CrossBoss Catheter

Device Description
The CrossBoss Catheter facilitates the placement and support of a guidewire into discrete regions of the coronary vasculature through its central guidewire lumen. The CrossBoss Catheter contains a rounded distal tip (1 mm diameter) mounted to a flexible and torquable proximal shaft. The CrossBoss Catheter is packaged with a dedicated torque device positioned at its proximal end. The distal end of the catheter is hydrophilic coated. The CrossBoss Catheter is compatible with RF guide catheters with minimum inner diameter of 0.010 in (0.31 mm), and may be used with guidewires ≥0.014 in (0.36 mm). All components of the CrossBoss Catheter are provided sterile and non-pyrogenic. For dimensional information refer to label.

Intended Use/Indications for Use
The CrossBoss Catheter is intended for use with a guidewire to access discrete regions of the coronary vasculature. When used as part of the system consisting of the CrossBoss Catheter, Stingray™ LP 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. A total of 147 patients were treated with the CrossBoss Catheter. Observed serious adverse event rates associated with the procedure are detailed in the following table.

Adverse Events
- 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 (0.05 ml) when flushing the catheter.
- Do not use an inflation or power assist device when flushing the catheter.

Warnings
- CONTENTS
- Quantity
- Material

Adverse Events
- Potential adverse effects include, but are not limited to, the following:
  - Acute myocardial infarction
  - Arterial Perforation (Surgery required)
  - Arterial spasm
  - Bleeding from the catheter insertion point
  - Blood Toxicity
  - Bruising at the catheter insertion point
  - Chest discomfort
  - Death
  - Deterioration of kidney function/kidney failure
  - Dissection or thrombosis with vessel occlusion
  - Drug reactions, allergic reaction to contrast media
  - Embolism
  - Fever
  - Hemorrhage at catheter insertion point
  - Hemoptysis or hematochezia
  - Infection
  - Infection at skin puncture site
  - Ischemia due to restenosis of the dilated segment
  - Myocardial infarction with release of CK-MB into circulation
  - Neurological defect
  - Occlusion of a branch of coronary artery
  - Prolonged procedure time
  - Provocation of heart attack/stroke
  - Recurrence of angina
  - Stroke
  - Surgery to recover failed devices
  - Surgery to repair a failed device
  - Tocolonic response
  - Vascular failure
  - Vessel trauma requiring surgical repair or intervention
  - When failures of PTCA occur, they are often treated using coronary artery bypass surgery

Clinical Studies
The CrossBoss Catheter has been evaluated in the Facilitated Antegrade Steining Technique in Chronic Total Occlusions (FAST-CTOs) Clinical Study. The study was a prospective, non-randomized, multi-center study in which a total of 147 patients were treated. The CrossBoss Catheter was utilized in 140 patients. Treatment of a patient with the system comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire allowed for the use of any combination of the devices in order to facilitate placement of an intraluminal guidewire into the true vessel lumen distal to the CTO. Typically the CrossBoss Catheter was used to cross the CTO and when needed, the Stingray Catheter and Stingray Guidewire were used to reenter from the subintimal space.

Exclusion Criteria
Candidates for this study must have met all of the following criteria:
- be a suitable candidate for non-emergent, coronary angioplasty
- have a documented de novo or restenotic coronary CTO lesion with the following characteristics:
  - i. distal vessel of at least 1.5 mm in diameter by visual evaluation
  - ii. at least 10 mm of visible distal vessel proximal to any major branch
  - iii. at least 15 mm of visible distal vessel proximal to any major branch by visual evaluation (i.e., potential true lumen re-entry zone in major vessel proximal to the branch)
  - have angiography or ischemia caused by the occluded artery
  - age of at least 18 years
  - have a Body Mass Index (BMI) ≤40 (weight in kg divided by height in m²)

Table 1 - Serious Adverse Events

<table>
<thead>
<tr>
<th>Adverse Effect</th>
<th>Reported Occurrence</th>
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<tbody>
<tr>
<td>Death</td>
<td>2/147 (1.4%)</td>
</tr>
<tr>
<td>D-Wave MI</td>
<td>0/147 (0.0%)</td>
</tr>
<tr>
<td>NOVMI</td>
<td>6/147 (4.1%)</td>
</tr>
<tr>
<td>Emergency CABG</td>
<td>0/147 (0.0%)</td>
</tr>
<tr>
<td>Target Lesion Recanalization</td>
<td>0/147 (0.0%)</td>
</tr>
<tr>
<td>CVA/Stroke</td>
<td>1/147 (0.7%)</td>
</tr>
<tr>
<td>Perforation</td>
<td>10/147 (6.8%)</td>
</tr>
<tr>
<td>Cardiac Tamponade</td>
<td>0/147 (0.0%)</td>
</tr>
<tr>
<td>Percutaneous Effusion</td>
<td>3/147 (2.0%)</td>
</tr>
<tr>
<td>Arrhythmia Requiring Treatment</td>
<td>5/147 (3.4%)</td>
</tr>
</tbody>
</table>
### Methods

