REAL-WORLD CLINICAL DATA

JET REGISTRY[1] — Treatment effects of Jetstream Atherectomy System

The JET Registry demonstrated a high freedom from TLR rate at 12-months and low distal embolization rate in patients with long (16.4 cm), real-world lesions.

Patient and Lesion Characteristics:
- 241 patients with 258 lesions
- 41% diabetic
- 16.4 cm lesion length
- 36.1% occluded
- 90% of lesions had visible calcium
- 47.7% Grade 3 and 4 calcium present

Procedure Details:
- 22.4% of cases used embolic protection
- 4.7 minutes average Jetstream Runtime
- 1.4% distal embolization rate

Key Clinical Results:

77.2%	81.7%	73.4%	58.2%
Patency*	Freedom from TLR	Rutherford Category Improvement	ABI Improvement

Drug Coated Balloons were not used in this study

70% of patients had no or minimal symptoms (Rutherford Category 0-1)

Post-Procedure: 98.3% of patients had ≤30% residual diameter stenosis

*Patency based on a DUS PSVR ≤2.5; Binary Restenosis was reported as 22.8%. The JET Registry had limited DUS follow-up at 12 months (57.241 patients)

JET-SCE[2] — Jetstream + DCB

In the JET-SCE, the TLR rate was significantly reduced with atherectomy and adjunctive DCB compared to atherectomy with adjunctive PTA at 18-months.

Patient and Lesion Characteristics:
- 81 patients
- 53.1 % diabetic
- 25.9% CTOs
- 14.9 cm average lesion length in PTA cohort
- 12.0 cm average lesion length in DCB cohort

Key Clinical Results:

At 18-months results demonstrated...

91%

JETSTREAM + DCB
Freedom from TLR*

*18-month Jetstream + PTA = 63.7% Freedom from TLR

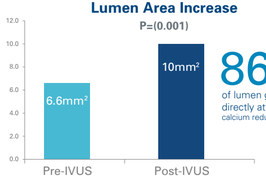
JETSTREAM CALCIUM STUDY[3]

The Jetstream Calcium study demonstrated Jetstream's ability to create statistically significant luminal gain in severe and moderate calcium as measured by IVUS.

Patient and Lesion Characteristics:
- 55 patients treated with Jetstream
- 56% Diabetic
- 63.6% Severe Calcium
- >90° superficial calcium, >5 mm in length

Key Clinical Results:

Lumen Area Increase
P=(0.001)



86%
of lumen gain was directly attributed to calcium reduction

6.6 ±3.7 mm², 10.0 ±3.6 mm²

SPECIFICATIONS

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter	Target Therapy Speed	GTIN	UPN/Order Code	Catalog Number	Unit	Qty
Jetstream™ 2.4/3.4 mm XC Atherectomy Catheter									
120 cm	7F	0.014"	2.4 mm 3.4 mm	70K rpm	08714729889922	112266-001	PV41340	Each	1
Jetstream™ 2.1/3.0 mm XC Atherectomy Catheter									
135 cm	7F	0.014"	2.1 mm 3.0 mm	70K rpm	08714729889892	112264-001	PV31300	Each	1
Jetstream™ 1.85 mm SC Atherectomy Catheter									
145 cm	7F	0.014"	1.85 mm	73K rpm	08714729889861	112262-001	PV3118F	Each	1
Jetstream™ 1.6 mm SC Atherectomy Catheter									
145 cm	7F	0.014"	1.6 mm	73K rpm	08714789889830	112260-001	PV3116F	Each	1
Jetstream™ Console									
—	—	—	—	—	08714729890430	50599-001	PVCN100	Each	1
Thruway™ Guidewire .014 in (.36 mm) 300 cm – Short Taper Straight									
Offers good rail support, strong PTFE coating adherence, and 3 radiopaque marker bands					08714729717188	M001492971	49-297	Box	1
Thruway™ Guidewire .014 in (.36 mm) 300 cm – Long Taper Straight									
Offers good rail support, strong PTFE coating adherence, and 3 radiopaque marker bands					08714729717195	M001492981	49-298	Box	1
Jetstream™ Jetwire Guidewire .014 in (.36 mm) 300 cm									
Offers long, floppy distal portion of wire and PTFE coating on remainder of wire					08714729888789	11525-001	PV014300	Box	5
Peripheral RotaGlide™ Lubricant 20 cc vial									
Intended to increase the lubricity of the Jetstream System during operation					08714729847557	M00114100062	141-0006	Box	6

The C-Code used for the Jetstream Atherectomy System is C1724. C-Codes are used for hospital outpatient device reporting for Medicare and some private payers. Note: Boston Scientific Corporation is not responsible for correct use of codes on submitted claims; this information does not constitute reimbursement or legal advice.

