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## **SASCI Position Statement on the BridgePoint CTO System**

**7 August 2014**

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A chronic total occlusion (CTO) is a complete occlusion of the coronary vessel with TIMI 0 flow, present for 3 months or longer.

Any fully occluded artery that the interventionalist can't immediately cross with a workhorse wire (patients with CTO's) are frequently left unrevascularised due to perceptions of high failure rates and technical complexity, even if they have symptoms of coronary disease or ischemia.

The mode of treatment selected for a patient with CTO is individualised on the basis of the severity of symptoms and ischemia and on the severity of concomitant coronary artery disease (CAD). Patients who remain symptomatic or have a large burden of ischemia despite maximal medical therapy can be considered for revascularisation. Choosing the better revascularisation mode, PCI or coronary artery bypass grafting (CABG) is not always simple. For patients with CTO and significant concomitant left main and /or multivessel CAD, CABG is often considered, given the complexities involved with PCI in this setting and greater likelihood of achieving complete revascularisation compared with PCI. There are, however many settings in which CABG is not an ideal option: single or double vessel disease, especially with a normal LAD, or post CABG with vein graft failure when symptoms demand recanalization of the native vessel CTO.

In recent years, through advances in specialist equipment and techniques, expert operators have significantly improved recanalization rates leading to a resurgence of interest in CTO PCI.

CTO patients that will most benefit from treatment are the following:

1. The patient is symptomatic, angina, positive stress test, shortness of breath and failure to engage in daily activities.
2. Collateral pathways exist, maintaining viability of the distal myocardium.
3. All other potential sources of symptoms have been ruled out. Multi-vessel disease has been treated.
4. The patient desires treatment, has been presented with all treatment options and consents to the procedure.

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The BridgePoint CTO Crossing System (consisting of the CrossBoSS™ Catheter, Stingray™ Orienting Balloon Catheter, and Stingray™ Guidewire) is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions) prior to Percutaneous Transluminal Coronary Angioplasty (PTCA) or stent intervention, using less contrast as well as radiation.

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. The Stingray CTO re-entry system is designed to facilitate wire passage from the sub-intimal space back into the true lumen of the distal vessel beyond the occlusion.

The CrossBoss Catheter is a single use, over-the-wire; disposable, single lumen percutaneous catheter is to be used in conjunction with a guidewire in order to access discrete regions of the coronary or peripheral vasculature. Coronary catheters and guidewires have a long history of clinical use which has established their safety and performance. The BridgePoint CTO system (CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) have evidence from a dedicated clinical trial program to support the clinical safety and performance. In addition to the multiple clinical trials conducted in various regions, and real-world usage data, further substantiates the safety of the BridgePoint CTO system:

In the FAST-CTO trial, overall CTO crossing success facilitated by BridgePoint devices was 77% significantly higher than that of previous studies. The use of the BridgePoint technologies resulted in a high success rate without increasing complications. In addition the Fast-CTO trial showed a 28% reduction in procedural time and a 17% reduction in fluoroscopy time. In 49% of the successful CTO's in this trial, the CrossBoss™ Catheter was the only step needed for successful crossing into the distal true lumen. 51% of successful CTO's used a combination of the CrossBoss™ Catheter and Stingray™ Re-entry system.

BridgePoint™ technology is funded or reimbursed globally.

Training of Physicians who have access to this technology is of utmost importance and only Interventional Cardiologists with the required experience of both Antegrade and Retrograde CTO work should have access to this technology following an extensive training programme involving guidance from International or Locally trained Proctors. Boston Scientific has formulated a strict proctoring programme for these technologies throughout the world

Based on the data reviewed and referenced, the BridgePoint CTO system is deemed capable of fulfilling the intended use and has demonstrated safety.

### **Summary:**

The BridgePoint CTO system is deemed appropriate based on the following:

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- The BridgePoint CTO system devices have similar indications to existing commercialised devices for coronary interventions.
- The safety and performance of coronary catheters and guidewires have been demonstrated over years of clinical experience as reported in the literature.
- The clinical safety and efficacy have been supported in multiple clinical trials conducted across several geographic regions and consistently reported low clinical event rates and high success rates with the BridgePoint CTO System.
- The Literature Review summary between 2008 and 2013 supports the clinical safety and performance of the BridgePoint CTO system in multiple reports. Furthermore, the summary demonstrates comparable safety and efficacy of the BridgePoint CTO System compared to existing approved CTO technologies.

