Boston Scientific
Advancing science for life™

ENROUTE ENFLATE™ Transcarotid RX Balloon Dilatation Catheter

The only transcarotid RX balloon catheter on the US market specifically designed for TCAR.

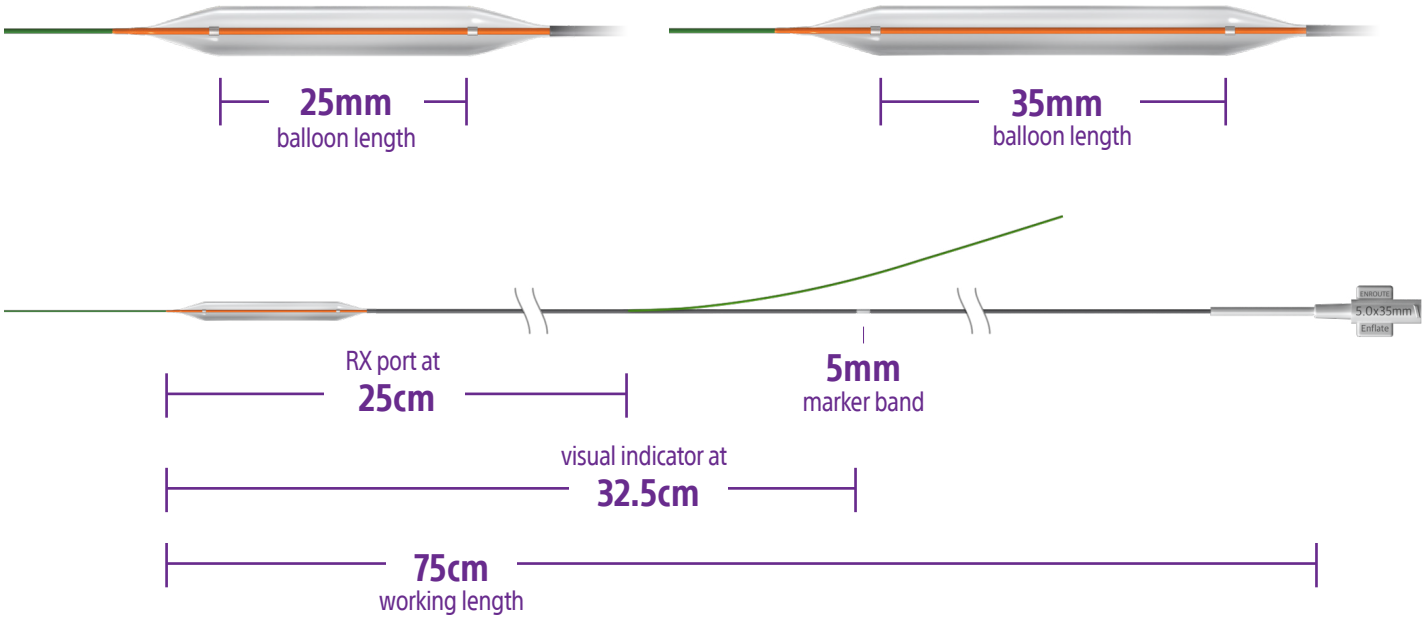
The latest addition to the TCAR portfolio features:

Short catheter working length

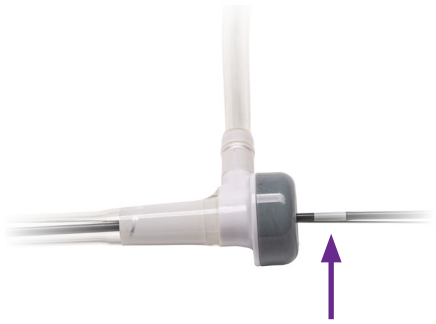
- Needle mark 5mm from beveled tip to safely indicate vessel depth

Balloon lengths optimized for ENROUTE Transcarotid stents

- Available balloon lengths of 25mm and 35mm are designed for optimal pairing with the ENROUTE Transcarotid stent and minimize unnecessary contact with healthy carotid tissue



Marker band provides non-fluoro visual indicator that signals when balloon tip is exiting the arterial sheath



- A 5mm-width marker band located at 32.5cm from the tip of the balloon catheter indicates when the balloon is about to exit the arterial sheath during advancement to the lesion
- Designed to indicate when to begin fluoroscopy and minimize fluoroscopy time during angioplasty

Highly visible radiopaque (RO) markers

- RO markers designed to clearly indicate the location of the balloon shoulders for accurate positioning

Additional features

- Nylon, semi-compliant balloon
- Nominal Pressure: 8 ATM
- Rated Burst Pressure: 14 ATM
- Rapid exchange (RX), 0.014" guidewire compatible
- Low-profile: 4Fr (5Fr for 6.0mm diameter)

