AngioJet™ Thrombectomy Systems Safety Information

Safety Statement for Peripheral Use

Prescriptive Information

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

AngioJet Solent Omni Proxi

INDICATIONS AND USAGE

The AngioJet SOLENT Proxi & Omni Thrombectomy Sets are intended for use with the AngioJet Ultra Console to break apart and remove thrombus from:

- Upper and lower extremity peripheral arteries ≥ 3.0mm in diameter
- Upper extremity peripheral veins ≥ 3.0mm in diameter
- Ileofemoral and lower extremity veins ≥ 3.0mm in diameter
- A-V access conduits ≥ 3.0mm in diameter and
- For use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system

CONTRAINDICATIONS

Do not use the Thrombectomy Set in patients:

- Who are contraindicated for endovascular procedures
- In whom the lesion cannot be accessed with the guide wire
- Who cannot tolerate contrast media

WARNINGS AND PRECAUTIONS

- The Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where the catheter was used in treatment of pulmonary embolism.
- The Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
- The Thrombectomy Set has not been evaluated for use in the coronary vasculature./li>
- Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.
- Use of the catheter may cause a vessel dissection or perforation.
- Do not use the AngioJet Ultra System in patients who have a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
- Do not use the Thrombectomy Set in vessels smaller than minimum vessel diameter for each Thrombectomy Set model as listed in Table 1 (in the DFU); such use may increase risk of vessel injury.
- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion in regards to the use of heparin is advised.
- Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the DFU) lists maximum recommended run times in a flowing blood field and total operating time for each Thrombectomy Set. Evaluate the patient's risk tolerance for hemoglobinemia and related sequelae prior to the procedure. Consider hydration prior to, during, and after the procedure as appropriate to the patient's overall medical condition.
- Large thrombus burdens in peripheral veins and other vessels may result in significant hemoglobinemia which should be monitored to manage possible renal, pancreatic, or other adverse events.
- Monitor thrombotic debris/fluid flow exiting the Thrombectomy Set via the waste tubing during use. If blood is not visible in the waste tubing during AngioJet Ultra System activation, the catheter may be occlusive within the vessel; verify catheter position, vessel diameter and thrombus status. Operation under occlusive conditions may increase risk of vessel injury.
- Obstructing lesions that are difficult to cross with the catheter to access thrombus may be balloon dilated with low pressure (≤ 2 atm). Failure to pre-dilate difficult-to-cross lesions prior to catheter operation may result in vessel injury.
- The potential for pulmonary thromboembolism should be carefully considered when the Thrombectomy Sets are used to break

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- The potential for pulmonary thromboembolism should be carefully considered when the Thrombectomy Sets are used to break up and remove peripheral venous thrombus.
- Do not retract the guide wire into the catheter during operation. The catheter is not designed to operate without the guide wire in place.
- Use of a J-tip guide wire is not recommended as it is possible for the tip of the guide wire to exit through a side window on the distal end of the catheter.
- If resistance is felt during the advancement of the Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath or guide catheter as a unit to prevent possible tip separation.
- Hand injection of standard contrast medium may be delivered through the thrombectomy catheter via the manifold port stopcock. Follow the steps to remove air from the catheter when delivering fluid through the catheter stopcock.
- Fluids should be injected only under the direction of a physician and all solutions prepared according the manufacturer instructions.
- The Thrombectomy Set waste lumen is rated for 50psi. Delivering a hand injection of contrast medium with excessive force can create injection pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
- Do not use a power injector to deliver contrast medium through the catheter stopcock. Power injectors can deliver pressures greater than 50psi, potentially causing leaks in the waste lumen of the catheter.
- Some fluids, such as contrast agents, can thicken in the catheter lumen and block proper catheter operation if left static too long. The catheter should be operated to clear the fluid within 15 minutes of injection.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:

- abrupt closure of treated vessel
- acute myocardial infarction
- acute renal failure
- arrhythmia
- bleeding from access site
- cerebrovascular accident
- death
- dissection
- embolization, proximal or distal
- hematoma
- hemolysis
- hemorrhage, requiring transfusion
- hypotension/hypertension
- infection at the access site
- pain
- pancreatitis
- perforation
- pseudoaneurysm
- reactions to contrast medium
- thrombosis/occlusion
- total occlusion of treated vessel
- vascular aneurysm
- vascular spasm
- vessel wall or valve damage

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AngioJet Solent Dista

INDICATIONS AND USAGE

The AngioJet SOLENT Dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apartand remove thrombus from:

- Upper and lower extremity peripheral arteries and
- For use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system. The minimum vessel diameter for each Thrombectomy Set model is listed in Table 1 (in the DFU).

