







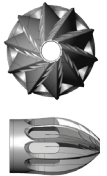

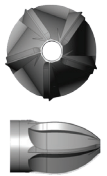




SYSTEM EVOLUTION

Continuous innovation to support your success

JETSTREAM	JETSTREAM G2™	JETSTREAM G2 NXT	JETSTREAM G3™	JETSTREAM G3 GTI	JETSTREAM Navitus™	JETSTREAM Navitus™ L	JETSTREAM™ XC/SC
							
September 2008	February 2009	August 2009	January 2010	December 2010	March 2011	April 2012	April 2013
<ul style="list-style-type: none"> • First commercially available Pathway Medical product • Expandable blades • Aspiration port integrated into distal cutter • 8 F introducer sheath  <p>Distal Cutter - 10 Flute Design</p>	<ul style="list-style-type: none"> • Aspiration port moved proximal of cutting blades • Macerator added - 10% increase in aspiration efficiency¹ • Approved for thrombectomy  <p>Macerator Added to Aspiration Port to Decrease Size of Plaque Before it is Aspirated</p>	<ul style="list-style-type: none"> • Pebax outer shaft and stainless steel hypotube (reduced OD, compared to earlier generation designs) • 7 F compatibility • Improved trackability (compared to earlier generation designs) 	<ul style="list-style-type: none"> • 5-flute distal cutter design • Increased torque (power) - 54% Increase in differential cutting efficiency¹ • 11% increase in aspiration efficiency²  <p>Distal Cutter - 5 Flute Design</p>	<ul style="list-style-type: none"> • Increased ease of use/ reliability (compared to JETSTREAM G3) <ul style="list-style-type: none"> - New liner over driveline - Improved distal bushing - Enhanced GW management - Improved User Interface 	<ul style="list-style-type: none"> • Robust Bushing and Distal Liner (same as GTI) <ul style="list-style-type: none"> - Elimination of bushing tail related wire sticking - Protection against thrombus stick - Durable liner with improved aspiration. • Guidewire management enhancements for smoother operation over the wire 	<ul style="list-style-type: none"> • Largest JetStream Catheter <ul style="list-style-type: none"> - 2.4 mm / 3.4 mm - 30% larger lumens³ • Shortened Coupler <ul style="list-style-type: none"> - Improved performance in torturous anatomy • Navitus technology integrated <ul style="list-style-type: none"> - Identical liner and bushing technology - Guidewire management enhancements 	<ul style="list-style-type: none"> • Entire portfolio redesign • New ergonomic POD design <ul style="list-style-type: none"> - 32% smaller than previous - Redesigned user interface - Improved wire GARD simplifies wire management - New package and POD design reduces environmental footprint 

1. Compared to JETSTREAM G2 NXT in blades down during bench testing

2. Compared to JETSTREAM G2 NXT in bench testing

3. Data on file report EV09194

JETSTREAM™ Atherectomy System is manufactured and distributed in EU by Bayer Interventional

All cited trademarks are the property of their respective owners. CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

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 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 **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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Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
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