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Summary of Safety and Clinical Performance for Users / Healthcare Professionals

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for Users/Healthcare Professionals

1. Device Identification and General Information

Device Trade Name
Route 92 Medical HiPoint® Reperfusion System
Route 92 Medical FreeClimb® Reperfusion System

Manufacturer's Name and Address
Route 92 Medical, Inc.
155 Bovet Road
Suite 100
San Mateo CA 94402 USA

Manufacturer's SRN

US-MF-000007441

Basic UDI-DI

0853799007NRSEC

EMDN #

C010401020501

Medical Device Nomenclature Description/ Text
Manual Cardiac Thrombectomy and Thromboaspiration Systems

Class of Device
Class III

Year of First CE Certification
2020

Authorized Representative
Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands
SRN: NL-AR-000000116

Notified Body
DQS Medizinprodukt GmbH
August-Schanz-Str. 21,
60433 Frankfurt am Main,
Germany
Single Identification Number: 0297

2. Intended Use

Intended Purpose

The Route 92 Medical HiPoint Reperfusion System and Route 92 Medical FreeClimb Reperfusion System are intended for use in the introduction of interventional devices into the neurovasculature and for aspiration of thrombus in ischemic stroke patients.

Indications

The Route 92 Medical Reperfusion System is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar and vertebral arteries) within 8 hours of symptom onset. The Route 92 Medical Reperfusion System is also indicated for the introduction of interventional/diagnostic devices into the neurovasculature.

Contraindications
There are no known contraindications.

Target Population
Adults 18 years or older.

3. Device Description

The Route 92 Medical FreeClimb and HiPoint Reperfusion Systems and Route 92 Medical FreeClimb Reperfusion Systems are provided in the following configurations:

- HiPoint 70
- HiPoint 88
- FreeClimb 54 (125cm and 148cm)
- FreeClimb 70
- FreeClimb 88 (125cm and 132cm)

A Delivery Catheter and Aspiration Catheter comprise each Route 92 Medical Reperfusion System. The Delivery Catheter is a single-lumen, variable stiffness catheter with a long, tapered tip delineated by two radiopaque markers. The proximal end has a luer hub. The Delivery Catheter is designed specifically for use with the Aspiration Catheter. The Aspiration Catheter is a single-lumen, variable stiffness catheter with a radiopaque marker at the distal tip. Both the Delivery Catheter and the Aspiration Catheter are coated with a hydrophilic coating to facilitate movement. All devices included in the Reperfusion Systems are Single Use, and sterilized using Ethylene Oxide.

HiPoint Reperfusion System
With the HiPoint Reperfusion System only, a Clip is provided to temporarily secure the Delivery Catheter to the Aspiration Catheter during delivery.

Figure 1 shows the HiPoint Reperfusion System with the Delivery Catheter inserted into the Aspiration Catheter.



Figure 1: HiPoint Reperfusion System- Delivery Catheter inserted through Aspiration Catheter

Figure 2 shows the HiPoint Reperfusion System with the Aspiration Catheter inserted into a long sheath and the Delivery Catheter removed.



Figure 2: HiPoint Reperfusion System - Aspiration Catheter inserted into Sheath

FreeClimb Reperfusion System
Figure 3 shows the FreeClimb Reperfusion System with the Delivery Catheter inserted into the Aspiration Catheter.



Figure 3: FreeClimb Reperfusion System- Delivery Catheter inserted through Aspiration Catheter

Figure 4 shows the FreeClimb Reperfusion System with the Aspiration Catheter inserted into a long sheath and the Delivery Catheter removed.

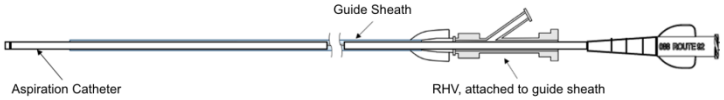


Figure 4: FreeClimb Reperfusion System - Aspiration Catheter inserted into Sheath

Previous Device Generation and Variants
Not applicable

Accessories
A clip is provided with the HiPoint Reperfusion System only.

Compatibility
FreeClimb 54 Reperfusion Systems are compatible with catheters or sheaths with an inner diameter of 0.070" (1.8 mm)

FreeClimb 70 and HiPoint 70 Reperfusion Systems are compatible with catheters or sheaths with an inner diameter of 0.088" (2.24 mm).

FreeClimb 88 and HiPoint 88 Reperfusion System are compatible with sheaths with an inner diameter of 0.106" (2.69 mm).

Only guidewires may be introduced through the Route 92 Medical Delivery Catheters. The Delivery Catheters are not compatible with embolic coils, stent retrievers or other interventional devices.
The Route 92 Medical Delivery Catheters are compatible with guidewires 0.016" or less in diameter.