CONTRAINDICATIONS

Do not use the catheter in patients:

- Who are contraindicated for endovascular procedures
- In whom the lesion cannot be accessed with the guide wire
- Who cannot tolerate contrast media

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- Who cannot tolerate contrast media

WARNINGS AND PRECAUTIONS

- The Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where the catheter was used in treatment of pulmonary embolism.
- The Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
- The Thrombectomy Set has not been evaluated for use in the coronary vasculature.
- Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.
- Use of the catheter may cause a vessel dissection or perforation.
- Do not use the AngioJet Ultra System in patients who have a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
- Do not use the Thrombectomy Set in vessels smaller than minimum vessel diameter for each Thrombectomy Set model as listed in Table 1 (in the DFU); such use may increase risk of vessel injury.
- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
- Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1(in the DFU) lists maximum recommended run times in a flowing blood field and total operating time for each Thrombectomy Set. Evaluate the patient's risk tolerance for hemoglobinemia and related sequelae prior to the procedure. Consider hydration prior to, during, and after the procedure as appropriate to the patient's overall medical condition.
- Large thrombus burdens in peripheral veins and other vessels may result in significant hemoglobinemia which should be monitored to manage possible renal, pancreatic, or other adverse events.
- Monitor thrombotic debris/fluid flow exiting the Thrombectomy Set via the waste tubing during use. If blood is not visible in the waste tubing during AngioJet Ultra System activation, the catheter may be occlusive within the vessel; verify catheter position, vessel diameter and thrombus status. Operation under occlusive conditions may increase risk of vessel injury.
- Obstructing lesions that are difficult to cross with the catheter to access thrombus may be balloon dilated with low pressure (≤ 2 atm). Failure to pre-dilate difficult-to-cross lesions prior to catheter operation may result in vessel injury.
- If resistance is felt during the advancement of the Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
- Do not exchange the guide wire. Do not retract the guide wire into the catheter during operation. The guide wire should extend at least 3 cm past the catheter tip at all times. If retraction of the guide wire into the Thrombectomy Set occurs, it may be necessary to remove both the Thrombectomy Set and the guide wire from the patient in order to re-load the catheter over the guide wire.
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath or guide catheter as a unit to prevent possible tip separation.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:

- abrupt closure of treated vessel
- acute myocardial infarction
- acute renal failure
- arrhythmia
- bleeding from access site
- cerebrovascular accident
- death
- dissection
- embolization, proximal or distal
- hematoma
- hemolysis
- hemorrhage, requiring transfusion
- hypotension/hypertension
- infection at the access site
- pain
- pancreatitis
- perforation
- pseudoaneurysm
- reactions to contrast medium
- thrombosis/occlusion
- total occlusion of treated vessel
- vascular aneurysm
- vascular spasm
- vessel wall or valve damage

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AngioJet Ultra 5000A Console

INDICATIONS AND USAGE

The AngioJet Ultra Console is intended for use only in conjunction with an AngioJet Thrombectomy Set. Refer to the individual Thrombectomy Set Directions for Use manual for specific clinical applications.

CONTRAINDICATIONS

Refer to the individual Thrombectomy Set Directions for Use manual for specific contraindications.