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Study type	Authors	Title	Date & Publication	Abstract
HTA Assessments	Institute of Health Economics (IHE), prepared by: Ken Bond, and Liz Dennett	Stingray™ catheter and guidewire for recanalization of coronary chronic total occlusions: a rapid evidence assessment	March 2013	<p>This response addressed a request for information from Alberta Health Services on behalf of the Royal Alexandra Hospital Cardiac Catheter Lab. The objective was to summarize the available evidence on the safety, efficacy, effectiveness, and potential cost-effectiveness on the use of the BridgePoint Medical System (consisting of the CrossBoss catheter, Stingray catheter, and Stingray guidewire) for the recanalization coronary chronic tot occlusions (CTOs). The response also describes the relevant outcomes for studies of percutaneous coronary intervention (PCI) for coronary CTOs.</p> <p>The specific aim of the response was to answer the following questions:</p> <ol style="list-style-type: none"><li>1. What is the clinical safety, efficacy, effectiveness, and cost-effectiveness of the Bridge Point System for recanalization for patients with coronary CTO eligible for PCI and refractory to conventional catheter and guidewire?</li><li>2. What potential outcomes might be relevant to collect if conducting a pilot study of the BridgePoint System for recanalization of coronary CTO's?</li></ol> <p>The HTA reported that BridgePoint Medical System has the potential to reduce fluoroscopy times, the volume of the contrast medium required and overall procedure times. Prolonged fluoroscopy time is generally associated with higher complexity of treated lesions and increased rates of periprocedural complications including early mortality, emergent CABG, contrast-induced nephropathy, and increased resource utilization<sup>12</sup>. These savings will act to reduce the overall cost of the procedure because of reduced OR time and reduced staffing time. In addition, the authors found that successful CTO recanalization appeared to reduce all-cause and in-hospital mortality, need for subsequent coronary</p>

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				artery bypass graft (CABG), and residual/recurrent angina.
National or International Guidelines	The European Society of Cardiology (ESC) 2013	Guideline on myocardial revascularization	European Society of Cardiology (ESC) 2013	The Stingray Catheter system has been presented at many conferences/societies such as PCR, TCT, etc., at present no specific societies such as ACC, SCAI or ESC have come up with specific guidelines for use. The technology is similar to other unique technologies such as Rota, where it is a generally accepted therapy but none of the organizations have created specific guidelines or

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				<p>recommendations for use (Please refer to the document attached Appendix B , page 5 of the published HTA by Institute of Health Economics).</p> <p>In addition, the European Society of Cardiology (ESC) 2013 has provided a general comments for treatment indicating the following:</p> <p>Percutaneous coronary intervention (PCI) of CTOs is technically challenging and requires familiarity with advanced techniques and specialized equipment. Surgical treatment, with the implantation of a distal bypass graft, is also a valid option for discussion.</p> <p>In addition the technology had been recently presented on the ESC Congress August 2013 by Thierry Lefevre. In his discussion Lefevre touched on Dr. S. Rinfret from Quebec algorithm called the hybrid approach, using the retrograde approach when there is ambiguity of the proximal or distal cap, long lesion or bifurcation at the level of the distal cap and failure to reach the distal lumen with the antegrade approach, using the crossboss/stingray technique in about 25% of cases.</p> <p>In a nutshell, the technology is a safe and effective for subintimal dissection and re-entry approach in CTO-PCI treatment; and that "hybrid approach" is a decision-making algorithm that guides the physicians in terms of what devices and technique to be used based on a set of specific clinical criteria, refer to the document attached Appendix C, page slide 11. In the case of The Stingray Catheter system application, the lesion needs to have good proximal cap, be longer than 2 cm with good distal reentry zone.</p>
Meta-analysis	Pancholy, S. et al.	Meta-analysis of effect on mortality of percutaneous recanalization of	Feb 2013 America Journal of Cardiology. 2013 Feb	The study performed a <b>systematic review and meta-analysis</b> comparing the all-cause mortality outcomes of successful percutaneous coronary intervention (PCI) for chronic total occlusions (CTOs) with unsuccessful CTO-PCI, using a stent-based strategy. Multiple studies comparing successful CTO-PCI with unsuccessful CTO-PCI have reported variable outcomes. No systematic review or meta-analysis has been performed after stenting became the default strategy for CTO-

