Stingray Catheter

**CONTRAINDICATIONS**

- Stenotic coronary lesions (including chronic total occlusions (CTOs)) prior to PTCA or stent intervention.

**PRECAUTIONS**

- Use prior to the Expiration Date.
- 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 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 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
  - Tocolytic response
  - Fever
  - Infection at skin puncture site
  - Deterioration of kidney function/kidney failure

**WARNINGS**

- Only physicians thoroughly trained in interventional procedures who have had prior experience with the Stingray Catheter 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 may meet resistance. Device kinking/breaking or vessel damage may occur. Fluoroscopy should always be used to aid device manipulation.

**Device Description**

The Stingray Catheter facilitates the placement, support and steering of a guidewire into discrete regions of the coronary and peripheral vasculature through the central guidewire lumen or through one of two side-ports. These side-ports are on opposite sides of the balloon and are identified by radiopaque markers. The side-ports communicate with the central guidewire lumen and facilitate guidewire steering (at an angle to the central lumen) by allowing the guidewire to exit the Stingray Catheter. The Stingray Catheter contains a small balloon used for fluoroscopic orientation on the distal tip of the catheter. The distal end of the catheter is hydrophilic coated. The Stingray Catheter is compatible with 0F guide catheters with minimum inner diameter of 0.070 in (1.7 mm), and may be used with guidewires ≤0.014 in (0.36 mm). All components of the Stingray Catheter are provided sterile and non-pyrogenic. For dimensional information refer to label.

**Contents**

- Quantity: 1
- 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

**HOW SUPPLIED**

- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

**CLINICAL STUDIES**

BridgePoint Medical FAST-CTOs Clinical Trial Observed Adverse Events

The Stingray Catheter has been evaluated in the Facilitated Antegrade Steering Technique in Chronic Total Occlusions (FAST-CTOs) Clinical Study for use in the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including CTOs) prior to PTCA or stent intervention. A total of 147 patients were treated in the study with 76 receiving treatment with the Stingray Catheter. Observed serious adverse event rates associated with the procedure are detailed in the following table.

<table>
<thead>
<tr>
<th>Table 1 – Serious Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Effect</td>
</tr>
<tr>
<td>Death</td>
</tr>
<tr>
<td>D-Wave MI</td>
</tr>
<tr>
<td>NDWMI</td>
</tr>
<tr>
<td>Emergency CABG</td>
</tr>
<tr>
<td>Target Lesion Revascularization</td>
</tr>
<tr>
<td>EVA/Stroke</td>
</tr>
<tr>
<td>Perforation</td>
</tr>
<tr>
<td>Cardiac Tamponade</td>
</tr>
<tr>
<td>Pericardial Effusion</td>
</tr>
<tr>
<td>Arrhythmia Requiring Treatment</td>
</tr>
</tbody>
</table>

**Clinical Study**

The clinical evaluation of the system comprised of the CrossBoss™ Catheter, Stingray Catheter, and Stingray Guidewire in the treatment of patients with stenotic coronary lesions (including CTOs) was performed through the FAST-CTOs Clinical Study. The study was a prospective, non-randomized, multi-center study in which a total of 147 patients were treated. The Stingray Catheter was utilized in 76 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 re-enter from the subintimal space.

The primary objectives of the study were to compare the collected data to an established historical control in both the safety 30-day major adverse cardiac events or MACE comprised of death, myocardial infarction, target lesion stenosis or bypass surgery.
revascularization, and emergent CABG) and the technical success of the System in CTOs demonstrated to be refractory to conventional guidewire crossing. Secondary endpoints of the study were procedure time and fluoroscopy time.

**Eligibility Criteria**

Candidates for this study must have met all of the following criteria:

**Inclusion Criteria**

- a suitable candidate for non-emergent, coronary angioplasty
- have a documented de-novo or restenotic coronary CTO lesion with the following characteristics:
  a) TIMI 0 flow for at least 90 days
  b) refractory to currently marketed guidewire crossing via one of the following:
     i. documentation of a previous failed attempt to cross lesion within the past 12 months; or
     ii. best effort to cross CTO with a guidewire antegrade within 10-15 minutes of fluoroscopy time is unsuccessful; or
  iii. best effort attempt to cross CTO with a guidewire ante-grade results in guidewire entering subintimal space
- satisfactory distal vessel visualization (collateral supply) with the following characteristics:
  i. distal vessel of at least 1.5 mm in diameter by visual estimation; and
  ii. at least 10 mm of visible distal vessel proximal to any major branch by visual estimation (i.e., potential true lumen re-entry zone in major vessel proximal to the branch)
- have angiography or ischemia caused by the occluded artery
- be at least 18 years of age
- have a Body Mass Index (BMI) <40 (weight in kg divided by height in m²)
- have a left ventricle ejection fraction ≥20%
- sign the Informed Consent Form

