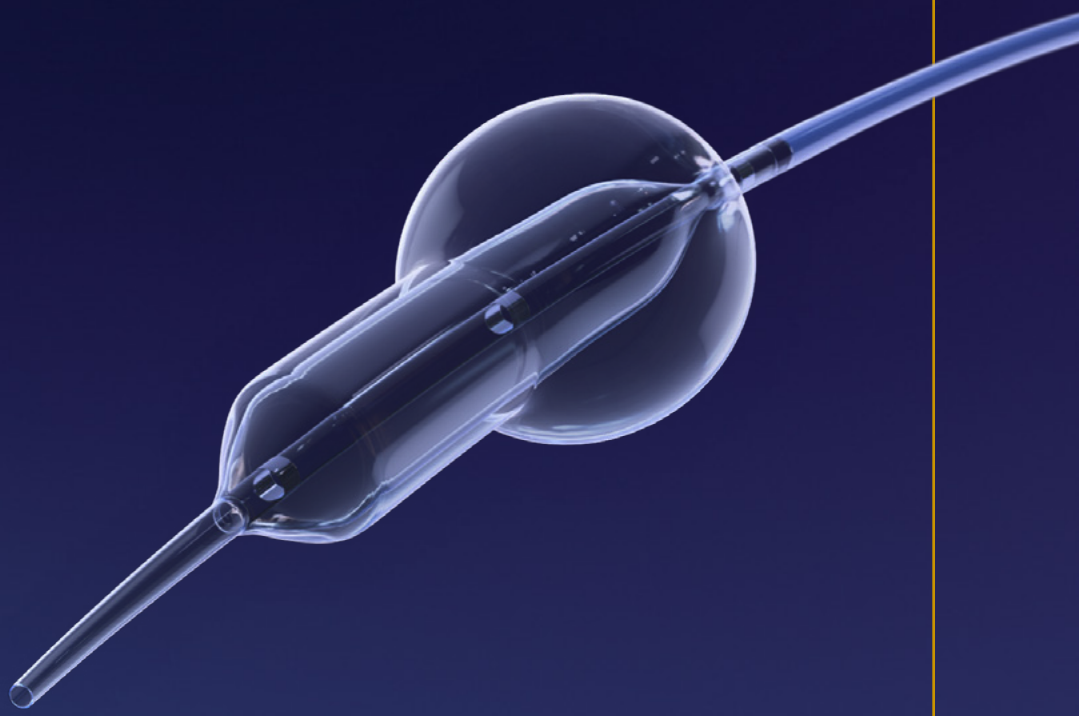


FLASH™

Aorto-Ostial Angioplasty System

TRUE 360°

Confidently treat aorto-ostial lesions

Ostial™ CORPORATION

FLASH™ Aorto-Ostial Angioplasty System

The first and only 2-in-1, dual-balloon catheter system designed for TRUE 360° stent apposition and total lesion coverage in coronary and peripheral ostial cases.

TRUE 360°

- OPTIMIZED PATIENT OUTCOMES
- TOTAL AND EFFICIENT LESION COVERAGE
- STREAMLINED VESSEL REACCESS

97%

of lesions demonstrated complete, 360° stent apposition[1,2]

"Adequate stent coverage of the ostial lesion is critical to procedural success, while maintaining access for possible future interventions... deploying a stent at the ostium, followed by molding the stent with FLASH addresses both of these goals.

–Richard Kovach, M.D., Deborah Heart & Lung Center, New Jersey

Confident Clinical Outcomes

The FLASH System demonstrates consistently low restenosis at 6 months, below the 9% rate reported for accurate stent placement in ostial lesions.[3§]

4.52%

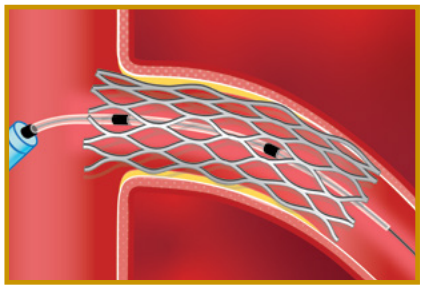
RESTENOSIS

at 6 mos.[2,4,5]

May reduce use of contrast volume, fluoroscopy exposure and procedure time.[3]