4. Risks and Warnings

Residual Risks and Undesirable Effects
Procedures requiring percutaneous catheter introduction should only be performed by physicians familiar with possible complications. Possible complications include but are not limited to the following: allergic reaction and anaphylaxis from contrast media; acute occlusion;

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additional surgical intervention: air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; sterile inflammation or granulomas at the access site; infection; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; residual thrombus; tissue necrosis, transient or long lasting: vasospasm; and vessel perforation or dissection.

Warnings

- Do not advance or retract catheter against resistance without careful assessment of cause using fluoroscopy. If cause cannot be determined, withdraw catheter. Movement against resistance may result in catheter damage or patient injury.
- Do not use a device that has been damaged in any way. Use of a damaged device may result in complications.
- The system should only be used by physicians trained in interventional neuro-endovascular techniques.

Precautions

- **Do not use high-powered contrast injection equipment. Use could result in damage to the device or vessel.**
- Ensure target vessel diameter is appropriate and can accommodate catheter.
- Do not reuse or resterilize. The device is intended for single use only. Structural integrity and/or function may be impaired through reuse or cleaning.
- Store in cool, dry, dark place.
- Do not use opened or damaged packages.
- Use prior to the "Use By" date.
- Upon removal from package, inspect each device to ensure no damage.
- Do not expose device to solvents.
- Use device with fluoroscopic visualization and proper anti-coagulation agents.
- Hydrate catheter with heparinized saline before use. Once hydrated, do not allow the catheter to dry.
- Torquing the catheter while kinked may cause damage which could result in separation of the catheter shaft.
- Maintain a constant, pressurized, Heparinized saline infusion on all devices.
- If intraluminal device becomes lodged in catheter, or if the catheter becomes severely kinked, withdraw the entire system (intraluminal device, catheter and introducer sheath).
- When aspirating, aspirate for the minimum time required to remove thrombus.
- Monitor intra-procedural blood loss and manage as appropriate.
- Use only a steam source to shape the Delivery Catheter tip.
- After steam shaping, inspect the Delivery Catheter tip for damage. Do not use a catheter that has been damaged.
- To avoid damaging the Delivery Catheter tip, do not steam shape the catheter tip more than twice.
- In between aspiration passes, withdraw the Aspiration Catheter(s) from the patient and clean any residual thrombus prior to reinsertion and subsequent contrast injection.

Other relevant aspects of Safety
Field Safety Corrective Action

One recall has been performed to date. Affected Route 92 Medical products containing the Tenzing 7 Delivery Catheter were recalled after two instances of distal tip separation at the proximal marker band. In both cases, the Tenzing 7 devices were being used to deliver an aspiration catheter to an occlusive thrombus in a patient suffering an ischemic stroke. In the first incident, the physician was able to snare and retrieve the separated tip without incident. In the second incident, the separated tip was left in the vasculature and the patient's ischemic stroke progressed and the patient expired. Both devices were manufactured by an outside contract supplier. Additional investigations determined that some of the Tenzing 7 Delivery Catheters manufactured by this outside supplier did not meet Route 92 Medical's quality standards particularly in the area of the proximal marker band so a voluntary recall of the Tenzing 7 Delivery Catheters manufactured by the outside supplier was initiated on March 8, 2024. The Tenzing 7 Delivery Catheters manufactured by Route 92 Medical were sampled and thoroughly inspected and found to meet Route 92 Medical's standards. As a result, the recall was limited to the parts manufactured by the outside supplier.

100% of affected customers responded and 100% of remaining product at the customer site was returned. Specific numbers of product affected and recalled are listed below:

	Country	*Recall ID*	*HiPoint 70*	*FreeClimb 70*
Devices Impacted	United States	RES # 94270	133	658
	New Zealand	MEDSAFE # 32696	3	102
Devices On-Hand	N/A	N/A	76	209
Devices Returned	N/A	N/A	76	209

All of the Tenzing 7 Delivery Catheters in inventory at Route 92 Medical that were manufactured by the outside supplier were quarantined and scrapped. Additionally, manufacturing of the Tenzing 7 Delivery Catheter at the outside supplier was disqualified.

5. Summary of Clinical Evaluation and Post-Market Clinical Follow-Up

5.1 SUMMIT NZ:

A post-market clinical follow-up study of 56 cases was completed after CE-marking of the Route 92 Medical Reperfusion System under MDD. The device was used for revascularization of patients with acute ischemic stroke. The primary efficacy endpoint, the rate of successful arterial revascularization as measured by a modified Thrombolysis in Cerebrovascular Infarction (mTICI) score of 2b or greater at the end of angiography after all endovascular treatments, was 96.4% (54/56). When evaluated by vessel, revascularization was achieved in 97.6% (40/41) of subjects with an occlusion of the middle cerebral artery (MCA) and 93.3% (14/15) of subjects with an occlusion of the internal carotid artery. In both of the failed cases, alternate adjunctive therapies were also attempted without success. The mean procedure time was 33.1 minutes and the mean NIH stroke scale (NIHSS)at 24-hour follow-up was 9. At 90-day follow up, 52.7% (29/55) of subjects reports a Modified Rankin score (mRS) of 0-2. The primary safety endpoints were 0% (0/56) rate of device-related peri-procedural complications such as dissection or perforation, 3.6% (2/56) rate of embolization to a previously uninvolved territory, and 0% (0/53) rate of Symptomatic Intracranial Cerebral Hemorrhage (sICH) at 24 hours.