1. Garcia, L. (2017). Jetstream atherectomy in treating de novo or non-stent restenotic femoropoliteal disease: One-year results from the JET registry. Registry results presented at the Leipzig Interventional Course (LINC), Leipzig, Germany
2. Shammas, N (2017). Long Term Outcomes with Jetstream Atherectomy System with or without Drug Coated Balloons in Treating Femoro-popliteal Arteries: A Single Center Experience (JET-SCE). JET-SCE results presented as a poster at Society for Cardiovascular Angiography and Interventions (SCAI) Scientific Sessions, New Orleans, LA.
3. Maehara A, Mintz G, Shimshak T, Ricotta J, Ramaiah V, Foster M, Davis T, Gray W. Intravascular ultrasound evaluation of JETSTREAM atherectomy removal of superficial calcium in peripheral arteries. EuroIntervention 2015;11:96-103

JETSTREAM™ CATHETERS COMBINED WITH CONSOLE
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **Catheter INTENDED USE/ INDICATIONS FOR USE:** The JETSTREAM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature. **Console INTENDED USE/ INDICATIONS FOR USE:** The PVCN100 Console is designed for use only with the JETSTREAM Catheter and Control Pod. See the current revision of the applicable Catheter and Control Pod Directions for Use for further information. **CONTRAINDICATIONS:** None known. **Catheter WARNINGS:** • Use room temperature infusate only. Use of heated infusate may lead to wrinkling, ballooning and/or bursting of the outer catheter sheath, which could lead to injury to the patient • Operating the Catheter over a kinked guidewire may cause vessel damage or guidewire fracture. • During treatment, do not allow the Catheter tip within 10.0 cm of spring tip portion of the guidewire. Interaction between the Catheter Tip and this portion of the guidewire may cause damage to or detachment of the guidewire tip or complicate guidewire management. • The guidewire must be in place prior to operating the Catheter in the patient. Absence of the guidewire may lead to inability to steer the Catheter and cause potential vessel damage. • If the guidewire is accidentally retracted into the device during placement or treatment, stop use, and remove the Catheter and the guidewire from the patient. Verify that the guidewire is not damaged before re-inserting the guidewire. If damage is noticed, replace the guidewire. • Check the infusate bag frequently and replace when needed. Do not run the JETSTREAM System without infusate as this may cause device failure. • Hold the guidewire firmly during Catheter retraction process. Failure to do so may result in guidewire rotation within the vessel, which could cause patient injury. • Do not manipulate the Catheter against resistance unless the cause for that resistance has been determined. • Prior to use of the JETSTREAM System, confirm the minimum vessel diameter proximal to the lesion per the following table:

Model	1.6	1.85	2.1/3.0	2.4/3.4
Minimum Vessel Diameter Proximal to Lesion	2.5 mm	2.75 mm	—	—
Minimum Vessel Diameter, Blades Down	—	—	3.0 mm	3.5 mm
Minimum Vessel Diameter, Blades Up	—	—	4.0 mm	4.5 mm

Catheter PRECAUTIONS • Do not bend or kink the Catheter during setup or during the procedure. This may damage the device and lead to device failure. • Do not inject contrast while the device is activated. • Use only listed compatible guidewires and introducers with the JETSTREAM System. The use of any supplies not listed as compatible may damage or compromise the performance of the JETSTREAM System. **Console WARNINGS AND PRECAUTIONS** • WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. • Do not open either pump door during operation of the System. Doing so could result in loss of aspiration and/or infusion and will halt device activation. • Ensure the PVCN100 Console display is visible during the entire procedure. • Observe normal safety practices associated with electrical/electronic medical equipment. • Avoid excessive coiling or bending of the power cables during storage. • Store the PVCN100 Console using appropriate care to prevent accidental damage. • Do not place objects on the PV Console. • Do not immerse the PV Console in liquids. **ADVERSE EVENTS:** Potential adverse events associated with use of this device and other interventional catheters include, but are not limited to the following (alphabetical order): • Abrupt or sub-acute closure • Amputation • Bleeding complications, access site • Bleeding complications, non-access site • Death • Dissection • Distal emboli • Hypotension • Infection or fever • Minor burn • Perforation • Restenosis of the treated segment • Vascular complications which may require surgical repair • Thrombus • Vasospasm

bostonscientific.com/jetstream

Jetstream System Components

Boston Scientific
Advancing science for life™

Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.

