

## Supplemental Online Content

Nogueira RG, Lobsien D, Klisch J, et al. Thrombectomy with the pRESET vs Solitaire stent retrievers as first-line large vessel occlusion stroke treatment: a randomized clinical trial. *JAMA Neurol*. Published online January 2, 2024.  
doi:10.1001/jamaneurol.2023.5010

**eTable 1.** Study Inclusion and Exclusion Criteria

**eTable 2.** Enrollment by Site

**eTable 3.** Schedule of Assessments

**eTable 4.** Primary and Secondary Efficacy Outcomes – Per Protocol

**eTable 5.** Baseline Patient and Procedural Characteristics in the Per-Protocol Population

**eTable 6.** Adverse Events – Per Protocol

**eTable 7.** Primary and Secondary Efficacy Outcomes – As Treated

**eTable 8.** Baseline Patient and Procedural Characteristics in the As-Treated Population

**eTable 9.** Adverse Events – As Treated

**eTable 10.** Exploratory End Points – ITT Population

**eTable 11.** Rescue Therapy in Patients Who Failed to Achieve eTIC Grade  $\geq 2$  Within 3 Passes With the Assigned Device

**eFigure 1.** Primary End Point in the Intention-to-Treat Population

**eFigure 2.** Forest Plot of Mantel-Haenszel Standardized Risk Estimates for the Secondary Efficacy End Point of Overall Disability at 90 Days (Ordinal mRS Score Shift)

This supplementary material has been provided by the authors to give readers additional information about their work.

**eTable 1.** Study Inclusion and Exclusion Criteria

Inclusion Criteria:
<ul style="list-style-type: none"><li>• Age <math>\geq 18</math> years</li><li>• Clinical signs consistent with acute ischemic stroke</li><li>• Subject is able to be treated within 8 hours of stroke symptom onset and within 1.5 hours (90 min) from screening CT / MRI to groin puncture.</li><li>• Pre-stroke modified Rankin Score of 0 or 1</li><li>• NIHSS <math>\geq 6</math> at the time of enrolment</li><li>• If tPA is indicated, initiation of IV tPA should be administered as soon as possible and no later than 3.0 hours of onset of stroke symptoms (onset time is defined as the last time when the patient was witnessed to be at baseline neurologic status), with investigator verification that the subject has received/is receiving the correct IV tPA dose (0.9mg/kg) for the estimated weight.</li><li>• Expanded Thrombolysis in Cerebral Infarction (eTICI) 0-1 flow confirmed by angiography that is accessible to the mechanical thrombectomy device in the following locations:<ul style="list-style-type: none"><li>a) Intracranial internal carotid</li><li>b) M1 and/or M2 segment of the MCA</li><li>c) Carotid terminus</li><li>d) Vertebral artery</li><li>e) Basilar artery</li></ul></li></ul> <p><u>NOTE:</u> M1 segment of the MCA is defined as the arterial trunk from its origin at the ICA to the first bifurcation or trifurcation into major branches neglecting the small temporo-polar branch.</p> <ul style="list-style-type: none"><li>• ASPECTS score must be 6-10 on NCCT or DWI-MRI. If automated core volume assessment software is used:<ul style="list-style-type: none"><li>- MR diffusion-weighted imaging (DWI) <math>\leq 50</math>cc</li><li>- Computed tomography perfusion (CTP) core <math>\leq 50</math> cc</li></ul></li><li>• Subject is willing to conduct protocol-required follow-up visits.</li><li>• A valid signed and dated informed consent by participant or LAR (Legally Authorized Representative) has been obtained.</li></ul> <p><u>NOTE:</u> If approved by the local Ethics Committee and country regulations, an independent physician is permitted to sign consent, to allow enrolment in the study.</p>

However, as soon as possible, the patient is informed and his/her consent is requested for the possible continuation of this research.

