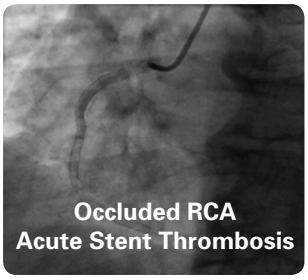
Boston Scientific
Advancing science for life™

ANGIOJET™

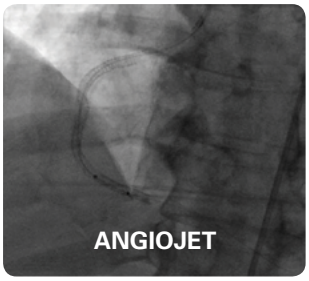
Ultra Coronary Thrombectomy System

CASE STUDY:

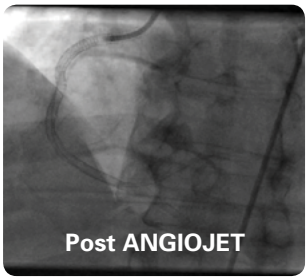
SPIROFLEX™ ANGIOJET thrombectomy of a native coronary artery in a patient presenting with a ST elevation myocardial infarction (STEMI) due to stent thrombosis



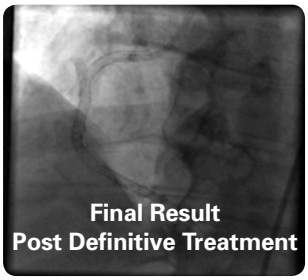
Cine 1
Click to view



Cine 2
Click to view



Cine 3
Click to view



Cine 4
Click to view

Patient History

- 52 year old male
- Former smoker, diabetes, hypertension, hyperlipidemia
- History of coronary artery disease
  - Prior stent to the LAD and D1
  - Prior stent to the circumflex
  - Prior stent to the RCA
  - Inferior MI secondary to stent thrombosis in January 2014 was treated with a second layer of stents in the proximal, mid, and distal RCA
  - Presented with a second stent thrombosis of the RCA in January 2015 which was treated with PTCA and stenting of the mid RCA (3rd layer)
- Patient presented with chest pressure and inferior ST elevation approximately 3 months later
- Patient was referred for coronary angiography

Diagnostic Angiogram

- Initial angiogram showed TIMI 0 flow
- Initial angiogram showed thrombus grade of 5
- The left main and left anterior descending arteries had no significant lesions. The stents in the LAD and D1 were patent
- The circumflex had no significant lesions. The stent in the first OM had a 50% lesion and the stents in the mid circumflex were patent
- The RCA was occluded in the mid vessel (Cine 1)

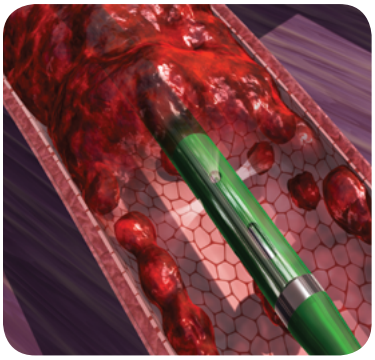
Procedure

- The patient was anticoagulated with heparin and Integrilin™
- Vascular access was gained utilizing a 6 F JR4 guiding catheter and a 190 cm wire
- Post wire TIMI flow was 0; post wire thrombus grade was 5
- The RCA was treated with ANGIOJET thrombectomy utilizing the SPIROFLEX catheter

TB
Thrombus Burden

Master the Complex

ANGIOJET™
Ultra Coronary Thrombectomy System



Procedure *(continued)*

- There was residual thrombus in the mid and distal stents (Cine 2)
- Initially the mid and distal RCA into the posterior lateral artery were treated with multiple SPIROFLEX passes for a total of 27.5 seconds
- A second series of runs was performed utilizing SPIROFLEX ANGIOJET for a total of 35 seconds
- Significant angiographic improvement was observed post mechanical thrombectomy
- Post ANGIOJET thrombus grade was 3 (Cine 3)

Definitive Treatment

Following PTCA with stenting, final TIMI flow was 3; final thrombus grade was 0 (Cine 4).

Physician Commentary

As in this case, patients presenting with recurrent thrombosis over a long stented segment often have a large thrombus burden.

The ANGIOJET Thrombectomy System is ideal to treat patients with a considerable amount of large thrombus and in this patient the ANGIOJET successfully removed a significant thrombus from the mid and distal RCA making definitive treatment easier and reestablishing TIMI 3 flow.

This case demonstrates the utility of mechanical thrombectomy with the ANGIOJET SYSTEM in a patient presenting with a STEMI secondary to stent thrombosis and a substantial thrombus burden in the culprit vessel.

