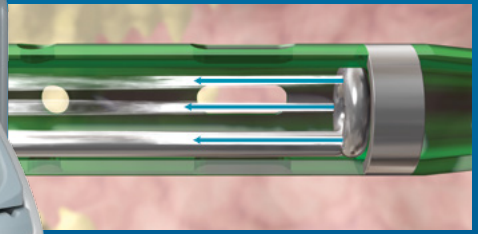
ANGIOJET™ ULTRA Thrombectomy System

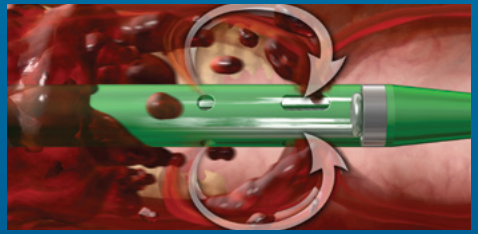
Boston Scientific
Advancing science for life™

1. The AngioJet Ultra Console monitors and controls the system.
2. The Console energizes the pump which sends pressurized saline to the catheter tip.

MECHANISM OF ACTION



3. Saline jets travel backwards to create a low pressure zone causing a vacuum effect.



4. Thrombus is drawn into the in-flow windows and the jets push the thrombus back down the catheter.

5. Thrombus is evacuated from the body and into the collection bag.

ANGIOJET™ Catheter Reference Guide

Model	Indication	Delivery Platform	Minimum Vessel Diameter	Catheter Length	Catheter Diameter	Guidewire Wire	Introducer Sheath	Power Pulse Delivery Enabled	Guidewire Swappable	Contrast Injection Port	Maximum Rate Times: Flow Rate	Maximum Rate Times: Total Run Time	Maximum Rate Times: Run Time with Blood Flow	Catalog Number
AngioJet Console														**105650-001**
ZelanteDVT™	Venous	OTW	6 mm	105 cm	8 F	0.035″	8 F	Yes	Yes	Yes	60mL/min	480 sec	240 sec	**114610-001**
Solent™ Omni	Peripheral Arterial and Venous, AV Access	OTW	3 mm	120 cm	6 F	0.035″	6 F	Yes	Yes	Yes	60mL/min	480 sec	240 sec	**109681-001**
Solent™ Proxi	Peripheral Arterial and Venous, AV Access	OTW	3 mm	90 cm	6 F	0.035"	6 F	Yes	Yes	Yes	60mL/min	480 sec	240 sec	**109676-001**
Solent™ Dista	Peripheral Arterial	OTW	1.5 mm	145 cm	4F/3 F	0.014″	4 F	Yes			23mL/min	600 sec	300 sec	**111303-001**
AVX™	AV Access Grafts and Fistula	OTW	3 mm	50 cm	6 F	0.035"	6 F			Yes	60mL/min	600 sec	300 sec	**105039-001**

Power Pulse™ Delivery

Delivers medication directly into the clot, where it's most effective, saturating and softening tough thrombus to facilitate removal

104834-0021
Power Pulse Kit of 5

SOLENT CATHETERS COMBINED WCONSOLE

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.

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 ≥ 3.0 mm 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. The AngioJet SOLENT dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and 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 IFU). **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 guide wire **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 (unless accompanied by a separate coronary IFU). • 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 nonhealed 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 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. • 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 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. • 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. (Dista only) • 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. (Omni, Proxi only) • 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. • 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. • 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 up and remove peripheral venous thrombus. **Omni, Proxi only**: • 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. **Console WARNINGS and PRECAUTIONS:** • Use the AngioJet Ultra Console only with an AngioJet Ultra Thrombectomy Set. This Console will not operate with a previous model pump set and catheter. • Do not attempt to bypass any of the Console safety features. • If the catheter is removed from the patient and/or is inoperative, the waste tubing lumen, guide catheter, and sheath should be flushed with sterile, heparinized solution to avoid thrombus formation and maintain lumen patency. Reprime the catheter by submerging the tip in sterile, heparinized solution and operating it for at least 20 seconds before reintroduction to the patient. • Refer to the individual AngioJet Ultra Thrombectomy Set Information for Use manual for specific warnings and precautions. • Do not move the collection bag during catheter operation as this may cause a collection bag error. • Monitor thrombotic debris/fluid flow exiting the catheter through the waste tubing during use. If blood is not visible during console activation, the catheter may be occlusive within the vessel or the outflow lumen may be blocked. • Ensure adequate patient anticoagulation to prevent thrombus formation in outflow lumen. • Refer to individual Thrombectomy Set Instructions for Use manual for specific instructions regarding heparinization of the Thrombectomy Set. • The Console contains no user-serviceable parts. Refer service to qualified personnel. • Removal of outer covers may result in electrical shock. • This device may cause electromagnetic interference with other devices when in use. Do not place Console near sensitive equipment when operating. • 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. • Where the "Trapping Zone Hazard for Fingers" symbol is displayed on the console, there exists a risk of trapping or pinching fingers during operation and care must be exercised to avoid injury. • 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. • The AngioJet Ultra Console should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the AngioJet Ultra Console should be observed to verify normal operation in the configuration in which it will be used. • Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT. • The use of accessories and cables other than those specified, with the exception of accessories and cables sold by Bayer HealthCare as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Ultra Console. • MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding Electro-Magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the tables provided in the IFU. **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

Boston Scientific

Advancing science for life™

Peripheral Interventions
Los Militares 4611, piso 10 Santiago, Chile
www.bostonscientific.cl

To order product or for more information contact customer service at 1.888.272.1001.

PI-1247212-AA MAR2022