AngioJet® LF140 Rheolytic™ Thrombectomy Catheter for Coronary Use

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Information for Use

Table of Contents

AngioJet® LF140 Rheolytic™ Thrombectomy Catheter 1
1. DEVICE DESCRIPTION 2
Figure 1. AngioJet LF140 Catheter 2
2. INDICATIONS AND USAGE* 2
3. CONTRAINDICATIONS 2
4. WARNINGS and PRECAUTIONS* 3
5. ADVERSE EVENTS 3
5.1 Observed Adverse Events 3
Table 1. Clinical Trial Patient Enrollment 3
Table 2. Major Adverse Events (to 30 Days) 4
6. CLINICAL STUDIES 6
Table 3. Principal Effectiveness And Safety Results 7
Figure 2. MACE (CK-MB)-Free Survival 8
7. PATIENT SELECTION AND TREATMENT 8
7.1 Individualization of Treatment 8
7.2 Specific Patient Populations 9
8. PATIENT COUNSELING INFORMATION 9
9. CONFORMANCE TO STANDARDS 9
10. CLINICIAN USE INFORMATION 10
10.1 Inspection Prior to Use – Precautions 10
10.2 Materials Required (not included in the package) 11
10.3 Preparation of the AngioJet LF140 Catheter 11
10.4 Patient Preparation (Warnings and Precautions) 11
10.5 Catheter Delivery and Operation 12
11. PATIENT INFORMATION 13
12. HOW SUPPLIED 13

1. DEVICE DESCRIPTION

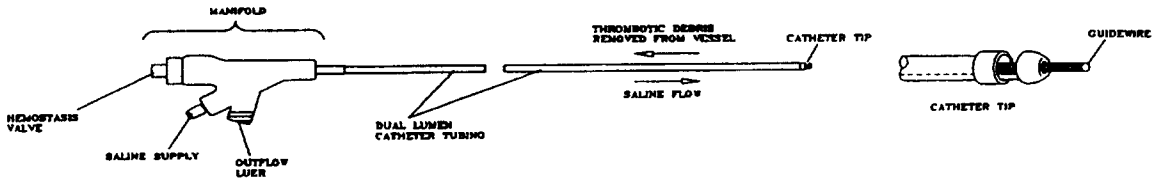


Figure 1. AngioJet LF140 Catheter

The AngioJet® LF140 Rheolytic™ Thrombectomy Catheter (AngioJet LF140 Catheter) is one component of the AngioJet® Rheolytic™ Thrombectomy System (AngioJet System). The other two components are the single-use AngioJet® Pump Set and the multi-use AngioJet® Drive Unit (both packaged and sold separately). The AngioJet LF140 Catheter may only be used in conjunction with the AngioJet Pump Set and AngioJet Drive Unit.

The AngioJet LF140 Catheter is a 140 cm, 5.0 French, dual lumen, sterile, single-use catheter designed for removing thrombus from coronary conduits. High velocity saline jets directed back into the catheter create a localized low pressure zone at the distal tip (Bernoulli effect) which results in the suction, break-up, and removal of thrombus through the exhaust lumen.

The AngioJet LF140 Catheter is introduced through a guide catheter. An 8 French high flow guide catheter (.080 inch minimum internal diameter) is sufficient to allow passage of the AngioJet LF140 Catheter with adequate clearance for injection of standard contrast media, if desired. The AngioJet LF140 Catheter tracks and operates over a standard .018 inch (or smaller) guide wire.

2. INDICATIONS AND USAGE*

The AngioJet System is intended for removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels $\geq$ 2.0 mm in diameter prior to balloon angioplasty or stent placement.

** See also section 7, PATIENT SELECTION AND TREATMENT*

3. CONTRAINDICATIONS

Do not use the AngioJet LF140 Catheter 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.

4. WARNINGS and PRECAUTIONS*

- **Do not use the AngioJet LF140 Catheter for coronary applications without first placing a temporary pacing catheter to support the patient through hemodynamically significant arrhyhthmias which may occur.**
- The AngioJet System should be used only by operators who have received appropriate training in its set-up and use.
- Use the AngioJet LF140 Catheter only with the AngioJet Pump Set and the multi-use AngioJet Drive Unit.
- The AngioJet LF140 Catheter is intended for single use only. Do not resterilize or reuse.

**See also Section 7, Patient Selection and Treatment, and Section 10, CLINICIAN USE INFORMATION.*

STERILE EO Sterilized with Ethylene Oxide Single Use Only

5. ADVERSE EVENTS

5.1 Observed Adverse Events

A total of 731 patients were enrolled in two multi-center clinical trials of the AngioJet System, as summarized in Table 1.

Table 1. Clinical Trial Patient Enrollment

All patients in all Clinical Studies (n=731)

Study Group	Feasibility patients (AngioJet)	VeGAS 2 Randomized Study		
		AngioJet patients	Urokinase (control)	Total VeGAS 2 Patients
Vein Graft AngioJet Study (VeGAS 1 feasibility study)	90		-	
VeGAS 2 Randomized Trial:				
Qualification phase	80		-	
Randomization phase	-	180	169	349
VeGAS 2 AMI Treatment Arm	-	107	-	107
VeGAS 2 TE Treatment Arm	-	105	-	105
Patient Totals	**170**	**392**	**169**	**561**

Adverse events from the second Vein Graft AngioJet Study (VeGAS 2) Randomized Trial (AngioJet treatment arm), the Acute Myocardial Infarction (AMI) Treatment Arm, and the Thrombolysis Exclusion (TE) Treatment Arm are shown in Table 2 (n= 561 patients).

Table 2. Major Adverse Events (to 30 Days)

% (number) difference [95% confidence interval]

All patients in the VeGAS 2 Randomized Trial, AMI Treatment Arm, and TE Treatment Arm (n=561)

	Randomized Trial			AMI Treatment Arm n=107	TE Treatment Arm n=105
	AngioJet Arm (n=180)	Urokinase Arm (n=169)	Difference [95% CI]		
Death	1.7% (3)	3.0% (5)	-1.3% [-4.5, 1.9][1]	7.5% (8)	1.9% (2)
MACE	13.9% (25)	21.9% (37)	-8.0% [-16.0, 0.0]	13.1% (14)	18.1% (19)
MACE (CK-MB)	15.6% (28)	32.5% (55)	-17.0% [-25.8, 8.2]	13.1% (14)	23.8% (25)
MI	11.1% (20)	19.5% (33)	-8.4% [-16.0, -0.9]	3.7% (4)	14.3% (15)
Q-MI	2.2% (4)	5.3% (9)	-3.1% [-7.1, 0.9]	0.0% (0)	1.0% (1)
Non-Q-MI	8.9% (16)	14.2% (24)	-5.3% [-12.0, 1.4]	3.7% (4)	14.3% (15)
MI (CK-MB)	14.4% (26)	30.8% (52)	-16.3% [-25.0, -7.7]	3.7% (4)	20.0% (21)
Q-MI	2.2% (4)	5.3% (9)	-3.1% [-7.1, 0.9]	0.0% (0)	1.0% (1)
Non-Q-MI	12.2% (22)	25.4% (43)	-13.2% [-21.3, -5.1]	3.7% (4)	20.0 (21)
TLR (TOTAL)	3.3% (6)	3.6% (6)	-0.2% [-4.0, 3.6]	2.8% (3)	5.7% (6)
CABG	0.6% (1)	3.0% (5)	-2.4% [-5.2, 0.4]	0.9% (1)	0.0% (0)
PTCA	2.8% (5)	0.6% (1)	2.2% [-0.5, 4.9]	1.9% (2)	5.7% (6)
Abrupt Closure	3.3% (6)	4.7% (8)	-1.4% [-5.5, 2.7]	4.7% (5)	5.7% (6)
Subacute Closure	2.8% (5)	4.1% (7)	-1.4% [-5.2, 2.5]	1.9% (2)	6.7% (7)
Bleeding Complication	5.0% (9)	11.8% (20)	-6.8% [-12.7, -1.0]	13.1% (14)	12.4% (13)
Vascular Complication	4.4% (8)	17.8% (30)	-13.3% [-19.8, -6.8]	12.1% (13)	9.5% (10)
CVA	1.7% (3)	1.2% (2)	0.5% [-2.0, 3.0]	1.9% (2)	1.0% (1)

MACE = Death, Q wave and non-Q wave MI (CPK > 2X upper limit normal), emergent CABG, repeat target lesion revascularization, or CVA within 30 days of index procedure, as determined by the Clinical Events Committee.