5.2 SUMMIT MAX:

Summary

SUMMIT MAX was a prospective, multi-center, randomized, controlled, interventional, open-label clinical trial evaluating safety and effectiveness of the Route 92 Medical HiPoint Reperfusion System for removing occlusions in acute ischemic stroke patients as compared to a predicate device (AXS Vecta Aspiration System).

Patient Population

Key inclusion criteria were as follows: age 18 and older, baseline National Institutes of Health Stroke Scale (NIHSS) ≥ 6, pre-stroke modified Rankin Scale (mRS) of 2 or less, baseline Alberta Stroke Program Early CT Score (ASPECTS) ≥ 6, and endovascular treatment initiated within 8 hours of symptom onset. Angiographic confirmation of a middle cerebral artery (MCA) M1 segment or internal carotid artery (ICA) occlusion was required. Intravenous thrombolysis was allowed. Complete inclusion and exclusion criteria are listed below.

Inclusion Criteria

1. The consent process has been completed and documented according to applicable country regulations and as approved by the IRB / Ethics Committee.
2. Age ³18 years.
3. Patient presenting with clinical signs consistent with an acute ischemic stroke.
4. Baseline National Institutes of Health Stroke Scale (NIHSS) score ³ 6.
5. Pre-stroke modified Rankin Score (mRS) £ 2.
6. Baseline ASPECTS ³ 6.
7. Endovascular treatment initiated (defined as time of groin puncture) within 8 hours from time last known well.
8. If indicated, thrombolytic therapy shall be initiated per clinical guidelines. If eligible for thrombolytic therapy, subjects should be treated as soon as possible, and lytic use should not be delayed regardless of potential eligibility for mechanical neurothrombectomy.
9. The patient was indicated for aspiration neurothrombectomy with the Route 92 Medical Reperfusion System as determined by the Investigator.

Angiographic Inclusion Criteria

10. Angiographic confirmation of a large vessel occlusion of the M1 segment of the middle cerebral artery or distal internal carotid artery (patency of the cervical ICA to the origin of the ophthalmic artery).

Exclusion Criteria

1. Known pregnancy or breast feeding.
2. In the Investigator's opinion, any known comorbidity (including COVID-19 positivity) that may complicate treatment or prevent improvement or follow-up.
3. Known serious, advanced, or terminal illness with anticipated life expectancy < 12 months.
4. Known history of severe allergy to contrast medium.
5. Known to have suffered a stroke in the past 90 days.
6. Known connective tissue disorder affecting the arteries (e.g., Marfan syndrome, Ehlers-Danlos syndrome).
7. Any known previous cerebral hemorrhagic event.
8. Any known pre-existing coagulation deficiency.
9. Known hemorrhagic diathesis, coagulation factor deficiency, or oral anticoagulant therapy with INR > 3.0.
10. Known baseline platelet count < 50,000/µL
11. Known baseline blood glucose of < 50 mg/dL or > 400 mg/dL.
12. Known to be participating in another study involving an investigational device or drug.
13. Clinical symptoms suggestive of bilateral stroke or stroke in multiple territories.

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14. Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) evidence of recent/fresh cerebral hemorrhage (the presence of microbleeds was allowed).
15. Baseline CT or MRI showing intracranial tumor (except small meningioma £ 2 cm) or significant mass effect with midline shift due to the tumor.
16. Presumed septic thrombus, or suspicion of bacterial endocarditis.
17. Inability to access the cerebral vasculature in the opinion of the neurointerventional team.
18. Unlikely to be available for a 90-day follow-up (e.g., no fixed home address).
19. Evidence of arterial dissection in a vessel that must be traversed.
20. Evidence of high-grade stenosis or occlusion (i.e., tandem occlusion) in a vessel that must be traversed.
21. Known active or recent history of cocaine or methamphetamine abuse (within last 6 months).
22. Known history or presence of aneurysm or arteriovenous malformation (AVM) in the territory of the target lesion.
23. For all patients, severe sustained (15 minutes or more) hypertension with SBP > 200 and/or DBP >120; for patients treated with a lytic, sustained hypertension despite treatment with SBP >185 and/or DBP >110.
24. Treatment with heparin within 48 hours with a partial thromboplastic time more than two times the laboratory normal or treatment with any low molecular weight heparin (LMWH) within 48 hours.
25. Renal failure with serum creatinine >3.0 or Glomerular Filtration Rate (GFR) < 30.
26. Ongoing seizure due to stroke.
27. Evidence of active systemic infection.
28. Known cancer with metastases.

