Summary of Safety & Clinical Performance, Tenzing 7 Delivery Catheter

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.

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

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
Prinsessegracht 20
2514 AP The Hague
The Netherlands
SRN: NL-AR-000000116

Notified Body
DQS
August-Schanz-Str. 21,
60433 Frankfurt am Main,
Germany

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.

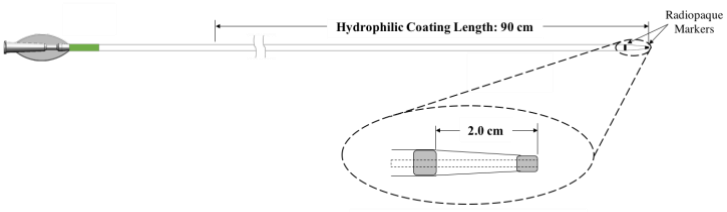
Indications
The Route 92 Medical Tenzing® 7 Delivery Catheter is indicated for use with compatible catheters in facilitating the insertion and guidance of catheters into a selected blood vessel in the neurovascular system.

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 Varients
Not applicable

Accessories
Not applicable

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.

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.

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

The Route 92 Medical Tenzing 7 Delivery Catheter is currently under investigation 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 is 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 is an interventional, prospective, multi-center, single-arm, open label clinical trial with 90-day follow-up and is currently enrolling patients. The data extracted from this study reports 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.

6. Therapeutic Alternatives

Other commercially available microcatheters may be used to deliver large-bore catheters to 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

10. 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