MACE (CK-MB) = Death, Q wave and CK-MB non-Q wave MI (CK-MB > 3X upper limit normal), emergent CABG, repeat target lesion revascularization, or CVA within 30 days of index procedure, as determined by the Clinical Events Committee.

MI includes non-Q wave MI = CPK > 2X upper limit normal

MI (CK-MB) includes non-Q wave MI = CK-MB > 3X upper limit normal

TLR= Target lesion revascularization.

Abrupt Closure = lesion-related new severely reduced flow (TIMI 0 or1) within the target vessel that persisted, and required rescue by a non-assigned treatment strategy, or persisted and resulted in MI or death.

Subacute closure = new reduced (TIMI 0 or 1) flow at the target vessel as a result of a mechanical obstruction, such as dissection or luminal thrombus, occurring after completion of the index procedure but within 30 days of the index procedure.

Bleeding Complications = procedure related blood transfusions.

Vascular Complications = hematoma > 4cm, retroperitoneal bleed, false aneurysm, AV fistula, peripheral ischemia/nerve injury, hemolysis and hemolytic anemia.

[1] Difference = $S_{AngioJet} - S_{urokinase}$, $SE_{diff} = sqrt(SE_{AngioJet}^2 + SE_{urokinase}^2)$, CI= Diff$\pm$ 1.96*SE_{diff}

Total Deaths: There were a total of 44 deaths among the 731 patients in all clinical studies. All deaths were reviewed by a masked, independent clinical events committee (ICEC). None of the deaths were judged by the ICEC to be directly attributable to the device. During the **Feasibility Study** 12 patient deaths occurred, four within 30 days of the assigned treatment (two due to cardiac arrest, and one each due to cardiogenic shock and intracerebral hemorrhage and cardiac arrest). In the **Randomized Trial,** 16 patients died, six in the AngioJet arm (one patient never received the assigned treatment) and ten in the urokinase treatment arm. Of the five patients that were treated with the AngioJet, the two deaths within 30 days were due to respiratory distress / electromechanical dissociation (n=1), and cardiomyopathy / congestive heart failure (n=1). The other three deaths occurred between 98 and 317 days post AngioJet treatment due to respiratory failure (n=1), and sudden cardiac death (n=2). Ten **AMI Treatment Arm** patients died during the study. The eight deaths which occurred within 30 days were due to cardiac arrest (n=4), cardiac tamponade (n=1), cardiogenic shock (n=1), myocardial rupture (n=1), and pericardial effusion / heart block (n=1). Six **TE Treatment Arm** patients died during the study. The two deaths within 30 days were due to cardiac arrest (n=1) and cardiogenic shock (n=1).

5.2 Potential Adverse Events

Potential adverse events (in alphabetical order) which may be associated with use of the AngioJet LF140 Catheter including those listed in Table 2 and the following:

- abrupt closure of treated vessel
- acute myocardial infarction
- arrhyhthmias, including VF and VT
- death
- dissection
- emboli, distal
- emergent CABG
- hemolysis
- hemorrhage, requiring transfusion
- hypotension/hypertension
- infection at the access site
- myocardial ischemia
- pain
- perforation
- pseudoaneurysm
- reactions to contrast medium
- stroke/CVA
- thrombosis/occlusion
- total occlusion of treated vessel
- vascular spasm

6. CLINICAL STUDIES

A total of 731 patients were treated at 41 sites in the United States and Canada in the VeGAS randomized clinical trial and registries (Table 1).

Purpose of the studies:
The purpose of the VeGAS studies was to establish the safety and effectiveness of thrombus removal by the AngioJet LF140 Catheter in saphenous vein bypass grafts or native coronary arteries $\geq$ 2.0 mm in diameter. The Randomized Trial was configured as a multicenter, 2-arm prospective trial comparing immediate AngioJet thrombectomy to urokinase thrombolysis (infusion for 6 to 30 hours), followed by definitive percutaneous treatment.

Outcome Measures:
Procedure success was defined as achievement of a final residual diameter stenosis of <50% (by QCA core laboratory), and TIMI 3 flow post-procedure in the absence of death, emergent bypass surgery, or Q wave MI prior to hospital discharge as determined by the ICEC. The **primary endpoint** for the Randomized Trial and the AMI and TE treatment arms was defined as procedure success, $\geq$ 20% change in diameter stenosis and survival to 30 days without death, Q wave MI, emergent CABG, target lesion revascularization, CVA, or stent rethrombosis.

