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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 Tenzing® 7 Delivery Catheter

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

**Manufacturer's SRN**
US-MF-000007441

**Basic UDI-DI**
08537990076001VF

**EMDN #**
C010401020501

**Medical Device Nomenclature Description/ Text**
GMDN # 17846 Vascular Guide-Catheter, Single Use

**Class of Device**
Class III

**Year of First CE Certification**
2019 (Directive 93/42/EEC)
2022 (Regulation 2017/745)

**Authorized Representative**
Emergo Europe
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 Tenzing 7 Delivery Catheter is intended to be used to deliver large-bore catheters with an inner diameter of 0.068" or greater to the neurovasculature for the intended population of adult males and females under fluoroscopy using standard endovascular techniques. If required, a standard 0.014" or 0.016" neurovascular guidewire may be inserted through the Tenzing 7 Catheter.

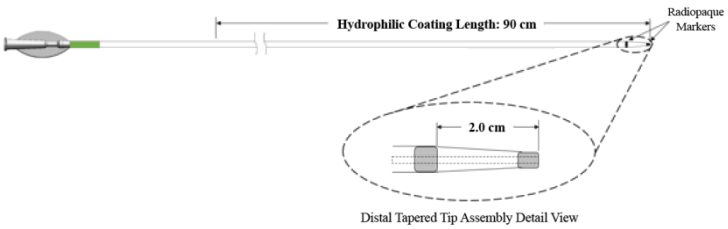
**Indications**
The Route 92 Medical Tenzing® 7 Delivery Catheter is indicated for use with compatible catheters in facilitating the insertion and guidance of catheters into a selected blood vessel in the neurovascular system.

**Contraindications**
There are no known contraindications.

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

### 3. Device Description

The Route 92 Medical Tenzing® 7 Delivery Catheter is a single-lumen, variable stiffness catheter with a long, tapered tip delineated by two radiopaque markers. The Delivery Catheter has a hydrophilic coating to increase lubricity. The proximal end has a luer hub. The Delivery Catheter is designed specifically for use with compatible catheters. The device is provided sterile by ethylene oxide for single-use.



Distal Tapered Tip Assembly Detail View

**Previous Device Generation and Variants**
Not applicable

**Accessories**
Not applicable

**Principles of Operation**
Before removal of the device from the packaging hoop, the hydrophilic coating is activated by flushing the hoop with heparinized saline. After removal of the catheter from the hoop, an RHV is attached to the Delivery Catheter to allow connection to a heparinized saline infusion line and if needed, insertion of a standard 0.014" or 0.016" neurovascular guidewire through the Tenzing 7 Catheter. The Tenzing 7 Delivery Catheter is inserted through the lumen of a large-bore catheter with an inner diameter of 0.068" or greater to aid advancement to the target location in the neurovasculature under fluoroscopy using standard endovascular techniques. The Tenzing 7 has a long, tapered tip delineated by two radiopaque markers that may be used to visualize the position of the tapered tip relative to the large-bore catheter or a guidewire under fluoroscopy.

**Patient-contacting Materials**

| Material |
|---|
| Polyether block amide with colorant / additive, Radiopaque inorganic compound, Polyether block amide with radiopaque filler, Hydrophilic polymer, Metal alloy, Polyether block amide, Polycarbonate |

**Compatibility**
If required, a standard 0.014" or 0.016" neurovascular guidewire may be inserted through the Tenzing 7. Catheters with an inner diameter of 0.068" or greater are compatible with the Tenzing 7.

### 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) |
|---|---|---|
| Air embolism | 0 | 1 |
| Vascular dissection | 0 | 1 |
| Ischemic Stroke resulting in death | 0 | 1 |
| Ischemic Stroke not resulting in death | 0 | 1 |

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| | | |
|---|---|---|
| Ischemic Stroke, patient outcome insufficiently reported | 1 | 2 |
| Foreign body in patient | 0 | 1 |
| Obstruction/Occlusion | 0 | 1 |
| Insufficient Clinical information | 0 | 1 |
| **Total** | **1** | **9** |
| **Complication Rate** | **0.014%** | **0.061%** |

**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.
- Do not use catheter with stent retriever, occlusion coils, glue, glue mixture or non-adhesive liquid embolic agent.

**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).
- Use only a steam source to shape the catheter tip.
- After steam shaping, inspect the catheter tip for damage. Do not use a catheter that has been damaged.
- To avoid damaging the catheter tip, do not steam shape the catheter tip more than twice.