Patients who met all inclusion criteria and did not meet any exclusion criteria were eligible for inclusion in the FAST-CTOs Study. Once the patients' CTO was demonstrated to be refractory to conventional guidewire crossing, the system (comprised of the CrossBoss™ Catheter, Stingray™ Catheter, and Stingray GuideWire) was used to cross the CTO and/or re-enter from the subintimal space. Upon successful crossing of the CTO and/or re-entry, definitive treatment (typical placement of stents) was performed at the discretion of the investigator. Post-procedure care was according to institutional standard practice with the following additional requirements: a minimum of 3 serial blood draws to test for cardiac enzyme elevations and/or re-enter from the subintimal space. Patients were required to have an office visit follow-up at 30-120 days post-procedure.

### Results

A total of 149 CTOs were treated in 147 patients. The following table outlines the baseline demographics observed in the FAST-CTOs Study.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Result</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td>63±9</td>
</tr>
<tr>
<td>Gender (% Male)</td>
<td>86±12</td>
</tr>
<tr>
<td>Diabetes mellitus (% Type I or II)</td>
<td>36±57</td>
</tr>
<tr>
<td>Hyperlipidemia (moderate/severe)</td>
<td>62±88</td>
</tr>
<tr>
<td>Hypertension (moderate/severe)</td>
<td>52±71</td>
</tr>
<tr>
<td>Family history of CAD</td>
<td>37±52</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>19±28</td>
</tr>
<tr>
<td>Prior myocardial infarction</td>
<td>39±58</td>
</tr>
<tr>
<td>Angina pectoris</td>
<td>88±12</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>22±33</td>
</tr>
<tr>
<td>Prior attempt to re-canalize CTO</td>
<td>46±37</td>
</tr>
</tbody>
</table>

The overall technical success for the study was 77% (115/149). This has met the performance goal of 74%. The following table summarizes the technical success by re-canalization category:

<table>
<thead>
<tr>
<th>Endpoint by CTO</th>
<th>Overall (n=150)</th>
<th>Failed Prior Procedural Attempt (n=9)</th>
<th>10-15 Min. of Flouroscopy (n=95)</th>
<th>Subintimal GuideWire (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>77% (115/150)</td>
<td>72% (6/9)</td>
<td>72% (69/95)</td>
<td>73% (28/38)</td>
</tr>
<tr>
<td>89% (34/38)</td>
<td>89% (34/38)</td>
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</table>

The 30-day MACE rates were calculated for subjects who had follow-up visits within the pre-defined window of 4-7 days (Close completion), and for subjects who had a follow-up visit on or after 30 days or had MACE event before 30 days (complete). The following tables identify the 30 day MACE rate estimators calculated after pooling data over centers. The 90% confidence interval upper bound was calculated after adjusting for center as random effects.

#### Conclusions

The FAST-CTOs Study has demonstrated that the CrossBoss Catheter utilized as a component of the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray GuideWire) is safe and effective in the treatment of patients with stenotic coronary lesions (including CTOs) prior to PTCA or stent intervention.

### OPERATIONAL INSTRUCTIONS

**Supplies**

The following supplies are not provided with the device and need to be available to prepare and proceed prior to the use of the CrossBoss Catheter:

- Catheter guidewire
- Angiographic imaging supplies (i.e. radiopaque contrast, manifold, tubing, etc.)
- Sterile heparinized saline
- GuideWire
- Other supplies as needed to complete the established laboratory protocol

**Product Preparation**

1. Remove the CrossBoss Catheter from the sterile packaging.
2. Flush the guidewire lumen with saline.
3. Ensure all device surfaces are exposed to heparinized and sterile saline.
4. Gently tighten the black knob of the CrossBoss Catheter torque device onto the proximal shaft in a position near the proximal heel.

**Product Operation**

- Access the vascular system and place the appropriate size introducer sheath per manufacturer's instructions.

**Usage**

- Engage the vena cava to be treated with an appropriate guidewire catheter per manufacturer's instructions. Connect a hemostatic Y-adapter to the guiding catheter hub.
- Assure the CrossBoss Catheter has been prepped per instructions.
- Remove the appropriate guidewire from its package and inspect for damage.
- Advance the guidewire to the target location using fluoroscopic guidance.
- Back-load the CrossBoss Catheter onto the proximal portion of the guidewire.

7. Loosen the knob on the hemostatic Y-adapter.
8. Track the CrossBoss Catheter over the wire and into the proximal guiding catheter lumen.
9. Tighten the hemostatic Y-adapter to create a seal around the CrossBoss Catheter, do not overtighten.
10. Advance the CrossBoss Catheter over the guiding wire using fluoroscopic guidance.

