

CORONARY USE

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. Note: The FLASH Ostial System was tested on the bench with Boston Scientific VeriFLEX™ (a.k.a Liberté) balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to differences in stent design. All stents should be deployed in accordance with manufacturers' indications and instruction for use.

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

WARNINGS (ALL SIZES): 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. To reduce the potential for vessel damage, the inflated diameter of the Angioplasty Balloon should approximate the diameter of the vessel or graft just proximal and distal to the stenosis. 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.

WARNINGS (FLASH™ MINI WITH PRESSURE RELIEF SYRINGE): If the pressure relief bladder at the distal end of the 1.0cc syringe barrel is inflated for more than 15 seconds, deflate both the Proximal Balloon and the Angioplasty Balloon and then reposition the catheter. Do Not switch to a different inflation device. Note: The pressure relief bladder is designed to inflate when the catheter has been incorrectly positioned. When repositioning the catheter, ensure that the marker bands are correctly positioned as indicated in the Angioplasty / Post-Delivery Stent Dilatation section of this IFU. Do not pinch or manipulate the pressure relief bladder when it is inflated. This could potentially result in vessel damage if the catheter has not been properly positioned.

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.

PRECAUTIONS: See full IFU for a list of Precautions.

PERIPHERAL USE

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. Note: The Flash Ostial System was tested on the bench with the Boston Scientific Express® SD balloon expandable stent. Consideration should be taken when this device is used with different manufacturers' stents due to differences in stent design. All stents should be deployed in accordance with manufacturers' indications and instruction for use.

CONTRAINDICATIONS: None known.

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 that 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.

POTENTIAL/ADVERSE EVENTS: The complications that may result from a peripheral 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.).

PRECAUTIONS: See full IFU for a list of Precautions.

FLASH™_{RX} and FLASH™_{OTW} Ostial System Dual Balloon Angioplasty Catheters

A novel dual balloon system Conforms to the ostium for stent post-dilatation

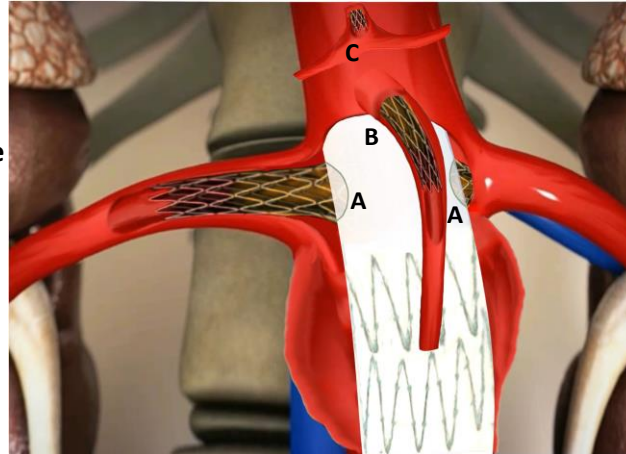


FLASH™_{RX} FLASH™_{OTW}

The FLASH™ Ostial System is a unique dual balloon catheter designed to post dilate and conform to the ostium during stent post-dilatation and angioplasty.

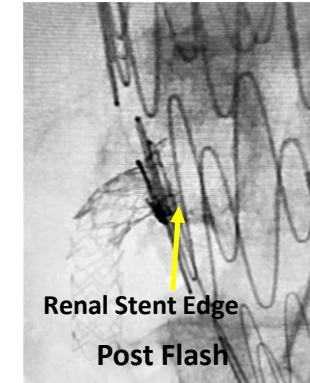
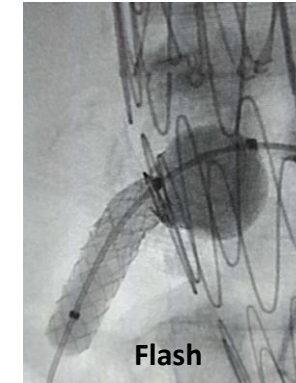
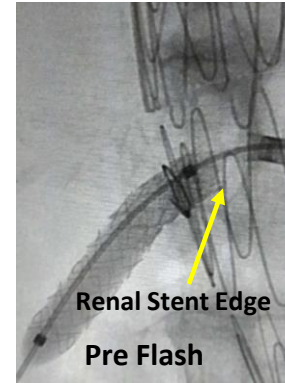
The FLASH™ Ostial System is available for both coronary and peripheral indications.¹

The FLASH balloon helps physicians to achieve stent wall apposition after post-dilatation at challenging aorto-ostial locations, including peripheral arteries, such as the renal and mesenteric arteries, which are commonly stented in FEVAR cases².



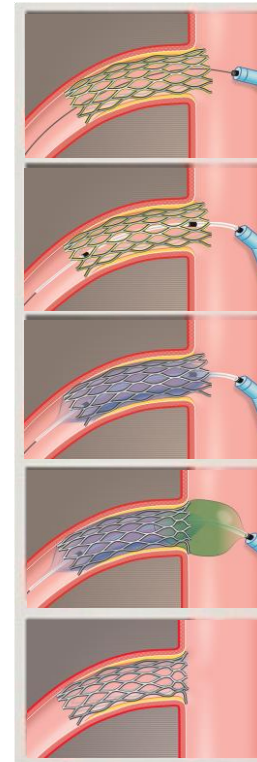
A: Renal Arteries. B: Superior Mesenteric Artery. C: Celiac Artery.

FEVAR Case Study



Images courtesy of Dr. J. Adams, Carilion Clinic Aortic Center.

Stent post-dilatation procedural overview¹



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 inside 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 the compliant, low-pressure proximal balloon using 1cc syringe

Final result²

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 reintervention when a miss occurs ±

Product Ordering Information

		Balloon Length (mm)	
		8	12
Balloon Diameter (mm)	RX (.014)		
	3.0	OCB3008BA [^]	
	3.5	OCB3508BA [^]	
	4.0	OCB4008BA [^]	
	4.5	OCB4508BA [^]	
	5.0		OCB5014BA ^{^*}
OTW (.035)			
	6.0		OTW6012BA [*]
	7.0		OTW7012BA [*]

[^] Coronary indication only

^{*} Peripheral indication only

^{^*} Coronary and peripheral indication.

Prescription use only

Customer Service Phone: 1-844-352-4711 - Fax: 1-408-716-2792.

1 Refer to the IFU for complete instructions for use.
 2 Do not exceed stent manufacturer's recommended maximum stent diameter.
 ± Dishman DA et al. High incidence of inaccurate stent placement in the Treatment of Coronary Aorto-Ostial Disease, Journal of Invasive Cardiology, Volume 23-Issue 8- August 2011.