Evidence-based Practice Center Systematic Review Protocol

Project Title: *Technical Brief: Neurothrombectomy Devices for Treatment of Acute Ischemic Stroke*

I. Background and Objectives for the Technical Brief

Definition and Prevalence of Ischemic Stroke

Stroke is the third leading cause of death following diseases of the heart and cancer.[1,2] A majority of strokes are classified as ischemic in nature (87 percent), with intracerebral hemorrhage (10 percent) and subarachnoid hemorrhage stroke (3 percent) accounting for the rest.[2] Every year in the United States, approximately 795,000 people develop a new or recurrent stroke, with 610,000 first attacks and 185,000 recurrent attacks.[2] Stroke occurs more commonly in females than males, especially at older ages.[3] Blacks have a two-fold higher risk of first-ever stroke than Caucasians, with age-adjusted incidences of 6.6 per 1000 in black men as compared with 3.6 in Caucasian men.[3] In 2006, 43.6 deaths occurred due to stroke per 100,000 people in the Unites States, averaging out to one death due to stroke every 3 to 4 minutes.[2,4] In 2005, the overall mortality rate from stroke was approximately 44.7 per 100,000 for Caucasian males, 70.5 per 100,000 for black males, 44.0 per 100,000 for Caucasian females, and 60.7 per 100,000 for black females.[5] Lower mortality rates were seen in Hispanic, Asian and American Indian populations as compared with Caucasian populations.[2]

Stroke is the leading causes of long-term disability in the United States. Thirty percent of stroke survivors require outpatient rehabilitation services[6,7] and 15 to 30 percent of patients remain permanently disabled.[2] Costs associated with acute stroke were estimated to approach $68.9 billion in 2009, with inpatient hospital costs accounting for 70 percent of the total cost in the first-year after stroke.[2,8] Significant decreases in health-related quality of life are also seen following a stroke.[2] Studies have shown that at-risk patients view the consequences of experiencing an ischemic stroke as being worse than death.[9] Additionally, evidence has demonstrated the significant impact of ischemic stroke on caregiver burden and quality of life in caregivers.[10-12]

Reperfusion Strategies for Treatment of Ischemic Stroke

The pathophysiologic basis for an acute ischemic stroke begins with the occlusion of an intracranial vessel either by an embolus or a local thrombus, reducing blood flow to the downstream brain region.[13] If blood flow is not restored to the affected area, ischemia and eventual cell death will occur in a time-dependent fashion.[13] Currently available treatment

options for acute ischemic stroke focus on restoring cerebral perfusion to the affected area as quickly as possible thereby reducing or preventing brain infarction and minimizing long-term disability and stroke-related mortality.[14]

Some thrombolytic agents, including recombinant tissue plasminogen activator (alteplase, rtPA), restore cerebral perfusion by activating plasminogen at the site of the occlusion, subsequently dissolving the clot.[15] Intravenous (IV) rtPA has been approved by the United States Food and Drug Administration (FDA) for the treatment of acute ischemic stroke and is currently recommended for use within the first 3 hours of onset of symptoms.[14] The National Institute of Neurological Disorders and Stroke (NINDS) rtPA Stroke Study Group conducted a randomized, double-blind trial evaluating the benefits of IV rtPA treatment (0.9 mg/kg) administered within 3 hours of ischemic stroke onset (n=624).[16] At 3 months, patients receiving IV rtPA had more favorable results [odds ratio (OR) 1.7, 95 percent confidence interval (CI) 1.2 to 2.6] than the group receiving placebo as measured by four commonly utilized tools to assess stroke-related deficits and disabilities. The global odds ratio for improvement included improvements in the Barthel Index (OR 1.6, 95 percent CI 1.1 to 2.5), modified Rankin Scale (mRS) (OR 1.7, 95 percent CI 1.1 to 2.5), Glasgow Outcome Scale (GOS) (OR 1.6, 95 percent CI 1.1 to 2.5) and the National Institute of Health Stroke Scale (NIHSS) (OR 1.7, 95 percent CI 1.0 to 2.8).

