Appendix A: MEDLINE and CENTRAL Search Strategies

**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
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
March 23, 2010

[Company Name]
[Contact FName] [Contact LName]
[Contact Title]
[Address 1]
[Address 2]
[City], [State] [ZIP]

Re: Endovascular Interventions for Treatment of Acute Ischemic Stroke.

Dear [Contact FName] [Contact LName]:

The Agency for Healthcare Research and Quality (AHRQ) has commissioned a comparative effectiveness review of the evidence for Endovascular Interventions for Treatment of Acute Ischemic Stroke. This review is one of several that are being conducted by the Evidence-based Practice Centers (EPC) for the AHRQ Effective Health Care program. These reviews are one aspect of the program, developed in response to Section 1013 of the Medical Modernization Act (MMA), which authorized AHRQ to conduct a range of activities pertinent to evaluating, generating, and disseminating evidence about the comparative effectiveness of medications, devices, and other interventions.

The program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual electronic database and hand searches of the literature by systematically requesting information (e.g. details of studies conducted) from pharmaceutical industry stakeholders. We are looking for studies that report Endovascular Interventions for Treatment of Acute Ischemic Stroke including those that describe adverse events, as specified in the attached Key Questions.

This letter is a request for industry stakeholders to submit the following:

- A current product label (preferably an electronic PDF file).
- Identify published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Identify unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: study number, study period, design, methodology, indication and diagnosis, drug dose and duration, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- For studies registered with ClinicalTrials.gov, please submit a list including the ClinicalTrials.gov identifier, condition, and intervention.
Your contribution is very beneficial to this program. However, we will not be considering any marketing or pharmacoeconomics information, or information on other indications. This is a voluntary and unsolicited request for information, and all costs for complying with this request must be borne by the submitter.

Please submit material by or before November 30th 2009 for consideration in this report. Material submitted after this date will be considered in any subsequent report updates. I apologize for the short response period.

If you wish to submit hardcopy materials please send them to:

Rose Campbell  
Effective Health Care Scientific Resource Center  
Mail Code: BICC  
3181 SW Sam Jackson Park Road  
Portland, OR 97239

Please Note: In accordance with the Freedom of Information Act, the contents of all submissions, regardless of format, will be available to the public upon request.

For information about the timeline for this Comparative Effectiveness Review and other reviews being conducted through the Effective Health Care Program, please check our website at: http://effectivehealthcare.ahrq.gov. The draft of this review will be available for public comment as part of the peer review process via the Effective Health Care website. If you would like to be notified when the draft is posted, please sign up for the ListServ at: http://effectivehealthcare.ahrq.gov/aboutUs/listserv.

If you are not the appropriate contact for this request, please forward this letter to the proper individual. Please don’t hesitate to contact Rose Campbell at campbros@ohsu.edu or call 503-494-0147 with questions.

Thank you for your willingness to participate in the AHRQ Effective Health Care program.

Sincerely,

Mark Helfand, MD, MPH  
Scientific Resource Center for the  
AHRQ Effective Health Care Program

CC: Lia Hotchkiss, MPH; Center for Outcomes and Evidence, AHRQ

Attached: Key Questions Endovascular Interventions for Treatment of Acute Ischemic Stroke
Appendix C: Citations for Included and Excluded Reports

Citations for Included Reports


23. Frei D, Bellon R. Mechanical thrombectomy in acute stroke patients who were refractory to intravenous thrombolytic therapy. Stroke 2009;40:E250.


Citations for Excluded Reports


80. Gobin A. Result of the MERCI (mechanical embolus removal in cerebral ischemia) trial. Am J Cardiol 2004;94(Suppl.1):128E.


A-19


### Appendix D. Tables of Included Study Characteristics, Inclusion and Exclusion Criteria

#### Table 1D. Characteristics of Prospective, Single-Arm or Retrospective Studies of the Penumbra System (Penumbra, Alameda, CA)

<table>
<thead>
<tr>
<th>Study, yr</th>
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</thead>
<tbody>
<tr>
<td>PPST, 2009</td>
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<tr>
<td>Grunwald, 2009</td>
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<tr>
<td>Bose, 2008</td>
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<tr>
<td>Struffert, 2009</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>N</th>
<th>Device</th>
<th>Design</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>Baseline Characteristics (mean/median)</th>
<th>Location of Emboli (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>125</td>
<td>Penumbra</td>
<td>Prospective</td>
<td>NIHSS≥8, presentation &lt;8 hours from symptoms onset, angiographic TIMI 0/1 occlusion of a treatable large, intracranial vessel, ineligible or refractory to IV rtPA if presenting &lt;3 hours from symptom onset</td>
<td>Infarction greater than one-third of the MCA, severe edema, intracerebral hemorrhage and pregnancy</td>
<td>NIHSS: 18 Age: 64 Female %: 49 TIMI 0/1 %: 100 ST: 258 minutes</td>
<td>ICA/ICA-T: 18 MCA: 70 VB: 9 Other: 3</td>
</tr>
<tr>
<td>29</td>
<td>Penumbra</td>
<td>Prospective</td>
<td>NIHSS≥8, &gt;18 years of age, presentation &lt;8 hours from symptom onset, TIMI 0/1 occlusion of a treatable large, intracranial vessel, ineligible or refractory to IV rtPA if presenting &lt;3 hours from symptom onset</td>
<td>Brain edema or intracerebral hemorrhage</td>
<td>NIHSS: 20 Age: 58 Female %: 48 TIMI 0/1%: 100 ST: 312 minutes</td>
<td>ICA/ICA-T: 28 MCA: 52 VB: 21 Other: 0</td>
</tr>
<tr>
<td>23</td>
<td>Penumbra</td>
<td>Prospective</td>
<td>&gt;18 years of age, presentation &lt;8 hours from symptoms onset, angiographic TIMI 0/1 occlusion of a treatable large, intracranial vessel, ineligible or refractory to IV rtPA if presenting &lt;3 hours from symptom onset</td>
<td>Risk of bleeding, vessels deemed too tortuous for Penumbra system, uncontrolled hypertension and pregnancy</td>
<td>NIHSS: 21 Age: 60 Female %: 40 TIMI 0/1%: 100 ST: 50% &gt; 3 hours from symptoms</td>
<td>ICA/ICA-T: 33 MCA: 24 VB: 43 Other: 0</td>
</tr>
<tr>
<td>15</td>
<td>Penumbra</td>
<td>Retrospective</td>
<td>Consecutive patients with large vessel occlusion (ICA, NR)</td>
<td></td>
<td>NIHSS: 15 Age: 60</td>
<td>ICA/ICA-T: 33 MCA: 47</td>
</tr>
</tbody>
</table>
Table 1D. Characteristics of Prospective, Single-Arm or Retrospective Studies of the Penumbra System (Penumbra, Alameda, CA)