Patients studied:
The study population was to include patients with angiographically evident thrombus in either a saphenous vein bypass graft or a native coronary artery $\geq$ 2.0 mm in diameter who had not experienced an AMI within 24 hours. Patients who warranted percutaneous revascularization of one or two discrete thrombotic lesions within the same target vessel were eligible for enrollment. Patients experiencing an AMI (within 24 hours of symptom onset) were eligible for enrollment in an AMI Treatment Arm. Diagnosis of AMI was based on clinical symptoms, ECG evidence of ischemic ST changes, and elevated cardiac enzymes. Patients ineligible for enrollment in the randomized trial due to contraindications for urokinase thrombolysis were eligible for enrollment in the TE Treatment Arm.

Methods:
Baseline clinical and angiographic data were collected to establish angiographic evidence of thrombus. Clinical follow-up was required at 30 days, six months, and one year. Quantitative coronary angiography was performed pre-procedure, following thrombectomy, and after final treatment. Endpoints for all clinical studies were immediately analyzed on an intent-to-treat basis. The ICEC adjudicated all major adverse events.

The Randomized Trial was designed to evaluate 520 patients, but was stopped after 349 patients were enrolled because of investigator unwillingness to continue to assign patients to the urokinase control arm. Patients receiving urokinase required continuous infusion, intensive monitoring and longer hospitalization. The resulting data was judged to be statistically valid and adequately powered to examine the study hypothesis.

Results:

The clinical trials enrolled patients with any duration of symptoms. Of the 440 patients reporting a duration of symptoms before AngioJet treatment, 135 (31%) reported symptoms less than 24 hours, 269 (61%) had symptom duration of 24 hours to two weeks, and 36 (8%) had symptoms lasting more than two weeks. Procedure success was 81%, 83%, and 75% for these three symptom duration categories, compared to 62%, 75%, and 63% for the same duration categories treated with the urokinase control. Examination of these results by lesion site (SVG vs. native) and post procedure minimum lesion diameter (MLD) did not show any interaction.

Table 3 shows the principal effectiveness and safety outcomes for the randomized cohort and the AMI and TE Treatment Arms. The primary endpoint for the trial combined efficacy measures at the end of treatment with freedom from major complications at 30 days. Results for this endpoint did not differ between randomized treatments (70.9% for AngioJet compared to 70.4% for urokinase).

Table 3. Principal Effectiveness And Safety Results

All Randomized, AMI, and TE Treatment Arm Patients Treated (561 Patients, 565 Lesions)

Cohort	AngioJet RCT (N=180)	Urokinase RCT (N=169)	% Difference (95% C.I.)	AMI Arm (N=107)	TE Arm (N=105)
Efficacy Measures					
Lesion Success	87.6% (156/178)	79.6% (129/162)	8.0 [0.1, 15.9]	83.0% (88/106)	77.9% (81/104)
Procedure Success	86.3% (151/175)	72.2% (117/162)	14.1 [5.5, 22.6]	77.1% (81/105)	76.0% (79/104)
Device Success	87.4% (153/175)	75.3% (122/162)	12.1 [3.9, 20.4]	82.9% (87/105)	76.9% (80/104)
Post-Procedure MLD (mm) Range (min, max)	2.59±0.82 (178) (0.00, 5.42)	2.45±1.08 (162) (0.00, 4.70)	0.14 [-0.1, 0.3]	2.41±0.81 (106) (0.00, 4.12)	2.61±1.03 (104) (0.00, 4.80)
Post-Procedure % DS Range (min, max)	22%±21% (178) (-30%, 100%)	28%±29% (162) (-31%, 100%)	-6.0 [-11.3, -0.7]	24%±24% (106) (-37%, 100%)	24%±27% (104) (-32%, 100%)
TLR-Free at 30 Days	96.7%	96.4%	0.2 [-3.6, 4.1]	97.1%	94.2%
TVR-Free at 30 Days	95.0%	95.8%	-0.8 [-5.2, 3.6]	96.2%	93.2%
TVF-Free at 30 Days	85.0%	77.5%	7.5, -0.7, 15.6]	86.0%	81.8%
MACE (CK-MB) Free at 30 Days	84.4%	67.5%	17.0 [8.1, 25.8]	86.9%	76.1%
Primary Endpoint-Free at 30 Days	70.9% (124/175)	70.4% (114/162)	0.5 [-9.2, 10.2]	75.2% (79/105)	68.9% (71/103)
Safety Measures					
In-Hospital MACE (CK-MB)	14.4% (26/180)	32.5% (55/169)	0.44 [0.30, 0.66]	13.1% (14/107)	20.0% (21/105)
Out-of-Hospital MACE (CK-MB) to 30 Days	3.9% (7/180)	1.2% (2/169)	3.29 [0.76, 14.23]	0.0% (0/107)	6.7% (7/105)
Abrupt Closure	3.3% (6/180)	4.7% (8/169)	0.70 [0.25, 1.98]	4.7% (5/107)	5.7% (6/105)
Subacute Closure	2.8% (5/180)	4.1% (7/169)	0.67 [0.22, 2.06]	1.9% (2/107)	6.7% (7/105)
Bleeding Complications	5.0% (9/180)	11.8% (20/169)	0.42 [0.20, 0.88]	13.1% (14/107)	12.4% (13/105)
Vascular Complications	4.4% (8/180)	17.8% (30/169)	0.25 [0.13, 0.49]	12.1% (13/107)	9.5% (10/105)
CVA to 30 Days	1.7% (3/180)	1.2% (2/169)	1.41 [0.24, 8.27]	1.9% (2/107)	1.0% (1/105)