Use of IV rtPA beyond the 3 hour timeframe has been limited. However, in a pooled analysis of 6 randomized, placebo-controlled trials evaluating IV rtPA in stroke, researchers found that although better results were achieved with earliest possible use of IV rtPA, there were potential benefits when used beyond the 3-hour window.[17] Patients who received IV rtPA between 3 and 4.5 hours after stroke onset were at an increased odds of a favorable outcome (a composite of stroke-related disabilities, severity of disabilities and abilities to conduct activities of daily living) as compared with placebo (OR 1.4, 95 percent CI 1.05 to 1.85). The subsequently published European Cooperative Acute Stroke Study (ECASS III), which was powered based on the prior discussed meta-analysis, specifically evaluated the benefits of IV rtPA administered between 3 and 4.5 hours after symptom onset.[18] When compared with placebo, patients receiving IV rtPA had significantly higher odds of a more favorable outcome (OR 1.34, 95 percent CI 1.02 to 1.76), with no differences in mortality (p=0.68) but higher incidence of intracranial hemorrhage seen (p=0.001).[18] In addition, two observational studies, the Safe Implementation of Thrombolysis in Stroke Monitoring Study (SITS-MOST)[19] and the SITS-international stroke treatment registry (SITS-ISTR)[20] confirmed the benefits of rtPA use at 3-4.5 hours after ischemic stroke. Based on these findings the American Heart Association and American Stroke Association issued a scientific advisory in 2009 recommending the use of IV rtPA in eligible patients presenting within 3 to 4.5 hours after the onset of stroke symptoms (Class I recommendation, B level of evidence).[21]

Despite appropriate IV rtPA use, rates of recanalization remain highly variable ranging from 30 to 92 percent during the initial 6 to 24 hours after treatment.[22] Recanalization rates vary depending on the site of the occlusion, with events in large cerebral vessels having particularly high clot burden which may not adequately respond to IV rtPA. More importantly, delays in arriving in the emergency department and unavailability of IV rtPA in some centers make thrombolytic reperfusion therapy viable in less than 5% of patients with acute stroke.[23]

In patients who have either failed IV rtPA therapy or who are either ineligible for or have contraindications to IV rtPA use, neurothrombectomy devices have been examined. A neurothrombectomy device is defined by the Food and Drug Adminstration (FDA) as a device intended to retrieve or destroy blood clots in the cerebral neurovasculature by mechanical, laser, ultrasound technologies, or combination of technologies.

These devices may offer a number of potential advantages when compared to pharmacologic thrombolysis including: more rapid achievement of recanalization vs IV rtPA; enhanced efficacy in treating large vessel occlusions; and greater efficacy with a lower risk for hemorrhagic events.[24] These putative advantages of neurothrombectomy devices have not been confirmed in direct comparisons against intravenous therapy. A variety of neurothrombectomy devices employing a variety of mechanisms including clot retrievers, aspiration/suction devices, snare-like devices, ultrasonography technologies and lasers, have been or are currently under study in patients with acute ischemic stroke. The Merci® retriever was the first endovascular device to receive FDA clearance in 2004 to "restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke.[25-27] Subsequently, the Penumbra System® was cleared by the FDA in 2007 "for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within 8 hours of system onset." Both of these clearances were granted through the FDA 510(k) process resulting in significant controversy given the relatively low number of patients included in the studies available at the time of clearance as well as the lack of clinical outcomes reported.[25] Various ongoing clinical trials are currently evaluating the impact of these, as well as other, endovascular devices for the treatment of acute ischemic stroke.

II. The Key Questions

Population: The population patients with acute ischemic stroke.

Intervention: The intervention is the use of a neurothromectomy device with or without intravenous or intraarterial thrombolytic therapy.

Comparators: Trials do not have to have comparators.

Outcomes: The outcomes are broken up into adverse events (e.g., failure to deploy the device or remove the clot, device breakage/fracture, perforation, dissection, thrombus formation proximal, adjacent, or distal to the clot site, vasospasm or hemorrhage (intracerebral and other)), intermediate outcomes (e.g. recanalization), and final health outcomes (e.g. mortality and impact of therapy on the mRS, NIHSS, Barthel index, and GOS scales).

Timing: The timing is not restrictive as long as the intervention was initiated within the period of the acute ischemic stroke.