<table>
<thead>
<tr>
<th>Study, yr N</th>
<th>Device</th>
<th>Design</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>Baseline Characteristics (mean/median)</th>
<th>Location of Emboli (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tarr, 2009 N=105 (Abstract Only)</td>
<td>Penumbra</td>
<td>Retrospective</td>
<td>NIHSS≥8, presentation &lt;8 hours from symptom onset, TIMI 0/1 occlusion of a treatable large, intracranial vessel (consistent with device approval indication)</td>
<td>NR</td>
<td>NIHSS: 17</td>
<td>NR</td>
</tr>
<tr>
<td>Frei, 2009 N=53 (Abstract Only)</td>
<td>Penumbra</td>
<td>Retrospective</td>
<td>Failed IV rtPA prior to therapy</td>
<td>NR</td>
<td>NIHSS: 18 Age: 66 Female %:55 TIMI 0/1 %: 100 ST: NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

Note: BA=basilar artery; ICA=internal carotid artery; ICA-T=internal carotid artery terminus; IV rtPA=intravenous recombinant tissue plasminogen activator; MCA=middle cerebral artery; N=total number of patients evaluated; NIHSS=National Institutes of Health Stroke Scale; NR=not reported; PPST=Penumbra Pivotal Stroke Trial; TIMI=Thrombolysis in Myocardial Infarction; ST=symptom time (to angiography or device deployment); VB=vertebrobasilar
Table 2D. Characteristics of Prospective, Single-Arm or Retrospective Studies of the MERCI Retrieval System (Concentric Medical Inc., Mountain View, CA)