Complete and Efficient Coverage and Reaccess

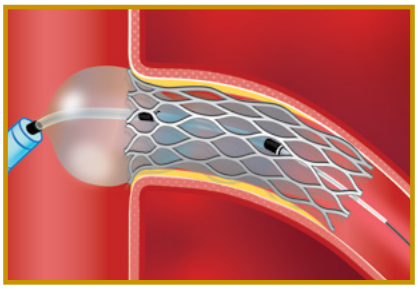
Unique dual-balloon post-dilatation technology precisely conforms aorto-ostial stents to challenging anatomy, improving reaccess for future interventions.[1,6]



2-in-1 DUAL-BALLOON CATHETER

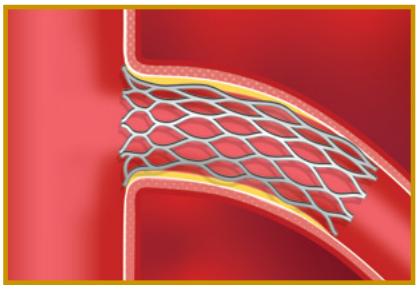
Three marker bands assist in easy delivery and catheter positioning.

1. Middle marker is at the ostium
2. Distal marker is always inside the distal edge of the stent
3. Proximal marker is outside of the guide catheter and in the aorta



TRUE 360° FLARED APPOSITION

Novel 2-in-1 dual balloon design allows for inflation of a non-compliant distal balloon to anchor the system, while inflation of the compliant, low-pressure proximal balloon conforms the stent to the wall of the ostium.

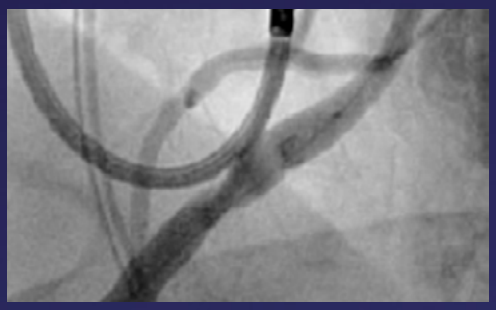


STREAMLINED REACCESS

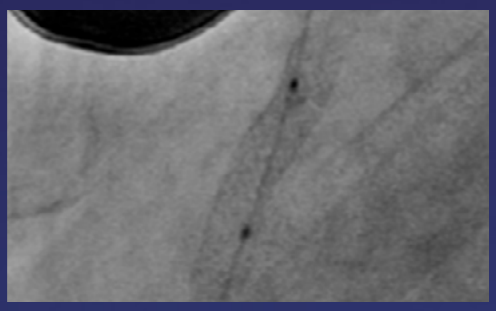
With TRUE 360° wall apposition achieved, a smooth transition is created for improved reaccess in future interventions.[1,2]