Setting: The setting is not limited.

Question 1:
What are the different types of neurothrombectomy devices in use or in development for treatment of acute ischemic stroke?

1a. What are the existing FDA indications for each device?
1b. Which devices are being are being used off-label for this indication?
1c. What is the status of FDA approval for each device?
1d. What are the theoretical advantages and disadvantages of the devices compared to other treatment options?
1e. What are the potential safety issues and harms associated with the use of the devices?
1f. What is the extent of utilization of the different devices?

Question 2:
From a systematic literature scan of studies on different types of neurothrombectomy devices, provide a synthesis of the following variables:

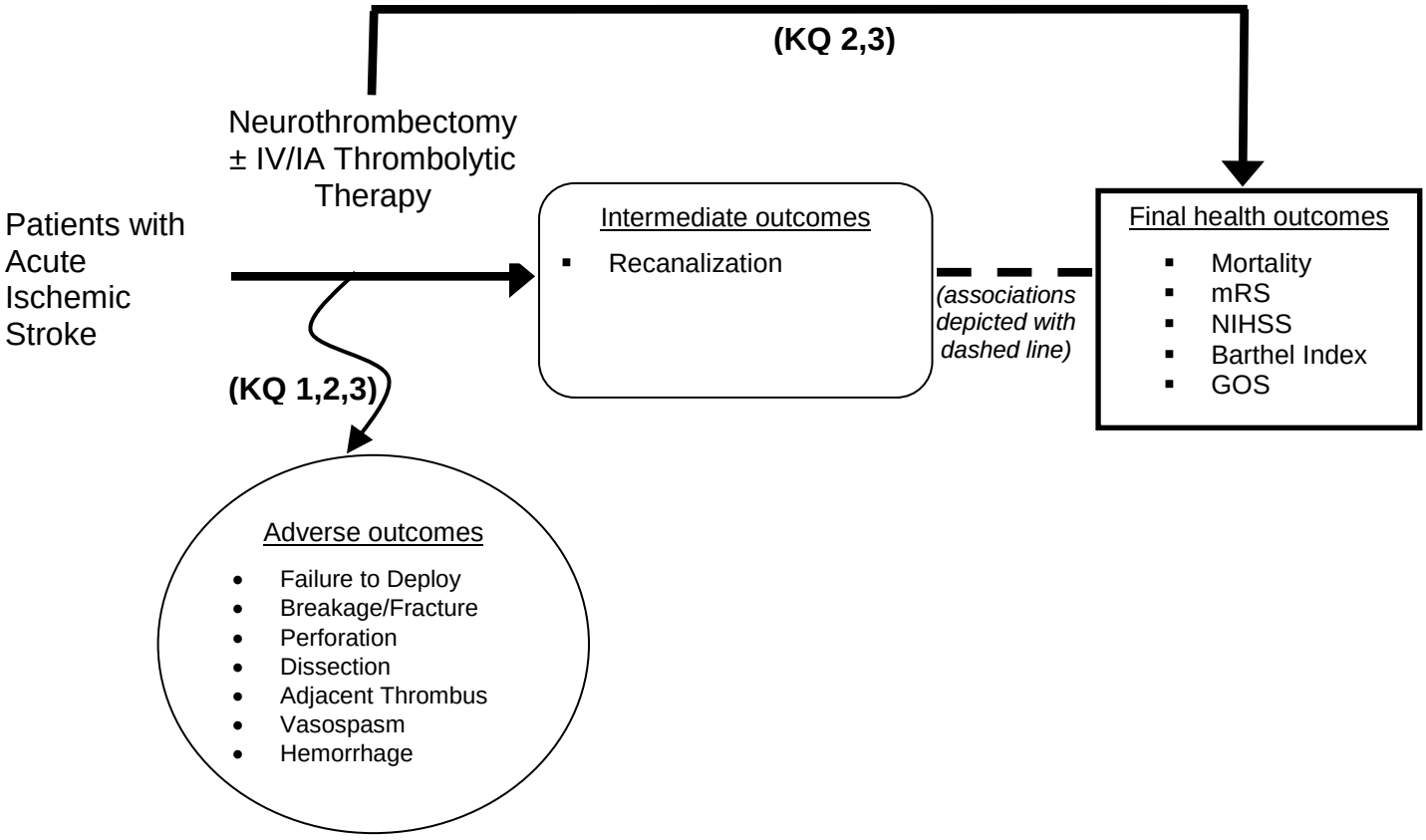
2a. Type(s) of devices
2b. Study design and size
2c. Patient characteristics
2d. Comparator used in comparative studies
2e. Length of follow-up
2f. Concurrent or prior therapy
2g. Outcomes measured
2h. Adverse events, harms and safety issues reported

