


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.



JETSTREAM™ Atherectomy System

System Set Up


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

Prior to use, please review DFU for indications, contraindications, warnings, precautions, adverse events and full operating instructions.

Indications, operating specifications and availability may vary by country. Check with local product representation and country-specific Information For Use for your country. This material is not approved for use or distribution in France.

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PV Console Troubleshooting Guide

Error Code	Problem	Likely Causes	Resolution
00:00			PV Console is ready for a Control POD to be connected.
F001-F009	Various system faults	Various system faults	<ol style="list-style-type: none"> Follow System Restart Sequence 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.
Err1	Various system faults	Various system faults	<ol style="list-style-type: none"> Follow System Restart Sequence 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.
Err2	General Pump alarm	<p>If fault occurs at startup: Pinched Baton tubing - Baton tubing pushed too far back on pump rollers</p> <p>If fault occurs mid-treatment: Various pump faults</p>	<ol style="list-style-type: none"> Turn off PV Console power Remove baton and re-load with tubing centered on pump rollers Follow System Restart Sequence 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. <ol style="list-style-type: none"> Follow System Restart Sequence 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.
Err3-Err9	Various system faults	Various system faults	<ol style="list-style-type: none"> Follow System Restart Sequence 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	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)	<ol style="list-style-type: none"> 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. 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)	<ol style="list-style-type: none"> Remove guidewire from GARD Restart PRIME sequence before re-inserting guidewire in GARD 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)	<ol style="list-style-type: none"> Release activation button Insert guidewire into GARD and resume therapy If the message persists, replace the Catheter and Control POD with a new one.
bubL	Bubble in infusion line detected	<p>If fault occurs during PRIME sequence: Bubble in Infusion line or Tubing not placed in bubble detector</p> <p>If fault occurs mid-treatment: Infusion Bag is empty or Blocked infusion lumen on Catheter</p>	<ol style="list-style-type: none"> Verify that tubing is placed in bubble detector Clear the bubble and press the Bubble Detector Reset button. Press Prime button on PV Console <ol style="list-style-type: none"> Verify infusion bag is not empty and catheter is not damaged 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. Press Reset button on PV Console If Catheter has a blocked infusion lumen or the Catheter is damaged, replace with a new one
POD	Problem with POD detected	<p>POD Connector and PV Console Connector misaligned or Connectors not fully engaged</p>	<ol style="list-style-type: none"> Ensure POD is fully connected and dots on POD Connector and PV Console Connector are aligned If the message persists, replace the Catheter and Control POD with a new one.

System Restart Sequence

- Turn on PV Console power
- Remove tube from Bubble Detector

- Remove guidewire from GARD
- Initiate PRIME sequence

- While PRIME sequence is running, replace tube in Bubble Detector

- Replace guidewire in GARD
- Re-initiate Treatment as desired