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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
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

EMDN #

C0104010202

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 – Base Camp Sheath System (90cm) Berenstein
2025 – Base Camp Sheath System 2.0 (80 & 90cm) Berenstein

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 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. The device is provided sterile by ethylene oxide for single-use.

Previous Device Generation and Variants
Not applicable

Accessories
Not applicable

Principles of Operation

To place the Base Camp Sheath System, a guidewire is placed in the femoral artery using standard arterial access techniques. The Dilator is advanced through the Sheath and the luer on the Dilator is designed to press fit in the luer on the Sheath. The Dilator/Sheath assembly is advanced over the guidewire for percutaneous introduction of the Sheath into the artery. The Dilator is then removed. The Navigating Catheter is then inserted through the Sheath and navigated under fluoroscopy to the targeted location using standard endovascular techniques. Alternatively, the Sheath with the Navigating Catheter may be inserted through an introducer placed in the femoral artery and advanced under fluoroscopy using standard endovascular techniques. Once the Sheath is positioned at the target site, the Navigating Catheter is removed. A compatible catheter may then be passed through the RHV attached to the Sheath and advanced through the Sheath to the targeted location in the vasculature.

Patient-contacting Materials

Materials
Polyether block amide, Radiopaque inorganic compound, Polyamide, Polymer stabilizer, Thermoplastic elastomer, Fluoropolymer, Hydrophilic polymer, Polyolefin, Colorant / pigment, Polyether block amide with radiopaque filler

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.

Serious Incident Complication Rate
The frequencies below are based on reportable post-market events relative to distributed devices. Where the same clinical event resulted in different patient outcomes, events are presented separately by reported outcome.

Clinical Effect/Patient Outcome	Current Reporting Period (January 1 – December 31, 2025)	Cumulative Events Since First Sale (2020)
Extravasation	0	1
Vessel Dissection	0	1
Total	**0**	**2**
Complication Rate	**0.000%**	**0.031%**

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.

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- Do not advance or retract catheters 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 catheters 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.
- Do not use device in vessels that are smaller than the outer diameter of the device or within tortuous vasculature.
- Do not use high-powered contrast injection equipment. Use could result in damage to the device or vessel.
- 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.
- Do not use opened or damaged packages.
- Do not expose device to solvents.
- The Sheath System is coated with a hydrophilic coating at the distal end of each device for a length of 8 cm for the Sheath, 15 cm for the Dilator and 40 cm for the Navigating Catheter. Please refer to the Directions for Use section for further information on how to prepare and use the system to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- Use caution when manipulating, advancing and/or withdrawing these devices through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage. This may result in adverse events requiring additional intervention.

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

-
- Store in cool, dry, dark place.
- Use prior to the “Use By” date.
- Upon removal from package, inspect device to ensure it is not damaged.
- Use device with fluoroscopic visualization and proper anti-coagulation agents.
- Hydrate each 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).
- Avoid wiping the device with dry gauze as this may damage the device coating.
- Avoid excessive wiping of the coated device
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
- Avoid pre-soaking the devices as this may impact the coating performance.

Other relevant aspects of Safety
Field Safety Corrective Action
None are applicable to this product.

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).

The Base Camp Sheath System was also used in a prospective, multi-center, randomized, controlled clinical trial to provide femoral access and guide sheath support in both the Route 92 Medical Reperfusion System treatment arm and the AXS Vecta control arm. The *Prospective, Randomized, Controlled, Interventional Clinical Trial to Evaluate the Safety and Effectiveness of the Route 92 Medical MonoPoint® Reperfusion System for Aspiration Embolectomy in Acute Ischemic Stroke Patients* (SUMMIT MAX) trial was conducted at 31 sites in the United States and New Zealand. 166 patients were randomized, treated using the Base Camp Sheath System, and met the inclusion/exclusion criteria.

Both the primary efficacy endpoint and the primary safety endpoint were met. The primary effectiveness endpoint was the achievement of reperfusion defined as mTICI 2b as adjudicated by a blinded, independent core lab with any use of adjunctive therapy prior to or following use of the study device defined as a failure. The endpoint of revascularization rate achieved by the subject device was 77.5% (69/89) which was non-inferior to the 50.6% (39/77) revascularization rate achieved by the predicate Vecta device (p<0.0001). Within the Modified Intent to Treat population (Route 92 arm: n=89, Vecta arm: n=77), 21/166 (12.7%) patients were treated for baseline occlusions in the internal carotid artery (ICA), 145/166 (87.3%) in the M1 segment of the middle cerebral artery.

The primary safety endpoint was symptomatic intracranial hemorrhage (sICH) within 24 hours. The safety endpoint observed with the subject device was 3.6% (3/84) which was non-inferior to the 2.7% (2/75) sICH rate.

Good clinical outcomes (mRS≤ 2) were achieved in 50.6% (44/87) of participants in the Route 92 arm as compared to 53.3% (40/75) of participants in the Vecta arm. The incidence of all intracranial hemorrhages was 42.7% (38/89) in the Route 92 arm compared to 49.4% (38/77) in the Vecta arm.

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 Common Specifications are currently applicable to these products. For Harmonized Standards applied see below:

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**