<table>
<thead>
<tr>
<th>Study, yr N</th>
<th>Device</th>
<th>Design</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>Baseline Characteristics (mean/median)</th>
<th>Location of Emboli (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith, 2008 N=164</td>
<td>MERCI</td>
<td>Prospective</td>
<td>NIHSS≥8, &gt;18 years of age, presentation &lt;8 hours from symptoms onset, angiographic TIMI 0/1 occlusion of a treatable large, intracranial vessel (ICA, ICA-T, MCA M1 or M2), ineligible or refractory to IV rtPA if presenting &lt;3 hours from symptom onset, otherwise similar to Smith, 2005</td>
<td>Excessive tortuosity of vessels, pregnancy, allergy to contrast media, life expectancy &lt;3months, &gt;50% stenosis of the artery proximal to target vessel, glucose &lt;50 mg/dL, prothrombin time &gt;2 times normal, hemorrhagic diathesis, coagulation factor deficiency, oral anticoagulation with INR&gt;3, use of heparin with partial thromboplastin time &gt;2 times normal, platelets &lt;30,000, severe hypertension, CT scan showing significant mass effect with midline shift</td>
<td>NIHSS: 19 Age: 68 Female %: 57 TIMI 0/1 %: NR ST: 258 minutes</td>
<td>ICA/ICA-T: 32 MCA: 60 VB: 8 Other: 0</td>
</tr>
<tr>
<td>Devlin, 2007 N=25</td>
<td>MERCI</td>
<td>Prospective</td>
<td>NIHSS≥8, &gt;18 years of age, presentation &lt;8 hours from symptoms onset, occlusion of a treatable large, intracranial vessel (ICA, ICA-T, MCA M1 or M2), ineligible or refractory to IV rtPA if presenting &lt;3 hours from symptom onset (n=9 were treated with IV rtPA)</td>
<td>Hypodensity &gt;one-third of MCA on CT, glucose &lt;50 mg/dL, hemorrhagic diathesis, coagulation factor deficiency, oral anticoagulation with INR&gt;3, use of heparin in past 48 hours with partial thromboplastin time &gt;2 times normal, platelets &lt;30,000,</td>
<td>NIHSS: 18 Age: 63 Female %: 36 TIMI 0/1 %: 96 ST: 312 minutes</td>
<td>ICA/ICA-T: 12 MCA: 48 VB: 8 Tandem ICA/MCA: 32</td>
</tr>
<tr>
<td>Study, yr</td>
<td>Device</td>
<td>Design</td>
<td>Inclusion Criteria</td>
<td>Exclusion Criteria</td>
<td>Baseline Characteristics (mean/median)</td>
<td>Location of Emboli (%)</td>
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<tr>
<td>Kim, 2006</td>
<td>MERCI</td>
<td>Prospective</td>
<td>NIHSS≥8, presentation &lt;8 hours from symptoms onset, angiographic TIMI 0/1 occlusion of a treatable large, intracranial vessel, ineligible or refractory to IV rtPA if presenting &lt;3 hours from symptom onset, otherwise similar to Gobin, 2004 and Smith, 2005</td>
<td>No large mismatch between core infarct and salvageable penumbra, enrolled in Gobin, 2004 and Smith, 2005</td>
<td>NIHSS: 21 Age: 64 Female %: 42 TIMI 0/1 %: NR ST: 303 minutes</td>
<td>ICA/ICA-T: 38 MCA: 58 VB: 4 Other: 0</td>
</tr>
<tr>
<td>Smith, 2005</td>
<td>MERCI</td>
<td>Prospective</td>
<td>NIHSS≥8, &gt;18 years of age, presentation &lt;8 hours from symptoms onset, angiographic TIMI 0/1 occlusion of a treatable large, intracranial vessel, ineligible for IV rtPA if presenting &lt;3 hours from symptom onset</td>
<td>Excessive tortuosity of cervical vessels, pregnancy, allergy to contrast media, life expectancy &lt; 3 months, &gt;50% stenosis of the artery proximal to target vessel, glucose &lt;50 mg/dL, prothrombin time &gt; 2 times normal, hemorrhagic diathesis, coagulation factor deficiency, oral anticoagulation with INR &gt; 1.7 in part 1 and &gt; 3.0 in part 2, use of heparin</td>
<td>NIHSS: 20 Age: 67 Female %: 46 TIMI 0/1 %: NR ST: 258 minutes</td>
<td>ICA/ICA-T: 33 MCA: 57 VB: 10 Other: 0</td>
</tr>
<tr>
<td>Study, yr N</td>
<td>Device</td>
<td>Design</td>
<td>Inclusion Criteria</td>
<td>Exclusion Criteria</td>
<td>Baseline Characteristics (mean/median)</td>
<td>Location of Emboli (%)</td>
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<td>Gobin, 2004 N=30</td>
<td>MERCI</td>
<td>Prospective</td>
<td>NIHSS≥10, &gt;18 years of age, presentation &lt;8 hours from symptoms onset, angiographic TIMI 0/1 occlusion of a treatable large, intracranial vessel, ineligible for IV rtPA if presenting &lt;3 hours from symptom onset</td>
<td>Hypodensity &gt;one-third of MCA on CT, glucose &lt;50 mg/dL, seizure at stroke onset, prothrombin time&gt;15 seconds, hemorrhagic diathesis, coagulation factor deficiency, oral anticoagulation with INR&gt;3, use of heparin with partial thromboplastin time &gt;2 times normal, platelets&lt;50,000, severe hypertension, CT scan showing significant mass effect with midline shift, severe arterial stenosis proximal to thrombus precluding thrombus removal</td>
<td>NIHSS:22 Age: 68 Female %: 50 TIMI 0/1 %: NR ST: 301 minutes</td>
<td>ICA/ICA-T: 18 MCA: 64 VB: 7 Tandem ICA/MCA: 11</td>
</tr>
<tr>
<td>Lin, 2009</td>
<td>MERCI</td>
<td>Retrospective</td>
<td>Consecutive patients with</td>
<td>NR</td>
<td>NIHSS: NR</td>
<td>ICA/MCA: 100</td>
</tr>
<tr>
<td>Study, yr</td>
<td>Device Design</td>
<td>Inclusion Criteria</td>
<td>Exclusion Criteria</td>
<td>Baseline Characteristics (mean/median)</td>
<td>Location of Emboli (%)</td>
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<tr>
<td>Jo, 2008</td>
<td>MERCI Retrospective</td>
<td>Consecutive patients with acute ischemic stroke, occlusion of the ICA with or without extension into the MCA, ineligible or refractory to IV rtPA if presenting &lt;3 hours from symptom onset</td>
<td>NR</td>
<td>Age: NR</td>
<td>NR</td>
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<tr>
<td>N=34</td>
<td></td>
<td></td>
<td></td>
<td>Female %: NR</td>
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<td></td>
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<td>TIMI 0/1 %: NR</td>
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<td></td>
<td>ST: NR</td>
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<tr>
<td>Madison, 2008</td>
<td>MERCI Retrospective</td>
<td>Consecutive patients with acute ischemic stroke with angiographically confirmed large vessel occlusion treated with intra-arterial intervention within 6 hours of symptom onset</td>
<td>NR</td>
<td>NIHSS: 19</td>
<td>NR</td>
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<td>N=54</td>
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<td></td>
<td></td>
<td>Age: NR</td>
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<td></td>
<td>Female %: NR</td>
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<td>TIMI 0/1 %: NR</td>
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<td></td>
<td>ST: NR</td>
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<tr>
<td>Kidwell, 2008</td>
<td>MERCI Retrospective</td>
<td>Patients within 8 hours of symptom onset and having a baseline MRI scan, FLAIR MRI within 7-days and endpoint data recorded out to 90-days. Receiving adjunctive thrombolysis</td>
<td>NR</td>
<td>NIHSS: 19</td>
<td>NR</td>
<td></td>
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<tr>
<td>N=18</td>
<td></td>
<td></td>
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<td>Age: 63</td>
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<td>Female %: 39</td>
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<td>TIMI 0/1 %: NR</td>
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<td>ST: NR</td>
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</table>

BA=basilar artery; FLAIR=fluid attenuated inversion recovery; ICA=internal carotid artery; ICA-T=internal carotid artery terminus; IV rtPA=intravenous recombinant tissue plasminogen activator; MCA=middle cerebral artery; MRI=magnetic resonance imaging; N=total number of patients evaluated; NIHSS=National Institutes of Health Stroke Scale; NR=not reported; PPST=Penumbra Pivotal Stroke Trial; TIMI=Thrombolysis in Myocardial Infarction; ST=symptom time (to angiography or device deployment); VB=vertebrobasilar
<table>
<thead>
<tr>
<th>Study, yr</th>
<th>Device</th>
<th>Design</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>Baseline Characteristics (mean/median)</th>
<th>Location of Emboli (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liebig, 2008 N=45 (Abstract Only)</td>
<td>Phenox</td>
<td>Prospective</td>
<td>Patients with ischemic stroke</td>
<td>NR</td>
<td>NIHSS: NR Age: NR Female %: NR TIMI 0/1 %: NR ST: NR minutes</td>
<td>ICA/ICA-T: 27 MCA: 38 VB: 27 Other: 8</td>
</tr>
<tr>
<td>Tomsick, 2008* N=35</td>
<td>EKOS Primo</td>
<td>Prospective</td>
<td>NIHSS≥10, &lt;81 years of age, presenting &lt;3 hours from symptom onset</td>
<td>NR</td>
<td>NIHSS: NR Age: NR Female %: NR TIMI 0/1 %: NR ST: NR</td>
<td>NR</td>
</tr>
<tr>
<td>Mahon, 2003 N=14</td>
<td>EKOS MicroLysUS</td>
<td>Prospective</td>
<td>Patients between 18-77 years with a treatable artery, NIHSS≥8, time from symptom onset of &lt;6 hours for anterior circulation or &lt;24 hours for posterior circulation occlusions, exclusion from IV thrombolysis protocol</td>
<td>Confounding prior neurologic event or hemorrhage on CT scan</td>
<td>NIHSS: 18 Age: 64 Female %: 50 TIMI 0/1 %: NR ST: 331 minutes</td>
<td>ICA/ICA-T: 36 MCA: 36 VB/Other: 28</td>
</tr>
<tr>
<td>Gonzalez, 2007 N=9</td>
<td>Amplatz Gooseneck</td>
<td>Prospective</td>
<td>NIHSS≥8, ineligible for IV rtPA, &lt;8 hours since symptoms for anterior and &lt;24 hours for posterior occlusions</td>
<td>CT scan showing hemorrhage or hypoattenuation involving more than one-third of the MCA, history of chronic severe illness, previous disabling stroke, and/or dementia</td>
<td>NIHSS: 16 Age: 55 Female %: NR TIMI 0/1 %: NR ST: 251 minutes</td>
<td>ICA/ICA-T: 11 MCA: 56 VB: 33 Other: 0</td>
</tr>
<tr>
<td>Mayer, 2005 N=12</td>
<td>AngioJet</td>
<td>Prospective</td>
<td>Consecutive patients with VB occlusion confirmed by angiography, diameter &gt;2mm</td>
<td>Coma &gt;8 hours, &gt;80 years of age, acute intracerebral hemorrhage and extensive</td>
<td>NIHSS: 20 Age: 56 Female %: 25</td>
<td>ICA/ICA-T: 0 MCA: 0 VB: 100</td>
</tr>
<tr>
<td>Study, yr</td>
<td>Device</td>
<td>Design</td>
<td>Inclusion Criteria</td>
<td>Exclusion Criteria</td>
<td>Baseline Characteristics (mean/median)</td>
<td>Location of Emboli (%)</td>
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<tr>
<td>Berlis, 2004 N=34</td>
<td>EPAR</td>
<td>Prospective</td>
<td>Patients 18-85 years, NIHSS&gt;3, stroke &lt;7 hours from projected EPAR use if anterior and ≤24 hours if posterior occlusion, occlusion of the ICA, MCA, PCA, basilar or vertebral arteries, diameter &gt;2mm, TIMI 0-1 flow</td>
<td>Pregnancy, evidence of aneurysm or dissection, uncontrolled bleeding diathesis, blood pressure &gt;200 mmHg systolic, 120 mmHg diastolic, intracranial tumor or massive infarct, markedly increasing improvement of neurologic symptoms by time of treatment initiation, evidence of intracranial hemorrhage</td>
<td>NIHSS: 19 Age: 68 Female %: 50 TIMI 0/1 %: 100 ST: 382 minutes</td>
<td>ICA/ICA-T: 29 MCA: 35 VB: 32 Other: 3</td>
</tr>
<tr>
<td>Mayer, 2002 N=5</td>
<td>Neuronet</td>
<td>Prospective</td>
<td>NIHSS&gt;5, treated within 8 hours for anterior and &lt;24 for posterior occlusion, TIMI 0, and a vessel diameter of 2-5 mm.</td>
<td>NR</td>
<td>NIHSS: 20 Age: 42 Female %: 20 TIMI 0/1 %: 100 ST: 388 minutes</td>
<td>ICA/ICA-T: 0 MCA: 0 VB: 100 Other: 0</td>
</tr>
<tr>
<td>Clark, 2000 N=2 (Abstract Only)</td>
<td>LaTIS</td>
<td>Prospective</td>
<td>NIHSS&gt;5, treated within 8 hours for anterior and &lt;24 for posterior occlusion, TIMI 0, and a vessel diameter of 2-5 mm.</td>
<td>NR</td>
<td>NIHSS: 20/26 Age: NR Female %: NR TIMI 0/1 %: 100 ST: 479/270 minutes</td>
<td>ICA/ICA-T: 0 MCA: 100 VB: 0 Other: 0</td>
</tr>
</tbody>
</table>