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	coronary chronic total occlusions using a stent-based strategy	15;111(4):521	PCI. Searching major electronic databases, 64 studies were identified using the keywords "CTO," "PCI," and "mortality." Using the Preferred Reporting Items for Systematic Reviews and Meta-analyses method, 13 studies met the criteria for inclusion in the present meta-analysis. The short-term ( $\leq 30$ days) and long-term ( $\geq 1$ year) mortality outcomes were analyzed comparing successful CTO-PCI and unsuccessful CTO-PCI. Coronary perforation and its association with CTO-PCI success was analyzed. A significant reduction in short-term mortality was noted with successful CTO-PCI compared to unsuccessful CTO-PCI (odds ratio 0.218, 95% confidence interval 0.095 to 0.498, $Z = -3.61$ , $p < 0.001$ ). A similar, significant reduction in long-term mortality was noted with successful CTO-PCI compared to unsuccessful CTO-PCI (odds ratio 0.391, 95% confidence interval 0.311 to 0.493, $Z = -7.957$ , $p < 0.001$ ). A significant association was present between coronary perforation and unsuccessful CTO-PCI (odds ratio 0.168, 95% confidence interval 0.104 to 0.271, $Z = -7.333$ , $p < 0.001$ ). In conclusion, successful CTO-PCI using a predominantly stent-based strategy is associated with a significant reduction in short- and long-term mortality compared to unsuccessful CTO-PCI. Coronary perforation was associated with CTO-PCI failure.
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Randomised controlled trials	Witlow, PL 2012, FAST –CTO trial, US	Use of a Novel Crossing and Re-Entry System in Coronary Chronic Total Occlusions That Have Failed Standard Crossing Techniques	Journal of American College of Cardiology. Vol 5, No 4 2012	<p><b>Objectives</b> This study sought to examine the efficacy and safety of 3 novel devices to recanalize coronary chronic total occlusions (CTOs).</p> <p><b>Background</b> Successful percutaneous coronary intervention (PCI) of CTOs improves clinical outcome in appropriately selected patients. CTO PCI success, however, remains suboptimal.</p> <p><b>Methods</b> A new crossing catheter and re-entry system was evaluated in a prospective, multicenter, single-arm trial of CTO lesions refractory to standard PCI techniques. The primary endpoint was the frequency of true lumen guidewire placement distal to the CTO efficacy (technical success).</p> <p><b>Results</b> Enrollment included 147 patients with 150 CTOs. The mean lesion length was <math>41 \pm 17</math> mm. A crossing catheter crossed 56 lesions into the distal true lumen, and a re-entry catheter facilitated tapered-wire cannulation of the distal lumen in 59 CTOs initially crossed subintimally (77% technical success). Success in the first 75 CTOs was 67%, rising to 87% in the last 75 CTOs. Mean fluoroscopy and procedure times were <math>45 \pm 16</math> min and <math>90 \pm 12</math> min, respectively, each significantly shorter than in historical controls (<math>p &lt; 0.0001</math> for both). Coronary perforation occurred in 14 cases (9.3%), requiring treatment in 3 cases (prolonged balloon inflation, with additional coil embolization in 1 case). No tamponade or hemodynamic instability occurred. Six patients had periprocedural non-ST-segment elevation myocardial infarction. No emergency surgery, ST-segment elevation myocardial infarction, or cardiac reintervention occurred. Two deaths occurred within 30 days, neither as a direct result of the procedure. The 30-day major adverse cardiac event rate was 4.8%.</p> <p><b>Conclusions</b> In CTOs failing standard techniques use of a new crossing and re-entry system results in a high success rate without increasing complications. (J Am Coll Cardiol Intv 2012;5:393-401) 2012 by the American College of Cardiology Foundation.</p>
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Systematic review	Polisenet al. Systematic Review	Post-marketing surveillance in the published medical and grey literature for percutaneous transluminal coronary angioplasty catheters; as systematic review.	American Journal of Cardiology. Vol 5, No 4 2012	<p><b>Background:</b> Post-marketing surveillance (PMS) may identify rare serious incidents of adverse events due to the long-term use of medical device, which was not captured in the pre-market process. Percutaneous transluminal coronary angioplasty (PTCA) is a non-surgical procedure that uses a balloon-tipped catheter to enlarge a narrowed artery. In 2011, 1,942 adverse event reports related to the use of PTCA catheters were submitted to the FDA by the manufacturers, an increase from the 883 reported in 2008. The primary research objective is to conduct a systematic review of the published and grey literature published between 2007 and 2012 for the frequency of incidents, adverse events and malfunctions associated with the use of PTCA catheters in patients with coronary artery disease (CAD). Grey literature has not been commercially published.</p> <p><b>Methods:</b> We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials and PubMed for medical literature on PMS for PTCA catheters in patients with CAD published between January 2007 and July 2012. We also searched the grey literature.</p> <p><b>Results:</b> This review included 11 studies. The in-hospital adverse events reported were individual cases of myocardial infarction and hematoma. In studies of patients with coronary perforation, more patients with balloon angioplasty were identified compared with patients who required stenting.</p> <p><b>Conclusions:</b> Our systematic review illustrates that the volume and quality of PMS studies associated with the use of PTCA catheters in patients with CAD are low in the published and grey literature, and may not be useful sources of information for decisions on safety. In most studies, the objectives were not to monitor the long-term safety of the use of PTCA catheters in clinical</p>
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				<p>practice. Future studies can explore the strengths and limitations of PMS databases administered by regulatory authorit<b>Keywords:</b> Post-marketing surveillance, Medical device, Incident, Adverse event, Malfunction</p> <p>Coronary chronic total occlusions (CTOs) are frequently identified during coronary angiography and remain the most challenging lesion group to treat. Patients with CTOs are frequently left unrevascularized due to perceptions of high failure rates and technical complexity even if they have symptoms of coronary disease or ischemia. In this review, the authors describe a North American contemporary approach for percutaneous coronary interventions for CTO. Two guide catheters are placed to facilitate seamless transition between antegrade wire-based, antegrade dissection re-entry-based, and retrograde (wire or dissection re-entry) techniques, the "hybrid" interventional strategy. After dual coronary injection is performed, 4 angiographic parameters are assessed:</p> <ol style="list-style-type: none"><li>1) Clear understanding of location of the proximal cap using angiography or intravascular ultrasonography;</li><li>2) lesion length;</li><li>3) presence of branches, as well as size and quality the of the target vessel at the distal cap; and</li><li>4) Suitability of collaterals for retrograde techniques.</li></ol> <p>On the basis of these 4 characteristics, an initial strategy and rank order hierarchy for technical approaches is established. Radiation exposure, contrast utilization, and procedure time are</p>
Brilakis et al. 2012	A percutaneous Treatment Algorithm for Crossing CTO	April 2012:367-79, Journal of American College of Cardiology		

