Technique Tips

- Maintain flat surfaces of Control POD oriented horizontally. Some leakage from Control POD vent holes on flat surface is normal.
- During treatment, advance the Catheter Tip deliberately and slowly across the treatment area at a rate of approximately 1 mm per second. The Catheter should never be forced or pushed through the lesion. All efforts should be made to avoid stalling the device during treatment.

**Wire GARD activation button on side of POD**

**Control buttons integrated into Mouse**

**JETSTREAM CATHETERS COMBINED WITH CONSOLE**

**CAUTION:** Federal (USA) law restricts this device to use 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 ablation 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. **PRECAUTIONS:** 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.

- 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 treatment. To avoid the risk of electric shock, this equipment may only be used with the PV Console. • Take care to avoid being pinched when closing the aspiration and infusion pump doors. • Do not bend the catheter during setup or during the procedure. This may damage the device and lead to device failure. • Operate the Catheter over a kinked guidewire may cause vessel damage or guidewire fracture. • During treatment, do not allow the Catheter tip within 0.5 cm of a side hole 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. • 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 reinserting 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 mm Minimum Vessel Diameter Proximal to Lesion 2.5 mm; Jetstream SC Atherectomy Catheter 1.85 mm Minimum Vessel Diameter Proximal to Lesion 2.75 mm; Jetstream XC Atherectomy Catheter 2.1-3.0 mm Minimum Vessel Diameter; Blades Up 3.5 mm; Minimum Vessel Diameter, Blades Up 4.5 mm. Consulnte 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 infusate 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 • JETSTREAM is a registered or unregistered trademark of Boston Scientific Corporation or its affiliates. All other trademarks are property of their respective owners.
Press the Main Power On/Off button on the upper right front corner of the PV Console to turn the power on.

Connect electrical cable from the Catheter and Control POD to the Control POD Power Connector located on the bottom left corner of the PV Console. Verify that the dot on the Control POD is aligned with the dot on the PV Console Connector.

Open both pump doors and insert the Baton into the PV Console such that the tubing is positioned over the pump rollers.

Press the tubing onto the center of the pump rollers. The Collection Bag should be hanging down if the Baton is orientated properly.

Close the pump doors and hang the Collection Bag from the hooks located below the pumps.

Using aseptic technique, insert the infusion tubing’s bag spike into a bag of normal room temperature saline and hang bag from pegs on the IV stand.

Insert the infusion tubing into the Bubble Detector. Hold the flush port and pull tubing into the Bubble Detector slot from the top.

Place the Catheter Tip in a sterile bowl of saline. Do not let the Tip touch the bottom or sides of the sterile bowl.

Press the Prime button on the PV Console. The Tip must remain immersed in saline during the entire priming process.

When the priming cycle is complete the PV Console will beep and the Infusion LED on the PV Console will turn green.

Verify that no air bubbles are exiting the distal catheter tip at the end of the prime cycle. Insert a guidewire into the GARD clamp. With the Catheter Tip immersed in saline, depress and hold down the Activation Switch. Confirm that the Catheter Tip is spinning by observing movement of saline in the bowl. Release the Activation Switch. To avoid introducing air into the system, do not remove the Catheter Tip from the bowl of saline until flow has completely stopped moving in the aspiration tubing.
## PV Console Troubleshooting Guide

### Error Code | Problem | Likely Causes
--- | --- | ---
00:00 | Various system faults | Various system faults
F001-F009 | Various system faults | Various system faults
Err1 | Various system faults | Various system faults

### Err2
General Pump alarm

- If fault occurs at startup:
  - Pinched Baton tubing - Baton tubing pushed too far back on pump rollers
- If fault occurs mid-treatment:
  - Various pump faults

### Err3-Err9
Various system faults

1. Follow System Restart Sequence
2. If a fault message appears on the display during operation, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

### door
Pump Door(s) are open

- Close door(s)

### tubE
Fluid-filled tube in Bubble Detector before PRIME sequence started

- Incorrect startup or restart sequence (user error)
  1. If the “tubE” message shows on the display at power up, remove the fluid filled tubing from the Bubble Detector and then proceed with setup.
  2. If the “tubE” message does not clear when the Bubble Detector is empty, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

### grd1
Guidewire in GARD before PRIME sequence started

- Incorrect startup or restart sequence (user error)
  1. Remove guidewire from GARD
  2. Restart PRIME sequence before re-inserting guidewire in GARD
  3. If the message persists, replace the Catheter and Control POD with a new one.