WARNINGS AND PRECAUTIONS

- Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Refer to the individual Ultra Thrombectomy Set Directions for Use manual for specific warnings and precautions.
- Refer to individual Thrombectomy Set Directions for Use manual for specific instructions regarding heparinization of the Thrombectomy Set.
- Do not attempt to bypass any of the Console safety features.
- The AngioJet System should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the Console should be observed to verify normal operation in the configuration in which it will be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the AngioJet System, including cables specified by the manufacturer. Otherwise, degradation of the performance of the equipment can result.
- Use of accessories, transducers and cables other than those specified or provided by Boston Scientific could result in increased electromagnetic emissions or decreased electromagnetic immunity of the AngioJet System and result in improper operation.
- The Console contains no user-serviceable parts. Refer service to qualified personnel.
- Removal of outer covers may result in electrical shock.
- Use the AngioJet Ultra Console only with an AngioJet Thrombectomy Set.
- The AngioJet System requires special precautions regarding electromagnetic emissions and immunity and needs to be installed and put into service according to the information included in the *Electronic and Electromagnetic Guidance Section* of the manual.
- This device may cause electromagnetic interference with other devices when in use. Do not place AngioJet System near sensitive equipment when operating.
- Do not move the collection bag during catheter operation as this may cause a waste tubing error.
- Do not reposition or push the Console from any point other than the handle designed for that purpose. A condition of overbalance or tipping may ensue.

ADVERSE EVENTS

Refer to the individual Thrombectomy Set Directions for Use manual for specific observed and/or potential adverse events.

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AngioJet ZelanteDVT Thrombectomy Set

INDICATIONS AND USAGE

The ZelanteDVT Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including deep vein thrombus (DVT), from:

- Iliofemoral and lower extremity veins ≥ 6.0 mm in diameter and
- Upper extremity peripheral veins ≥ 6.0 mm in diameter.

The ZelanteDVT Thrombectomy Set is also intended for use with the AngioJet Ultra Power Pulse® technique for the controlled and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

CONTRAINDICATIONS

Do not use the catheter in patients:

- Who are contraindicated for endovascular procedures
- Who cannot tolerate contrast media
- In whom the lesion cannot be accessed with the guidewire

WARNINGS AND PRECAUTIONS

The ZelanteDVT Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where other thrombectomy catheters were used during treatment of pulmonary embolism.

- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the carotid or cerebral vasculature.
- The ZelanteDVT Thrombectomy Set has not been evaluated for use in the coronary vasculature.
- Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be

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- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed, if needed.
- Use of the catheter may cause a vessel dissection or perforation.
- Do not use the AngioJet Ultra System in patients who have a non-healed injury due to recent mechanical intervention, in the vessel to be treated, to avoid further injury, dissection, or hemorrhage.
- Do not use the ZelanteDVT Thrombectomy Set in vessels smaller than minimum vessel diameter as listed in Table 1 of the IFU; such use may increase risk of vessel injury.
- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag. Physician discretion with regard to the use of heparin is advised.
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath as a unit to prevent possible tip separation.
- If resistance is felt during the advancement of the ZelanteDVT Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
- The potential for pulmonary thromboembolism should be carefully considered when the ZelanteDVT Thrombectomy Set is used to break up and remove peripheral venous thrombus.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:

- abrupt closure of treated vessel
- acute myocardial infarction
- acute renal failure
- bleeding from access site
- cerebrovascular accident
- death
- dissection
- embolization, proximal or distal
- hematoma
- hemolysis
- hemorrhage, requiring transfusion
- hypotension/hypertension
- infection at the access site
- pain
- pancreatitis
- perforation
- pseudoaneurysm
- reactions to contrast medium
- thrombosis/occlusion
- total occlusion of treated vessel
- vascular aneurysm
- vascular spasm
- vessel wall or valve damage

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ZelanteDVT ClotHunter

INTENDED USE/INDICATIONS FOR USE

The ZelanteDVT Thrombectomy System, which includes the ZelanteDVT Thrombectomy Set and the ClotHunter Helical Rotation Device, is intended for use with the AngioJet Ultra Console to break apart and remove thrombus,including deep vein thrombus (DVT), from:

- iliofemoral and lower extremity veins ≥ 6.0 mm in diameter and
- upper extremity peripheral veins ≥ 6.0 mm in diameter.

