EMBOLX

Sniper®

Balloon Occlusion Microcatheter

Instructions for Use

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IMPORTANT! Please read before use.

Description

The Sniper is a dual lumen catheter comprised of an inner guidewire/infusion lumen and an outer, annular lumen to inflate and deflate the balloon. The guidewire/infusion port may be used to inject contrast media or therapeutic agents following the removal of the guidewire. The catheter has two radiopaque markers: one marker at the distal tip and another in the center of the balloon. The Sniper is available in a variety of working configurations[1]: lengths (110 cm, 130 cm, 150 cm, 165 cm); tip shapes (straight and angled) to support challenging anatomy (See Figure 1 and Table 1).

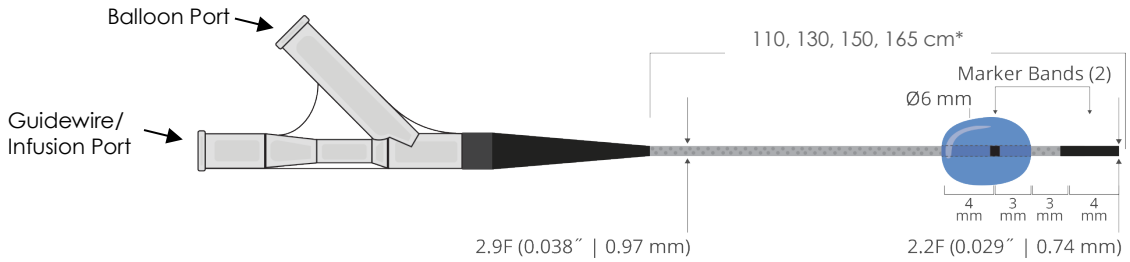

Figure 1: Sniper Balloon Occlusion Microcatheter (applicable to straight and angled tip)

Product Specifications / Compatibility

OUTER DIAMETER Distal/Proximal	INNER DIAMETER	GUIDEWIRE	MINIMUM DIAGNOSTIC CATHETER ID	HYDROPHILIC COATING LENGTH	DEAD SPACE VOLUME	MAX INJECTION PRESSURE
2.2/2.9F (0.74/0.97mm)	0.020"/0.5 mm	0.014" or 0.016"	≥ 0.038"/0.9 mm compatibility	70 cm (110 cm device) 70 cm (130 cm device) 140 cm (150 cm device) 140 cm (165 cm device)	0.32 ml (110 cm) 0.36 ml (130 cm) 0.41 ml (150 cm) 0.45 ml (165 cm)	900 psi

FLOW RATES	BALLOON DIAMETER	BALLOON DEFLATION TIME	BALLOON INFLATION TIME	BALLOON INFLATION VOLUME	EMBOLIC AGENTS[2]	COILS	EMBOLIC BEADS[3]
≥ 1.0 ml/s (110 cm) ≥ 0.9 ml/s (130 cm) ≥ 0.8 ml/s (150 cm) ≥ 0.7 ml/s (165 cm)	Up to 6 mm (Occludes up to 4.5 mm vessel)	40-60 sec (50% contrast solution[4])	<20 sec (50% contrast solution[4])	Up to 0.25 ml	Lipiodol®, Y-90 microsphere, Gelfoam, Glue (n-bCA), DMSO, EtOH	≤ 0.018"	Up to 900 µm

Table 1: Product Specifications / Compatibility Information

Packaging Contents

- (1) Sniper occlusion balloon microcatheter

1 Consult your sales representative for local market clearance and availability. Please refer to the product packaging for catheter length and tip angle.

2 Physician reported cases. