ENROUTE Enflate™

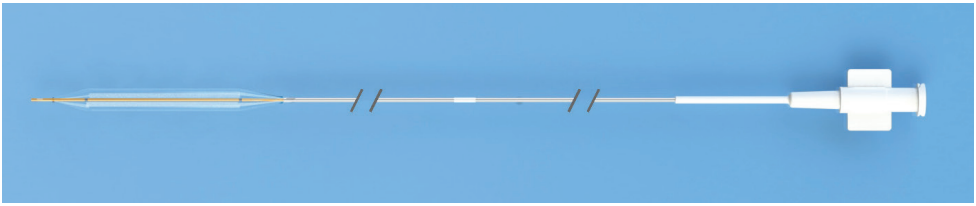
Transcarotid RX Balloon Dilatation Catheter

SILKROAD MEDICAL®

DEVICE DESCRIPTION

The Silk Road Medical ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter (Figure 1) is a standard rapid exchange (RX) 0.014″ Percutaneous Transluminal Angioplasty (PTA) catheter with a proximal single lumen and distal coaxial lumen tubing with a dilatation balloon, and an atraumatic tip. The proximal luer lock hub allows for connection with a balloon inflation device for inflation with diluted contrast medium. The second lumen in the distal shaft permits the use of an 0.014″ guidewire to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon has two radiopaque marker bands to aid in positioning the balloon in the stenosis, located either 25 or 35 mm apart as indicated on the package label. An external position marker is located 32.5 cm from the distal tip to indicate the relative position of the catheter tip to the guiding catheter/introducer sheath. The total working length of the catheter is 75 cm. The Silk Road Medical ENROUTE Enflate Transcarotid RX Balloon Dilatation Catheter will complement the TCAR procedure.

Figure 1. ENROUTE Enflate Transcarotid RX Balloon Dilatation Catheter



The maximum guidewire diameter and minimum guiding catheter or introducer sheath inner diameter that may be used are printed on the package label. The working pressure range for the balloon is between the nominal pressure and the rated burst pressure. Consult the compliance table (Table 1) below for diameters of the balloon at given pressures.

Table 1. Balloon Diameter vs. Inflation Pressure

	Pressure		Balloon Diameter				
	atm	kPa	4.0 mm	4.5 mm	5.0 mm	5.5 mm	6.0 mm
Balloon Diameter at Nominal Pressure	**8**	**811**	**3.92**	**4.51**	**4.92**	**5.38**	**5.76**
	9	912	4.02	4.62	5.01	5.52	5.89
	10	1013	4.09	4.70	5.08	5.62	5.98
	11	1115	4.15	4.77	5.14	5.70	6.06
	12	1216	4.20	4.83	5.20	5.79	6.14
	13	1317	4.26	4.90	5.25	5.87	6.22
Balloon Diameter at Rated Burst Pressure	**14**	**1419**	**4.30**	**4.97**	**5.31**	**5.96**	**6.29**

Contents: One (1) ENROUTE Enflate Transcarotid RX Balloon Dilatation Catheter

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 cross-contamination 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.

- 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 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).

PREPARATION AND USE

1. Inspect the device and packaging prior to use.
2. Do not use if the sterile barrier is opened or damaged or the device is damaged.
3. Remove the inner package from the box.
4. Open the inner package and carefully extract the packaging hoop with the balloon catheter.
5. Hold the packaging hoop in one hand. With the other hand, gently grasp the hub and carefully remove the balloon catheter from the hoop.
6. Without twisting, slide the stylet and protective tube off the balloon.
7. Flush the guidewire lumen from the distal tip of the balloon catheter with heparinized saline solution.
8. Attach a three-way stopcock to the balloon catheter's inflation port.
9. Purge the air from a syringe partially filled with diluted contrast medium, and connect the syringe to the stopcock.
10. Open the stopcock and induce negative pressure.
11. Hold the syringe and the proximal end of the balloon catheter vertically with the balloon tip pointing down.
12. While maintaining the negative pressure, close the stopcock to the inflation port.
13. Remove the syringe and purge the air.
14. To ensure all air is removed from the balloon and inflation lumen repeat steps 9-13.
15. Prepare an inflation device with contrast medium that has been diluted 50/50 by volume with normal saline.
16. Purge the air from the inflation device and connect the inflation device to the stopcock that is connected to the catheter inflation port.
17. Open the stopcock to the balloon catheter. The inflation lumen and the balloon will slowly be filled with diluted contrast medium.

Caution: Non-ionic contrast medium has higher viscosity and precipitation levels than does the ionic type, which may prolong inflation/deflation times.

Caution: Do not apply positive pressure to the balloon at this time.

INSERTION AND INFLATIONS

Note: For introduction of the balloon catheter, an introducer sheath, guiding sheath or a guiding catheter may be used. In cases where only an introducer sheath or a guiding sheath is used, some of the details in the following procedures may not be applicable.

Note: To preserve the folded balloon shape during insertion and catheter manipulation, do not apply pressure to the inflation lumen. Do not advance or retract the device unless the balloon is fully deflated under vacuum.

1. Introduction of guiding catheter/introducer sheath and guidewire.
    a. Prepare the guiding catheter/introducer sheath with a minimum ID as specified on the label.
    b. If applicable, connect a Tuohy-Borst type device to the guiding catheter/introducer sheath.

Caution: If a Tuohy-Borst type device is used, avoid over tightening since this may restrict the flow of contrast media in and out of the balloon, thereby prolonging the inflation/deflation times.