**Exclusion Criteria:**

- Subject who has received IA-tPA prior to enrolment in the study
- Female who is pregnant or lactating or has a positive pregnancy test at time of admission.
- Rapid neurological improvement prior to study enrolment suggesting resolution of signs/symptoms of stroke
- Known serious sensitivity to radiographic contrast agents
- Known sensitivity to nickel, titanium metals, or their alloys
- Subjects already enrolled in other investigational studies that would interfere with study endpoints.
- Known hereditary or acquired hemorrhagic diathesis, coagulation factor deficiency. (A subject without history or suspicion of coagulopathy does not require INR or prothrombin time lab results to be available prior to enrolment.)
- Known renal failure as defined by a serum creatinine > 2.0 mg/dl (or 176.8 µmol/l) or glomerular filtration rate (GFR) < 30.
- Subject who requires hemodialysis or peritoneal dialysis, or who has a contraindication to an angiogram for whatever reason.
- Life expectancy of less than 90 days
- Clinical presentation suggests a subarachnoid hemorrhage, even if initial CT or MRI scan is normal
- Suspicion of aortic dissection
- Subject with a comorbid disease or condition that would confound the neurological and functional evaluations or compromise survival or ability to complete follow-up assessments.
- Subject is known to currently use or has a recent history of illicit drug(s) or abuses alcohol (defined as regular or daily consumption of more than four alcoholic drinks per day).
- Known arterial condition (e.g., proximal vessel stenosis or pre-existing stent) that would prevent the device from reaching the target vessel and/or preclude safe recovery of the device
- Subject who requires balloon angioplasty or stenting of the carotid artery at the time of the index procedure.
- Angiographic evidence of carotid dissection

**Imaging Exclusion Criteria:**

- CT or MRI evidence of hemorrhage on presentation
- CT or MRI evidence of mass effect or intra-cranial tumor (except small meningioma)
- CT or MRI evidence of cerebral vasculitis
- CT or MRI-DWI showing ASPECTS 0-5. Alternatively, if automated core volume assessment software is used, MRI-DWI or CTP core > 50cc.
- CT/MRI shows evidence of carotid dissection or complete cervical carotid occlusion requiring a stent
- Any imaging evidence that suggests, in the opinion of the investigator, the subject is not appropriate for mechanical thrombectomy intervention (e.g., inability to navigate to target lesion, moderate/large infarct with poor collateral circulation, etc.).
- Occlusions in multiple vascular territories (e.g., bilateral anterior circulation, or anterior/posterior circulation) as confirmed by angiography, or clinical evidence of bilateral strokes or strokes in multiple territories

**eTable 2.** Enrollment by Site

Site Name	Subject Enrolled
Baptist Health Research Institute	31
Oregon Health and Science University	33
University of Iowa Hospitals & Clinics	24
Rush University Medical Center	15
Valley Baptist Medical Center	7
Buffalo General Hospital	15
Mount Sinai Hospital	7
Emory University School of Medicine / Grady Memorial Hospital	22
Ohio Health Research Institute	6
Advocate Lutheran General Hospital	23
JFK Hackensack Meridian	1
University of Miami	5
NYU Grossman School of Medicine	5
University of Massachusetts Medical School	1
Providence Little Company of Mary Medical Center	6
UPMC Mercy Hospital	12
Montefiore Medical Center	5
Swedish Medical Center	3
HonorHealth Research Institute – Neuroscience Research	1
University of Heidelberg	31
Helios Klinikum Erfurt	53
University of Lübeck	17
Klinikum Bremen-Mitte	10
Klinikum rechts der Isar TU Munich	7

**eTable 3.** Schedule of Assessments

	Screening	Procedure	24 Hour Post-Procedure	7 Day	30 Day	90 Day
Timeframe / Assessment	0 h	Index	16-36 h	5-7 d <sup>^</sup>	21-37 d	75-105 d
Eligibility Criteria	X					
Demographics & Medical History	X					
NIHSS	X		X	X	X*	X*
Pre-Stroke mRS	X					
mRS	X			X	X	X
MR or CT Imaging	X		X	X*		
Catheter Angiogram	X	X				
ASPECTS (0-8 h symptom onset)	X					
Core Infarct Size	X					
MR or CT Angiography	X*			X*		
Procedure Characteristics		X				
Medications/AE's	X	X	X	X	X	X
Barthel Index	X			X	X	X
Randomization	X					
Device Intervention		X				

\* Optional Assessments:

- Imaging was based on Standard of Care / Institutional Protocol
- NIHSS was not required if follow-up was completed over the phone

<sup>^</sup> 7 Day follow-up was conducted 5-7 days post-procedure or at discharge, whichever occurred first.