Question 3:
What are the variables associated with use of the devices that may impact outcomes (e.g. time to deployment, training/expertise of interventionalist, location of infarct, concurrent therapies)?

III. Analytic Framework

To guide our assessment of studies examining the association between neurothrombectomy devices with benefits and harms in our target population, we developed an analytic framework mapping specific linkages from comparisons to subpopulations of interest, mechanisms of benefit, and outcomes of interest (Figure 2.1). It is a logic chain that supports the link from the intervention to the outcomes of interest.

Figure 2.1. Analytic Framework for Neurothrombectomy Devices for Treatment of Acute Ischemic Stroke



Legend: GOS = Glasgow Outcome Scale; IV/IA = intravenous or intraarterial; mRS = modified Rankin Scale; NIHSS = National Institute of Health Stroke Scale.

Narrative for Figure 2.1:

In this analytic framework figure, the links between the use of an intervention in a population and outcomes are described. The population includes patients experiencing an acute ischemic stroke. The intervention is the use of a neurothromectomy device with or without IV or IA thrombolytic therapy. While most of these trials do not have comparators, the comparator in clinical practice would be no reperfusion therapy or thrombolytic therapy alone. The outcomes are broken up into adverse events, intermediate outcomes, and final health outcomes. The adverse events of note include failure of the device to employ, breakage or fracture, perforation, dissection, adjacent thrombosis, vasospasm, and hemorrhage. The intermediate outcome is recanalization. The final health outcomes include mortality and impact of therapy on the mRS, NIHSS, Barthel index, and GOS scales.

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IV. Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review

We will develop of list of neurothrombectomy devices based on the FDA's guidance definition of a neurothrombectomy device, published literature and create a list of current manufacturing companies. After verifying products in current clinical practice and those in development, we will ask the Scientific Resource Center (SRC) at the Oregon Evidence-based Practice Center to contact the different manufacturers. We will finalize a database of the available neurothrombectomy devices with information and data provided to us. In addition, we will search the FDA Center for Devices and Radiological Health (CDRH) database to identify neurothrombectomy devices that have received FDA approval.

Two investigators will independently screen citations at the abstract level to identify potentially relevant studies. All potentially eligible citations will be retrieved for full text review and examined for eligibility. We will include human studies of any design or case reports/series which included patients with an acute ischemic stroke and report any clinical outcome (e.g., recanalization, mortality, mRS, or outcome score including NIHSS, Barthel Index or GOS) or any harm (e.g., failure to deploy the device or remove the clot, device breakage/fracture, perforation, dissection, thrombus formation proximal, adjacent, or distal to the clot site, vasospasm or hemorrhage (intracerebral and other)). No language restrictions will be used.

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions.

Two independent investigators will conduct systematic literature searches of MEDLINE, the Cochrane Central Register of Controlled Trials, SCOPUS and Web of Science as well as the Cochrane Database of Systematic Reviews, from the earliest possible date until September 2009. No language restrictions will be imposed. In addition, a manual search of references from reports of studies or review articles will be conducted. A preliminary search strategy, including proposed search terms, is listed in Appendix 1. We will also conduct a grey literature search for abstracts, studies and available devices utilizing Google and specific search terms. Additionally, we will survey enrolling and ongoing clinical trials through ClinicalTrials.gov.