Caution: If the balloon is inserted through a hemostasis valve without the guidewire already in place, the valve may cause damage to the device.

    c. Prior to use, flush the guiding catheter/introducer sheath lumen with a heparinized saline solution.
    d. Introduce the guiding catheter/introducer sheath into the vasculature using the introduction technique of choice.
    e. Introduce the guidewire with a maximum OD as specified on the label. Advance the guidewire to the target lesion and close the hemostasis valve, if applicable, around the guidewire.

Caution: Use care during advancement of the guiding catheter/introducer sheath to prevent bleeding, dissection or patient discomfort.

2. Place the prepared balloon catheter over the proximal section of the guidewire and advance the tip to the hemostasis device of the guiding catheter/introducer sheath.
3. Open the hemostasis valve, if applicable, as widely as possible and carefully advance the balloon catheter over the guidewire until the balloon section of the balloon catheter is introduced into the guiding catheter/introducer sheath. As appropriate, look for and confirm back flow over the balloon and adjust the valve of the hemostasis device to maintain a snug seal.

Caution: If there is a tight fit between the balloon section of the balloon catheter and the guiding catheter/introducer sheath, a failure to maintain a snug seal of the hemostasis valve over the balloon catheter during insertion and advancement could result in air introduction and air entrainment in the guiding catheter/introducer sheath.

4. Advance the balloon catheter until the guidewire exit port has passed the valve of the hemostasis device. Again adjust the valve of the hemostasis device to maintain a snug seal as needed. Continue to advance the balloon catheter to the end of the guiding catheter/introducer sheath.

Note: For the balloon catheter with a usable catheter length of 75 cm, the external position marker located 32.5 cm from the distal tip indicates the relative position of the balloon catheter tip to the end of the guiding catheter or introducer sheath.

Note: When used with the ENROUTE™ Arterial sheath, the 32.5 cm position marker indicates when the distal tip of the balloon catheter is aligned with the distal tip of the ENROUTE Arterial sheath.

Note: Perform all further device manipulations under fluoroscopy.

5. Using fluoroscopy and the radiopaque balloon marker bands, advance the balloon catheter to the target lesion and position the balloon catheter at the intended site. Carefully close the hemostasis valve, if applicable.

Caution: Care should be taken to control the position of the guiding catheter/introducer sheath tip during manipulation of the balloon catheter.

Caution: If strong resistance is met during advancement or withdrawal of the balloon catheter, discontinue movement and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, withdraw the entire system.

6. Steadily inflate the balloon under fluoroscopy. Expand the balloon to the desired diameter. Reference compliance table (Table 1) for balloon sizing. Inflation time for the balloon is less than or equal to 20 seconds.

Caution: Overstretching of the artery may result in rupture and life-threatening bleeding.

Caution: Balloon inflation should be performed with the guidewire extended beyond the balloon catheter tip.

Note: It is strongly recommended that the guidewire remains across the target lesion until the procedure is complete.

Note: Dilatation of healthy vessel segments should be kept as limited as possible.

WITHDRAWAL AND DISASSEMBLY PROCEDURE

1. Deflate the balloon by pulling vacuum on the inflation device, allowing adequate time for the balloon to fully deflate prior to removal. Deflation time for the balloon is less than or equal to 20 seconds.

Note: Do not advance or retract the device unless the balloon is fully deflated under vacuum.

2. If applicable, open the hemostasis valve as wide as possible and carefully withdraw and remove the balloon catheter from the guiding catheter/introducer sheath while keeping the guidewire in place.
3. Close the hemostasis valve to maintain a snug seal around the guidewire.
4. Perform angiography to confirm angioplasty and/or stent post-dilatation.

Note: In case of post-dilatation, use a new balloon catheter. After post-dilatation, slowly withdraw the balloon from the stent. Observe removal of the balloon under fluoroscopy to ensure that the balloon disengages from the stent.

5. Remove guidewire and guiding catheter/introducer sheath from the patient and discard the devices.

Caution: Whenever the balloon catheter is withdrawn, fully deflate the balloon. Always advance or withdraw the balloon catheter within the vasculature over a guidewire. Monitor guidewire position under fluoroscopy.

Note: If the balloon cannot be withdrawn through the guiding catheter/introducer sheath, withdraw the balloon catheter and guiding catheter/introducer sheath as a single unit.

Note: All stents should be deployed in accordance with the manufacturer's indications and instructions for use.

STORAGE

Store in a cool, dry place.

SYMBOLS GLOSSARY

Symbol	Title	Standard and reference number
	Caution	ISO 7000 0434A
	Consult Electronic Instructions for Use	ISO 7000 1641
	Sterilized using Ethylene Oxide	ISO 7000 2501
	Caution: Federal (US) law restricts this device to sale by or on the order of a physician	N/A
	Batch code /Lot Number	ISO 7000 2492
	Manufacturer	ISO 7000 3082
	Do Not Use if Package is Damaged	ISO 7000 2606
	Unique Device Identification System	ISO 15223-1 5.7.10
	Not Made with Natural Rubber Latex	ISO 15223-1 5.4.5
	Use by Date	ISO 7000 2607
	Catalog Number	ISO 7000 2493
	Do Not Reuse	ISO 7000 1051
	Do Not Resterilize	ISO 7000 2608
	Non-pyrogenic	ISO 7000 2724
	Keep dry	ISO 7000 0626
	Keep away from sunlight	ISO 7000 0624

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