Angiographic Exclusion Criteria

29. Angiographic evidence of a dissection in the extracranial or intracranial cerebral arteries.
30. Arterial stenosis requiring balloon angioplasty or stenting at the time of the procedure.
31. Angiographic evidence of multiple cerebrovascular occlusions (e.g., bilateral anterior circulation, anterior/posterior circulation, tandem occlusion).
32. Angiographic evidence of known or suspected underlying intracranial vasculopathy or atherosclerotic lesions responsible for the target occlusion.
33. Angiographic evidence or suspicion of aortic dissection.
34. Angiographic evidence of an aneurysm or arteriovenous malformation (AVM) in the territory of the target lesion.

Analysis Populations

Different analysis populations were identified depending on the type and extent of analysis being performed. The endpoints were analyzed using the “Modified Intent to Treat Cohort.”

- Intent to Treat (ITT) Cohort
  All randomized subjects.
- Modified Intent to Treat (mITT) Cohort
  Subjects from the ITT cohort who met inclusion and exclusion criteria and for whom the index procedure was planned, or an attempt was made to perform the index procedure, independent of the success of the procedure.
- Per-Protocol Cohort
  All subjects in the mITT cohort in whom there were no major protocol deviations or violations that may have an effect on the integrity of the study data and in whom the procedure was completed.

Disposition of Participants

Of the 250 patients that were enrolled, 50 did not meet the inclusion/exclusion criteria prior to randomization. The remaining 200 patients were randomized (N=107 Route 92 arm, N=93 Vecta arm) and comprise the intent-to-treat randomized cohort (ITT Randomized).

This ITT Randomized cohort included patients who did not meet the inclusion/exclusion criteria after randomization (e.g., no occlusion on angiogram). As a result of not meeting the inclusion/exclusion criteria, 19 participants did not undergo the study procedure with an investigational device or control device after randomization.

The 181 participants (N=97 Route 92 arm, N=84 Vecta arm) who were randomized and attempted treatment with a study or control device comprise the “ITT Randomized and Treated” cohort. This is the population for whom procedure and outcome data are available. Of the 181 “ITT Randomized and Treated” patients, an additional 15 participants did not meet the inclusion/exclusion criteria resulting in 166 participants who were randomized, attempted treatment, and met the inclusion/exclusion criteria. The most common reasons for exclusion of these patients were treatment not within 8 hours (n=5) and no confirmation of a large vessel occlusion (n=3). These 166 participants (N=89 Route 92 arm, N=77 Vecta arm) comprise the modified intent-to-treat cohort (mITT). The treated patients in this cohort include those in whom the use of the study or control device was attempted regardless of success. There were six patients with major protocol deviations that had an effect on the integrity of the data resulting in 160 participants (N=85 Route 92 arm, N=75 Vecta arm) in the per-protocol cohort (PP). Of the six patients with major protocol deviations that had an effect on the integrity of the data, two were randomization errors in which the patient was randomized to the Vecta arm but the site mistakenly used the Route 92 Medical device. For the other four patients, the operator failed to use the assigned device and instead used adjunctive therapy due to guide sheath incompatibility issues.

Subject Follow-up

Patients were followed for 90 days with endpoint evaluations at 24 hours (sICH) and 90 days (modified Rankin Scale score). As shown below, the 24-hour assessment was completed in 99.4% (165/166) of patients. The 90-day assessment was completed in 97.6% (162/166) of patients. Patients who expired prior to the 90-day assessment were considered to have completed the study.

Subject Disposition	Overall (N=166)	Route 92 (N=89)	Vecta (N=77)
Subjects who completed 24-hour assessment	99.4% (165/166)	98.9% (88/89)	100.0% (77/77)
Discontinued	2.4% (4/166)	2.2% (2/89)	2.6% (2/77)
Lost-to-follow-up	1.2% (2/166)	1.1% (1/89)	1.3% (1/77)
Subject withdrew consent	0.6% (1/166)	0.0% (0/89)	1.3% (1/77)
90-day assessment missed (site error)	0.6% (1/166)	1.1% (1/89)	0.0% (0/77)
Subjects who completed the study (90-day follow up)	97.6% (162/166)	97.8% (87/89)	97.4% (75/77)

