# Summary of Safety & Clinical Performance for Users/Healthcare Professionals, Neurovascular Reperfusion System

**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**

0853799007NRSEF

**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

## 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 HiPoint Reperfusion Systems and Route 92 Medical FreeClimb Reperfusion Systems are each provided in two sizes, 070 and 088. 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.

**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.

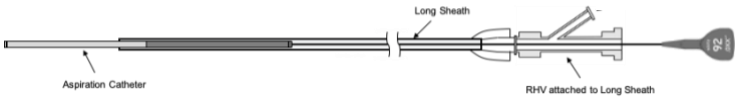


**Figure 2**: HiPoint Reperfusion System - Aspiration Catheter inserted into Sheath

**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.

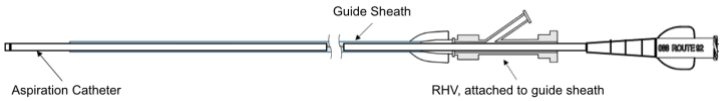


**Figure 4**: FreeClimb Reperfusion System - Aspiration Catheter inserted into Sheath

**Previous Device Generation and Variants**
Not applicable

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

**Compatibility**
The 070 Reperfusion Systems are compatible with catheters or sheaths with an inner diameter of 0.088" (2.24 mm).

The 088 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; 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.

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

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.

**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 Harmonized Standards or Common Specifications have been applied

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

# Summary of Safety & Clinical Performance for Patients,

# Neurovascular Reperfusion System

**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**

# Summary of Safety & Clinical Performance for Patients,
# Neurovascular Reperfusion System

**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 |