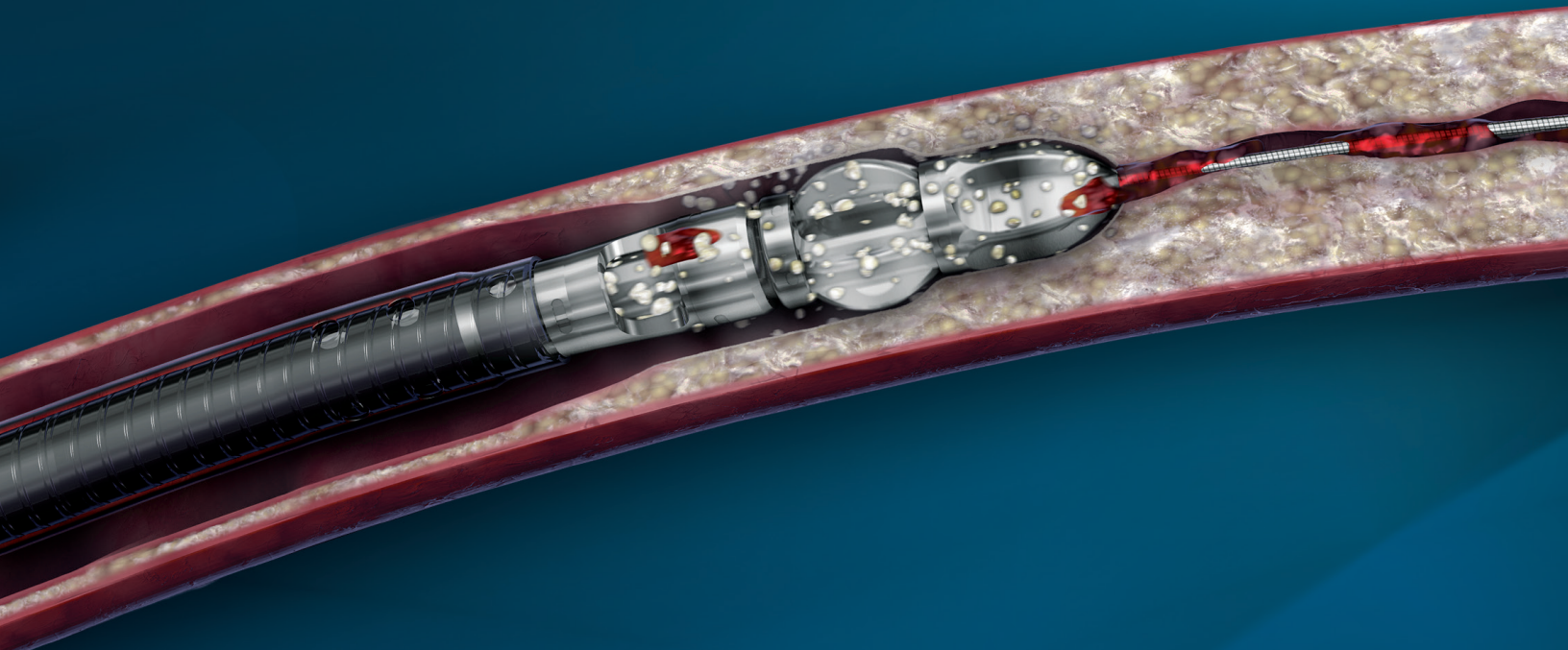


**JETSTREAM™** Atherectomy System

# DELIVERING VERSATILITY TO RESTORE FLOW



# DISCOVER THE VALUE OF VERSATILITY

## Versatility means not having to guess the morphology!

Peripheral arterial lesions can present with a range of morphologies from soft thrombus to plaque and difficult calcification – often in the same vessel. The Jetstream™ Atherectomy System is indicated for both thrombectomy and atherectomy and has demonstrated its ability to deliver luminal gain in soft, hard and calcified lesions.<sup>1,2</sup>

## Versatility means not having to switch in the middle of a procedure!

The Jetstream™ Atherectomy System offers the XC Catheter for above the knee and the SC Catheter for below the knee. In addition, the XC series has expandable blade technology that can deliver two lumen sizes with the same catheter.