Numbers are % (counts/sample size) and Mean±Standard Deviation. CI = Confidence Interval.

Relative Risk =AJ/UK SE = $\text{sqrt}\{(1-p_1)/n_{11}+(1-p_2)/n_{21}\}$ CI = $RR^{*}\exp(\pm 1.96^{*}SE_{RR})$

Difference =AJ–UK SE = $\text{sqrt}(p_1^{*}q_1/n_1+p_2^{*}q_2/n_2)$ CI = $\text{Diff}\pm 1.96^{*}SE_{Diff}$

Lesion Success = Achievement of a final residual diameter stenosis of <50% (by QCA core laboratory), and TIMI 3 flow post-procedure using any percutaneous method.

Procedure Success = Achievement of a final residual diameter stenosis of <50% (by QCA core laboratory), and TIMI 3 flow post-procedure in the absence of death, emergent bypass surgery, or Q wave MI prior to hospital discharge as determined by the independent Clinical Events Committee.

Device Success = Achievement of a final residual diameter stenosis of <50% (by QCA core laboratory), and TIMI 3 flow post-procedure, using the assigned device only (without crossover use of AngioJet in patients randomized to urokinase).

Minimal Lumen Diameter = Mean minimum lumen diameter using the "worst view" analysis method.

Diameter Stenosis (DS) = 100% X (1-[MLD/RVD]), based on the mean value from 2 orthogonal views (when available) using QCA.

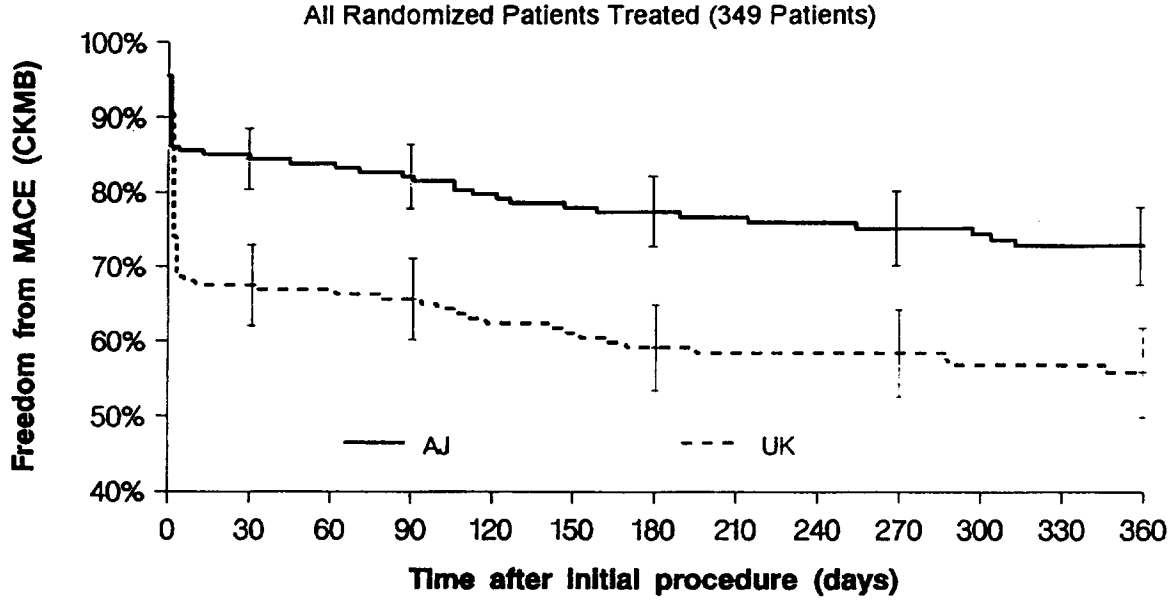
TLR-free = No target lesion revascularization.

