat Even the Most Complex Lesions Safely, with Maximum Efficiency and Success



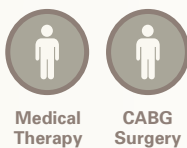
Master the Complex

HUNDREDS OF THOUSANDS Left with Untreated CTOs

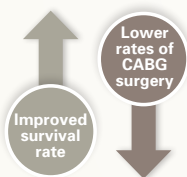
Patients with coronary Chronic Total Occlusions (CTOs) represent one of the biggest challenges in interventional cardiology today. CTOs have been described as the last great barrier to percutaneous coronary intervention (PCI) success.¹



CTOs are very common, occurring in as many as **30% of patients** with significant coronary artery disease.^{2,3} With successful CTO intervention, they typically experience immediate and dramatic symptom relief.



Patients with CTOs are most often treated with medical therapy or coronary artery bypass graft (CABG) rather than PCI. One large multi-center registry found that half the patients with CTOs were treated medically, and 25% underwent CABG.⁴



Recent meta-analyses and large registries have shown that successful CTO PCI is associated with symptom relief, a reduction in long-term mortality, and a lower need for coronary artery bypass graft (CABG) surgery.^{5,6}

While historic complication rates for CTO PCI have been similar to that of standard angioplasty (about 1%)⁷, CTO PCI has only been attempted in a small percentage of cases. In these attempted cases, the success rates have been suboptimal—usually only around 65%⁷—**UNTIL NOW.**



The HYBRID CTO PCI APPROACH

In 2011, a consensus algorithm was developed by 13 high-volume CTO operators in order to establish a framework that can be used to strategize treatment for patients considered for CTO PCI.

The Algorithm Emphasizes:

- Procedural efficiency and minimizing the amount of radiation and contrast
- Quick transition to alternate plans when failure mode occurs; always make progress—don't let the case stall

New techniques and technologies, including the CROSSBOSS™ and STINGRAY™ Coronary Crossing and Re-Entry Devices, have supported this new approach to CTO PCI.

Three Basic Techniques



High Technical Success/ Reduced Procedure Time

In 193 patients, CTO crossing success was > 90% with the hybrid approach.⁴



The hybrid approach has demonstrated lower procedure times compared to other CTO techniques.⁴

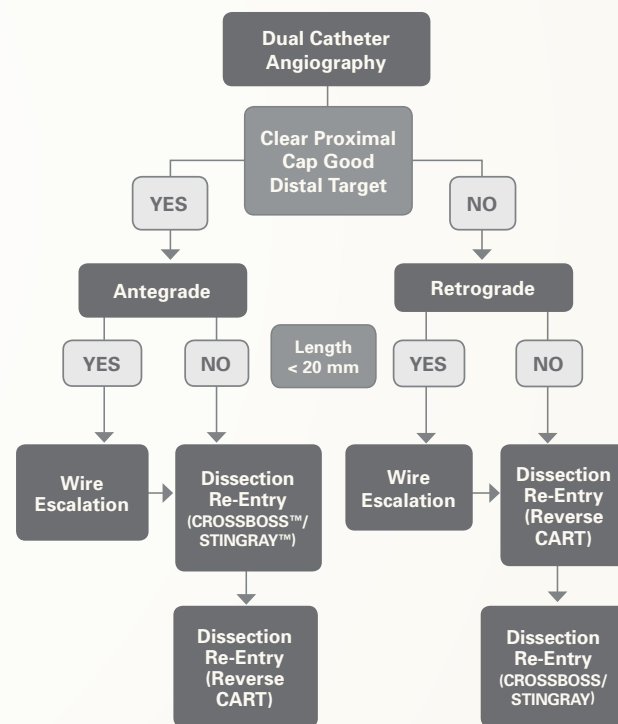


Putting It ALL TOGETHER

Four Angiographic Characteristics Dictate Strategy:

- 1 Proximal cap clear or ambiguous by angio +/- IVUS
- 2 Quality of distal target
- 3 Lesion length < or ≥ 20 mm
- 4 Suitability of “interventional” collaterals

Hybrid Algorithm for CTO PCI⁸



Visit bostonscientific.com/CTO-System to view a technology animation of the CROSSBOSS and STINGRAY Coronary CTO Crossing and Re-Entry Devices.