**eTable 4.** Primary and Secondary Efficacy Outcomes – Per Protocol

<b>Characteristics</b>	<b>pRESET (N=138)</b>	<b>Solitaire (N=128)</b>	<b>Difference (%) [pRESET minus Solitaire]</b>	<b>Asymptotic 1- Sided 95% Confidence Limit (Lower, Upper)</b>
Primary efficacy outcome				
mRS <2 at Day 90	82 (59.42%)	71 (55.47%)	3.95	-6.02 to 13.93
Secondary efficacy outcomes				
eTICI $\geq 2$ b50 achieved $\leq 3$ passes	118 (85.51%)	115 (89.84%)	-4.34	-10.94 to 2.27
eTICI $\geq 2$ c achieved with first pass	64 (46.38%)	54 (42.19%)	4.19	-5.83 to 14.20

**eTable 5.** Baseline Patient and Procedural Characteristics in the Per-Protocol Population

Characteristics	pRESET (N=138)	Solitaire (N=128)	Per Protocol Population (N=266)	P-Value
Age (years)	72.1 (11.32)	71.7 (13.94)	71.9 (12.63)	0.775
Male	71 (51.4%)	62 (48.4%)	133 (50.0%)	0.7128
Female	67 (48.6%)	66 (51.6%)	133 (50.0%)	
NIHSS score, median (IQR)	16.0 (12.0 to 20.0) [n = 138]	16.0 (12.0 to 20.5) [n = 128]	16.0 (12.0 to 20.0) [n = 266]	0.6902
ASPECTS, (median IQR), score	9 (8.0 to 10.0)	9 (8.0 to 10.0)	9 (8.0 to 10.0)	0.4933
Glucose, median (IQR)	117 (101.0 to 143.0) [n = 110]	117 (98.0 to 138.0) [n = 97]	117 (101.0 to 141.0) [n = 207]	0.8558
Medical History				
Hypertension	110 (79.7%)	99 (77.3%)	209 (78.6%)	0.6524
Atrial Fibrillation	66 (47.8%)	52 (40.6%)	118 (44.4%)	0.212
Diabetes Mellitus	35 (25.4%)	37 (28.9%)	72 (27.1%)	0.493
Current Smoking	33 (23.9%)	26 (20.3%)	59 (22.2%)	0.5516
Dyslipidemia	67 (48.6%)	55 (43.0%)	122 (45.9%)	0.3814
Previous Stroke or Transient Ischemic Attack	25 (18.1%)	30 (23.4%)	55 (20.7%)	0.2889
Previous Myocardial Infarction	30 (21.7%)	33 (25.8%)	63 (23.7%)	0.4684
Systolic blood pressure, mm Hg	150.5 (132.0 to 166.0) [n = 136]	147 (131.0 to 164.0) [n = 127]	150 (132.0 to 165.0) [n = 263]	0.8639
Pre-Stroke mRS				
mRS 0	101 (73.2%)	93 (72.7%)	194 (72.9%)	
mRS 1	37 (26.8%)	35 (27.3%)	72 (27.1%)	
Site of occlusion				
Cervical ICA	0.7%	0.8%	0.8%	
Intracranial ICA/Carotid T	14.4%	14.9%	14.7%	
Other	0.7%	2.3%	1.5%	
MCA - M1	52.0%	57.2%	54.5%	
MCA - M2	26.1%	18.8%	22.6%	