Baseline Demographics

Characteristic	Overall (N=166)	Route 92 (N=89)	Vecta (N=77)
Gender Female, % (n/N)	54.2% (90/166)	56.2% (50/89)	51.9% (40/77)
Age			
N	166	89	77
Mean (SD)	67.0 (14.2)	68.6 (13.5)	65.1 (14.8)
Median	69.0	71.0	66.0
Min, Max	18.0, 94.0	33.0, 94.0	18.0, 90.0
Race, % (n/N)			
American Indian or Alaska Native	0.0% (0/166)	0.0% (0/89)	0.0% (0/77)
Asian	4.2% (7/166)	3.4% (3/89)	5.2% (4/77)
Black or African American	10.2% (17/166)	9.0% (8/89)	11.7% (9/77)
Native Hawaiian or Other Pacific Islander	0.6% (1/166)	0.0% (0/89)	1.3% (1/77)
White	77.7% (129/166)	75.3% (67/89)	80.5% (62/77)
Maori	0.6% (1/166)	1.1% (1/89)	0.0% (0/77)
Other	2.4% (4/166)	3.4% (3/89)	1.3% (1/77)
Declined to Answer/Unknown	4.2% (7/166)	7.9% (7/89)	0.0% (0/77)
Hispanic or Latino Ethnicity	7.2% (12/166)	9.0% (8/89)	5.2% (4/77)
Baseline ASPECTS			
N	166	89	77
Mean (SD)	8.9 (1.3)	9.0 (1.3)	8.8 (1.2)
Median	9.0	10.0	9.0

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Characteristic	Overall (N=166)	Route 92 (N=89)	Vecta (N=77)
Min, Max	6.0, 10.0	6.0, 10.0	6.0, 10.0
Pre-stroke mRS, % (n/N)			
0	80.7% (134/166)	79.8% (71/89)	81.8% (63/77)
1	15.1% (25/166)	16.9% (15/89)	13.0% (10/77)
2	4.2% (7/166)	3.4% (3/89)	5.2% (4/77)
Baseline NIHSS Score			
N	166	89	77
Mean (SD)	17.0 (5.8)	16.7 (5.6)	17.3 (6.0)
Median	17.0	16.0	18.0
Min, Max	6.0, 30.0	6.0, 29.0	6.0, 30.0
Last Known Well to Arterial Puncture (Hours)			
N	166	89	77
Mean (SD)	4.1 (1.8)	4.0 (1.8)	4.2 (1.7)
Median	3.8	3.6	4.2
Min, Max	1.3, 8.0	1.3, 7.9	1.4, 8.0
Medical History, % (n/N)[1]			
Hypertension	77.2% (125/162)	84.9% (73/86)	68.4% (52/76)
Heart Failure	21.3% (35/164)	20.7% (18/87)	22.1% (17/77)
Coronary Artery Disease	22.4% (36/161)	22.4% (19/85)	22.4% (17/76)
Carotid Artery Disease	2.5% (4/160)	3.5% (3/85)	1.3% (1/75)
Atrial Fibrillation	42.3% (69/163)	44.2% (38/86)	40.3% (31/77)
Patent Foramen Ovale	2.5% (4/163)	1.1% (1/87)	3.9% (3/76)
Hematologic Disorder	3.0% (5/164)	3.4% (3/87)	2.6% (2/77)
Previous Intracerebral Hemorrhage	0.0% (0/166)	0.0% (0/89)	0.0% (0/77)
Peripheral Vascular Disease	5.6% (9/160)	7.1% (6/85)	4.0% (3/75)
Diabetes Mellitus	24.4% (40/164)	19.3% (17/88)	30.3% (23/76)
Kidney Disease	10.4% (17/164)	10.3% (9/87)	10.4% (8/77)
Seizures	2.4% (4/164)	2.3% (2/87)	2.6% (2/77)
Dyslipidemia	59.6% (99/166)	66.3% (59/89)	51.9% (40/77)
Current Smoker	16.5% (26/158)	14.5% (12/83)	18.7% (14/75)
Past Smoker	20.8% (33/159)	15.5% (13/84)	26.7% (20/75)
Previous TIA	9.1% (15/165)	9.1% (8/88)	9.1% (7/77)
Previous Ischemic Stroke	12.1% (20/165)	10.2% (9/88)	14.3% (11/77)

[1]Denominators reflective of patients without missing medical history data for a given medical history covariate. Patients with missing data not included in the denominator.

Occlusion Location and Procedural Characteristics

Occlusion Location	Overall (N=166)	Route 92 (N=89)	Vecta (N=77)
Angiographically confirmed baseline occlusion location, % (n/N)			
ICA	12.7% (21/166)	13.5% (12/89)	11.7% (9/77)
M1	87.3% (145/166)	86.5% (77/89)	88.3% (68/77)
Side of occlusion, % (n/N)			
Left	47.0% (78/166)	49.4% (44/89)	44.2% (34/77)
Right	53.0% (88/166)	50.6% (45/89)	55.8% (43/77)