The ZelanteDVT Thrombectomy System is also intended for use with the AngioJet Ultra Power Pulse technique for the controlled and selective infusion of physician-specified fluids, including thrombolytic agents, into the peripheral vascular system.

CONTRAINDICATIONS

Do not use the ZelanteDVT Thrombectomy System in patients:

- who are contraindicated for endovascular procedures.
- n whom the lesion cannot be accessed with the guidewire.
- who cannot tolerate contrast media.

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- **The Thrombectomy System has not been evaluated for treatment of pulmonary embolism. There are reports of s adverse events, including death, associated with cases where the catheter was used in treatment of pulmonary**
- The Thrombectomy System has not been evaluated for use in the carotid or cerebral vasculature

- The Thrombectomy System has not been evaluated for use in the carotid or cerebral vasculature
- The Thrombectomy System has not been evaluated for use in the coronary vasculature.
- The Thrombectomy System has not been evaluated for use in the pediatric populations.
- Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, can be employed, if needed.
- Do not use the AngioJet™ Ultra System in patients who have an injury in the target vessel to avoid further vessel injury or hemorrhage.
- Do not use the Thrombectomy System in vessels smaller than minimum vessel diameter as listed in Table 1 (in the eIFU); such use may increase risk of vessel injury.
- In addition to the heparin added to the saline supply bag systemic heparinization is advisable to avoid pericatheter thrombus and acute rethrombosis.
- Use of the Thrombectomy Set in peripheral vessels may result in significant hemolysis which should be monitored to manage possible renal, pancreatic, or other adverse events. Excessive hemolysis may require additional intervention such as blood transfusion, dialysis. Table 1 (in the eIFU) lists maximum recommended run times in a flowing blood field and total operating time for each Thrombectomy Set. Evaluate the patient's risk tolerance for hemolysis and related sequelae prior to the procedure. Consider hydration prior to, during, and after the procedure as appropriate to the patient's overall medical condition.
- Obstructed lesions that are difficult to cross with the catheter may be predilated with low pressure (≤ 2 atm). Failure to predilate difficult-to-cross lesions prior to catheter operation may result in vessel injury.
- The potential for pulmonary thromboembolism should be carefully considered when the Thrombectomy Set is used to break up and remove peripheral venous thrombus.

PRECAUTIONS

- Use the Thrombectomy System only with the AngioJet Ultra Console.
- The Thrombectomy Set waste tubing is rated for 100 psi. Delivering a hand injection of contrast medium with excessive force can create injection pressures greater than 100 psi, potentially causing leaks in the waste tubing of the Thrombectomy Set.

POTENTIAL ADVERSE EVENTS

Potential adverse events (in alphabetical order) which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:

- Allergic reaction (to drug, contrast, device or other)
- Aneurysm
- Arrhythmia
- Bleeding/hemorrhage
- Cerebrovascular accident (CVA), stroke, transient ischemic attack (TIA)
- Death
- Embolism (air, plaque, thrombus, device or other)
- Hematoma
- Hemolysis
- Hypotension/hypertension
- Infection/sepsis
- Myocardial infarction
- Need for urgent intervention or surgery
- Pain
- Pancreatitis
- Renal insufficiency/failure
- Thrombus/thrombosis
- Vasospasm
- Vessel injury (perforation, trauma, rupture, dissection, pseudoaneurysm)
- Vessel occlusion

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AngioJet Ultra AVX Thrombectomy Set

INDICATIONS AND USAGE

The AngioJet Ultra AVX Thrombectomy Set is intended for use with the AngioJet Ultra System in breaking apart and removing thrombus from A-V access conduits ≥ 3.0 mm in diameter.