Characteristics	pRESET (N=138)	Solitaire (N=128)	Per Protocol Population (N=266)	P-Value
Basilar Artery	5.1%	5.5%	5.4%	
Target occlusion location, left	61 (44.2%)	54 (42.2%)	115 (43.2%)	
Symptom to IV tPA (min) Median / IQR	92.0 (73.0 to 115.0) [n = 44]	86.0 (69.0 to 115.0) [n = 42]	89.5 (71.0 to 115.0) [n = 86]	0.6065
General Anesthesia	52 (37.7%)	49 (38.3%)	101 (38.0%)	1.000
Symptom to puncture (min) Median / IQR	186.0 (129.0 to 246.0) [n = 132]	190.0 (130.0 to 272.0) [n = 121]	189.0 (130.0 to 257.0) [n = 253]	0.5806
Symptom to deployment (min) Median / IQR	204 (150 to 270) [n = 128]	216 (144 to 294) [n = 121]	210 (150 to 282) [n = 249]	0.4858
Symptom to Revascularization 2b50> (min) Median / IQR	198 (150 to 270) [n = 104]	216 (150 to 300) [n = 100]	204 (150 to 282) [n = 204]	0.1588
Puncture to Revascularization 2b50> (min)	27 (19 to 36) [n = 107]	27 (19 to 37) [n = 107]	27 (19 to 37) [n = 214]	0.8391
Balloon Guide Catheter (BCG) Only	25 (18.1%)	27 (21.1%)	52 (19.5%)	0.6428
Intermediate Catheter (IC) Only	55 (39.9%)	50 (39.1%)	105 (39.5%)	0.9009
BGC + IC	42 (30.4%)	33 (25.8%)	75 (28.2%)	0.4163

**eTable 6.** Adverse Events – Per Protocol

	pRESET (N=138)	Solitaire (N=128)	Per Protocol Population (N=266)	2-Sided 90% Confidence Interval (Lower, Upper)	P-Value
Primary Safety Outcome					
slCH per SITS-MOST Criteria	0 (0.0%)	2 (1.6%)	2 (0.8%)		0.2306
Evidence of new infarct outside the original at-risk territory	1 (0.7%)	4 (3.1%)	5 (1.9%)		0.2003
Mass effect or Intra-cranial tumor	1 (0.7%)	0 (0.0%)	1 (0.4%)		1.0000
Evidence of carotid dissection or complete cervical occlusion	0 (0.0%)	0 (0.0%)	0 (0.0%)		-
Intracranial Hemorrhage at 24 Hours	55 (39.86%)	50 (39.06%)		-0.1066 to 0.0907	0.9009
Mortality – Stroke Related	4 (2.90%)	5 (3.91%)		-0.0468 to 0.0266	0.7419

**eTable 7.** Primary and Secondary Efficacy Outcomes – As Treated

Characteristics	pRESET (N=166)	Solitaire (N=156)	Difference (%) [pRESET minus Solitaire]	Asymptotic 1-Sided 95% Confidence Limit (Lower, Upper)
Primary efficacy outcome				
mRS <2 at Day 90	92 (55.42%)	87 (56.05%)	-0.63	-9.72 to 8.47
Secondary efficacy outcomes				
eTICI $\geq 2$ b50 achieved $\leq 3$ passes	141 (84.94%)	139 (89.10%)	-4.16	-10.30 to 1.98
eTICI $\geq 2$ c achieved with first pass	73 (43.98%)	67 (42.95%)	1.03	-8.06 to 10.12