C. Data Abstraction and Data Management

Through the use of a standardized data abstraction tool, two reviewers will independently collect data, with disagreement resolved by a third reviewer. The following information will be obtained from each study, where applicable: author identification, year of publication, source of study funding, study design characteristics (prospective single arm study, retrospective study, randomized controlled trial, nonrandomized comparative study, case series or reports), study population (including study inclusion and exclusion criteria, duration of patient follow-up), patient baseline characteristics (age, gender), disease severity (baseline NIHSS, baselne TIMI flow), location of occluded artery, time from symptom onset to device deployment or angiography, use of concurrent standard medical therapies (including use of concurrent IV/IA

thrombolysis, angioplasty, stents), whether outcomes assessment was blinded, and the device used. Effectiveness outcomes will include: recanalization as measured by post-TIMI flow grade (0/1=no recanalization, 2=partial recanalization, 3=complete recanalization) or similar methodology, mortality, mRS (≤2=good outcome, ≥3=poor outcome), NIHSS score [including a NIHSS decrease ≥ 4 points deemed significant by the FDA), Barthel Index and GOS score. Harms will include: failure to deploy the device or remove the clot (technical success), device breakage/fracture, perforation, dissection, thrombus formation (proximal, adjacent, or distal to the clot site), vasospasm, or hemorrhage (including symptomatic and asymptomatic intracranial and subarachnoid hemorrhage from vessel injury and other).

D. Assessment of Methodological Quality of Individual Studies

We will assess the study design and classify it as prospective, retrospective enrolling consecutive patients, and case reports/series. For prospective and retrospective studies enrolling consecutive patients, we will assess if outcome assessment was blinded.

E. Data Synthesis

We will utilize in depth tables summarizing what is known about the relevant trials and a study density figure to summarize the totality of information available in this technical brief. Quantitative synthesis will not be employed.

F. Grading the Evidence for Each Key Question

This is not applicable for technical briefs.

V. References

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VI. Definition of Terms

Acronym	Abbreviation
AHRQ	Agency for Healthcare Research and Quality
CDRH	Center for Devices and Radiological Health
CI	Confidence Interval
ECASS	European Cooperative Acute Stroke Study
FDA	U.S. Food and Drug Administration
GOS	Glascow Outcome Scale
IA	Intraarterial
ICH	Intracerebral Hemorrhage
IV	Intravenous
mRS	Modified Rankin Scale
NIHSS	National Institute of Health Stroke Scale
NINDS	National Institute of Neurological Disorders and Stroke
OR	Odds Ratio
rtPA	Recombinant tissue plasminogen activator
SICH	Symptomatic Intracerebral Hemorrhage
SRC	Scientific Resource Center
TIMI	Thrombolysis in Myocardial Infarction Study Group

VII. Summary of Protocol Amendments

None

NOTE: The following protocol elements are standard procedures for all protocols.

VIII. Review of Key Questions

For Comparative Effectiveness reviews (CERs) the key questions were posted for public comment and finalized after review of the comments. For other systematic reviews,
key questions submitted by partners are reviewed and refined as needed by the EPC and the Technical Expert Panel (TEP) to assure that the questions are specific and explicit about what information is being reviewed.

IX. Technical Expert Panel (TEP)

A TEP panel is selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design and/or methodological approaches do not necessarily represent the views of individual technical and content experts. The TEP provides information to the EPC to identify literature search strategies, review the draft report and

recommend approaches to specific issues as requested by the EPC. The TEP does not do analysis of any kind nor contribute to the writing of the report.

X. Peer Review

Approximately five experts in the field will be asked to peer review the draft report and provide comments. The peer reviewer may represent stakeholder groups such as professional or advocacy organizations with knowledge of the topic. On some specific reports such as reports requested by the Office of Medical Applications of Research, National Institutes of Health there may be other rules that apply regarding participation in the peer review process. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the Evidence report.

It is our policy not to release the names of the Peer reviewers or TEP panel members until the report is published so that they can maintain their objectivity during the review process.

Appendix 1.