Study and cines courtesy of Jeffrey Chambers, MD, Metropolitan Heart and Vascular Institute, Minneapolis, MN. Results from case studies are not predictive of results in other cases. Results in other cases may vary.

ANGIOJET™ Thromb System for Coronary Use

Intended Use/Indications for Use: The ANGIOJET Ultra System, with the Thrombectomy Set, is intended for removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions prior to balloon angioplasty or stent placement. The minimum vessel diameter for each Thrombectomy Set model is listed in Table 1 (in the IFU). * See also section 7, Patient Selection and Treatment (of the IFU).

Contraindications: Do not use the Thrombectomy Set in patients: • Who are contraindicated for other intracoronary interventional procedures, as the device only removes thrombus in preparation for balloon angioplasty or stent placement. • 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. • Before ANGIOJET treatment, verify the presence of thrombus by angiography or other objective means. As used in the AiMI study, routine ANGIOJET treatment in all STEMI lesions was associated with increased mortality risk. • Do not use the catheter for coronary applications without first placing a temporary pacing catheter to support the patient through hemodynamically significant arrhythmias which may occur. • Use the Thrombectomy Set only with the multi-use ANGIOJET Ultra Console. • Do not use the System in vessels smaller than indicated in Table 1 (of the IFU). • Some patients have reported chest discomfort during System operation for the coronary application. A short acting pain medication may be administered to relieve this discomfort. • Transient alterations in blood flow may occur during System use for the coronary application. Routine treatment with calcium channel blockers is suggested. • 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 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. • 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. • 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. • Operation of the catheter may cause hemolysis. Table 1 of the IFU lists maximum recommended run times in a flowing blood field and total operating time for each Thrombectomy Set. Excessive hemolysis may require blood transfusion. In investigational clinical studies, hemolysis induced by ANGIOJET Ultra System operation was not associated with any significant systemic response.

Potential Adverse Events: Potential adverse events (in alphabetical order) which may be associated with use of the Thrombectomy Set are similar to those associated with other interventional procedures and include but are not limited to those listed in Table 3 of the IFU (which include target lesion revascularization, bleeding complications and vascular complications) and the following: • abrupt closure of treated vessel • acute myocardial infarction • acute renal failure • arrhythmias, including VF and VT • bleeding from access site • cerebrovascular accident • 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.

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.

REVAA

ANGIOJET™ Ultra Console

Intended Use/Indications for Use: The Console is intended for use only in conjunction with an ANGIOJET Ultra Thrombectomy Set. Refer to the individual Thrombectomy Set Information for Use manual for specific clinical applications.

Contraindications: Refer to the individual Thrombectomy Set Information for Use manual for specific contraindications.

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

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ANGIOJET™ Ultra SPIROFLEX Coro

Indications and Usage: The ANGIOJET Ultra System, with the Thrombectomy Set, is intended for removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions prior to balloon angioplasty or stent placement. The minimum vessel diameter for each Thrombectomy Set model is listed in Table 1 (in the IFU).

Contraindications: Do not use the Thrombectomy Set in patients: • Who are contraindicated for other intracoronary interventional procedures, as the device only removes thrombus in preparation for balloon angioplasty or stent placement. • 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. **• Before ANGIOJET treatment, verify the presence of thrombus by angiography or other objective means. As used in the AiMI study, routine ANGIOJET treatment in all STEMI lesions was associated with increased mortality risk. • Do not use the catheter for coronary applications without first placing a temporary pacing catheter to support the patient through hemodynamically significant arrhythmias which may occur.** • Use the Thrombectomy Set only with the multi-use ANGIOJET Ultra Console. • Do not use the System in vessels smaller than indicated in Table 1 (of the IFU). • Some patients have reported chest discomfort during System operation for the coronary application. A short acting pain medication may be administered to relieve this discomfort. • Transient alterations in blood flow may occur during System use for the coronary application. Routine treatment with calcium channel blockers is suggested. • 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 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. • 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. • 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. • Operation of the catheter may cause hemolysis. Table 1 (of the IFU) lists maximum recommended run times in a flowing blood field and total operating time for each Thrombectomy Set. Excessive hemolysis may require blood transfusion. In investigational clinical studies, hemolysis induced by ANGIOJET Ultra System operation was not associated with any significant systemic response. • Refer to ANGIOJET Ultra System Console *Operations Manual* for other warnings, precautions, and system set-up instructions.

Potential Adverse Events: Potential adverse events (in alphabetical order) which may be associated with use of the Thrombectomy Set are similar to those associated with other interventional procedures and include but are not limited to those listed in Table 3 (of the IFU) and the following: • abrupt closure of treated vessel • acute myocardial infarction • acute renal failure • arrhythmias, including VF and VT • bleeding from access site • cerebrovascular accident • 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.

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