**eTable 8.** Baseline Patient and Procedural Characteristics in the As-Treated Population

Characteristics	pRESET (N=166)	Solitaire (N=156)	As Treated Population (N=322)	P-Value
Age (years) Mean	71.7 (12.07)	72.1 (13.56)	71.9 (12.79)	0.7886
Male	85 (51.2%)	74 (47.4%)	159 (49.4%)	0.5058
Female	81 (48.8%)	82 (52.6%)	163 (50.6%)	
NIHSS score, median (IQR)	16.0 (12.0 to 20.0) [n = 166]	16.0 (12.0 to 21.0) [n = 156]	16.0 (12.0 to 20.0) [n = 332]	0.4197
ASPECTS, (median IQR), score	9 (8.0 to 10.0)	9 (8.0 to 10.0)	9 (8.0 to 10.0)	0.2900
Glucose, median (IQR)	114 (97.0 to 139.0) [n = 134]	119 (96.0 to 142.0) [n = 119]	116.0 (97.0 to 141.0) [n = 253]	0.7469
Medical History				
Hypertension	131 (78.9%)	124 (79.5%)	255 (79.2%)	0.8889
Atrial Fibrillation	74 (44.6%)	65 (41.7%)	139 (43.2%)	0.5685
Diabetes Mellitus	42 (25.3%)	45 (28.8%)	87 (27.0%)	0.4505
Current Smoking	42 (25.3%)	35 (22.4%)	77 (23.9%)	0.5983
Dyslipidemia	78 (47.0%)	63 (40.4%)	141 (43.8%)	0.3025
Previous Stroke or Transient Ischemic Attack	33 (19.9%)	32 (20.5%)	65 (20.2%)	0.8896
Previous Myocardial Infarction	35 (21.1%)	38 (24.4%)	73 (22.7%)	0.504
Systolic blood pressure, mm Hg	149.5 (132.0 to 165.0) [n = 164]	146 (132.0 to 161.0) [n = 155]	148 (132.0 to 164.0) [n = 319]	0.848
Pre-Stroke mRS				
mRS 0	123 (74.1%)	115 (73.7%)	238 (73.9%)	
mRS 1	41 (24.7%)	40 (25.6%)	81 (25.2%)	
mRS $\geq 2$	1 (0.6%)	1 (0.6%)	2 (0.6%)	
Not Reported	1 (0.6%)	0 (0.0%)	1 (0.3%)	
Site of Occlusion				
Cervical ICA	0.6%	0.6%	0.6%	
Intracranial ICA/Carotid T	13.9%	15.4%	14.5%	
Other	0.6%	2.6%	1.6%	

Characteristics	pRESET (N=166)	Solitaire (N=156)	As Treated Population (N=322)	P-Value
MCA - M1	53.7%	56.2%	54.8%	
MCA - M2	25.2%	19.2%	22.4%	
Basilar Artery	5.4%	5.0%	5.3%	
Target occlusion location, left	77 (46.4%)	68 (43.6%)	145 (45.0%)	
Symptom to IV tPA (min)	92.0 (73.0 to 115.0)	86.0 (69.0 to 115.0)	89.5 (71.0 to 115.0)	0.6065
Median/IQR	[n = 44]	[n = 42]	[n = 86]	
General Anesthesia	62 (37.3%)	61 (39.1%)	123 (38.2%)	0.8186
Symptom to puncture (min)	186.0 (129.0 to 246.0)	190.0(130.0 to	189.0 (130.0 to 257)	0.5806
Median/IQR	[n = 132]	272.0) [n = 121]	[n = 253]	
Symptom to deployment (min)	204 (150 to 270)	216 (144 to 294)	210 (150 to 282)	0.4858
Median /IQR	[n = 128]	[n = 121]	[n = 249]	
Symptom to Revascularization	198 (150 to 270)	216 (150 to 300)	204 (150 to 282)	0.1588
2b50> (min) Median/IQR	[n = 104]	[n = 100]	[n = 204]	
Puncture to Revascularization	27 (19 to 36)	27 (19 to 37)	27 (19 to 37)	0.8391
2b50> (min) Median/IQR	[n = 107]	[n = 107]	[n = 214]	
Balloon Guide Catheter (BCG) Only	27 (16.3%)	33 (21.2%)	60 (18.6%)	0.3163
Intermediate Catheter (IC) Only	65 (39.2%)	63 (40.4%)	128 (39.8%)	0.9093
BGC + IC	52 (31.3%)	39 (25.0%)	91 (28.3%)	0.2179

