AngioJet® Ultra Thrombectomy System

Efficient. Effective. Accessible.

The Elegance of the AngioJet Ultra Thrombectomy System.

ANGIOJET®
ULTRA

ANGIOJET® ULTRA

The Benefits of Mechanical Thrombus Removal

Efficient

The AngioJet® Ultra Thrombectomy Console features an advanced control system that automatically detects the catheter model and configures the console to meet the requirements of each catheter. Throughout the procedure the Ultra Console monitors system performance to ensure the procedure is running smoothly. Runtime and infused fluid volume displays provide information and offer physician convenience. The patented Ultra Series Thrombectomy Set integrates the pump and the catheter into a single unit for fast and easy loading.

Effective[1,2]

The AngioJet® Ultra Thrombectomy System removes clot from a range of vessel diameters. The core technology, AngioJet Thrombectomy, has been used in over 600,000 cases worldwide and is the leading choice for eliminating large thrombus burden.

Accessible

The compact and highly mobile Ultra Console glides into place on large easy-rolling wheels and three simple steps prepare the console for operation. Even less-experienced users will find the self-prompted and automated set-up procedure easy and intuitive. When tough thrombus requires patented Power Pulse® Delivery, the Ultra Console quickly guides the user through the set-up steps and infusion is automatically controlled by the console.

Offering an unmatched range of therapies and indications

- Proven technology, sleek design and a user-friendly interface ensure reliability, easy set-up and maneuverability.
- Full range of compatible AngioJet catheters with indications for native coronary arteries and grafts, peripheral arteries and veins, and AV access conduits.
- Advanced control system designed to accommodate highly specialized future innovations.

AngioJet Ultra Thrombectomy System Features

- Patented Cross-Stream® technology for enhanced thrombus removal
- Full range of Catheters for Coronary, Peripheral and AV Access applications
- Ultra Console features an advanced control system that automates set-up and monitors operation
- System self-configures for each catheter model
- Ultra Console automates the set-up of Power Pulse® delivery
- Highly maneuverable console, clear set-up prompts and fast system preparation time
- Single-use components are integrated and packaged together

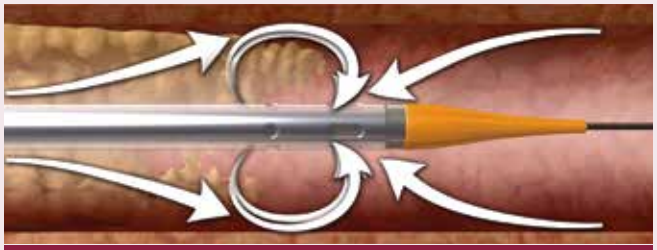
Drive Unit Specifications

Equipment Class	IEC Class 1 Type CF device
Power Requirements	110/120 VAC and 220/240 VAC 50/60 Hz 10 Amps Max
Processor Memory Backup	60 Seconds
Enclosure Protection	IPX1
Foot Switch Protection	IPX8
Size (D x W x H)	23 x 15 x 52.5 inches 58 x 38 x 133 cm
Weight	150 pounds 68 kg
Order Number	105650-TAB

AngioJet Thrombectomy

Proven Performance

Saline jets travel backwards at high speed to create a negative pressure zone (less than -600 mmHg) causing a powerful vacuum effect.



Cross-Stream® windows optimize the fluid flow for more effective thrombus removal.

Thrombus is drawn into the catheter where it is fragmented by the jets and evacuated from the body.

1. Antoniucci, D, et al. The JETSTENT Trial. *J. Am. Coll. Cardiol.* published online Aug 4, 2010; doi:10.1016/j.jacc.2010.06.011.
2. The PEARL Registry, a Bayer HealthCare sponsored study. Data on file.

Indications, operating specifications and availability may vary by country. Check with local product representation and country-specific *Information for Use* for your country.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

AngioJet® Thrombectomy Systems

Indications/Contraindications
AngioJet and AngioJet Ultra peripheral indications include: breaking up and removing thrombus from infra-inguinal peripheral arteries, upper and lower extremity peripheral arteries, upper extremity peripheral veins, ileofemoral and lower extremity veins, A-V access conduits, and for use with the AngioJet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system. Coronary indications include: removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions prior to balloon angioplasty or stent placement. Do not use in patients: who are contraindicated for intracoronary or endovascular procedures, who cannot tolerate contrast media, and in whom the lesion cannot be accessed with the wire guide.

Warnings and Precautions
The system has not been evaluated for treatment of pulmonary embolism or for use in the carotid or cerebral vasculature. Some AngioJet devices have not been evaluated for use in coronary vasculature. Operation of the catheter may cause embolization of some thrombus and/or thrombotic particulate debris. Cardiac arrhythmias may occur and cardiac rhythm should be monitored during catheter use and appropriate management employed, if needed. Systemic heparinization is advisable to avoid pericatheterization thrombus and acute rethrombosis. Operation of the system causes transient hemolysis. Large thrombus burdens may result in significant hemoglobinemia which should be monitored. Consider hydration, as appropriate. Before coronary AngioJet treatment, verify the presence of thrombus because routine use of AngioJet in every STEMI patient, without proper selection for thrombus, has been associated with increased mortality risk. Do not use the system in the coronary vasculature without placing a temporary pacing catheter to support the patient through hemodynamically significant arrhythmias which may occur.

Potential Adverse Events
Potential adverse events (in alphabetical order) which may be associated with use of the system are similar to those associated with other interventional procedures and include but are not limited to the following: abrupt closure of treated vessel, acute myocardial infarction, acute renal failure, arrhythmias (including VF and VT), bleeding from access site, death, dissection, embolization (proximal or distal), emergent CABG, hematoma, hemolysis, hemorrhage requiring transfusion, hypotension/hypertension, infection at access site, myocardial ischemia, pain, pancreatitis, perforation, pseudoaneurysm, reactions to contrast medium, stroke/CVA, thrombosis/occlusion, total occlusion of treated vessel, vascular aneurysm, vascular spasm, vessel wall or valve damage.

Refer to product labeling for device-specific indications, contraindications, warnings/precautions, and adverse events. Rx only. – COM January 2011

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