CT=computed tomography; EPAR=Endovascular Photoacoustic Recanalization; ICA=internal carotid artery; ICA-T=internal carotid artery terminus; IV rtPA=intravenous recombinant tissue plasminogen activator; MCA=middle cerebral artery; N=total number of patients evaluated; N=total number of patients evaluated; NIHSS=National Institutes of Health Stroke Scale; NR=not reported;
PCA=posterior cerebral artery; PPST=Penumbra Pivotal Stroke Trial; TIMI=Thrombolysis in Myocardial Infarction; ST=symptom time (to angiography or device deployment); VB=vertebrobasilar

*Data from Tomsick, 2008 publication of Interventional management of Stroke (IMS)-II Trial. Data for EKOS Primo only.
Appendix E. Summary Figures and Tables

**Figure 1E. Proportion of patients achieving recanalization with MERCI retriever**

<table>
<thead>
<tr>
<th>Prospective Studies</th>
<th>Events (n/N)</th>
<th>Proportion (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith, 2008</td>
<td>90/164</td>
<td>0.55 (0.47, 0.63)</td>
</tr>
<tr>
<td>Devlin, 2007</td>
<td>14/25</td>
<td>0.56 (0.35, 0.76)</td>
</tr>
<tr>
<td>Kim, 2006</td>
<td>13/24</td>
<td>0.54 (0.33, 0.74)</td>
</tr>
<tr>
<td>Smith, 2005</td>
<td>68/141</td>
<td>0.48 (0.40, 0.57)</td>
</tr>
<tr>
<td>Gobin, 2004</td>
<td>12/28</td>
<td>0.43 (0.24, 0.63)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Retrospective Studies</th>
<th>Events (n/N)</th>
<th>Proportion (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lin, 2009</td>
<td>24/34</td>
<td>0.71 (0.53, 0.85)</td>
</tr>
<tr>
<td>Jo, 2008</td>
<td>75/114</td>
<td>0.66 (0.56, 0.74)</td>
</tr>
<tr>
<td>Madison, 2008</td>
<td>28/54</td>
<td>0.52 (0.38, 0.66)</td>
</tr>
<tr>
<td>Kidwell, 2008</td>
<td>14/18</td>
<td>0.78 (0.52, 0.94)</td>
</tr>
</tbody>
</table>

CI=confidence interval; n=number of patients with outcome; N=total number of patients evaluated

**Narrative for Figure 1E:** This figure shows the five prospective and four retrospective studies that provided data on recanalization for the MERCI retriever. The proportion of patients achieving recanalization in each study ranged from 0.43 to 0.78.
Figure 2E. Proportion of patients achieving recanalization with Penumbra System

<table>
<thead>
<tr>
<th>Prospective Studies</th>
<th>Events (n/N)</th>
<th>Proportion (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPST, 2009</td>
<td>102/125</td>
<td>0.82 (0.74, 0.88)</td>
</tr>
<tr>
<td>Grunwald, 2009</td>
<td>25/29</td>
<td>0.86 (0.68, 0.96)</td>
</tr>
<tr>
<td>Bose, 2008</td>
<td>20/20</td>
<td>1.00 (0.83, 1.00)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Retrospective Studies</th>
<th>Events (n/N)</th>
<th>Proportion (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Struffert, 2009</td>
<td>12/15</td>
<td>0.80 (0.52, 0.96)</td>
</tr>
<tr>
<td>Tarr, 2009</td>
<td>87/105</td>
<td>0.83 (0.74, 0.90)</td>
</tr>
<tr>
<td>Frei, 2009</td>
<td>44/53</td>
<td>0.83 (0.70, 0.92)</td>
</tr>
</tbody>
</table>

CI=confidence interval; n=number of patients with outcome; N=total number of patients evaluated

Narrative for Figure 2E: This figure shows the three prospective and three retrospective studies that provided data on recanalization for the penumbra System. The proportion of patients achieving recanalization in each study ranged from 0.80 to 1.00.
<table>
<thead>
<tr>
<th>Prospective Studies</th>
<th>Events (n/N)</th>
<th>Proportion (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liebig, 2008 (Phenox)</td>
<td>27/45</td>
<td>0.60 (0.44, 0.74)</td>
</tr>
<tr>
<td>Tomsick, 2008 (EKOS)</td>
<td>18/29</td>
<td>0.62 (0.42, 0.79)</td>
</tr>
<tr>
<td>Mahon, 2003 (EKOS)</td>
<td>10/14</td>
<td>0.71 (0.42, 0.92)</td>
</tr>
<tr>
<td>Gonzalez, 2007 (eV3 Microsnare)</td>
<td>7/9</td>
<td>0.78 (0.40, 0.97)</td>
</tr>
<tr>
<td>Mayer, 2005 (Angiojet)</td>
<td>9/10</td>
<td>0.90 (0.60, 0.98)</td>
</tr>
<tr>
<td>Berlis, 2004 (EPAR)</td>
<td>14/34</td>
<td>0.41 (0.25, 0.59)</td>
</tr>
<tr>
<td>Clark, 2000 (LeTIS)</td>
<td>1/2</td>
<td>0.50 (0.01, 0.99)</td>
</tr>
<tr>
<td>Mayer, 2002 (Neuronet)</td>
<td>3/5</td>
<td>0.60 (0.15, 0.95)</td>
</tr>
</tbody>
</table>

