Instructions for Use

TRYTON Side Branch Stent™
Mounted on Standard Balloon Delivery Catheter
and
TRYTON Side Branch Stent™
Mounted on Stepped Balloon Delivery Catheter

- Moderate to severe calcification
- Implantation of the TRYTON Side Branch Stent™ alone, without a main branch stent is contraindicated
- Patients in whom the use of a drug eluting stent is contraindicated, e.g., who cannot receive the recommended dual anti-platelet (aspirin and an approved thienopyridine) and/or anticoagulation therapy

Warnings
Use of this type of device is known to be associated with the following risks:
- Subacute thrombosis
- Increased vascular and/or bleeding complications (due to anticoagulation)
- Increased length of hospital stay relative to those of coronary balloon angioplasty alone. Judicious selection of patients to receive this device rather than balloon angioplasty alone is strongly advised.
- Infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm or rupture
- The stent may cause spasm, distal embolization, thrombus, or could migrate from the site of implantation down the arterial lumen. Excessive stretching of the artery may cause rupture and life-threatening bleeding
- Stents can be partially deployed in particularly resistant lesions. Stent dislodgment from the balloon surface during deployment and/or dislodgment from the target site post-deployment can occur.
- Reuse or re-implantation of the TRYTON Side Branch Stent™ and any of its components may result in reduced product performance or product failure leading to complications and adverse events such as but not limited to stent dislodgement, premature balloon burst or other events as listed under POTENTIAL COMPLICATIONS and ADVERSE EFFECTS below.

Precautions
- Use of this product should be performed only in hospitals with access to emergency coronary artery bypass graft surgery that can be performed quickly in the event of a potentially injurious or life-threatening complication.
- All TRYTON Side Branch Stent™/Stent Delivery Systems are intended for single use only. Under no circumstances should this device or any part thereof be resterilized or reused. Reuse may result in device malfunction and subsequent patient complications as outlined in Potential Complication and Adverse Effects
- All equipment required for the implantation of this stent must be carefully examined prior to use to verify proper function.
- Special care should be taken to not disrupt the stent on the delivery catheter, particularly during removal of its packaging, placement over guidewire, and advancement and withdrawal through hemostasis valve and guiding catheter.
- When the delivery catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Excessive manipulation may cause dislodgment of the stent from the delivery catheter.
- For deployment of the stent, use a mixture of radiographic contrast media and sterile saline. Do not infuse the delivery system with air or any gaseous media
- Do not exceed the rated burst pressure as indicated on product label. Use of a pressure monitoring device is required to prevent over-pressurization.
- Do not attempt to reposition a partially deployed stent. Attempted repositioning may result in severe vessel damage.
- When recoiling a recently implanted stent, care should be taken to assure the guidewire is placed within the lumen and not in between the stent and the vessel wall. Otherwise, inadvertent dislodgment of the stent may occur leading to faulty positioning of the stent.
- Do not attempt to pull an unexpanded stent back into the guide catheter, as stent damage or stent dislodgement may occur. Movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. To withdraw the TRYTON Side Branch Stent™ system, the entire system with the guiding catheter should be removed as a single unit.
- Stent retrieval methods (use of additional wires, snare, and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications may include bleeding, hematoma or pseudoaneurysm.
- The TRYTON Side Branch Stent™ has not been evaluated in cases of in-stent restenosis or previously stented lesions.
- The TRYTON Side Branch Stent™ in pediatric subjects has not been evaluated.

Potential Complications and Adverse Effects
Potential complications and adverse effects due to the use of this product include, but are not limited to, the following:
- coronary artery spasm
- hematoma or hemorrhage
- stent migration
- infection

Contraindications
The TRYTON Side Branch Stent™ is contraindicated for use in patients with the following conditions:
- Totally occluded vessel
- Target lesion has excessive tortuosity unsuitable for stent delivery and deployment
- Angiographic evidence of thrombus
- A significant (> 50%) stenosis proximal or distal to the target lesion
- Impaired runoff in the treatment vessel with diffuse distal disease
- Ejection fraction ≤ 30%
- Impaired renal function (creatinine > 2.0 mg/dl or 150 mmol/l)
- Any patient who has a platelet count < 100,000 cells/mm3 or > 700,000 cells/mm3, a WBC of < 3,000 cells/mm3, or documented or suspected liver disease (including laboratory evidence of hepatitis)
- Recipient of heart transplant
- Known allergies to aspirin, clopidogrel bisulphate (Plavix®), ticlopidine (Ticlid®), or heparin
- Anticipated use of rotational atherectomy
- Lesion in which complete angioplasty balloon inflation cannot be achieved during the pre-dilatation
- Placement of the TRYTON Side Branch Stent™ without pre-dilatation of the target lesion with an angioplasty balloon (Direct Stenting) is not indicated
- Hypersensitivity or contraindication to Cobalt Chromium or structurally related compounds, cobalt, chromium, nickel, tungsten

Device Description
The TRYTON Side Branch Stent™ is a cobalt chromium stent provided pre-mounted on one of two balloon delivery catheters: Standard Stent Delivery System and Stepped Stent Delivery System. Both variants will utilize these Instructions for Use. Currently available products may be found in Table I below.

