# Summary of Safety & Clinical Performance for Users/Healthcare Professionals, Base Camp Sheath® 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**
Base Camp® Sheath System (90cm) Berenstein
Base Camp Sheath System 2.0 (90cm) Berenstein
Base Cam Sheath System 2.0 (80cm) Berenstein

**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**

0853799007NSSEF

**Medical Device Nomenclature Description/ Text**
Non-Action, Non-Implantable, guide catheters, balloon catheters, guidewires, introducers, filters, and related tools

**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 Base Camp Sheath System is intended to be used to introduce interventional devices into the neuro vasculature. The Dilator and Navigating Catheter may each be used individually through the Sheath to assist in placement of the Sheath using fluoroscopy and standard endovascular techniques. Devices compatible with the Sheath lumen may be placed through the Sheath as needed.

**Indications**
The Route 92 Medical Sheath System is indicated for the introduction of interventional devices into the neuro vasculature.

**Contraindications**
There are no known contraindications.

**Target Population**
Adults 18 years or older.

## 3. Device Description

The Route 92 Medical Base Camp Sheath System is comprised of a Sheath, a Dilator, a Navigating Catheter and an RHV (rotating hemostasis valve). The Base Camp Sheath is a single-lumen, variable stiffness catheter with a radiopaque marker on the distal end. The inner lumen of the catheter is compatible with 8F or smaller catheters. The Dilator may be placed within the Sheath to facilitate percutaneous introduction of the Sheath into a femoral artery. The Dilator has a radiopaque marker at the distal tip. The Navigating Catheter is a single-lumen, variable stiffness catheter with a radiopaque marker at the distal tip. The Navigating Catheter is a compatible with the Sheath and has a shaped distal end to facilitate placement. All of the catheters are coated with hydrophilic coating.

**Previous Device Generation and Variants**
Not applicable

**Accessories**
Not applicable

**Compatibility**
The Route 92 Medical Sheath is intended to be used with 8F or smaller catheters. An 0.035" guidewire may be used through the Dilator and the Navigating Catheter.

## 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; air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; infection; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; 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 catheter should only be used by physicians trained in interventional neuro-endovascular techniques.
- Testing has been limited to contrast media and saline. The use of this catheter for delivery of other solutions is not recommended.

**Angiography and Fluoroscopy Precautions**
X-ray exposure from fluoroscopy and angiography poses risks including alopecia, burns ranging from skin reddening to ulcers, cataracts and delayed neoplasia. The probability of these risks occurring increases as procedure time and number of procedures increase. Care should be taken to minimize the X-ray radiation exposure of the patient and the operator by using sufficient shielding, reducing fluoroscopy times and modifying X-ray imaging techniques whenever possible.

**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 device to ensure it is not damaged.
- 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 infusion of appropriate flush solution.
- If intraluminal device becomes lodged in catheter, or if the catheter becomes severely kinked, withdraw the entire system (intraluminal device, catheter and introducer sheath).

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

A post-market clinical follow-up study of 42 cases was completed after CE-marking of the Route 92 Medical Base Camp Sheath System under MDD. The device was used to deliver the compatible Route 92 Reperfusion System in the neurovasculature in order to treat patients presenting with ischemic stroke. The primary efficacy endpoint, the rate of successful placement of the Base Camp Sheath in the internal (N=40) or common (N=2) carotid artery, was 100% (42/42). In 90% (38/42) of cases, the Base Camp Sheath was used to deliver the Route 92 Reperfusion System to the neurovasculature. In the remaining 10% (4/42) of cases, introduction of the Route 92 Reperfusion System via the Base Camp Sheath was no longer indicated because the clot had either resolved with tPA (tissue Plasminogen Activator) or migrated to an exclusionary distal location within the neurovasculature. The primary safety endpoint, the rate of occurrence of severe, device-related complications such as arterial dissection or perforation, was 0% (0/42).

## 6. Therapeutic Alternatives

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

## 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, Base Camp Sheath® 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, Base Camp Sheath® System

**Revision History**

| Rev | Date Issued | Change Description | Revision Validated by the Notified Body |
|---|---|---|---|
| A | 5-Nov- 2021 | Initial Release | No |
| B | 29-Mar-2022 | - Change to Production status - Inadvertently released as Pre-Production.<br>- Update legal status and Trade Mark - Out of date | No |
| C | 17-Jan-2024 | Add statement on SSCP for Users/Healthcare Professionals and Patients. | No |
| D | 2-Nov-2024 | Add Base Camp 2.0, updated Emergo Address | No |