TVR-free = No target vessel revascularization.

TVF-free = No death, Q wave and WHO non-Q wave MI, or target vessel revascularization.
In-Hospital MACE (CK-MB) = Death, Q wave and non-Q wave (CK-MB > 3X upper limit normal) MI, emergent CABG, repeat target lesion revascularization, or CVA prior to hospital discharge as determined by the independent Clinical Events Committee.
Out-of-Hospital MACE (CK-MB) = Death, Q wave and non-Q wave (CK-MB > 3X upper limit normal) MI, emergent CABG, repeat target lesion revascularization, or CVA after hospital discharge as determined by the independent Clinical Events Committee.
Primary Endpoint Free at 30 Days = No death, Q wave MI, emergent CABG, target lesion revascularization, CVA, or stent thrombosis to 30 days as determined by the independent Clinical Events Committee, with TIMI 3 flow and DS <50% post-procedure, and a ≥0.20 change in diameter stenosis.
Bleeding Complications = Procedure related blood transfusions.
Vascular Complications = Hematoma >4 cm, retroperitoneal bleed, false aneurysm, AV fistula, peripheral ischemia/nerve injury, hemolysis and hemolytic anemia.
*Survival estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula:
Difference = $S_{AJ}-S_{UK}$ $SE_{Diff} = sqrt\{SE_{AJ}^2+SE_{UK}^2\}$ $CI = Diff \pm 1.96*SE_{Diff}$

Non-Q wave MI is an indicator of distal embolization and myocardial necrosis. MACE (CK-MB) is a composite of Death, Q wave and non-Q wave (CK-MB > 3X upper limit normal) MI, emergent CABG, repeat target lesion revascularization, or CVA. Figure 2 displays Kaplan-Meier actuarial curves of MACE (CK-MB)-free survival out to one year for the two treatments.

Figure 2. MACE (CK-MB)-Free Survival
Kaplan-Meier estimates and ± 1.5 standard errors of the mean
All Randomized Patients Treated (349 Patients)



Numbers of Patients at	30 days	90 days	180 days	270 days	360 days
AngioJet	152	142	130	120	95
Urokinase	114	105	94	87	73

7. PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before

using the AngioJet System.

- Patient selection factors to be assessed should include a judgement of the risk of a PTCA procedure. Since use of the AngioJet System is most often followed by PTCA, patients considered at high risk for PTCA should be considered for CABG.
- The relation of baseline and procedure variables to 30-day MACE was examined. The only significant predictors of increased 30-day MACE were:
  - saphenous vein grafts *vs.* native coronary arteries.
  - Smaller minimum lumen diameter (MLD) after the final interventional procedure.

7.2 Specific Patient Populations

The safety and effectiveness of the AngioJet System has not been shown or adequately studied in:

- Patients with thrombotic lesions in an unprotected left main coronary artery.
- Patients with thrombotic ostial lesions.

8. PATIENT COUNSELING INFORMATION

The physician should consider the following points in counseling the patient about the AngioJet System:

- Discuss the risk/benefit issues for this particular patient, both for AngioJet use and for other interventional treatments likely to be employed.
- Discuss post procedure home-care and rehabilitation guidelines.
- Discuss alterations to current lifestyle following treatment, both short and long term.

9. CONFORMANCE TO STANDARDS

The AngioJet System was designed, tested, and manufactured in conformance with all or applicable parts of the standards which follow. This information should not be used as a basis of comparisons among devices, since different parts of the listed standards may have been used.