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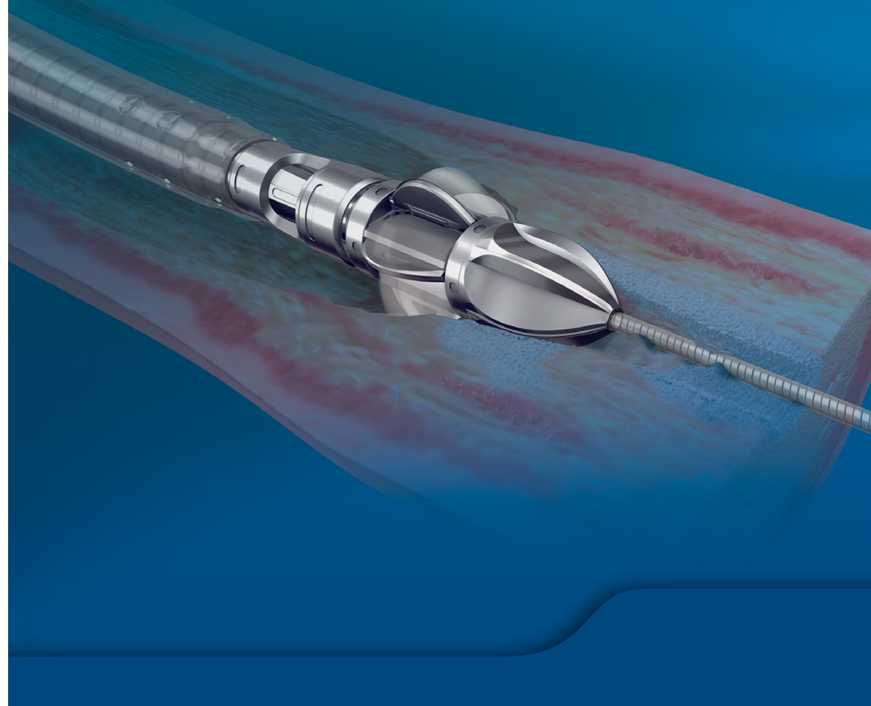
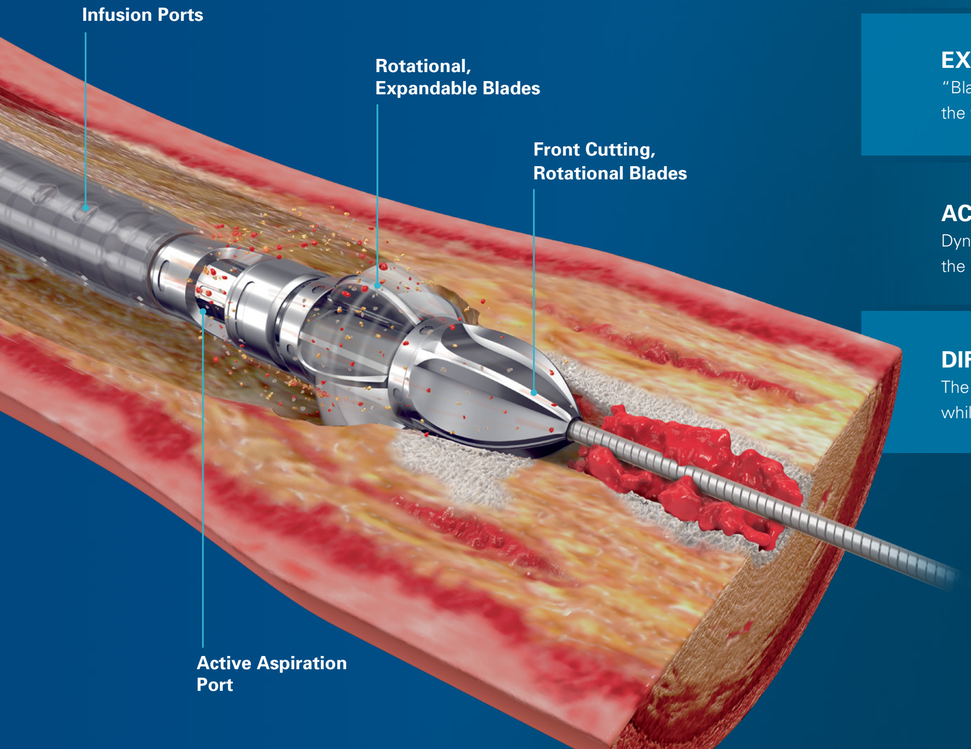
JETSTREAM™ Atherectomy System