FEATURE		Jetstream	Orbital	Directional	Laser	BENEFIT
Labeling Indication	Atherectomy	✓	✗	✗	✗	Complex lesions and total occlusion often contain mixed morphology lesions, requiring a device capable of managing it all.
	Thrombectomy	✓				
Active Aspiration		✓				Aspiration of liberated debris may minimize the risk of distal embolization.
Front Cutting / Rotational Device		✓	✗		✗	Total occlusions are common in PAD, front cutting enables engagement of tightest lesions.
Concentric Lumens		✓	✗			Concentric lumens facilitate straight line laminar flow.
Differential Cutting		✓	✗			Differential cutting targets only the plaque, minimizing the risk of vessel damage.
Expandable Blade Technology		✓				Expandable blades deliver more versatility, facilitating treatment from SFA to TPT.
Lesion Type	Total Occlusions	✓		✗	✗	Peripheral arterial disease rarely manifests as a single lesion type. A mix of disease morphologies is common, driving the need for a single device capable of addressing them all.
	Thrombus	✓			✗	
	Calcium	✓	✗	✗		
	Soft Plaque	✓		✗	✗	
	Fibrous Plaque	✓		✗	✗	

# RESTORE FLOW WITH THE MOST VERSATILE ATHERECTOMY SYSTEM AVAILABLE

## Treat It All with One Device<sup>1</sup>

From thrombus to difficult calcium, both above and below the knee.

## Dual Indication

Both atherectomy and thrombectomy from the same catheter.

## CTOs and Tight Stenoses

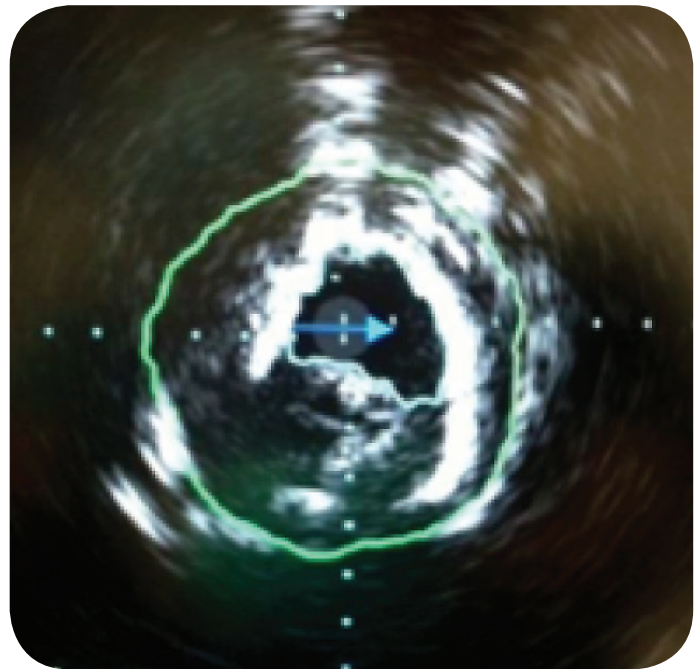
True front-cutting tips follow the guidewire through tight lesions without pre-dilation.

## Increase / Remodel Lumen Area

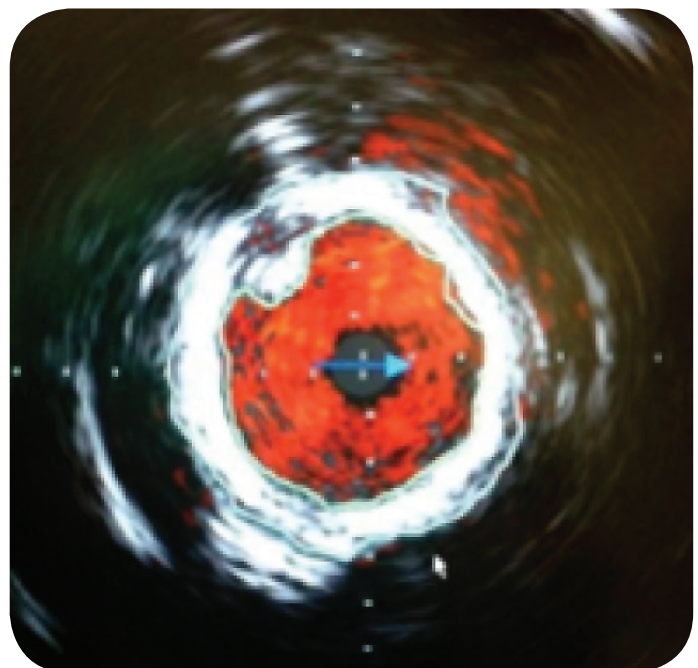
Rotational design supports concentric lumens, which facilitate laminar flow.

