Coronary Catheter Reference Guide

AngioJet™ Thrombectomy System & Fetch™2 Aspiration Catheter

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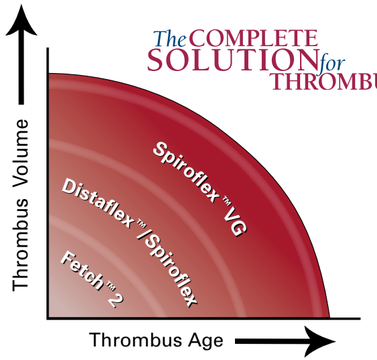
Model	Coronary Indication	Delivery Platform	Minimum Vessel Diameter	Catheter Length	Catheter Diameter	Guide Wire	Guide Catheter	Flow Rate	Maximum Run Times: Total Run Time	Maximum Run Times: Run Time with Blood Flow	Order Information
Spiroflex™	Coronary Arteries & SVGs	RX	2 mm	135 cm	4 F	0.014"	6 F > .070"	40 mL/min	600 sec	300 sec	**106553-001** (Ultra)
Spiroflex™ VG	Coronary Arteries & SVGs	RX	3 mm	135 cm	5 F	0.014"	7 F > .076"	60 mL/min	600 sec	300 sec	**106608-001** (Ultra)
Distaflex™	Coronary Arteries & SVGs	OTW	2 mm	145 cm	4 F/3 F	0.014"	6 F > .070"	23 mL/min	600 sec	300 sec	**111304-001** (Ultra)
XMI™	Coronary Arteries & SVGs	OTW	2 mm	135 cm	4 F	0.014"	6 F > .068"	40 mL/min	600 sec	300 sec	**105041-001** (Ultra)
Aspiration Catheter **Fetch 2**	Coronary Vasculature	RX	2 mm	135 cm	4 F	0.014"	6 F > .070"				**109400-001** (Fetch 2)

A Complete Range of Tools to Treat the Full Range of Thrombus



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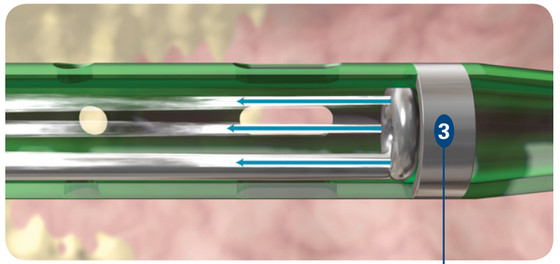
IC-274802-AA OCT2014

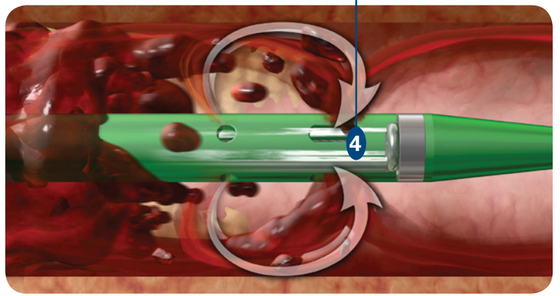
AngioJet™ Ultra Thrombectomy System Mechanism of Action

1 The AngioJet Ultra Console monitors and controls the system.



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

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



AngioJet™ Thrombectomy Systems

General Indications/Contraindications—AngioJet System peripheral indications include: breaking up and removing thrombus from infra-inguinal peripheral arteries, upper and lower extremity peripheral arteries, upper extremity peripheral veins, ileofemoral , infra-iliac and lower extremity veins, A-V access conduits, and for use with the AngioJet Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system. AngioJet 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.

General Warnings and Precautions—The System has not been evaluated for treatment of pulmonary embolism in the US and some other countries 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.

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 (USA) Law restricts the device to sale by or on the order of a physician.