Ordering Information

ENROUTE ENFLATE™ Transcarotid RX Dilatation Catheter

Catalog Number	Balloon Length (mm)	Balloon Diameter (mm)
SR-4025-BC	25	4.0
SR-4525-BC	25	4.5
SR-5025-BC	25	5.0
SR-5525-BC	25	5.5
SR-6025-BC	25	6.0

Catalog Number	Balloon Length (mm)	Balloon Diameter (mm)
SR-4035-BC	35	4.0
SR-4535-BC	35	4.5
SR-5035-BC	35	5.0
SR-5535-BC	35	5.5
SR-6035-BC	35	6.0

ENROUTE ENFLATE™ Transcarotid RX Balloon Dilatation Catheter
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE** The ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter is intended for percutaneous transluminal angioplasty and post-dilatation of self-expanding stents in the carotid arteries. **CONTRAINDICATIONS** The ENROUTE Enflate Transcarotid RX Balloon Dilatation Catheter is contraindicated for use in coronary arteries. Generally, further contraindications include, but may not be limited to: • Patients with highly calcified lesions resistant to PTA. • Patients with a target lesion with a large amount of adjacent acute or sub acute thrombus. • Patients with uncorrected bleeding disorders. • Patients that have not been anti-coagulated. **WARNINGS** • Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device. • Do not use the balloon if there are any abnormalities in the sterile barrier (e.g. broken seal, torn or breached barrier) or the product. • The device is provided sterile and for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of crosscontamination which in turn, may result in patient injury, illness or death. • Do not expose the device to organic solvents (e.g. alcohol). • Do not use with Ethiodol or Lipiodol* contrast media. *Ethiodol and Lipiodol are Trademarks of Guerbet SA. • To reduce the potential for vessel damage or the risk of dislodgement of particles, it is very important that the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the lesion. • When the balloon catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the device unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Failure to do so may result in damage to the product or harm to the patient. • Balloon pressure should not exceed the rated burst pressure. Use of a pressure monitoring device is recommended to prevent over-pressurization. • To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium (a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium to inflate the balloon. **PRECAUTIONS** • Caution: Federal (USA) law restricts device to sale by or on the order of a physician. • Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications. • The device should only be used by physicians who are trained in the performance of arteriography and who have received appropriate training in percutaneous transluminal angioplasty in the indicated arteries. PL20950 rev 02 Release Date 11/2022 Page 2 of 8 • Use the balloon prior to the "Use Before" date specified on the package. • Prior to use, the device should be examined to verify functionality, integrity, and ensure that its size is suitable for the specific procedure. Always inspect the balloon catheter carefully for bends, kinks or other damage prior to insertion. • Before and during the procedure, appropriate anticoagulant/antiplatelet therapy should be provided to the patient, as needed. • The minimal acceptable guide catheter/introducer sheath size is printed on the package label. Do not attempt to pass the balloon catheter through a smaller size guide catheter/introducer sheath than indicated on the label. Use of a smaller than indicated accessory device can lead to introduction of air into that device as the balloon catheter is advanced, which may not be removed during air aspiration. • Caution should be taken when treating patients with poor renal function who, in the physician's opinion, may be at risk for contrast-induced nephropathy. • Embolic protection is recommended when using the balloon catheter in a carotid angioplasty procedure. If an embolic protection device is used, follow the applicable instructions for use. • Exposure to X-ray radiation doses to patients and physicians should be limited by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible. **POTENTIAL PROCEDURE AND / OR DEVICE RELATED ADVERSE EVENTS** Potential complications, which may lead to additional intervention, include, but are not limited to: • Abrupt Closure • Acute Myocardial Infarction • Acute vessel closure • Allergic reaction (device, contrast medium and medications) • Amputation • Aneurysm • Angina • Arrhythmias (major, minor), including ventricular fibrillation • Arteriovenous fistula • Artery spasm • Coma • Death • Drug reactions, allergic reaction to contrast medium • Embolism • Hematoma • Hemorrhage, including bleeding at puncture site • Hypotension / hypertension • Infection • Ischemia • Necrosis • Nephropathy • Neurological events, including peripheral nerve injury and neuropathies • Organ failure (single, multiple) • Paralysis • Pyrogenic reaction • Renal failure • Restenosis • Seizures • Sepsis / infection / inflammation • Shock • Stroke, air embolism and embolization or fragmentation of thrombotic or athlerosclerotic material • Thrombosis • Transient Ischemic Attack • Vascular Complications (e.g. intimal tear, dissection, pseudoaneurysm, perforation, rupture, spasm, occlusion) • Weakness • X-ray radiation exposure may cause adverse events including, but not limited to, alopecia, burns, cataracts, or delayed neoplasia (cancers). **PI-2027807-AA**

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To order product or for more information contact customer service at 1.888.272.1001

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