## Remove the Debris

The Jetstream™ System is the only atherectomy device with continuous active aspiration.



Prior to treatment, IVUS shows tight, irregular lesion



After treatment with Jetstream™ XC catheter, IVUS shows concentric luminal gain

Images show result from one case, results may vary.

# EFFECTIVELY TREAT LESIONS ABOVE AND BELOW THE KNEE

**ATK**

**Jetstream™ XC Atherectomy Catheter**

○ 2.4 mm ⚙ 3.4 mm

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter	Target Therapy Speed
120cm	7F	0.014"	2.4mm 3.4mm	70K rpm

**Jetstream™ XC Atherectomy Catheter**

○ 2.1 mm ⚙ 3.0 mm

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter	Target Therapy Speed
135cm	7F	0.014"	2.1mm 3.0mm	70K rpm

**Jetstream™ SC Atherectomy Catheter**

○ 1.85 mm

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter	Target Therapy Speed
145cm	7F	0.014"	1.85mm	73K rpm

**Jetstream™ SC Atherectomy Catheter**

○ 1.6 mm

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter	Target Therapy Speed
145cm	7F	0.014"	1.6mm	73K rpm

**BTK**

# ERGONOMIC, SINGLE OR DUAL-OPERATOR DESIGN

The lighter, more ergonomic XC and SC catheters are designed to enhance ease of use. Control buttons are integrated into the mouse, which can be used either in the pod or removed for remote activation. The improved Wire GARD simplifies wire management.



- Ergonomic design with 32% smaller\* POD enhances user experience
- Intuitive user interface facilitates single or dual operator use
- Improved wire GARD\* simplifies wire management
- Advanced package and POD design reduces environmental footprint

\*As compared to previous, G3 version catheters.



## ORDERING INFORMATION

Product Description	Catalog Number
Jetstream™ SC Atherectomy Catheter 1.85 mm	PV3118F
Jetstream™ SC Atherectomy Catheter 1.6 mm	PV3116F
Jetstream™ XC Atherectomy Catheter 2.4 mm / 3.4 mm	PV41340
Jetstream™ XC Atherectomy Catheter 2.1 mm / 3.0 mm	PV31300

Product Description	Catalog Number
Jetstream™ JETWIRE	PV014300

1 Zeller T et al. One-year outcome of percutaneous rotational atherectomy with aspiration in infrainguinal peripheral arterial occlusive disease: the multicenter pathway PVD trial. *J Endovasc Ther.* 2009 Dec;16(6):653-62.

2 <http://www.eventscribe.com/2013/posters/isetcio/SplitViewer.asp?PID=MTEwNTg2MjU2> "Jetstream Atherectomy System Can Remove Superficial Calcium in Severely Calcified Peripheral Arteries"

**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.

### Jetstream™ System

**INDICATIONS:** 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.

**CONTRAINDICATIONS:** No known contraindications.

**WARNINGS:** The Jetstream Catheter and Control Pod may only be used with the PV Console.

**PRECAUTIONS:** Do not manipulate the Catheter against resistance unless the cause for that resistance has been determined. 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.

Prior to use of the Jetstream System, confirm the minimum vessel diameter proximal to the lesion per the following table: Jetstream SC Atherectomy Catheter 1.6 : Minimum Vessel diameter proximal to lesion: 2.5mm • Jetstream SC Atherectomy Catheter 1.85: Minimum Vessel Diameter Proximal to Lesion 2.75 mm • Jetstream XC Atherectomy Catheter 2.1/3.0: Minimum Vessel Diameter, Blades Down 3.0 mm • Minimum Vessel Diameter, Blades Up 4.0 mm • Jetstream XC Atherectomy Catheter 2.4/3.4: Minimum Vessel Diameter, Blades Down 3.5 mm • Minimum Vessel Diameter, Blades Up 4.5 mm

**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 • Perforation • Restenosis of the treated segment • Vascular complications which may require surgical repair • Thrombus • Vasospasm

### Jetstream PV Console

**INDICATIONS:** The PV Console is designed for use only with the Jetstream Catheter and Control Pod. See the current revision of the applicable Catheter and Control Pod Instructions for Use for further information.

**PRECAUTIONS AND WARNINGS: 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 PV 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 PV Console using appropriate care to prevent accidental damage. • Do not place objects on the PV Console. • Do not immerse the PV Console in liquids.

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