CONTRAINDICATIONS

Do not use the Thrombectomy Set in patients:

- Who are contraindicated for endovascular procedures
- In whom the lesion cannot be accessed with the guide wire
- Who cannot tolerate contrast media

WARNINGS AND PRECAUTIONS

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- The Thrombectomy Set has not been evaluated for treatment of pulmonary embolism. There are reports of serious adverse events, including death, associated with cases where the catheter was used in treatment of pulmonary embolism.
- Use the Thrombectomy Set only with the multiple-use AngioJet Ultra Console.
- Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Debris embolization may cause distal vessel occlusion, which may further result in hypoperfusion or tissue necrosis.
- Cardiac arrhythmias during catheter operation have been reported in a small number of patients. Cardiac rhythm should be monitored during catheter use and appropriate management, such as temporary pacing, be employed if needed.
- Do not use the AngioJet Ultra System in patients who have a nonhealed injury due to recent mechanical intervention in the vessel to be treated to avoid further injury, dissection, or hemorrhage.
- Do not use the catheter in vessels smaller than 3.0 mm in diameter which may increase risk of vessel injury.
- Obstructing lesions that are difficult to cross with the catheter to access thrombus may be balloon dilated with low pressure (≤ 2 atm). Failure to pre-dilate difficult-to-cross lesions prior to catheter operation may result in vessel injury.
- Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. This is in addition to the heparin added to the saline supply bag.
- Operation of the AngioJet System causes transient hemolysis which may manifest as hemoglobinuria. Table 1 (in the IFU) lists maximum recommended run times in a flowing blood field and total operating time for each Thrombectomy Set. Evaluate the patient's risk tolerance for hemoglobinemia prior to the procedure. Consider hydration prior to, during, and after the procedure as appropriate to the patient's overall medical condition.
- Large thrombus burdens in peripheral veins and other vessels may result in significant hemoglobinemia which should be monitored to manage possible renal, pancreatic or other adverse events.
- The catheter should be operated over a 0.035" guide wire. Attempting to use a larger guide wire will damage the catheter and the guide wire.
- Monitor thrombotic debris/fluid flow exiting the Thrombectomy Set via the waste tubing during use. If blood is not visible in the waste tubing during AngioJet Ultra System activation, the catheter may be occlusive within the vessel; verify catheter position, vessel diameter and thrombus status. Operation under occlusive conditions may increase risk of vessel injury.
- Do not exchange the guide wire. Do not retract the guide wire into the catheter during operation. The guide wire should extend at least 3 cm past the catheter tip at all times. If retraction of the guide wire into the Thrombectomy Set occurs, it may be necessary to remove both the Thrombectomy Set and the guide wire from the patient in order to re-load the catheter over the guide wire
    - If resistance is felt during the advancement of the Thrombectomy Set to lesion site, do not force or torque the catheter excessively as this may result in deformation of tip components and thereby degrade catheter performance.
- Do not pull the catheter against abnormal resistance. If increased resistance is felt when removing the catheter, remove the catheter together with the sheath or guide catheter as a unit to prevent possible tip separation.
- Fluids should be injected only under the direction of a physician and all solutions prepared according the manufacturer instructions.
- The Thrombectomy Set waste lumen is rated for 100 psi. Delivering a hand injection of contrast medium with excessive force can create injection pressures greater than 100 psi, potentially causing leaks in the waste lumen of the catheter.
- Do not use a power injector to deliver contrast medium through the catheter stopcock. Power injectors can deliver pressures greater than 100 psi, potentially causing leaks in the waste lumen of the catheter.
- Some fluids, such as contrast agents, can thicken in the catheter lumen and block proper catheter operation if left static too long. The catheter should be operated to clear the fluid within 15 minutes of injection.

ADVERSE EVENTS

Potential adverse events which may be associated with use of the AngioJet Ultra Thrombectomy System are similar to those associated with other interventional procedures and include, but are not limited to:

- abrupt closure of treated vessel
- acute myocardial infarction
- acute renal failure
- bleeding from access site
- cerebrovascular accident
- death
- dissection
- embolization, proximal or distal
- hematoma
- hemolysis
- hemorrhage, requiring transfusion
- hypotension/hypertension
- infection at the access site
- pain
- pancreatitis
- perforation
- pseudoaneurysm
- reactions to contrast medium
- thrombosis/occlusion
- total occlusion of treated vessel
- vascular aneurysm
- vascular spasm
- vessel wall or valve damage

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