**eTable 9.** Adverse Events – As Treated

<b>Adverse Events - AT</b>					
	<b>pRESET (N=166)</b>	<b>Solitaire (N=156)</b>	<b>As Treated Population (N=322)</b>	<b>2-Sided 90% Confidence Interval (Lower, Upper)</b>	<b>P-Value</b>
Primary Safety Outcome					
sICH per SITS-MOST Criteria	0 (0.0%)	2 (1.3%)	2 (0.6%)		0.2339
Evidence of new infarct outside the original at-risk territory	2 (1.2%)	4 (2.6%)	6 (1.9%)		0.4370
Mass effect or Intra-cranial tumor	1 (0.6%)	0 (0.0%)	1 (0.3%)		1.0000
Evidence of carotid dissection or complete cervical occlusion	0 (0.0%)	0 (0.0%)	0 (0.0%)		-
Intracranial Hemorrhage at 24 Hours	71 (42.77%)	61 (39.10%)		-0.1268 to 0.0534	0.5709
Mortality – Stroke Related	7 (4.22%)	5 (3.21%)		-0.0245 to 0.0447	0.7715

**eTable 10.** Exploratory End Points – ITT Population

The strategy for determining the results from the individual hypothesis tests is based on the examination of the confidence limits of the difference (pRESET minus Solitaire). Table 10 contains the endpoint, a priori threshold for examination, and the hypothesis being tested. It is important to note that exploratory endpoints 3 and 4 have multiple parts.

	Exploratory Endpoints	A priori thresholds	Hypotheses
1	Global disability (mRS ≤ 1) after 90 days following the stroke	-12.5%	$H_0$ : pRESET – Solitaire ≤ -12.5% [inferior] $H_a$ : pRESET – Solitaire > -12.5% [non-inferior]
2	eTICI 2c or greater flow following the last pass (≤3 passes)	-12.1%	$H_0$ : pRESET – Solitaire ≤ -12.1% [inferior] $H_a$ : pRESET – Solitaire > -12.1% [non-inferior]
3a	eTICI 2b50 or greater flow following the final pass (≤3 passes)	-12.1%	$H_0$ : pRESET – Solitaire ≤ -12.1% [inferior] $H_a$ : pRESET – Solitaire > -12.1% [non-inferior]
3b	eTICI 2c or greater flow following the final pass (≤3 passes)	-12.1%	$H_0$ : pRESET – Solitaire ≤ -12.1% [inferior] $H_a$ : pRESET – Solitaire > -12.1% [non-inferior]
4a	eTICI 2b50 flow following the first pass	-12.1%	$H_0$ : pRESET – Solitaire ≤ -12.1% [inferior] $H_a$ : pRESET – Solitaire > -12.1% [non-inferior]
4b	eTICI 2b67 flow following the first pass	-12.1%	$H_0$ : pRESET – Solitaire ≤ -12.1% [inferior] $H_a$ : pRESET – Solitaire > -12.1% [non-inferior]
4c	eTICI 2c flow following the first pass	-12.1%	$H_0$ : pRESET – Solitaire ≤ -12.1% [inferior] $H_a$ : pRESET – Solitaire > -12.1% [non-inferior]
4d	eTICI 3 flow following the first pass	-12.1%	$H_0$ : pRESET – Solitaire ≤ -12.1% [inferior] $H_a$ : pRESET – Solitaire > -12.1% [non-inferior]
5	Early responders at Day 7 or Discharge based on the NIHSS [1]	0%	$H_0$ : pRESET – Solitaire does not contain 0 $H_a$ : pRESET – Solitaire contains 0
6	Intracranial hemorrhage at 90 days	0%	$H_0$ : pRESET – Solitaire does not contain 0 $H_a$ : pRESET – Solitaire contains 0
7	Stroke-related mortality 90 days	0%	$H_0$ : pRESET – Solitaire does not contain 0 $H_a$ : pRESET – Solitaire contains 0
8	Neurological deterioration through 7 days	0%	$H_0$ : pRESET – Solitaire does not contain 0 $H_a$ : pRESET – Solitaire contains 0
9	Procedure-related and device-related serious adverse events 24 hours post-procedure	0%	$H_0$ : pRESET – Solitaire does not contain 0 $H_a$ : pRESET – Solitaire contains 0

**eTable 10a.** ITT Population - Results for Exploratory Endpoints 1 - 4

Table 10a contains the results from exploratory endpoints 1 through 4. In summary, exploratory endpoints 1 through 4 were tested against an a priori threshold to establish non-inferiority of pRESET to Solitaire. Non-inferiority was established for exploratory endpoints 1, 3a, and 4b through 4d. Non-inferiority failed to be demonstrated for exploratory endpoints 2, 3b, and 4a.