CI=confidence interval; n=number of patients with outcome; N=total number of patients evaluated

**Narrative for Figure 3E:** This figure shows the eight prospective studies that provided data on recanalization for “off-label” devices. The proportion of patients achieving recanalization in each study ranged from 0.41 to 0.90.
Table 1E. Key Efficacy Endpoint Results of Prospective, Single-Arm or Retrospective Studies of the Penumbra System (Penumbra, Alameda, CA)

<table>
<thead>
<tr>
<th>Study, yr</th>
<th>Device</th>
<th>Design</th>
<th>Blinded Outcome Assessment</th>
<th>TIMI II/III</th>
<th>NIHSS decrease ≥4#</th>
<th>mRS≤2*</th>
<th>Death^</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPST, 2009</td>
<td>Penumbra</td>
<td>Prospective</td>
<td>Yes</td>
<td>102/125</td>
<td>27/125</td>
<td>25/125</td>
<td>33/125</td>
</tr>
<tr>
<td>Grunwald, 2009</td>
<td>Penumbra</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>25/29</td>
<td>19/29</td>
<td>11/29</td>
<td>4/29</td>
</tr>
<tr>
<td>Bose, 2008</td>
<td>Penumbra</td>
<td>Prospective</td>
<td>Yes</td>
<td>20/20</td>
<td>9/20</td>
<td>7/20</td>
<td>9/20</td>
</tr>
<tr>
<td>Tarr, 2009</td>
<td>Penumbra</td>
<td>Retrospective</td>
<td>Unclear/No</td>
<td>87/105</td>
<td>59/105</td>
<td>34/105</td>
<td>22/105</td>
</tr>
<tr>
<td>Frei, 2009</td>
<td>Penumbra</td>
<td>Retrospective</td>
<td>Unclear/No</td>
<td>44/53</td>
<td>30/53</td>
<td>19/53</td>
<td>19/53</td>
</tr>
</tbody>
</table>

mRS=modified Rankin Scale; n=number of patients with outcome; N=total number of patients evaluated; NIHSS=National Institutes of Health Stroke Scale; PPST=Penumbra Pivotal Stroke Trial; TIMI=Thrombolysis in Myocardial Infarction
#NIHSS decrease of at least 4-points at 30-days except PPST, 2009 (NIHSS 0-1 or improved by at least 10-points at discharge); Tarr, 2009 and Frei, 2009 (each assessed only at discharge).
*mRS at 90-days except Grunwald, 2009 and Bose, 2008 (30-day)
^Death at 90-days except Grunwald, 2009 and Bose, 2008 (30-day)
Table 2E. Key Efficacy Endpoint Results of Prospective, Single-Arm or Retrospective Studies of the MERCI Retrieval System (Concentric Medical Inc., Mountain View, CA)

<table>
<thead>
<tr>
<th>Study, yr</th>
<th>Device</th>
<th>Design</th>
<th>Blinded Outcome Assessment</th>
<th>TIMI II/III</th>
<th>NIHSS decrease ≥4#</th>
<th>mRS≤2*</th>
<th>Death^</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith, 2008</td>
<td>MERCI</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>90/164</td>
<td>38/146</td>
<td>59/164</td>
<td>56/164</td>
</tr>
<tr>
<td>Devlin, 2007</td>
<td>MERCI</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>14/25</td>
<td>-</td>
<td>6/25</td>
<td>9/25</td>
</tr>
<tr>
<td>Kim, 2006</td>
<td>MERCI</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>13/24</td>
<td>-</td>
<td>6/24</td>
<td>7/24</td>
</tr>
<tr>
<td>Smith, 2005</td>
<td>MERCI</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>68/141</td>
<td>46/141</td>
<td>36/130</td>
<td>60/138</td>
</tr>
<tr>
<td>Gobin, 2004</td>
<td>MERCI</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>12/28</td>
<td>-</td>
<td>6/28</td>
<td>10/28</td>
</tr>
<tr>
<td>Lin, 2009</td>
<td>MERCI</td>
<td>Retrospective</td>
<td>Unclear/No</td>
<td>24/34</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Jo, 2008</td>
<td>MERCI</td>
<td>Retrospective</td>
<td>Unclear/No</td>
<td>75/114@</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Madison, 2008</td>
<td>MERCI</td>
<td>Retrospective</td>
<td>Unclear/No</td>
<td>28/54</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Kidwell, 2008</td>
<td>MERCI</td>
<td>Retrospective</td>
<td>Yes</td>
<td>14/18</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

mRS=modified Rankin Scale; n=number of patients with outcome; N=total number of patients evaluated; NIHSS=National Institutes of Health Stroke Scale; TIMI=Thrombolysis in Myocardial Infarction

#NIHSS decrease of at least 4-points at 30-days except Smith, 2008 (NIHSS improved by at least 10-points or 0 score at 24-hours); Smith, 2005 (NIHSS improved by at least 10-points at 90-days)