**Scenario 1 – CrossBoss Catheter**

- **Access** – atop the coronary artery and place the appropriate size introducer sheath per manufacturer’s instructions.
- **Engage** – the coronary vessel with the CTO and an appropriate guiding catheter per manufacturer’s instructions. Connect a hemostatic Y-adapter to the guiding catheter hub.
- **Tighten** – the hemostatic Y-adapter to the guiding catheter hub.
- **Position** – the guiding wire over the CTO in case the CrossBoss Catheter tip exits the guiding catheter.
- **Loosen** – the knob on the hemostatic Y-adapter.
- **Retract** – the guiding wire distal to the CTO.
- **Advance** – the device to the proximal guiding catheter lumen.
- **Advance** – the device over the wire to the target location.
- **Adjust** – the device encounters significant tortuous resistance, the device is designed to slip while emitting an audible and tactile “click.” Upon torque device slip in one direction, reverse the direction of rotation and continue advancement. Continue clockwise and counterclockwise rotations as needed to advance to the target location.
- **Advance** – the CrossBoss Catheter can also be withdrawn slightly and re-advanced in the event of torque device slip.
- **Advance** – the CrossBoss Catheter over the acute angle and discard. Catheter rotation may also be advantageous during withdrawal.
- **Advance** – complete the use of the device with caution according to hospital standards and national legal requirements.

**PRODUCT OPERATION TO TREAT STENOTIC CORONARY LESIONS (INCLUDING CTOs)**

The general scenario exists where the CrossBoss Catheter, Stingray™ LP Catheter, and Stingray GuideWire could be used in the treatment of stenotic coronary lesions. The first scenario involves the CrossBoss Catheter crossing the CTO lumen. The second scenario occurs when the initial guidewire used is advanced distal of the CTO but remains in the subintimal space. The Stingray™ LP Catheter and Stingray GuideWire are used to re-enter the vessel true lumen. The third scenario occurs when the CrossBoss Catheter crosses the CTO lesion, but remains in the subintimal space. The Stingray™ LP Catheter and Stingray GuideWire are then used to re-enter the vessel true lumen.
3. Assure the Stingray™ LP Catheter and Stingray Guidewire have been prepped per instructions.

4. Remove the appropriate guidewire (physician’s choice) from its package and inspect for damage.

5. Advance the guidewire across the CTO using fluoroscopic guidance. In this scenario the guidewire remains in the subintimal space.

6. Back-load the Stingray LP Catheter onto the proximal portion of the guidewire.

7. Loosen the knob on the hemostatic Y-adapter.

8. Track the Stingray LP Catheter over the wire and into the proximal guiding catheter lumen.

9. Tighten the hemostatic Y-adapter to create a seal around the Stingray LP Catheter. Do not over-tighten.

10. Advance the Stingray LP Catheter over the guidewire using fluoroscopic guidance. Position the Stingray LP Catheter ports (using the radiopaque markers) at the target location distal of the CTO.

11. Exchange the guidewire for a Stingray Guidewire.

12. Connect the balloon inflation device to the 3-way stopcock and purge the stopcock with contrast medium mixture.

13. Inflate the balloon to 3-4 atm (304-405 kPa) and confirm inflation via fluoroscopy.

14. Adjust the fluoroscopic view until the balloon is shown at its minimum width and the coronary vessel true lumen direction can be identified.

15. Steer the Stingray Guidewire through the port facing the true lumen by slowly rotating the guidewire immediately proximal of the marker band until the Stingray Guidewire begins to exit the port.


17. If the Stingray Guidewire position or direction is incorrect, target the other side port by steering the Stingray Guidewire through the desired port by slowly rotating the Stingray Guidewire immediately proximal of the marker band until the Stingray Guidewire begins to exit the port.

18. Advance the Stingray Guidewire through the port to penetrate the intimal tissue for access to the vessel true lumen distal of the CTO.

19. Use fluoroscopic images to confirm that the Stingray Guidewire is in the true lumen distal of the CTO.

20. If a 185 cm Stingray Guidewire was used an extension wire can be attached prior to catheter exchange. Insert the guide pin on the proximal end of the 185 cm Stingray Guidewire into the distal end of the extension wire. Once the guide pin is inserted, rotate the extension wire in a clockwise direction (with respect to the Stingray Guidewire) until the two guidewires are pulled together securely.

21. Check for secure attachment by pulling firmly on both guidewires.

22. Deflate the balloon and withdraw the Stingray LP Catheter leaving the Stingray Guidewire in place.

23. Advance a balloon catheter or microcatheter over the Stingray Guidewire and exchange for a guidewire of the physician’s choice.

Scenario 3 — CrossBoss™ Catheter, Stingray LP Catheter and Stingray Guidewire

1. Follow instructions from scenario 1 in steps 1-14.

2. Once the CrossBoss Catheter has been successfully delivered to the target location distal of the CTO, advance an appropriate guidewire through the central guidewire lumen of the CrossBoss Catheter and use fluoroscopic images to confirm that the CrossBoss Catheter is in the subintimal space distal of the CTO.

3. Withdraw the CrossBoss Catheter over the guidewire. Catheter rotation may also be advantageous during withdrawal.

4. Follow instructions from scenario 2 in steps 6-23.

WARRANTY

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