**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* | *Tenzing 7* |
|---|---|---|---|
| Devices Impacted | United States | RES # 94270 | 195 |
| | New Zealand | MEDSAFE # 32696 | 5 |
| Devices On-Hand | N/A | N/A | 22 |
| Devices Returned | N/A | N/A | 22 |

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**

The Route 92 Medical Tenzing 7 Delivery Catheter was evaluated in the SUMMIT NZ, or *A Prospective, **S**ingle-arm, Interventional Clinical Trial to Eval**u**ate the Safety and Effectiveness of the Route 92 **M**edical **M**onoPoint® Reperfusion System for Asp**i**ration Embolec**t**omy in Acute Ischemic Stroke Patients*, clinical trial in New Zealand.

- The Route 92 Medical Tenzing 7 Delivery Catheter was used in the SUMMIT NZ clinical trial to deliver the Route 92 Medical 070 Aspiration Catheter to the target location in the neurovasculature.
- The SUMMIT NZ clinical trial was an interventional, prospective, multi-center, single-arm, open label clinical trial with 90-day follow-up. The data extracted from this study reported the rate of successful delivery of the Route 92 070 aspiration catheter to the targeted location in the neurovasculature and the rate of occurrence of serious, device-related complications such as arterial dissection or perforation.
- Tenzing 7 was used to successfully deliver the Route 92 070 aspiration catheter to the targeted location in the neurovasculature in 88% (23/26) of cases analyzed. There were 0% (0/26) serious, device-related complications such as arterial dissection or perforation.

A post-market clinical follow-up study of 30 cases was completed after CE-marking of the device under MDD. The Tenzing 7 Delivery Catheter was used to deliver compatible large-bore catheters to the target location in the neurovasculature. The primary efficacy endpoint, the rate of successful delivery of the large bore catheter to the targeted location in the neurovasculature, was 83% (25/30). The primary safety endpoint, the rate of occurrence of severe, device-related complications such as arterial dissection or perforation, was 0% (0/30).

Overall, the Tenzing 7 has been used to successfully deliver a large-bore catheter to the targeted location in the neurovasculature in 86% (48/56) of cases reported and there have been 0% reported severe or serious device-related complications in the 56 cases combined from the SUMMIT NZ study and the completed PMCF.

The Tenzing 7 Delivery Catheter was also used in the Route 92 Medical Reperfusion System treatment arm of the SUMMIT MAX trial, a prospective, multi-center, randomized, controlled clinical trial, to deliver the Route 92 Medical 070 Aspiration Catheter to the target location in the neurovasculature. The *Pro**s**pective, Randomized, Controlled, Interventional Clinical Trial to Eval**u**ate the Safety and Effectiveness of the Route 92 **M**edical **M**onoPoint® Reperfusion System for Asp**i**ration Embolec**t**omy in Acute Ischemic Stroke Patients* (SUMMIT MAX) trial was conducted at 31 sites in the United States and New Zealand. 89 patients were randomized and treated using the Route 92 Medical Reperfusion System, 28 (31.5%) of whom were treated using the Tenzing 7 as part of the 070 Reperfusion System. Some of these patients were treated with both the 070 Reperfusion System and the 088 Reperfusion System[1].

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 microcatheters may be used to deliver large-bore catheters to neurovasculature.

[1] Because primary endpoints were analyzed at the subject level and Reperfusion System type could vary within a subject, subgroup analysis by Reperfusion System type is problematic and not statistically valid.

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**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 this product. 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**

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**Revision History**

| SSCP Revision Number | Date Issued | Change Description | Revision Validated by the Notified Body |
|---|---|---|---|
| A | March 12, 2021 | Initial Release | No |
| B | August 30, 2021 | Update with SRN # | No |
| C | December 07, 2021 | Update GMDN and intended purpose. | Yes, CE Certification received |
| D | August 2, 2022 | Update with new CE Certification | Not required, changes minor |
| E | July 19, 2023 | Update to include Danish, German, French, Hungarian, Dutch, Swedish, and Spanish translations. | No |
| F | January 8, 2026 | - Add EMDN<br>- Add NB's single identification number (0297)<br>- Add summary of field safety corrective action.<br>- Add section for why a part for patients is not required.<br>- Add a section for harmonized standards and those applied.<br>- Add a section for common specifications.<br>- Remove translations. | Yes |
| 1.0 | January 8, 2026 | Equivalent to rev F | Yes |
| 2.0 | Mar 5, 2026 | Add Summit Max Clinical Data<br>Add ISO 14155 to harmonized standards | No |