Table I: Stent Matrix

<table>
<thead>
<tr>
<th>Reference</th>
<th>Proximal Diameter (mm)</th>
<th>Distal Diameter (mm)</th>
<th>Stent Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TS-15-355</td>
<td>2.5</td>
<td>2.5</td>
<td>19</td>
</tr>
<tr>
<td>TS-15-350</td>
<td>3.0</td>
<td>3.0</td>
<td>19</td>
</tr>
<tr>
<td>TS-15-305</td>
<td>3.5</td>
<td>3.5</td>
<td>19</td>
</tr>
<tr>
<td>TS-15-300</td>
<td>4.0</td>
<td>3.5</td>
<td>18</td>
</tr>
</tbody>
</table>

Indications
The TRYTON Side Branch Stent™ is a coronary stent designed for improving coronary luminal diameter in de novo bifurcated lesions in native coronary arteries with reference diameters ranging from 2.35 mm to 3.5 mm in the side branch and 2.5 mm to 4.0 mm in the main vessel. This device should be used in accordance with the Instructions for Use.

The TRYTON Side Branch Stent™ is intended to be used in conjunction with an approved balloon expandable coronary stent, please refer to the Clinical Procedure.
Use of the TRYTON Side Branch Stent™/Stent Delivery System

Instructions provide technical guidance but do not obviate formal training for the physician in the use of coronary stents and delivery systems.

Recommended Additional Materials
- Angiographic contrast media diluted 1:1 with sterile saline
- An appropriately sized vascular sheath introducer and dilator set
- A guide catheter of appropriate size (as indicated on product label), tip shape and length
- A guidewire with maximum diameter of 0.014" (for delivery of stent)
- A hemostatic Y-adapter (I.D. of at least 0.096" is recommended)
- An inflation device with manometer readings from 0 to 20 ATM in 1 ATM increments
- An appropriately sized PTCA predilation catheter
- 20cc syringe
- Sterile heparinized normal saline
- Balloon Expandable Coronary Stent (main vessel)

Clinical Procedure

Use of this coronary stent and delivery system requires advanced angioplasty skills. The following instructions provide technical guidance but do not obviate formal training for the physician in the use of coronary stents and delivery systems.

1. Choose the appropriate stent/balloon size using the results of diagnostic angiography and the stent matrix in Table I above.
2. Remove the stent delivery system from the packaging and place in a sterile area using sterile technique.
3. Prior to using this device, all equipment, including the entire TRYTON Side Branch Stent™/Stent Delivery System should be visually examined carefully for defects. Specifically, examine the distal balloon region for leaks or bends in the catheter and damage to the stent. Do not use any defective equipment.
4. Utilize standard techniques and the manufacturer’s instructions to place the vascular sheath, guiding catheter, coronary stent (main vessel), and guidewire.

Stent Delivery System Preparation

- Utilize standard techniques for preparation of the TRYTON Side Branch Stent™/Stent Delivery System.
- Visually inspect the balloon/stent assembly to assure proper placement of the stent between the most distal and most proximal marker bands. Do not use any defective equipment.

Note: You may not be able to see the two middle marker bands as they are located under the stent. Do not wipe the balloon/stent assembly as this may cause damage or dislodgement of the stent.
- Remove the protective mandrel from the guidewire lumen by pulling on the loop end of the mandrel at the guidewire exit port.

Use of the TRYTON Side Branch Stent™/Stent Delivery System

Note: The physician(s) should consider and select an appropriate anticoagulation regimen.

1. Place a guidewire across the lesion into the side branch and a second guidewire across the lesion into the distal main vessel.
2. Pre-dilate the lesion with an appropriately sized balloon in order to facilitate the tracking of the stent across the lesion.
3. Advance the TRYTON Side Branch Stent™/Stent Delivery System prepared in the CLINICAL PROCEDURE over the side branch guidewire to the treatment site.
4. Position TRYTON Side Branch Stent™ at the lesion site.
5. Pay special attention to ensure that the side branch origin is straddled by mid markers on TRYTON Side Branch Stent Delivery System. The two mid markers should straddle the ostium of the side branch.

Mid Markers

Caution: Do not apply excessive force to advance the TRYTON Side Branch Stent™/Stent Delivery System. If the advancement of the system is not possible in spite of adequate guidewire support, consider removing the TRYTON Side Branch Stent™/Stent Delivery System to perform additional predilation.

