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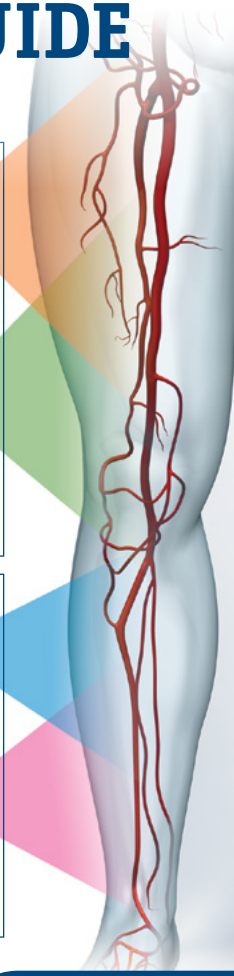
JETSTREAM™ Atherectomy System

SELECTION GUIDE



Jetstream XC Atherectomy Catheters

2.4/3.4 — **Ordering information: PV41340**

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter
120 cm	7 F	0.014″	2.4 mm 3.4 mm

2.1/3.0 — **Ordering information: PV31300**

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter
135 cm	7 F	0.014″	2.1 mm 3.0 mm

Jetstream SC Atherectomy Catheters

1.85 — **Ordering information: PV3118F**

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter
145 cm	7 F	0.014″	1.85 mm

1.6 — **Ordering information: PV3116F**

Catheter Length	Min. Introducer Size	Max. Guidewire Diameter	Tip Diameter
145 cm	7 F	0.014″	1.6 mm

Caution

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.

Wire Compatibility

Compatible Guidewires

- Boston Scientific Thruway™ .014 in (.36 mm) 300 cm
- Boston Scientific Jetwire™ .014 in (.36 mm) 300 cm
- Abbott Vascular Hi-Torque Spartacore™ 14
- Abbott Vascular Hi-Torque Iron Man™ .014 in

Sheath Compatibility

7F or larger with minimum inner diameter of .098 in or 2.5 mm
Do not use Tuohy Borst valve type introducers.

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Catheter 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. **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. **CONTRAINDICATIONS:** No known contraindications. **Catheter WARNINGS/PRECAUTIONS:** • The Jetstream Catheter and Control Pod may only be used with the PV Console. • Take care to avoid being pinched when closing the aspiration and infusion pump doors. • Use room temperature infusate only. Use of heated infusate may lead to wrinkling, ballooning and/or bursting of the outer catheter sheath. • Do not bend or kink the Catheter during setup or during the procedure. This may damage the device and lead to device failure. • 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. • Do not inject contrast while the device is activated. • 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. • 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:* **Jetstream SC Atherectomy Catheter 1.6** Minimum Vessel Diameter Proximal to Lesion 2.5 mm; **Jetstream SC Atherectomy Catheter 1.85** Minimum Vessel Diameter Proximal to Lesion 2.75 mm; **Jetstream XC Atherectomy Catheter2.1-3.0** Minimum Vessel Diameter, Blades Down 3.0 mm; Minimum Vessel Diameter, Blades Up 4.0 mm; **Jetstream XC Atherectomy Catheter2.4-3.4** Minimum Vessel Diameter, Blades Down 3.5 mm; Minimum Vessel Diameter, Blades Up 4.5 mm. **Console WARNINGS/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 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. **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

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