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				monitored throughout the procedure, and thresholds are established for intraprocedural strategy conversion to maximize safety, efficiency, and effectiveness. (J Am Coll Cardiol Intv 2012;5:367-79) 2012 by the American College of Cardiology Foundation
Reviews by independent registries / professional societies	Tsuchikane E. et.al 2012	New re-entry device for revascularization of chronic coronary total occlusions: preliminary single Japanese center experience.	The Journal of invasive cardiology 24:8 2012 Aug pg 396-4	<p><b>BACKGROUND:</b> Although retrograde approach for coronary chronic total occlusion (CTO) has been introduced, the procedure is still time and resource consuming. A simplified antegrade approach might be another resort. The aim of this study was to evaluate a new device designed to facilitate guidewire re-entry into the true lumen of a CTO from the adjacent subintimal space.</p> <p><b>METHODS:</b> Patients with CTO were entered into a prospective registry regardless of lesion characteristics. A new metal-tip catheter was used initially in primary use cases. If it created subintimal tracking, a new re-entry tool (a flat balloon with 2 exit ports offset by 180 degrees) was used as a platform to attempt guidewire penetration into the distal true lumen. In rescue use cases after unsuccessful conventional wiring, the re-entry procedure was subsequently attempted.</p> <p><b>RESULTS:</b> In 11 CTO lesions attempted, device success was achieved in 8 cases (72.7%). Re-entry procedure success rate was higher in primary use cases (80%) compared to rescue use cases (33.3%). Retrograde approach was conducted immediately after unsuccessful antegrade procedure using this device in the other 3 cases and successful recanalization was achieved in all cases. All lesions were stented, resulting in TIMI 3 flow without major complications.</p>