Procedural Characteristics	Overall (N=166)	Route 92 (N=89)	Vecta (N=77)
Adjunctive therapy, % (n/N)			
Use of adjunctive therapy at site of occlusion, % (n/N)[2]	33.7% (56/166)	20.2% (18/89)	49.4% (38/77)
Alternative aspiration catheter (AC)	21.1% (35/166)	14.6% (13/89)	28.6% (22/77)
Stent retriever (SR)	27.1% (45/166)	15.7% (14/89)	40.3% (31/77)
IA lytic	0.0% (0/166)	0.0% (0/89)	0.0% (0/77)
Other	2.4% (4/166)	1.1% (1/89)	3.9% (3/77)
Number of Passes			
N	166	89	77
Mean (SD)	2.3 (1.9)	2.0 (1.7)	2.8 (2.1)
Median	1.0	1.0	2.0
Min, Max	1.0, 10.0	1.0, 9.0	1.0, 10.0
Procedure Time (Time from Groin Puncture to Groin Closure), mins			
N	166	89	77
Mean (SD)	57.4 (47.9)	57.8 (56.3)	56.9 (36.2)
Median	42.0	40.0	47.0
Min, Max	10.0, 427.0	10.0, 427.0	10.0, 178.0
IV Lytic, % (n/N)			
TNK	39.8% (66/166)	43.8% (39/89)	35.1% (27/77)
t-PA	18.7% (31/166)	16.9% (15/89)	20.8% (16/77)
Not administered	41.6% (69/166)	39.3% (35/89)	44.2% (34/77)
Anesthesia, % (n/N)[2]			
General anesthesia	53.0% (88/166)	46.1% (41/89)	61.0% (47/77)
IV sedation	27.1% (45/166)	32.6% (29/89)	20.8% (16/77)
General anesthesia and IV sedation	1.8% (3/166)	1.1% (1/89)	2.6% (2/77)
Other	18.1% (30/166)	20.2% (18/89)	15.6% (12/77)

[2] Not mutually exclusive, subjects may fall into more than one sub-category.

Endpoints

The primary effectiveness endpoint was successful reperfusion (defined as mTICI ≥ 2b, adjudicated by an independent blinded core lab) using only the assigned study device, with use of any adjunctive therapy either before or after use of the study device considered a failure.

The primary safety endpoint was symptomatic intracranial hemorrhage (sICH) within 24 h (-8/+24) post-procedure, defined by the Heidelberg bleeding classification. Intracranial hemorrhage was identified by the core lab and adjudicated by the clinical events committee.

Both the primary effectiveness endpoint and the primary safety endpoint were met. Specifically, the effectiveness endpoint of revascularization rate (with adjunctive therapy counted as a failure) achieved by the subject device (77.5% [69/89]) was non-inferior to the revascularization rate achieved by the predicate device (50.6% [39/77]).

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Endpoint	Route 92 (N=89)	Vecta (N=77)	Difference (95% Confidence Interval)[3]	P-value[4]
Successful arterial revascularization, any adjunctive therapy considered a failure, % (n/N)	77.5% (69/89)	50.6% (39/77)	26.9% (12.7%, 41.0%)	< 0.0001

[3] Wald confidence interval.
[4] One-sided p-value from a two sample Z-test for proportions in a non-inferiority context using a non-inferiority margin of 12.5%. The one-sided p-value from a two-sample Z-test for proportions in a superiority context is 0.0001.

The clinical protocol limited the use of the Route 92 Medical HiPoint Reperfusion System to three passes. Additional analyses of the primary effectiveness endpoint that consider more than three passes as a failure were also performed:

Endpoint	Route 92 (N=89)	Vecta (N=77)	Difference (95% Confidence Interval)[5]	P-value[6]
Successful arterial revascularization, any adjunctive therapy and > 3 passes considered a failure, % (n/N)	76.4% (68/89)	48.1% (37/77)	28.4% (14.1%, 42.6%)	< 0.0001

[5] Wald confidence interval.
[6] One-sided p-value from a two sample Z-test for proportions in a non-inferiority context using a non-inferiority margin of 12.5%. The one-sided p-value from a two-sample Z-test for proportions in a superiority context is 0.0001.

Similarly, the primary safety endpoint of symptomatic intracranial hemorrhage (sICH) at 24 hours as adjudicated by an independent, blinded core lab and similarly blinded and independent clinical events committee was 3.6% (3/84) with the subject device as compared to 2.7% (2/75) with the predicate device which was non-inferior.

Endpoint	Route 92 (N=89)	Vecta (N=77)	Difference (95% Confidence Interval)[7]	P-value[8]
Incidence of symptomatic intracranial hemorrhage (sICH) within 24 (-8/+ 24) hours post-procedure, % (n/N)	3.6% (3/84)	2.7% (2/75)	0.9% (-4.5%, 6.3%)	<0.0001

[7] Wald confidence interval.
[8] One-sided p-value from a two sample Z-test for proportions in a non-inferiority context using a non-inferiority margin of 12.5%.