5. Do not attempt to pull an unexpanded stent back into the guiding catheter, as stent damage or stent dislodgement may occur. Movement in and out through the distal end of the guiding catheter should not be performed as the stent may be damaged when retracting the undeployed stent back into the guiding catheter. To withdraw the TRYTON Side Branch Stent™ system, the entire system with the guiding catheter should be removed as a single unit.
6. When removing the delivery system as a single unit:
   a. Do not retract the delivery system into the guiding catheter.
   b. Position the proximal balloon marker just distal to the tip of the guiding catheter.
   c. Advance the guidewire into the coronary anatomy as far distally as safely possible.

d. Tighten the rotating hemostatic valve to secure the delivery system to the guiding catheter, then remove the guiding catheter and delivery system as a single unit.
7. Failure to follow these steps and/or applying excessive force to the delivery system can potentially result in loss or damage to the stent and/or delivery system components.
8. Initiate the TRYTON Side Branch Stent™ Delivery System balloon, expanding the stent to optimize stent apposition against the arterial wall. Do not exceed the rated burst pressure of the balloon as provided in the Compliance Chart included with the device.
9. After stent deployment, deflate the balloon catheter and withdraw it while maintaining the guidewire in position.
Caution: Do not begin withdrawal of the delivery catheter until the balloon is fully deflated. Using fluoroscopic guidance, observe the withdrawal of the TRYTON Side Branch Stent™ Delivery System to ensure that the catheter does not catch onto the stent. If resistance is encountered, carefully advance the TRYTON Side Branch Stent™ Delivery System and gently withdraw.
10. Select an angioplasty balloon catheter using the proximal main branch reference vessel diameter as a guide. Position the catheter with the distal marker at the side branch origin and dilate the balloon to a maximum of 1.1 balloon to artery ratio.
11. Perform post-Tryton Side Branch Stent™ deployment angiography following administration of intracoronary nitroglycerin unless contradicted. Confirm the position of the Tryton Side Branch Stent™ within the artery and its proper apposition against the arterial wall.

12. Retract the post-dilation balloon while maintaining both guidewires.
13. Do not exceed the rated burst pressure for each balloon as specified in the Instructions for Use.
14. With the assistance of fluoroscopy, re-position guidewire previously in side branch into main vessel distal to the side branch origin.
15. If the advancement of the system is not possible in spite of special attention to ensure that the guidewire enters the proximal portion of the TRYTON Side Branch Stent™.
16. Select an appropriate Balloon Expandable Coronary Stent to treat the main vessel.
17. Select stent with sufficient length to cover the entire lesion as well as to cover proximal portion of the TRYTON Side Branch Stent™.
18. Prepare the Balloon Expandable Coronary Stent to treat main vessel according to its Instructions for Use.
19. Track Balloon Expandable Coronary Stent to lesion site within the main vessel such that the distal portion of the main vessel stent extends through the TRYTON Side Branch Stent™. In addition, the proximal portion of the main vessel stent should cover the main vessel region of the TRYTON Side Branch Stent™.
20. If resistance is encountered when tracking the Balloon Expandable Coronary Stent across the proximal portion of the TRYTON Side Branch Stent™, do not use excessive force.
   a. Consider removal of Balloon Expandable Coronary Stent (main vessel) and perform post-dilation of the main vessel portion of the TRYTON Side Branch Stent™.
21. Under fluoroscopic guidance, advance the guidewire through proximal portion of the main vessel stent and into the side branch. Use special attention to ensure that the guidewire enters the proximal portion of the main vessel stent via the lumen.
22. Utilizing appropriately sized balloon catheters, perform simultaneous balloon inflations in both the side branch and main vessel stent.
   a. Use special attention to ensure that both balloons are positioned within the stented arterial segments.
   b. Do not exceed the rated burst pressure for each balloon as specified in the Instructions for Use.
23. Remove both angioplasty balloon catheters.
24. Repeat angiography to confirm adequate stent expansion. Remove the guidewires.
25. Repeat angiography to re-confirm angiographic result.
27. Discard all disposable devices used during this procedure per local requirements for medical device waste disposal.

MRI (Magnetic Resonance Imaging) Compatibility

Through non-clinical testing, the TRYTON Side Branch Stent™ (alone and in combination with 4 drug-eluting stainless steel stents) has been shown to be MRI safe at field strengths of 3 Tesla or less and a maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of MRI. The TRYTON Side Branch Stent™ should not migrate in this MRI environment.

Non-clinical testing has not been performed to evaluate the possibility of stent migration at field strengths higher than 3 Tesla. In testing the TRYTON stent, alone and in combination with 4 drug-eluting stainless steel stents, produced a temperature rise of less than 1.7 and 2.7 degrees C, respectively, at a maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of MRI. MRI image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.
References
The physician should consult recent literature on current medical practice on coronary stent procedures and balloon dilatation, such as those published by the American College of Cardiology and the American Heart Association.

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