Search Terms and Citations

MEDLINE (OVID)

1. thrombectomy
2. embolectomy
3. endovascular recanalization
4. endovascular embolectomy
5. mechanical thrombolysis
6. mechanical embolus removal
7. mechanical thrombus removal
8. endovascular intervention
9. endovascular device
10. mechanical device
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. stroke
13. acute stroke
14. cerebrovascular accident
15. cva
16. vascular accident
17. artery occlusion
18. cerebral ischemia
19. acute ischemic stroke
20. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. 11 and 20

CENTRAL (OVID)

1. thrombectomy
2. embolectomy
3. endovascular recanalization
4. endovascular embolectomy
5. mechanical thrombolysis
6. mechanical embolus removal
7. mechanical thrombus removal
8. endovascular intervention
9. endovascular device
10. mechanical device
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. stroke
13. acute stroke

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14. cerebrovascular accident
15. cva
16. vascular accident
17. artery occlusion
18. cerebral ischemia
19. acute ischemic stroke
20. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. 11 and 20

Appendix 2.

Manufacturer	Device Name	Device Type (Mechanism)	FDA Status
Concentric Medical 301 E. Evelyn Ave Mountain View, CA, 94041 P: 650-938-2100 F: 650-938-2700	Merci Retriever	Thrombus Retriever	FDA Approved (510k) Acute Ischemic Stroke
Penumbra, Inc 1351 Harbor Bay Pkwy Alameda, CT 64502 P: 888-272-4606 F: 510-748-3232	Penumbra System	Catheter Aspiration	FDA Approved (510k) Acute Ischemic Stroke
Chestnut Medical Technologies, Inc 173 Jefferson Dr. Menlo Park, CA 94025 P: 650-566-0057 F: 650-566-0072	Alligator Retrieval Device	Endovascular Snare Device	FDA Approved (510k) "Peripheral and neuro-vasculature for foreign body removal"
Possis Medical 9055 Evergreen Blvd NW Minneapolis, MN 55433 P: 800-810-7677 F: 763-783-8463	AngioJet System	Catheter Aspiration	FDA Approved (510K) Peripheral vascular thrombi
OmniSonics Medical Technologies 66 Concord St, Suite A Wilmington, MA 01887 P: 978-657-9980 F: 978-657-9982	OmniWave Endovascular System	Continuous Flush Catheter	FDA Approved (510k) "Infusion of physician specified fluids into peripheral vasculature"
Boston Scientific, Target	In-Time Retrieval	Retriever Device	FDA Approved (510k)

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47900 Bayside Pkwy Fremont, CA 94538 P: 510-440-7700 F: 510-440-7752	Device		"Retrieval of intravascular foreign objects"
Boston Scientific One Boston Scientific Place Natick, MA 01760	Oasis Thrombectomy Catheter System	Catheter Aspiration	N/A
	Neuronet Device	Purchased from Guidant Corp Endovascular Thrombectomy	N/A
	Attractor-18 device	Purchased from Target Therapeutics Endovascular Thrombectomy	N/A
	TriSpan	Endovascular Thrombectomy	N/A
Phenox GmbH Lise-Meitner-Allee 31 D-44801 Bochum, Germany P: + 49 234 36 919-0	Phenox Clot Retriever	Thrombus Retriever	N/A
Balt Extrusion Montmorency, France www.balt.fr/?lang=en	Vasco35	Endovascular Thrombectomy	N/A
	The Catch device	Endovascular Thrombectomy	N/A
Ev3 Medical 9600 54th Ave North Plymouth, Minnesota 55442 P: 763-398-7000 F: 763-398-7200	Amplatz Goosneck Microsnare	Thrombus Disruption	N/A
	Amplatz Thrombectomy Device	Catheter Aspiration	N/A
Angiotech Pharmaceuticals, Inc 1618 Station Street Vancouver, BC V6A1B6 P: 604-221-7673 F: 604-221-2330	EnSnare Device	Purchased from InterV Endovascular Snare Device	N/A

W.L. Gore 555 Paper Mill Rd Neward, DE 19711 P: 877-467-3636	EPAR Laser	Thrombus Disruption	N/A
Spectanetics 9965 Federal Drive Colorado Springs, CO 80921 P: 800-633-0960 F: 877-447-2022	LaTis Laser Device	Thrombus Disruption	N/A
EKOS Corporation 11911 North Creek Pkwy South Bothell, WA 98011 P: 425-415-3100 F: 425-415-3102	EkoSonic Endovascular System	Continuous Flush Catheter	FDA Approved (510k) "Infusion of physician specified fluids into peripheral vasculature
	MicroLysUs Infusion Catheter	Continuous Flush Catheter	N/A