Candidates were excluded from the study if any of the following conditions applied:

**Exclusion Criteria**

- a saphenous vein graft (SVG) CTO or an in-stent CTO
- an aorto-ostial CTO location. (Distal bifurcation origins may be considered)
- an intolerance to aspirin or a neuprotic response to ticlopidine or clopidogrel
- the appearance of thrombus or intraluminal filling defects
- severe cerebrovascular disease including a history of prior stroke or TIA (within 1 month)
- Family history of CAD
- Hypertension (mild/severe)
- Diabetes mellitus (Type I or II)
- Severe uncontrolled hypertension (systolic pressure ≥180 mm Hg or diastolic pressure ≥110 mm Hg)
- Severe left ventricular dysfunction (ejection fraction ≤30%)
- Severe uncontrolled systemic hypertension (systolic blood pressure ≥220 mm Hg and/or diastolic blood pressure ≥120 mm Hg)
- a severe electrolyte imbalance
- documented anaphylaxis to angio graphic contrast media unless appropriately medicated
- congestive heart failure (NYHA Class IV)
- unstable angina requiring emergent PTCA or CABG
- have a recent MI (within the past two weeks)
- uncontrolled diabetes (≥2 serum glucose concentrations ≥150 mg/dl within the past 7 days)
- participation in another investigational protocol
- unwillingness or inability to comply with any protocol requirements
- pregnant or nursing
- target vessel with severe tortuosity
- an extensive dissection from refractory guidewire use that may prevent safe intervention or reduce the chance of a successful case
- crossing of the CTO into the true lumen with a currently marketed guidewire within 10-15 minutes of fluoroscopy time
- target true lumen re-entry area with severe calcification defined as readily apparent densities noted within the apparent vascular wall at the site of the stenosis including radio opacities noted without cardiac motion prior to contrast injection generally involving both sides of the arterial wall.

**Methods**

Patients who met all inclusion criteria and did not meet any exclusion criteria were eligible for inclusion into the FAST-CTOs Study. Once the patient’s 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 (typically placement of stents) was performed at the discretion of the investigator. Post-procedure care was according to institutional standard practice with the additional requirement of 3 serial blood draws to test for cardiac enzyme elevation. Patients were required to have an office visit follow-up at 30-days post-procedure.

**Results**

A total of 150 CTOs were treated in 147 patients. The following table outlines the technical success by refractory category:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Result</th>
<th>Age</th>
<th>Gender (%) Male</th>
<th>Diabetes mellitus (Type 1 or II)</th>
<th>Hypertension (moderate/severe)</th>
<th>Hypertension (severe)</th>
<th>Family history of CAD</th>
<th>Tobacco use</th>
<th>Prior myocardial infarction</th>
<th>Angina pectoris</th>
<th>Prior CABG</th>
<th>Prior attempt to recanalize CTO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>63±3 (9.1)</td>
<td>86% (127/147)</td>
<td>36% (53/147)</td>
<td>68% (88/134)</td>
<td>72% (75/104)</td>
<td>37% (52/142)</td>
<td>19% (28/147)</td>
<td>39% (58/157)</td>
<td>80% (120/150)</td>
<td>22% (33/147)</td>
<td>40% (67/147)</td>
</tr>
</tbody>
</table>

The overall technical success for the study was 77% (115/150). This has met the performance goal of 94%.

The following table summarizes the technical success by refractory category:

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Overall (n=150)</th>
<th>Failed Prior Procedure (n=61)</th>
<th>10-15 Min. of Fluoroscopy (n=51)</th>
<th>Subintimal Guidewire (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success</td>
<td>77% (115/150)</td>
<td>72% (44/61)</td>
<td>73% (37/51)</td>
<td>89% (34/38)</td>
</tr>
</tbody>
</table>

The 30-day MACE rates were calculated for subjects who had follow-up visit within the pre-defined window of 0-7 days (true completers), and for subjects who had a follow-up visit on or after 30 days or had MACE event before 30 days (completers). The following tables identify the 30-day MACE rate estimates calculated after pooling data over all centers. The 90% confidence interval upper bound was calculated after adjusting for center as random effects.

**30-day MACE rate – Complete (n=136)**

<table>
<thead>
<tr>
<th>MACE Component</th>
<th>Rate Estimate</th>
<th>90% CI upper bound*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>6.9% (7/102)</td>
<td>14.2%</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>2.0% (2/102)</td>
<td>7.1%</td>
</tr>
<tr>
<td>Q-wave MI</td>
<td>0.0% (0/102)</td>
<td>---</td>
</tr>
<tr>
<td>NO2WMI</td>
<td>5.9% (6/102)</td>
<td>12.8%</td>
</tr>
<tr>
<td>Target Lesion Revascularization</td>
<td>0.0% (0/102)</td>
<td>---</td>
</tr>
<tr>
<td>Emergency CABG</td>
<td>0.0% (0/102)</td>
<td>---</td>
</tr>
</tbody>
</table>

*With center as random effect

The study performance goal for MACE rate was 14%. In addition, the results of the secondary endpoints were 105±54 minutes for procedure time and 44±25 minutes for fluoroscopy time. The performance goals of 146 minutes and 52 minutes were met for procedure time and fluoroscopy time, respectively.