Post-Stenting with *FLASH*™

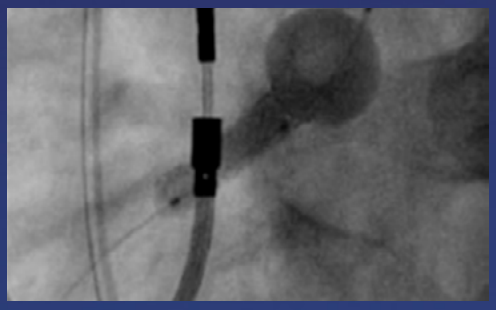
RCA OSTIAL STENOSIS



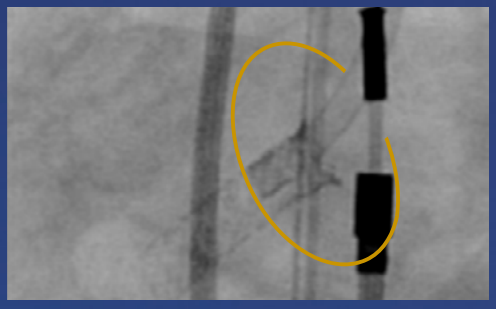
Prior to stent deployment



Stent protruding into aorta



Post-dilatation with FLASH

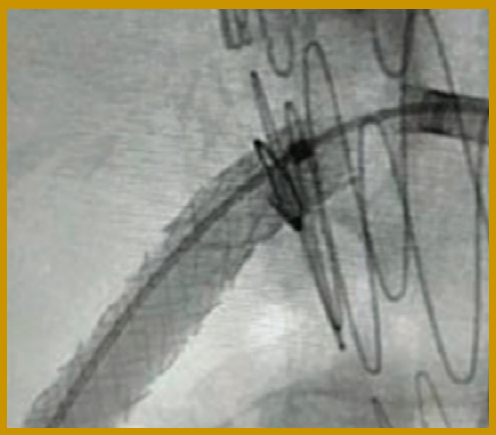


TRUE 360° result

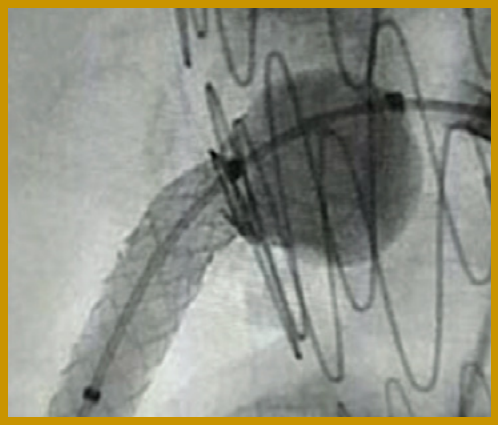
Angiography courtesy of Barry Weinstock, M.D., Orlando Health

Excellent Final Result

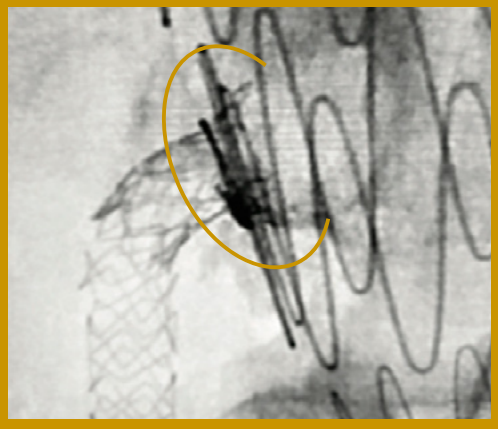
FEVAR



Stent protruding into aorta



Post-dilatation with FLASH



TRUE 360° result

Images courtesy of J. Adams, M.D., Carilion Clinic Aortic Center

Achieve TRUE 360°

PRODUCT ORDERING INFORMATION

Balloon Diameter (mm)		Balloon Length (mm) 8	Balloon Length (mm) 12
RX (.014)			
3.0	FLASH MINI	OCB3008BA^	
3.5	FLASH MINI	OCB3508BA^	
4.0	FLASH MINI	OCB4008BA^	
4.5	FLASH MINI	OCB4508BA^	
5.0			OCB5014BA+
6.0			OAB6014BA*
OTW (.035)			
6.0			OTW6012BA*
7.0			OTW7012BA*

*Prescription use only. ^Coronary indication only +Coronary/Peripheral indication *Peripheral indication only*

Contact an Ostial sales representative today

Ostial™ CORPORATION

Customer Service
844.FLASH.11 (844.352.7411)
Fax: 408.716.2792
customerservice@ostialflash.com
OstialFLASH.com

§Compared to non-ostial lesions

1. Data on file at Ostial Corporation. 2. Sanghvi K, Morris T, Kovach R. Optimal Aorto-ostial Lesion Treatment With Flash Ostial Balloon Is Feasible and Safe. JACC. 2016;9(4). Supplement S. 3. Dishmon D, Elhaddi A, Packard K, et al. High Incidence of Inaccurate Stent Placement in the Treatment of Coronary Aorto-Ostial Disease. JIC. 2011;23(8). 4. Nguyen-Trong P, Martinez Parachini J, Resendes E, et al. Procedural Outcomes With Use of the Flash Ostial System in Aorto-Coronary Ostial Lesions. Catheter Cardiovasc Interv. 2016;88(7):1067-1074. 5. Data on file at Ostial Corporation. 6. Data on file: VAR00678 & TM00174.

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. 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.

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. 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

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

WARNINGS, PRECAUTIONS, and POTENTIAL ADVERSE EVENTS

The FLASH™ Ostial System should only be used by and under the prescription of physicians who have received appropriate training in percutaneous transluminal angioplasty techniques for addressing coronary and peripheral lesions. For complete product information, including warnings, precautions, and harms, see the IFU included in the product packaging or visit the following link: ostialFLASH.com

Play FLASH Training Video

M01381 Rev. A.