@TICI II/III not TIMI II/III for Jo, 2008

*mRS at 90-days except Gobin, 2004 (30-day)

^Death at 90-days except Gobin, 2004 (30-day)
Table 3E. Key Efficacy Endpoint Results of Prospective, Single-Arm or Retrospective Studies of “Off-Label” Neurothrombectomy Devices

<table>
<thead>
<tr>
<th>Study, yr</th>
<th>Device</th>
<th>Design</th>
<th>Blinded Outcome Assessment</th>
<th>TIMI II/III</th>
<th>NIHSS decrease ≥4#</th>
<th>mRS≤2*</th>
<th>Death^</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liebig, 2008</td>
<td>Phenox</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>27/45</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tomsick, 2008</td>
<td>EKOS Primo</td>
<td>Prospective</td>
<td>Yes</td>
<td>18/29@</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gonzalez, 2007</td>
<td>Amplatz Gooseneck</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>7/9</td>
<td>3/7</td>
<td>2/7</td>
<td>2/7</td>
</tr>
<tr>
<td>Mayer, 2005</td>
<td>AngioJet</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>9/10</td>
<td>-</td>
<td>4/12</td>
<td>3/10</td>
</tr>
<tr>
<td>Berlis, 2004</td>
<td>EPAR</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>14/34</td>
<td>7/34</td>
<td>5/34</td>
<td>13/34</td>
</tr>
<tr>
<td>Mayer, 2002</td>
<td>Neuronet</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>3/5</td>
<td>4/5</td>
<td>3/5</td>
<td>0/5</td>
</tr>
<tr>
<td>Clark, 2000</td>
<td>LaTIS</td>
<td>Prospective</td>
<td>Unclear/No</td>
<td>1/2</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

EPAR=Endovascular Photoacoustic Recanalization; mRS=modified Rankin Scale; n=number of patients with outcome; N=total number of patients evaluated; NIHSS=National Institutes of Health Stroke Scale; TIMI=Thrombolysis in Myocardial Infarction @TICI II/III not TIMI II/III for Tomsick, 2008
#NIHSS decrease of at least 4-points at 90-days except Berlis 2004 (30-day, NIHSS ≥ 50% decrease)
*mRS at 90-days except Berlis, 2004 (30-day)
^Death at 90-days except Berlis, 2004 (30-day)
Table 4E. Key Safety Endpoint Results of Prospective, Single-Arm or Retrospective Studies of the Penumbra System (Penumbra, Alameda, CA)

<table>
<thead>
<tr>
<th>Study, yr</th>
<th>Device</th>
<th>Design</th>
<th>Outcome (n/N)</th>
<th>SICH</th>
<th>AICH</th>
<th>Other Hemorrhage</th>
<th>Perforation / Dissection</th>
<th>Thrombus Formation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPST, 2009</td>
<td>Penumbra</td>
<td>Prospective</td>
<td>14/125</td>
<td>21/125</td>
<td>-</td>
<td>6/125</td>
<td>1/125</td>
<td></td>
</tr>
<tr>
<td>Grunwald, 2009</td>
<td>Penumbra</td>
<td>Prospective</td>
<td>2/29</td>
<td>3/29</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Bose, 2008</td>
<td>Penumbra</td>
<td>Prospective</td>
<td>2/20</td>
<td>6/20</td>
<td>2/20</td>
<td>0/20</td>
<td>0/20</td>
<td></td>
</tr>
<tr>
<td>Struffert, 2009</td>
<td>Penumbra</td>
<td>Retrospective</td>
<td>0/15</td>
<td>-</td>
<td>0/15</td>
<td>0/15</td>
<td>0/15</td>
<td></td>
</tr>
<tr>
<td>Tarr, 2009</td>
<td>Penumbra</td>
<td>Retrospective</td>
<td>5/105</td>
<td>1/105</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Frei, 2009</td>
<td>Penumbra</td>
<td>Retrospective</td>
<td>3/53</td>
<td>5/53</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

AICH=asymptomatic intracerebral hemorrhage; n=number of patients with outcome; N=total number of patients evaluated; PPST=Penumbra Pivotal Stroke Trial; SICH=symptomatic intracerebral hemorrhage
<table>
<thead>
<tr>
<th>Study, yr</th>
<th>Device</th>
<th>Design</th>
<th>Outcome (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>SICH</td>
</tr>
<tr>
<td>Smith, 2008</td>
<td>MERCI</td>
<td>Prospective</td>
<td>16/164</td>
</tr>
<tr>
<td>Devlin, 2007</td>
<td>MERCI</td>
<td>Prospective</td>
<td>1/25</td>
</tr>
<tr>
<td>Kim, 2006</td>
<td>MERCI</td>
<td>Prospective</td>
<td>2/24</td>
</tr>
<tr>
<td>Smith, 2005</td>
<td>MERCI</td>
<td>Prospective</td>
<td>11/141</td>
</tr>
<tr>
<td>Gobin, 2004</td>
<td>MERCI</td>
<td>Prospective</td>
<td>0/28</td>
</tr>
<tr>
<td>Jo, 2008</td>
<td>MERCI</td>
<td>Retrospective</td>
<td>-</td>
</tr>
<tr>
<td>Madison, 2008</td>
<td>MERCI</td>
<td>Retrospective</td>
<td>-</td>
</tr>
<tr>
<td>Kidwell, 2008</td>
<td>MERCI</td>
<td>Retrospective</td>
<td>-</td>
</tr>
</tbody>
</table>