	Exploratory Endpoints	pRESET (N=173)	Solitaire (N=167)	Difference (%) [pRESET minus Solitaire]	Asymptotic 1-Sided 95% Confidence Limit (Lower, Upper)	A Priori Thresholds for Lower Bound of the 1-Sided 95% Confidence Interval	Interpretation
1	mRS≤1 after 90 days	70/173 (40.46%)	71/167 (42.51%)	-2.05%	-10.84%, 6.74%	-12.5%	pRESET is non-inferior to Solitaire
2	eTICI 2c or greater after ≤3 passes	94/173 (54.60%)	104/167 (62.28%)	-7.68%	-16.43%, 1.07%	-12.1%	pRESET is not non-inferior to Solitaire
3a	eTICI 2b50 or greater flow following the final pass (≤3 passes)	146/173 (84.39%)	149/167 (89.22%)	-0.0483	-10.84%, 1.19%	-12.1%	pRESET is non-inferior to Solitaire
3b	eTICI 2c or greater flow following the final pass (≤3 passes)	94/173 (54.60%)	104/167 (62.28%)	-7.68%	-16.43%, 1.07%	-12.1%	pRESET is not non-inferior to Solitaire
4a	eTICI 2b50 flow following the first pass	102/166 (61.45%)	104/156 (66.67%)	-5.22	-14.00%, 3.56%	-12.1%	pRESET is not non-inferior to Solitaire
4b	eTICI 2b67 flow following the first pass	90/166 (54.22%)	87/156 (55.77%)	-1.55%	-10.68%, 7.57%	-12.1%	pRESET is non-inferior to Solitaire
4c	eTICI 2c flow following the first pass	73/166 (43.98%)	67/156 (42.95%)	1.03%	-8.06%, 10.12%	-12.1%	pRESET is non-inferior to Solitaire
4d	eTICI 3 flow following the first pass	37/166 (22.29%)	26/156 (16.67%)	5.62%	-1.61%, 12.86%	-12.1%	pRESET is non-inferior to Solitaire



**eTable 10b.** ITT Population - Results for Exploratory Endpoints 5 – 9

Table 10b contains the results for exploratory endpoints 5 through 9. In summary, exploratory endpoints 5 through 9 were evaluated to determine if the confidence limit of the difference (pRESET minus Solitaire) contained zero. For exploratory endpoints 5 through 9, the confidence limit of the difference contained zero for all 5 of the endpoints.

	Exploratory Endpoints	pRESET (N=173)	Solitaire (N=167)	Difference (%) [pRESET minus Solitaire]	A priori thresholds for the 2- Sided 90% Confidence Interval	Actual 2-Sided 90% Confidence Interval	Interpretation
5	<i>Early responders at Day 7 or Discharge based on the NIHSS [1]</i>	95/152 (62.50%)	94/144 (65.28%)	-2.78	0%	-11.96, 6.40% [2]	No difference in the proportions
6	Intracranial hemorrhage at 90 days [3]	78/173 (45.09%)	70/167 (41.92%)	3.17%	0%	-5.67%, 12.01% [2]	No difference in the proportions
7	Stroke-related mortality 90 days	7/173 (4.05%)	6/167 (3.59%)	0.45%	0%	-2.96%, 3.87% [2]	No difference in the proportions
8	Neurological deterioration through 7 days	10/152 (6.58%)	9/144 (6.25%)	0.33%	0%	-4.36%, 5.01% [2]	No difference in the proportions
9	Procedure-related and device-related serious adverse events 24 hours post-procedure	36/173 (20.81%)	37/167 (22.16%)	-1.35%	0%	-8.68%, 5.98% [2]	No difference in the proportions

1: Early Response was defined as a NIHSS reduction of  $\geq 10$  points from baseline or an NIHSS score 0 or 1.