### grd2
No guidewire present in GARD during activation

- Incorrect startup or restart sequence (user error)
  1. Release activation button
  2. Insert guidewire into GARD and resume therapy
  3. If the message persists, replace the Catheter and Control POD with a new one.

### bubL
Bubble in infusion line detected

- If fault occurs during PRIME sequence:
  - Bubble in Infusion line
  - Tubing not placed in bubble detector
- If fault occurs mid-treatment:
  - Infusion Bag is empty
  - Blocked infusion lumen on Catheter
  1. Verify that tubing is placed in bubble detector
  2. Clear the bubble and press the Bubble Detector Reset button.
  3. Press Prime button on PV Console
  4. Verify infusion bag is not empty and catheter is not damaged
  5. If necessary, the Flush Port on the infusion tubing line may be used to clear a bubble from the infusion line. Insert a sterile syringe with a 16 gauge or higher needle tip into the Flush Port and extract the bubble.
  6. Press Reset button on PV Console
  7. If Catheter has a blocked infusion lumen or the Catheter is damaged, replace with a new one

### POD
Problem with POD detected

- POD Connector and PV Console Connector misaligned
- Connectors not fully engaged

### System Restart Sequence

1. Turn on PV Console power
2. Remove tube from Bubble Detector
3. Remove guidewire from GARD
4. Initiate PRIME sequence
5. While PRIME sequence is running, replace tube in Bubble Detector
6. Replace guidewire in GARD
7. Re-initiate Treatment as desired
Error Code

Problem

Likely Causes

Resolution

PV Console is ready for a Control POD to be connected.

1. Follow System Restart Sequence
2. If a fault message appears on the display during power up, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

1. Follow System Restart Sequence
2. If a fault message appears on the display during operation, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

PV Console is ready for a Control POD to be connected.

1. Follow System Restart Sequence
2. If a fault message appears on the display during power up, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

1. Turn off PV Console power
2. Remove baton and re-load with tubing centered on pump rollers
3. Follow System Restart Sequence
4. If a fault message continues on the display during operation, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

1. Follow System Restart Sequence
2. If a fault message appears on the display during operation, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

1. Follow System Restart Sequence
2. If a fault message appears on the display during operation, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

1. Follow System Restart Sequence
2. If a fault message appears on the display during operation, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

Close door(s)

1. If the “tubE” message shows on the display at power up, remove the fluid filled tubing from the Bubble Detector and then proceed with setup.
2. If the “tubE” message does not clear when the Bubble Detector is empty, discontinue use of the device and turn off the PV Console. Contact Bayer Interventional to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

1. Remove guidewire from GARD
2. Restart PRIME sequence before re-inserting guidewire in GARD
3. If the message persists, replace the Catheter and Control POD with a new one.

1. Release activation button
2. Insert guidewire into GARD and resume therapy
3. If the message persists, replace the Catheter and Control POD with a new one.

1. Verify that tubing is placed in bubble detector
2. Clear the bubble and press the Bubble Detector Reset button.
3. Press Prime button on PV Console

1. Verify infusion bag is not empty and catheter is not damaged
2. If necessary, the Flush Port on the infusion tubing line may be used to clear a bubble from the infusion line. Insert a sterile syringe with a 16 gauge or higher needle tip into the Flush Port and extract the bubble.
3. Press Reset button on PV Console
4. If Catheter has a blocked infusion lumen or the Catheter is damaged, replace with a new one

1. Ensure POD is fully connected and dots on POD Connector and PV Console Connector are aligned
2. If the message persists, replace the Catheter and Control POD with a new one.