1. EN 46001. Quality Systems- Medical Devices- Particular Requirements for the Application of EN ISO 9001,1996.
2. Quality System Regulation 1996: 21CFR 820.
3. EN 550. Sterilization of Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization, 1994.
4. ISO 11135. Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization, 1994.
5. ASTM F1140-88. Standard Test Method for Failure Resistance of Unrestrained and Non-rigid Packages for Medical Applications, 1988.

6. prEN 1041. Terminology, Symbols, and Information Provided with Medical Devices; Information Supplied by the Manufacturer with Medical Devices, 1994.

7. FED STD 209E Airborne Particulate Cleanliness Classes in Cleanrooms, 1988.

8. Guidance for Validation of the *Limulus* Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices, as proposed by CDRH, 1988.

9. ISO 10993. Biological Evaluation of Medical Devices.
   Part 1- Guidance on Selection of Tests, 1992
   Part 4- Selection of Tests for Interactions with Blood, 1992
   Part 5- Tests for Cytotoxicity: *In Vitro* Methods, 1992
   Part 7- Ethylene Oxide Sterilization Residuals, 1995
   Part 10-Tests for Irritation and Sensitization, 1995
   Part 11-Tests for Systemic Toxicity, 1993

10. Tripartite Biocompatibility Guidance Document for Blood Contact Devices, and General Program Memorandum G95-1, Use of International Standard 10993- Biological Evaluation of Medical Devices, 1995.

11. prEN 1441. Medical Devices- Risk Analysis, 1994.

12. Good Laboratory Practice Regulations (GLP) 21 CFR 58.

13. ISO 10555-1. Sterile, Single-Use Intravascular Catheters. 1995.

10. CLINICIAN USE INFORMATION

Caution: A thorough understanding of each component of the AngioJet System is required. Follow this Catheter Information for Use and the instructions packaged with the AngioJet Drive Unit and AngioJet Pump Set.

10.1 Inspection Prior to Use – Precautions

Step 1. Inspect sealed sterile package before opening. Do not use after the "Use By" date as sterility or function may be compromised. If packaging integrity has been compromised, do not use or resterilize the contents, and contact a Possis Medical, Inc. representative.

Step 2. Remove the AngioJet LF140 Catheter from the package using sterile technique and inspect prior to use to ensure that no damage has occurred during shipment. Do not use, or straighten and use a severely kinked product; such use may result in rupture and/or vessel injury. Do not use product if any defects are noted, and contact a Possis Medical, Inc. representative.

10.2 Materials Required (not included in the package)

- AngioJet Pump Set
- AngioJet Drive Unit
- Appropriate guide catheter (0.080 inch minimum ID)
- Appropriate exchange length guide wire (0.014 - .018 inch)
- Heparinized normal saline (HepNS), in bowl for wipe-downs and AngioJet LF140 Catheter priming (2000U/L suggested)
- HepNS for injection, in bag hung on AngioJet Drive Unit, and to be connected to the AngioJet Pump Set (5000 U/L suggested)

10.3 Preparation of the AngioJet LF140 Catheter

Step 1. Set up the AngioJet Drive Unit and AngioJet Pump Set according to the Operator's Manual packaged with the AngioJet Drive Unit and the Instructions for Use packaged with the AngioJet Pump Set. The MODE 2 AngioJet Drive Unit setting must be selected to operate the AngioJet LF140 Catheter.

Step 2. Attach the saline supply line from the AngioJet Pump Set to the saline supply connector on the AngioJet LF140 Catheter manifold and tighten securely by hand.

Step 3. Attach the outflow tubing from the AngioJet Pump Set to the outflow Luer connector on the AngioJet LF140 Catheter manifold.

Step 4. Tighten the hemostasis valve on the AngioJet LF140 Catheter manifold to prevent leakage, then submerge the tip in HepNS. Depress the AngioJet Drive Unit footswitch to prime the AngioJet LF140 Catheter. Continue for approximately 20 seconds to ensure that air is displaced by HepNS and that bubbles are moved past the outflow bubble detector on the AngioJet Drive Unit prior to patient use. Reset any alarms as needed to complete priming.

The Catheter is ready for use after priming has been completed.

10.4 Patient Preparation (Warnings and Precautions)

Warning: Operation of the AngioJet LF140 Catheter may cause arrhyhthmias, especially during use in distal circulation supplying the AV node. It is suggested that a temporary pacing catheter be placed and tested for adequate ventricular capture prior to beginning AngioJet LF140 Catheter operation. The patient should be monitored for arrhyhthmias and ST segment elevation/depression during operation. Considerable variation in patient sensitivity towards the occurrence of arrhyhthmias has been noted.