During the course of the FAST-CTOs study, perforations were reported as any observed exit of a device from the vessel lumen including wire exits, myocardial staining, and angiographic (free-flowing) perforation. A perforation was reported in 6.8% (10/147) of the procedures. It was determined by the site investigator and the study Data Safety Monitoring Committee that the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) was involved in half of the events for a perforation rate of 3.4% (5/147). It was determined by the investigator that 4 events were caused by the CrossBoss Catheter located in a small side branch artery and one instance of a Stingray Catheter balloon rupture. The five perforations in which the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) was not involved were caused by a non-study guidewire (n=4) and in one case a non-study device-related pericardial effusion was noted post-procedure.

**Note:** During clinical studies it was noted that use of the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) was not involved 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 and need to be available and prepared prior to use of the System:

- Guiding catheter
- Angiographic imaging supplies (i.e. radiopaque contrast, manifold, tubing, etc.)
- Sterile heparinized normal saline
- Guidewire
- Other supplies as needed to complete the established laboratory protocol

**Product Preparation**

1. Remove the Stingray Catheter from the sterile packaging.
2. Remove the balloon protector and stylet.
3. Flush the guidewire lumen with saline.
4. Ensure all device surfaces are exposed to heparanized saline.
5. Prepare balloon with either method 1 or 2 below:
   - Prepare method 1:
     a. Prepare a 1:1 mixture of contrast medium and sterile saline.
     b. Aspirate 3 to 4 cc (ml) of contrast mixture into a 20 cc (ml) or larger syringe and purge air from the syringe barrel.
     c. Attach the syringe to a female luer lock on a 3-way stopcock and fill the stopcock lumens with contrast medium mixture.

Boston Scientific (Master Brand DFU Template 8.2677in x 1 1.6929in A4, 90105918AM), DFU, MB, Stingray, EN, 90874493-01A

Black (K) ∆E ≤5.0
d. Attach the 3-way stopcock and syringe to the Stingray™ Catheter inflation port.
e. Hold the syringe with the nozzle pointing downward and aspirate for 5 seconds.
f. Close the Stingray Catheter inflation port with the 3-way stopcock and purge the syringe.
g. Reconnect the syringe to the 3-way stopcock and purse air from the barrel.
h. Open the stopcock, aspirate until bubbles no longer appear, release the plunger, and disconnect the syringe from the 3-way stopcock.
i. Reconnect the syringe to the 3-way stopcock and close stopcock side-port.
j. Connect Stingray Catheter inflation port to stopcock.
k. Hold the syringe with the nozzle pointing downward and aspirate for 15 seconds.
l. Close stopcock to Stingray Catheter.
m. Remove the syringe and evacuate all air from the barrel.
n. Reconnect the syringe to the stopcock and close the side-port.
o. Hold the syringe with the nozzle pointing downward and aspirate for 15 seconds.
p. Close stopcock to Stingray Catheter and remove the syringe.
q. Fill 3 cc (ml) syringe with 3 cc (ml) of 100% contrast.
r. Purge air from 3 cc (ml) syringe.
s. Connect 3 cc (ml) syringe to stopcock and purge air from stopcock.
t. Open stopcock between 3 cc (ml) syringe and Stingray Catheter to allow contrast to draw into Stingray Catheter.
u. Close stopcock to Stingray Catheter and remove 3 cc (ml) syringe.

Prep method 2:

a. Connect a new/unused stopcock to a new/unused 20 cc (ml) syringe and close stopcock side-port.
b. Connect Stingray Catheter inflation port to stopcock.
c. Hold the syringe with the nozzle pointing downward and aspirate for 15 seconds.
d. Close stopcock to Stingray Catheter.
e. Remove the syringe and evacuate all air from the barrel.
f. Reconnect the syringe to the stopcock and close the side-port.
g. Hold the syringe with the nozzle pointing downward and aspirate for 15 seconds.
h. Close stopcock to Stingray Catheter and remove the syringe.
i. Fill 3 cc (ml) syringe with 3 cc (ml) of 100% contrast.
j. Purge air from 3 cc (ml) syringe.
k. Connect 3 cc (ml) syringe to stopcock and purge air from stopcock.
l. Open stopcock between 3 cc (ml) syringe and Stingray Catheter to allow contrast to draw into Stingray Catheter.
m. Close stopcock to Stingray Catheter and remove 3 cc (ml) syringe.

