CORONARY: INDICATIONS FOR USE
The FLASH™ Ostial System is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion. The FLASH™ Ostial System is also indicated for the post delivery expansion of balloon expandable stents within the coronary vasculature.

CONTRAINDICATIONS: Unprotected left main coronary artery; Coronary artery spasm in the absence of a significant stenosis.

WARNINGS: Contents are supplied STERILE using radiation (e-beam) and are non-pyrogenic. Do not use if sterile barrier is opened or damaged. This device is intended for single use only. Do not reuse, reprocess or re-sterilize. Balloon and/or catheter integrity may be compromised by reprocessing or re-sterilization and could lead to serious patient injury. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloons are fully deflated under vacuum. If resistance is felt during manipulation, determine the cause of the resistance before proceeding. Applying excessive pull force to the catheter can result in tip breakage or balloon separation. Do not exceed the rated burst pressure or maximum inflation volume recommended per the compliance table on the product labeling. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their rated burst pressure. To prevent over pressurization, use of a pressure monitoring device is recommended for Angioplasty Balloon inflation. To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium (50% Contrast / 50% Sterile Saline). Never use air or other gaseous medium to inflate the balloon. PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery warrants careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk. The FLASH™ Ostial System is not cleared for expanding balloon expandable stents within the neurovasculature.

PRECAUTIONS: See IFU for a list of Precautions. POTENTIAL ADVERSE EVENTS: The complications that may result from a balloon dilatation procedure include: death, acute myocardial infarction, acute vessel closure, total occlusion of the coronary artery or bypass graft, coronary vessel dissection, perforation, rupture or injury, restenosis of the dilated vessel, hemorrhage or hematoma, unstable angina, arrhythmias, including ventricular fibrillation, drug reactions, allergic reaction to contrast medium, hypotension, hypertension, infection, coronary artery spasm, arteriovenous fistula, stroke, air embolism and embolization or fragmentation of thrombotic or atherosclerotic material.

PERIPHERAL: INDICATIONS FOR USE
The FLASH™ Ostial System is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This device is also indicated for post-dilatation of balloon expandable stents in the peripheral vasculature.

CONTRAINDICATIONS: There are no known contraindications for the FLASH™ Ostial System.

WARNINGS: Contents are supplied STERILE using radiation (e-beam) and non-pyrogenic. Do not use if sterile barrier is opened or damaged. This device is intended for single use only. Do not reuse, reprocess or re-sterilize. Balloon and/or catheter integrity may be compromised by reprocessing or re-sterilization and could lead to serious patient injury. Use the catheter prior to the “Use By” date specified on the package. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is felt during manipulation, determine the cause of the resistance before proceeding. Applying excessive pull force to the catheter can result in tip breakage or balloon separation. Do not exceed 2.0 lbs when retracting the device into the guide catheter. To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length of the vessel or graft just proximal and distal to the stenosis. Do not exceed the maximum burst pressure or maximum inflation volume recommended per the compliance table on the product labeling. To prevent over pressurization, use of a pressure monitoring device is recommended for angioplasty balloon inflation. Use the recommended balloon inflation medium (50% Contrast / 50% Sterile Saline). Never use air or other gaseous medium to inflate the balloon.

PRECAUTIONS: See IFU for a list of Precautions.

POTENTIAL ADVERSE EVENTS: The complications that may result from a balloon dilatation procedure include: additional intervention, allergic reaction to drugs or contrast medium, embolization, hematoma, hemorrhage, inflammation, ischemia, sepsis/ infection, thrombosis, vascular trauma (vessel dissection, spasm), etc.
FLASH™ and FLASH™ MINI

FLASH™ Ostial System is designed to conform to the ostium during stent post-dilatation and angioplasty. The dual balloon design enables the physician to achieve stent wall apposition after post-dilatation and stability during angioplasty of challenging ostial lesions. The FLASH™ Ostial System is available for both coronary and peripheral indications.

Additional peripheral arteries include celiac, superior and inferior mesenteric, and iliac arteries.

Stent post-dilatation procedural overview

1. The middle marker is at the ostium
2. The distal marker is proximal to the distal edge of the stent. Never beyond the distal edge of the stent
3. The proximal marker is outside of the guide catheter

Inflate distal balloon with indeflator

Inflate compliant, low-pressure proximal balloon using 1cc syringe

Final result

There are significantly higher costs associated with stent placement procedures occurring at the aortal ostium:

- 50% of ostial stenting cases result in a proximal or distal miss
- There is a three-fold increase in restenosis and reinterventions when a miss occurs

Product ordering information

<table>
<thead>
<tr>
<th>Balloon length (mm)</th>
<th>8</th>
<th>12</th>
<th>17</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0 OCB3008BA^</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.5 OCB3508BA^</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.0 OCB4008BA^</td>
<td>OCB4014BA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.5 OCB4508BA^</td>
<td>OCB4514BA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.0 OCB5014BA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.0 OAB6014BA*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.0 OTW6012BA^</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.0 OTW7012BA^</td>
<td>OAB7019BA*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.0 OTW7017BA*</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

^ Coronary indication only

* Peripheral indication only

* 0.035" OTW compatible

RX ONLY

Case study

Stenting and post-dilatation with FLASH™ Ostial System

Images courtesy of Dr. Ajay Kalra of Surgical Specialists of Southwest Florida

Placement of a Boston Scientific Express® LD stent.

Post-dilatation with FLASH™ Ostial System showing guid wall apposition

Stent already in place

Position each of the 3 marker bands ensuring that:

1. The middle marker is at the ostium
2. The distal marker is proximal to the distal edge of the stent. Never beyond the distal edge of the stent
3. The proximal marker is outside of the guide catheter

Inflate distal balloon with indeflator

Inflate compliant, low-pressure proximal balloon using 1cc syringe

Final result

There are significantly higher costs associated with stent placement procedures occurring at the aortal ostium:

- 50% of ostial stenting cases result in a proximal or distal miss
- There is a three-fold increase in restenosis and reinterventions when a miss occurs

1 Refer to IFU for complete Instructions for Use.
2 Do not exceed stent manufacturer’s recommended maximum stent diameter