AICH=asymptomatic intracerebral hemorrhage; n=number of patients with outcome; N=total number of patients evaluated; SICH=symptomatic intracerebral hemorrhage
### Table 6E. Key Safety Endpoint Results of Prospective, Single-Arm or Retrospective Studies of “Off-Label” Neurothrombectomy Devices

<table>
<thead>
<tr>
<th>Study, yr</th>
<th>Device</th>
<th>Design</th>
<th>Outcome (n/N)</th>
<th>SICH</th>
<th>AICH</th>
<th>Other Hemorrhage</th>
<th>Perforation/ Dissection</th>
<th>Thrombus Formation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liebig, 2008</td>
<td>Phenox</td>
<td>Prospective</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tomsick, 2008</td>
<td>EKOS Primo</td>
<td>Prospective</td>
<td>7/29</td>
<td>-</td>
<td>-</td>
<td>0/29</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Mahon, 2003</td>
<td>EKOS MicroLysUS</td>
<td>Prospective</td>
<td>2/14</td>
<td>-</td>
<td>-</td>
<td>0/14</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gonzalez, 2007</td>
<td>Amplatz Gooseneck</td>
<td>Prospective</td>
<td>1/7 1/7</td>
<td>-</td>
<td>-</td>
<td>0/7 0/7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Mayer, 2005</td>
<td>AngioJet</td>
<td>Prospective</td>
<td>3/12 2/12</td>
<td>-</td>
<td>-</td>
<td>0/12 1/12</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Berlis, 2004</td>
<td>EPAR</td>
<td>Prospective</td>
<td>2/34 2/34</td>
<td>-</td>
<td>-</td>
<td>0/34</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Mayer, 2002</td>
<td>Neuronet</td>
<td>Prospective</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>2/5</td>
</tr>
<tr>
<td>Clark, 2000</td>
<td>LaTIS</td>
<td>Prospective</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

AICH=asymptomatic intracerebral hemorrhage; EPAR=Endovascular Photoacoustic Recanalization; n=number of patients with outcome; N=total number of patients evaluated; SICH=symptomatic intracerebral hemorrhage
Table 7E. All Device Failure-To-Deploy or Breakage/Fracture

<table>
<thead>
<tr>
<th>Study, yr</th>
<th>Design</th>
<th>Outcome (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Failure to Deploy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0/125</td>
</tr>
<tr>
<td>PPST, 2009</td>
<td>Penumbra</td>
<td>Prospective</td>
</tr>
<tr>
<td>Grunwald, 2009</td>
<td>Penumbra</td>
<td>Prospective</td>
</tr>
<tr>
<td>Bose, 2008</td>
<td>Penumbra</td>
<td>Prospective</td>
</tr>
<tr>
<td>Struffert, 2009</td>
<td>Penumbra</td>
<td>Retrospective</td>
</tr>
<tr>
<td>Tarr, 2009</td>
<td>Penumbra</td>
<td>Retrospective</td>
</tr>
<tr>
<td>Frei, 2009</td>
<td>Penumbra</td>
<td>Retrospective</td>
</tr>
<tr>
<td>Smith, 2008</td>
<td>MERCI</td>
<td>Prospective</td>
</tr>
<tr>
<td>Devlin, 2007</td>
<td>MERCI</td>
<td>Prospective</td>
</tr>
<tr>
<td>Kim, 2006</td>
<td>MERCI</td>
<td>Prospective</td>
</tr>
<tr>
<td>Smith, 2005</td>
<td>MERCI</td>
<td>Prospective</td>
</tr>
<tr>
<td>Goitin, 2004</td>
<td>MERCI</td>
<td>Prospective</td>
</tr>
<tr>
<td>Lin, 2009</td>
<td>MERCI</td>
<td>Retrospective</td>
</tr>
<tr>
<td>Jo, 2008</td>
<td>MERCI</td>
<td>Retrospective</td>
</tr>
<tr>
<td>Madison, 2008</td>
<td>MERCI</td>
<td>Retrospective</td>
</tr>
<tr>
<td>Kidwell, 2008</td>
<td>MERCI</td>
<td>Retrospective</td>
</tr>
<tr>
<td>Liebig, 2008</td>
<td>Phenox</td>
<td>Prospective</td>
</tr>
<tr>
<td>Tomsick, 2008</td>
<td>EKOS Primo</td>
<td>Prospective</td>
</tr>
<tr>
<td>Mahon, 2003</td>
<td>EKOS MicroLysUS</td>
<td>Prospective</td>
</tr>
<tr>
<td>Gonzalez, 2007</td>
<td>Amplatz Gooseneck</td>
<td>Prospective</td>
</tr>
<tr>
<td>Mayer, 2005</td>
<td>AngioJet</td>
<td>Prospective</td>
</tr>
<tr>
<td>Berlis, 2004</td>
<td>EPAR</td>
<td>Prospective</td>
</tr>
<tr>
<td>Mayer, 2002</td>
<td>Neuronet</td>
<td>Prospective</td>
</tr>
<tr>
<td>Clark, 2000</td>
<td>LaTIS</td>
<td>Prospective</td>
</tr>
</tbody>
</table>

EPAR=Endovascular Photoacoustic Recanalization; n=number of patients with outcome; N=total number of patients evaluated; PPST=Penumbra Pivotal Stroke Trial
*Refers to number of breakages/fractures divided by total number of devices used