CALCIUM. PLAQUE. THROMBUS.
TREAT IT ALL



CALCIUM. PLAQUE. THROMBUS.

Jetstream rotational atherectomy is engineered to predictably treat real-world lesions. Patients with PAD display a wide range of lesion characteristics such as long, diffuse disease and CTOs — which often include mixed morphologies like calcium, plaque and thrombus. **Jetstream is the only atherectomy device designed to *treat it all*.**



ROTATIONAL BLADES – Create Concentric Lumens

Rotational blades spin at ~70,000 RPMs to create concentric lumens, optimizing balloon-to-wall apposition for DCB or other adjunctive therapies.

FRONT-CUTTING BLADES – Immediately Engage Lesions

Five front-cutting blades immediately engage lesions and help enable the treatment of tight or occluded vessels.

EXPANDABLE BLADES – Provide Sizing Flexibility

"Blades Down/Blade Up" technology enables maximum luminal gain while providing the flexibility to treat multiple vessel diameters with the same catheter.

ACTIVE ASPIRATION – Helps Reduce Embolization Risk

Dynamic and continuous aspiration mechanically removes debris, helping to minimize the risk of distal embolization, and debulk the lesion.

DIFFERENTIAL CUTTING – Deflects Away from Healthy Tissue

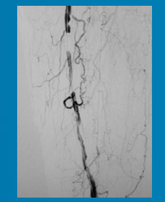
The mechanism of action allows the blades to cut the diseased, inelastic, tissue while deflecting away from the healthy, elastic, tissue.

TREAT IT ALL

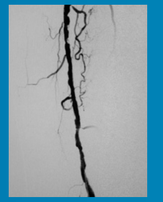
JETSTREAM CASE EXAMPLES

CASE 1:

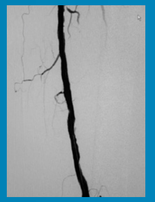
Chronic Total Occlusion of the Superficial Femoral Artery



Hydrophilic 0.035" wire and support catheter used to cross SFA CTO



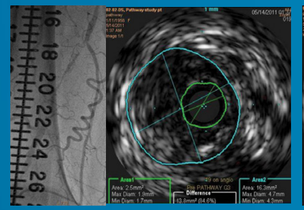
Stand-alone Jetstream result 2 passes blades down, 1 pass blades up with 2.4/3.4 mm XC catheter



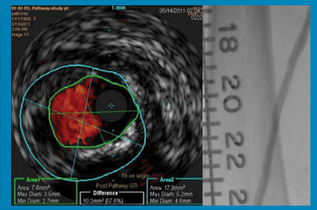
Post DCB Two 6.0 x 100 mm drug-coated balloons

CASE 2:

Adductor Canal Disease



Adductor Canal disease

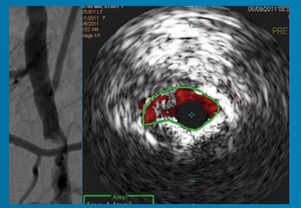


Stand-alone Jetstream result (IVUS image above) 2.1/3.0 mm XC catheter

Final angiogram following 5 x 80 balloon

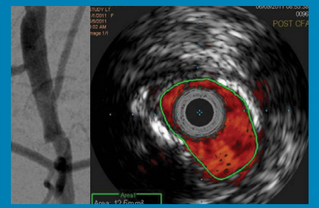
CASE 3:

Common Femoral Artery Disease



Left Common Femoral disease

IVUS baseline of 4.4 mm² pre-treatment (270 degree arc of calcium)



Stand-alone Jetstream result, revealed by angiogram (prior to PTA)

IVUS imaging revealed lumen area of 12.5 mm² post-treatment

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary. Case 1: Images courtesy of John Adeniyi, MD, Cases 2 and 3: Jetstream Calcium Study Boston Scientific images on file