At 90 days, good clinical outcome (mRS ≤ 2) was achieved in 50.6% of patients treated with the subject device as compared to 53.3% of patients treated with the predicate device. The overall incidence of any hemorrhage within 24 (-8/+24) hours post-procedure as adjudicated by the independent, blinded core lab was 42.7% (38/89) for the subject device as compared to 49.4% (38/77) for the predicate device. Other secondary endpoints are shown below.

Endpoint	Route 92 (N=89)	Vecta (N=77)	Difference (95% CI)[13]
Successful arterial revascularization after use of assigned device, subsequent use of adjunctive therapy not counted as failure, % (n/N)[9]	80.9% (72/89)	70.1% (54/77)	10.8% (-2.3%, 23.9%)
Device-related SAEs, % (n/N) [10]	5.6% (5/89)	2.6% (2/77)	3.0% (-2.9%, 9.0%)
Good clinical outcome (mRS ≤ 2 at 90-day follow-up visit), % (n/N)	50.6% (44/87)	53.3% (40/75)	-2.8% (-18.2%, 12.7%)
Incidence of all intracranial hemorrhages within 24 (-8/+24) hours post-procedure, % (n/N)[11]	42.7% (38/89)	49.4% (38/77)	-6.7% (-21.8%, 8.5%)
Time from groin puncture to final angiogram (minutes), mean	41.82	47.12	5.31 (-5.86, 16.47)
Proportion of subjects with First Pass Effect (mTICI ≥ 2b) (FPE), % (n/N)[12]	60.5% (52/86)	54.5% (36/66)	5.9% (-9.9%, 21.8%)

[9] Successful arterial revascularization is defined as a modified Thrombolysis in Cerebrovascular Infarction (mTICI) score of 2b or greater, as judged by an independent adjudicating core laboratory, after last pass with assigned device. If an mTICI score of 2b or greater was achieved after use of the assigned device, subsequent use of IA lytic or another mechanical neurothrombectomy device other than the assigned device is not counted as a failure.
[10] As adjudicated by the CEC.
[11] ICH identified by the independent adjudicating core laboratory.
[12] FPE defined as achievement of successful recanalization (mTICI ≥ 2b) as judged by an independent adjudicating core laboratory after the first pass with only the assigned device.
[13] Nominal two-sided 95% confidence intervals (i.e., Wald confidence intervals) are reported for differences in proportions and for difference in means.

All intracranial hemorrhages were reviewed and classified by the core lab.

	Route 92 % (n/N)	Vecta % (n/N)
All Intracranial Hemorrhages	42.7% (38/89)	49.4% (38/77)
PH2	0.0% (0/89)	0.0% (0/77)
SAH	3.4% (3/89)	3.9% (3/77)
SAH + PH1	0.0% (0/89)	0.0% (0/77)
HI1	16.9% (15/89)	23.4% (18/77)
HI2	11.2% (10/89)	9.1% (7/77)
RIH	0.0% (0/89)	1.3% (1/77)
PH1 + HI2	1.1% (1/89)	0.0% (0/77)
RIH + HI1	0.0% (0/89)	1.3% (1/77)
SAH + HI1	3.4% (3/89)	7.8% (6/77)
SAH + HI2	0.0% (0/89)	1.3% (1/77)
SAH + RIH	1.1% (1/89)	0.0% (0/77)
SAH + IVH	2.2% (2/89)	0.0% (0/77)
SAH + IVH + PH1	1.1% (1/89)	0.0% (0/77)
SAH + HI2+ PH2	0.0% (0/89)	1.3% (1/77)
SAH + IVH + PH2	1.1% (1/89)	0.0% (0/77)
PH-1 + SAH + IVH + HI-2	1.1% (1/89)	0.0% (0/77)

***Note:** The overall rate of core lab adjudicated subarachnoid hemorrhage (SAH) in the SUMMIT MAX trial included 12/89 (13.5%) of subjects in the Route 92 arm and 11/77 (14.3%) of the Vecta arm.

****Note:** Within the Route 92 arm, 1/12 subjects with SAH were not treated with any Route 92 devices; 7/11 subjects with SAH treated with Route 92 devices were treated with 1-2 passes of the 88 Aspiration Catheter alone; 8/11 subjects with SAH were treated with Route 92 devices for 1-2 passes without use of adjunctive devices; the average number of passes was 2.8 in the 11 subjects with SAH in the Route 92 arm. SAH incidence in subjects where only the Route 92 devices were used for mechanical neurothrombectomy in the Route 92 arm was 8/89 (9%).
Within the Vecta arm, 2/11 subjects with SAH were treated with 1-2 passes of the Vecta catheters, and 9/11 subjects with SAH were treated with adjunctive devices and multiple passes, with an average of 5.8 passes in the 11 subjects with SAH in the Vecta arm. SAH incidence in subjects where only the Vecta devices were used for mechanical neurothrombectomy in the Vecta arm was 2/77 (2.6%).