2: 2-sided 90% binomial confidence interval

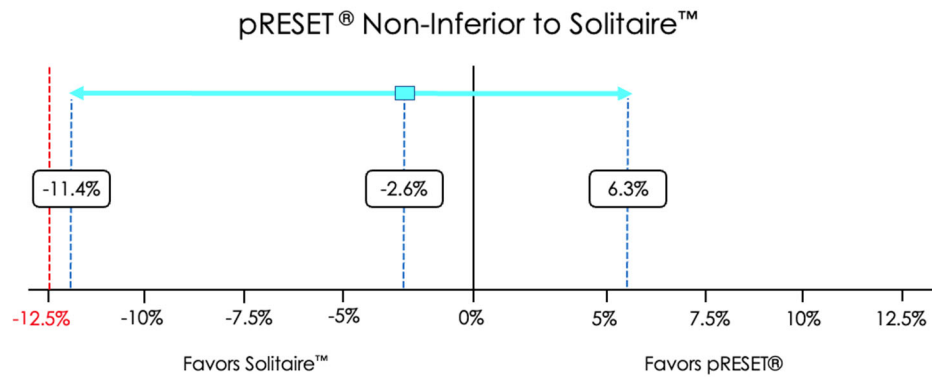
3: Heidelberg Bleeding classification

**eTable 11.** Rescue Therapy in Patients Who Failed to Achieve eTIC Grade  $\geq 2b50$  Within 3 Passes With the Assigned Device

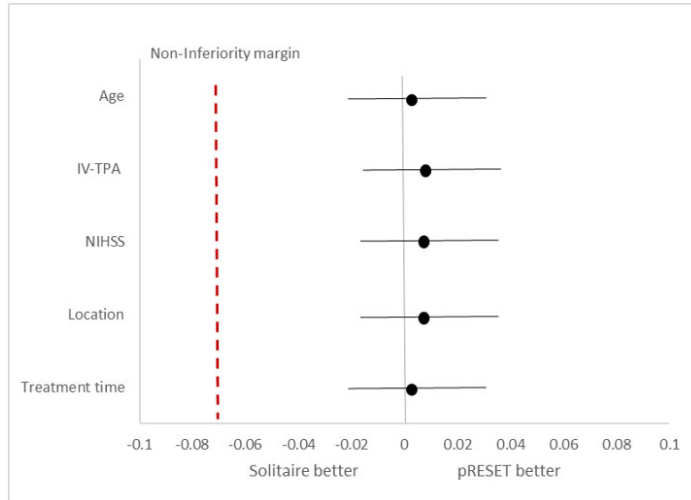
Device	Solitaire (n)	Solitaire (%)*	PRESET (n)	PRESET (%)*
Aspiration Catheter	3	1.8%	5	2.89%
Aspiration Catheter, Intracranial stenting	0	0%	1	0.58%
Intracranial stenting	0	0%	1	0.58%
Mechanical Thrombectomy device	4	2.4%	6	3.47%
Mechanical Thrombectomy device, Aspiration Catheter	3	1.8%	3	1.73%
Mechanical Thrombectomy device, Aspiration Catheter, Intracranial stenting	0	0%	1	0.58%
Mechanical Thrombectomy device, Aspiration Catheter, Other	0	0%	1	0.58%
Mechanical Thrombectomy device, Intracranial stenting	1	0.6%	0	0%
Mechanical Thrombectomy device, Intracranial stenting, Other	0	0%	1	0.58%
Other	1	0.6%	0	0%
<b>Total</b>	<b>12</b>	<b>7.19%</b>	<b>19</b>	<b>10.98%</b>

\*Percentages are based on the ITT Population.

**eFigure 1.** Primary End Point in the Intention-to-Treat Population



**eFigure 2.** Forest Plot of Mantel-Haenszel Standardized Risk Estimates for the Secondary Efficacy End Point of Overall Disability at 90 Days (Ordinal mRS Score Shift)



Results adjusted for each randomization factor: Age (<65 vs. ≥65), IV tPA (Yes or No), NIHSS (<17 vs. ≥17), Location (Basilar/ICA vs. MCA) & Onset (<4 hours vs. ≥4 hours). Red dashed line is non-inferiority margin, set at -12.5% of the Solitaire crude risk