Prepare a balloon inflation device according to the manufacturer's instructions.

Product Operation — To Access Discrete Regions of the Coronary or Peripheral Vasculature

1. Access the vascular system and place the appropriate size introducer sheath per manufacturer's instructions.
2. Engage the vessel to be treated with an appropriate guiding catheter per manufacturer's instructions. Connect a hemostatic Y-adapter to the guiding catheter hub.
3. Assure the Stingray Catheter has been prepped per instructions.
4. Remove the appropriate guidewire from its package and inspect for damage.
5. Advance the guidewire to the target location using fluoroscopic guidance.
6. Back-load the Stingray Catheter onto the proximal portion of the guidewire.
7. Open the knob on the hemostatic Y-adapter.
8. Track the Stingray Catheter over the wire into the proximal guiding catheter lumen.
9. Tighten the hemostatic Y-adapter to create a seal around the Stingray Catheter. Do not over-tighten.
10. Advance the Stingray Catheter over the guidewire using fluoroscopic guidance. Position the Stingray Catheter ports (using the radiopaque markers) at the target location.
11. Exchange the guidewire for a shaped guidewire (~45˚ bend at the distal 1.5 mm segment).
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).
14. Adjust the fluoroscopic view until the balloon is shown at its minimum width.
15. Steer the shaped guidewire through the desired port by slowly rotating the shaped guidewire immediately proximal of the marker band until the shaped guidewire begins to exit the port.
16. Assess proper guidewire position and direction.
17. If the guidewire position or direction is incorrect, target the other side port by steering the shaped guidewire through the desired port by slowly rotating the shaped guidewire immediately proximal of the marker band until the shaped guidewire begins to exit the port.
18. Advance the shaped guidewire through the port as needed.
19. After completing the procedure, deflate the balloon, withdraw the Stingray Catheter over the guidewire, and discard according to hospital standards and national legal requirements.

Product Operation — To Treat Stenotic Coronary Lesions (Including CTOs)

Three general scenarios exist where the CrossBoss™ Catheter, Stingray Catheter, and Stingray Guidewires could be used in the treatment of stenotic coronary lesions. The first scenario involves the CrossBoss Catheter crossing the CTO lesion in the vessel true lumen. The second scenario occurs when the initial guidewire used is advanced distal of the CTO but remains in the subintimal space. The Stingray 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 Catheter and Stingray Guidewire are then used to re-enter the vessel true lumen.

Scenario 1 — CrossBoss Catheter

1. Access the coronary vascular system and place the appropriate size introducer sheath per manufacturer's instructions.
2. Engage the coronary vessel with the CTO with an appropriate guiding catheter per manufacturer's instructions. Connect a hemostatic Y-adapter to the guiding catheter hub.
3. Remove the appropriate guidewire (physician's choice) from its package and inspect for damage.
4. Advance the guidewire to the target coronary CTO location using fluoroscopic guidance.
5. Assure the CrossBoss Catheter has been prepped per instructions.
6. 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 guidewire and into the proximal guiding catheter lumen.
9. Tighten the hemostatic Y-adapter to create a seal around the CrossBoss Catheter. Do not over-tighten.
10. Advance the CrossBoss Catheter over the guidewire using fluoroscopic guidance.
11. Once the CrossBoss Catheter tip exits the guiding catheter, loosen the black knob on the torque device, slide the torque device to the appropriate position along the proximal shaft and firmly tighten the black knob onto the proximal shaft.
12. While holding the torque device, advance while rotating the CrossBoss Catheter in the clockwise or counterclockwise direction. The CrossBoss Catheter may be advanced over the wire or in front of the wire to the target location.
13. In the event the device encounters significant torsional resistance, the torque device is designed to slip while emitting an audible and tactile “click.” Upon torque device slip in one direction, reverse the rotation and continue advancement. Continue clockwise and counterclockwise rotations as needed to advance to the target location.
14. In addition, the CrossBoss Catheter can also be withdrawn slightly and re-advanced in the event of torque device slip.
15. 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 device are in the true lumen distal of the CTO.
16. Withdraw the CrossBoss Catheter over the wire and discard. Catheter rotation may also be advantageous during withdrawal.

Scenario 2 — Stingray Catheter and Stingray Guidewire

1. Access the coronary vascular system and place the appropriate size introducer sheath per manufacturer’s instructions.
2. Engage the coronary vessel with the CTO with an appropriate guiding catheter per manufacturer’s instructions. Connect a hemostatic Y-adapter to the guiding catheter hub.
3. Assure the Stingray Catheter and Stingray Guidewire have been prepped per instructions.
4. Remove the appropriate guidewire (physician’s choice) from its package and inspect for damage.
WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. BSC’s obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.