Hybrid Algorithm for CTO PCI[1]

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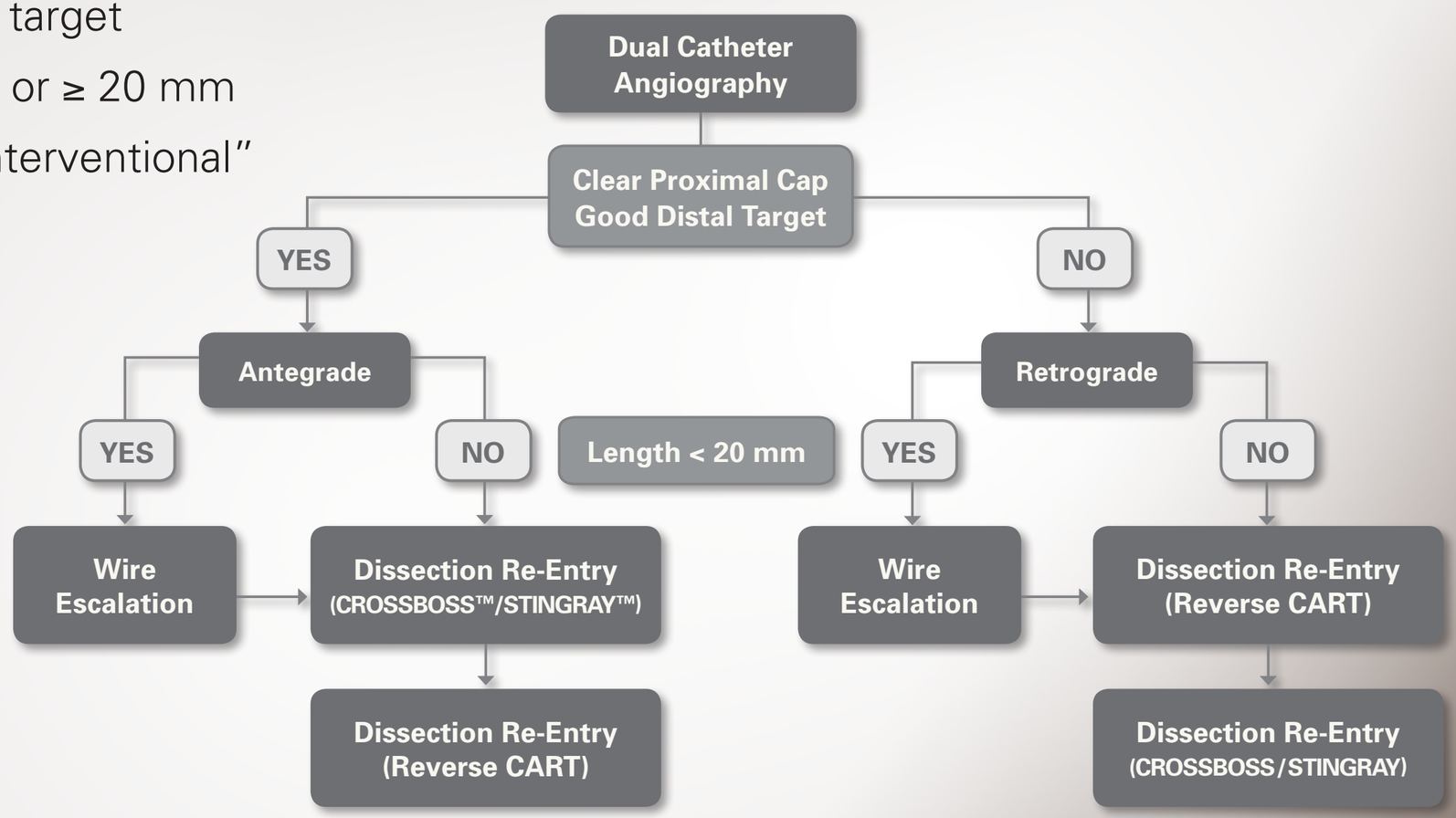
Angiographic Characteristics Dictate Strategy

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



CTO
Chronic Total Occlusion

Master the Complex

Please see reverse side for prescriptive information.

[1] Brilakis ES, Grantham JA, Rinfret S, Wyman M, Burke MN, Karmpaliotis 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.

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

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STINGRAY™ Guidewire with Hydrophilic Coating

Intended Use /Indications for Use: The STINGRAY Guidewires are intended to facilitate placement of balloon dilatation catheters or other intravascular devices during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). STINGRAY Guidewires are not to be used in cerebral blood vessels. When used as part of the system consisting of the CROSSBOSS™ Catheter, STINGRAY Catheter, and STINGRAY Guidewire, the STINGRAY Guidewire 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: None known.

Warnings: • Only physicians thoroughly trained in interventional procedures should use the STINGRAY Guidewires.

Precautions: • In coronary applications, the STINGRAY Guidewires 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 guidewire, administer appropriate anticoagulant and vasodilator therapy. • The STINGRAY Guidewires should be handled with care. Prior to use and during the procedure, inspect the packaging and guidewire for bends, kinks, or other damage. Discontinue use if the guidewire becomes damaged. • Exercise care during a procedure to reduce the possibility of accidental breakage, kinking, bending or coil separation. • Do not attempt to straighten a guidewire that has been kinked. • To reduce the potential for guidewire breakage, do not advance a kinked guidewire into a vessel or endovascular catheter. • Do not rotate the guidewire if significant resistance is felt. • The STINGRAY Guidewires 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 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 • Hematoma 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

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