JETSTREAM™ Atherectomy System

CALCIUM. PLAQUE. THROMBUS.
TREAT IT ALL
CALCIUM. PLAQUE. THROMBUS.

Jetstream is engineered to predictably treat multiple lesion morphologies and CTOs with rotational, front-cutting blades that target the diseased tissue and deflect away from healthy tissue. And, as the only atherectomy device with active aspiration, Jetstream is designed to actively remove debris and reduce the risk of distal embolization.
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.
### 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**

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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.
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:**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patency*</td>
<td>77.2%</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>81.7%</td>
</tr>
<tr>
<td>Rutherford Category Improvement</td>
<td>73.4%</td>
</tr>
<tr>
<td>ABI Improvement</td>
<td>58.2%</td>
</tr>
</tbody>
</table>

*Drug Coated Balloons were not used in this study

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

*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**

<table>
<thead>
<tr>
<th>Pre-IVUS</th>
<th>Post-IVUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.6 mm²</td>
<td>10 mm²</td>
</tr>
</tbody>
</table>

*P=(0.001)

86% of lumen gain was directly attributed to calcium reduction

6.6 ±3.7 mm², 10.0 ±3.6 mm²
### SPECIFICATIONS

<table>
<thead>
<tr>
<th>Catheter Length</th>
<th>Min. Introducer Size</th>
<th>Max. Guidewire Diameter</th>
<th>Tip Diameter</th>
<th>Target Therapy Speed</th>
<th>GTIN</th>
<th>UPN/Order Code</th>
<th>Catalog Number</th>
<th>Unit</th>
<th>Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 cm</td>
<td>7F</td>
<td>0.014&quot;</td>
<td>2.4 mm</td>
<td>3.4 mm</td>
<td>70K rpm</td>
<td>08714729889922</td>
<td>112266-001</td>
<td>PV41340</td>
<td>Each</td>
</tr>
<tr>
<td>135 cm</td>
<td>7F</td>
<td>0.014&quot;</td>
<td>2.1 mm</td>
<td>3.0 mm</td>
<td>70K rpm</td>
<td>08714729889892</td>
<td>112264-001</td>
<td>PV31300</td>
<td>Each</td>
</tr>
<tr>
<td>145 cm</td>
<td>7F</td>
<td>0.014&quot;</td>
<td>1.85 mm</td>
<td></td>
<td>73K rpm</td>
<td>08714729889861</td>
<td>112262-001</td>
<td>PV3118F</td>
<td>Each</td>
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<tr>
<td>145 cm</td>
<td>7F</td>
<td>0.014&quot;</td>
<td>1.6 mm</td>
<td></td>
<td>73K rpm</td>
<td>08714789889830</td>
<td>112260-001</td>
<td>PV3116F</td>
<td>Each</td>
</tr>
</tbody>
</table>

### Jetstream™ Console

- Offers good rail support, strong PTFE coating adherence, and 3 radiopaque marker bands
- Intended to increase the lubricity of the Jetstream System during operation
- GTIN: 08714729890430
- UPN/Order Code: 50599-001
- Catalog Number: PVCN100
- Unit: Each
- Qty: 1

### Thruway™ Guidewire .014 in (.36 mm) 300 cm – Short Taper Straight

- Offers long, floppy distal portion of wire and PTFE coating on remainder of wire
- GTIN: 08714729717188
- UPN/Order Code: M001492971
- Catalog Number: 49-297
- Unit: Box
- Qty: 1

### Jetstream™ Jetwire Guidewire .014 in (.36 mm) 300 cm

- Offers good rail support, strong PTFE coating adherence, and 3 radiopaque marker bands
- GTIN: 08714729717195
- UPN/Order Code: M001492981
- Catalog Number: 49-298
- Unit: Box
- Qty: 1

### Peripheral RotaGlide™ Lubricant 20 cc vial

- GTIN: 08714729847557
- UPN/Order Code: M00114100062
- Catalog Number: 141-0006
- Unit: Box
- Qty: 6

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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.


**JetSTREAM CATHETERS COMBINED WITH CONSOLE**

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician. Use only. Prior to use, please see the complete "Directions for Use" for more information on Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions. **Catheter INTENDED USE/INDICATIONS FOR USE:** The JetSTREAM System is intended for use in the catheterization 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 linked guidewire may cause vessel damage or guidewire fracture. • During treatment, do not allow the Catheter tip within 10.0 cm of any 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:

<table>
<thead>
<tr>
<th>Model</th>
<th>Diameter</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum Vessel Diameter Proximal to Lesion</td>
<td>2.5 mm</td>
<td>2.75 mm</td>
</tr>
<tr>
<td>Minimum Vessel Diameter, Blades Down</td>
<td>—</td>
<td>3.0 mm</td>
</tr>
<tr>
<td>Minimum Vessel Diameter, Blades Up</td>
<td>—</td>
<td>4.5 mm</td>
</tr>
</tbody>
</table>

**Jetstream System Components**

**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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PI-420106-AC JAN2018