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Syrseloudis et.al	Increase in J-CTO lesion complexity score explains the disparity between recanalisation success and evolution of chronic total occlusion (CTO) strategies: insights from a single-centre 10-year experience	May 20, 2014 - Published by group.bmj.com	Objective To investigate whether treatment of lesions of greater complexity is now undertaken and to assess the rates of procedural success per class of lesion complexity. Design Observational study. Setting Despite impressive progress in treatment strategies and equipment, the success rate of percutaneous coronary intervention for chronic total occlusion (CTO) has remained relatively stable. Participants 483 patients consecutively treated with CTO from 2003 to 2012. Main outcome measures The Multicentre CTO Registry of Japan (J-CTO) score was used to classify lesion complexity. The study population was subdivided into an early (period 1, n=288) and a late (period 2, n=195) period according to the routine implementation of novel techniques and advanced equipment. Results Period 2 was marked by more 'difficult' and 'very difficult' lesions (J-CTO grades 2 and 3) being attempted, with procedural success increasing from 68.4% to 88.1% ( p<0.001) and from 42.0% to 78.9% (p<0.001), respectively. 'Easy' and 'intermediate' lesions ( J-CTO grades 0 and 1) were less common, but with similarly high success rates (89.1% vs 96.6% (p=0.45) for easy, and 86.3% vs 86.1% (p=0.99) for intermediate). Period 2 was characterised by a trend for more successful procedures overall (by 6.1%, p=0.09). Procedural complications were similarly low in both periods. J-CTO score and technical era were identified as independent correlates of success in	

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				<p>the total population by logistic regression analysis.</p> <p>Conclusions Advanced CTO techniques and equipment have resulted in an increase in the successful treatment of highly complex lesions. Total success rate did not substantially improve, as it was counterbalanced by the increased rate at which complex lesions were attempted.</p>
Cohort studies	Werner et.al.2011 Germany	Multicentre experience with the BridgePoint devices to facilitate recanalisation of chronic total coronary occlusions through controlled subintimal re-entry	Eurointervention 2011;7(2):192-200	<p>Prospective non randomized study:</p> <p><b>Aims:</b> The major challenge for the interventional treatment of chronic total coronary occlusion (CTO) is a low primary success rate. A common problem is the passage of the recanalisation wire into a subintimal position. New devices, which were evaluated in the first multicentre study in CTOs resistant to a conventional wire approach, may help to facilitate a controlled re-entry into the true lumen. The aim of this study was to assess the safety and efficiency of this approach, with successful true lumen distal wire passage as the primary endpoint.</p> <p><b>Methods and results:</b> Forty-two patients were enrolled in four centres with high expertise in PCI for CTOs. All CTOs were of at least three months duration, and were initially attempted with dedicated recanalisation wires. After failure to pass or creation of a subintimal dissection, the BridgePoint devices were applied, consisting of a ball-tipped catheter (CrossBoss) to pass the proximal occlusion cap, and a flat-shaped balloon catheter (Stingray catheter) to be inflated within the subintimal space to guide the re-entry into the true vessel lumen with a special wire (Stingray guidewire). The primary endpoint was met in 67% of all patients. A higher success rate seemed to be possible when all devices were used in sequenced beginning with the CrossBoss, and in the case of a subintimal passage, followed by the Stingray. True lumen re-entry failed because of the</p>

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