Atherectomy of Calcified 2 cm Eccentric CTO

Pre Procedure
2 cm Calcified CTO/Severe Calcium

Post Jetstream™ XC 2.4/3.4 Atherectomy
2 Passes Blades Down
2 Passes Blades Up

Post Adjunctive Therapy
6 x 40 PTA at 6 ATM

Collection Bag
4:34 runtime

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.
Jetstream emboli include, but are not limited to the following (alphabetical order
and description)
- Abrupt 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

CONSOLE WARNINGS/PRECAUTIONS:
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Avoid excessive coiling or bending of the power cables during storage.
- Store the PV Console using appropriate care to prevent accidental damage.
- Do not open either pump door during operation of the System. Do 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.
- Operate 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 reinserting the guidewire. If damage is noticed, replace the guidewire.
  • Check 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 4.5 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 operate the PV Console without the PV Console display visible during the entire procedure.
  • Observe normal safety practices associated with electrical/electronic medical equipment.

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.

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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