Adverse Events

AE Name	Route 92 % (n/N)	Vecta % (n/N)
Nervous system disorders	49.4% (44/89)	53.2% (41/77)
Cerebral haemorrhage	12.4% (11/89)	9.1% (7/77)
Headache	9.0% (8/89)	11.7% (9/77)
Cerebral infarction	6.7% (6/89)	7.8% (6/77)
Cerebral vasoconstriction	9.0% (8/89)	9.1% (7/77)
Brain oedema	13.5% (12/89)	1.3% (1/77)
Subarachnoid haemorrhage	6.7% (6/89)	2.6% (2/77)
Cerebrovascular accident	2.2% (2/89)	6.5% (5/77)
Haemorrhagic transformation stroke	5.6% (5/89)	2.6% (2/77)
Intracranial artery dissection	2.2% (2/89)	1.3% (1/77)
Stroke in evolution	2.2% (2/89)	1.3% (1/77)
Syncope	2.2% (2/89)	1.3% (1/77)
Cerebral artery occlusion	3.4% (3/89)	0.0% (0/77)
Dizziness	2.2% (2/89)	1.3% (1/77)

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AE Name	Route 92 % (n/N)	Vecta % (n/N)
Intraventricular haemorrhage	2.2% (2/89)	1.3% (1/77)
Carotid artery occlusion	1.1% (1/89)	1.3% (1/77)
Encephalopathy	2.2% (2/89)	0.0% (0/77)
Haemorrhage intracranial	2.2% (2/89)	0.0% (0/77)
Neuralgia	1.1% (1/89)	1.3% (1/77)
Seizure	0.0% (0/89)	2.6% (2/77)
Somnolence	1.1% (1/89)	1.3% (1/77)
Aphasia	0.0% (0/89)	1.3% (1/77)
Basal ganglia infarction	0.0% (0/89)	1.3% (1/77)
Basal ganglia stroke	1.1% (1/89)	0.0% (0/77)
Carotid artery dissection	0.0% (0/89)	1.3% (1/77)
Cerebral atrophy	0.0% (0/89)	1.3% (1/77)
Cerebral mass effect	0.0% (0/89)	1.3% (1/77)
Cerebrovascular pseudoaneurysm	1.1% (1/89)	0.0% (0/77)
Cognitive disorder	0.0% (0/89)	1.3% (1/77)
Cytotoxic oedema	1.1% (1/89)	0.0% (0/77)
Depressed level of consciousness	1.1% (1/89)	0.0% (0/77)
Grimacing	1.1% (1/89)	0.0% (0/77)
Intracranial aneurysm	0.0% (0/89)	1.3% (1/77)
Intracranial mass	1.1% (1/89)	0.0% (0/77)
Ischaemic stroke	0.0% (0/89)	1.3% (1/77)
Lethargy	1.1% (1/89)	0.0% (0/77)
Memory impairment	0.0% (0/89)	1.3% (1/77)
Metabolic encephalopathy	1.1% (1/89)	0.0% (0/77)
Restless legs syndrome	1.1% (1/89)	0.0% (0/77)
Vagus nerve disorder	1.1% (1/89)	0.0% (0/77)

6. Therapeutic Alternatives

Other commercially available distal intracranial catheters may be used to deliver interventional devices into the neurovasculature or aspirate thrombus.

7. User Profile and Training

The catheter should only be used by physicians trained in interventional neuro-endovascular techniques.

8. Harmonized Standards or Common Specifications Applied

No Common Specifications are currently applicable to these products. For Harmonized Standards applied see below:

Standard ID / Year	*Description*
EN 556-1:2024	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2019	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice

9. Instructions for Use: www.r92m.com/IFU

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Summary of Safety & Clinical Peformance for Patients

Per Regulation 2017/745 and MDCG 2019-9 Route 92 Medical has considered the need for a SSCP for patients. This is not required as:

- **This device is not implantable**
- **This device is not a Class III which is used by patient.**
- **This device has a medical purpose**

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Revision History

SSCP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
A	20-Mar-2023	Initial Release	No
B	18-Apr-2023	Update with FreeClimb	No
C	11-Feb-2024	Update REG 2432 to match the format per the template in MDCG 2019-09.	No
D	23-Oct-2024	Update with Notified Body Validation	Yes
E	27-Jun-2025	Add Summit Max Clinical Trial	No
F / 1.0	8-Jan-2026	- Add EMDN - Add NB's single identification number (0297)- Add that the device is for single use and method of sterilization. - Add recall info. - Add a section for harmonized standards and those applied. - Add a section for common specifications.	Yes
2.0	6-Mar-2026	Add ISO 14155 to harmonized standards	No
3.0	18-Mar-2026	Administrative fix.	No