Warning: Transient alterations in blood flow may occur during AngioJet LF140 Catheter use. Routine treatment with calcium channel blockers is suggested.

Caution: Some patients have reported chest discomfort during AngioJet LF140 Catheter operation. A short acting pain medication may be administered to relieve this discomfort.

10.5 Catheter Delivery and Operation

Step 1. The AngioJet LF140 Catheter is introduced through a guide catheter. Position the guide catheter and guide wire to support delivery of the device through the target lesion site.

Ensure that the hemostasis valve on the AngioJet LF140 Catheter manifold is sufficiently tight around the guide wire to prevent leakage.

Caution: Crossing the thrombotic lesion with the AngioJet LF140 Catheter should be attempted first. If the lesion cannot be readily crossed, the affected vessel segment should be dilated with low pressure ($\leq$ 2 atm) prior to device passage and operation. Failure to dilate difficult-to-cross lesions prior to AngioJet LF140 Catheter operation may result in vessel injury.

Step 2. Advance the AngioJet LF140 Catheter over the wire to or through the thrombotic lesion.

Caution: Do not retract the guide wire into the AngioJet LF140 Catheter during operation; the wire may not re-advance correctly and device tracking may be compromised. The guide wire should extend at least 3 cm past the AngioJet LF140 Catheter tip at all times. If retraction of the guide wire into the AngioJet LF140 Catheter occurs, it may be necessary to remove both the AngioJet LF140 Catheter and the guide wire from the patient in order to re-load the AngioJet LF140 Catheter over the guide wire.

Step 3. Verify that AngioJet Drive Unit MODE 2 has been selected, then activate the AngioJet LF140 Catheter by depressing the AngioJet Drive Unit footswitch. Thrombectomy may be achieved by either distal-to-proximal or proximal-to-distal passes of the AngioJet LF140 Catheter through the thrombus. Passes should be made at a rate of approximately 1 mm/sec.

The distal-to-proximal method should be used if the AngioJet LF140 Catheter can be positioned safely and when the thrombus lesion is highly mobile with a proximal attachment point.

Step 4. For optimal results, serial passes with the AngioJet LF140 Catheter may be required. Hand injection of standard contrast medium delivered through the guide catheter may be used to evaluate treatment. The AngioJet LF140 Catheter need not be removed for contrast injections.

Caution: Operation of the AngioJet LF140 Catheter may cause hemolysis. Hemolysis indicators in the blood should be monitored if total operation time exceeds 15 minutes, or if operation in a flowing blood field exceeds 10 minutes. Excessive hemolysis may require blood transfusion. In investigational clinical studies, hemolysis induced by AngioJet LF140 Catheter treatment was not associated with any significant systemic response.

AngioJet LF140 Catheter thrombectomy treatments can be performed in conjunction with

definitive treatments of the residual stenosis such as PTCA or stent placement.

If the AngioJet LF140 Catheter is removed and inoperative for > 15 minutes, the outflow lumen, guide catheter and sheath should be flushed with HepNS. Re-prime the AngioJet LF140 Catheter by submerging the tip in HepNS for approximately 20 sec before reintroduction to the patient.

11. PATIENT INFORMATION

No separate patient information is provided because the AngioJet LF140 Catheter is used in association with standard balloon angioplasty or stenting. Risks and benefits to the patient are similar to and, from the patient's perspective, a part of those interventional procedures.

12. HOW SUPPLIED

STERILE: The AngioJet LF140 Catheter is sterilized with ethylene oxide gas. It is intended for single use only. Non-pyrogenic. Do not use if package is opened or damaged.

CONTENTS: One (1) AngioJet LF140 Catheter
One (1) Information for Use insert

STORAGE: Store in a cool, dry, dark place.

Possis Medical Inc.
9055 Evergreen Boulevard N.W.
Minneapolis, MN 55433-8003 USA
Phone: 800-810-7677
FAX: 612-780-2227

Manufacturer's Official EU Representative:
Possis Medical Europe b.v.
Keizergracht 62-64
1015 CS Amsterdam
The Netherlands
Phone: 31(0)-20-520-75-35
FAX: 31(0)-20-520-75-10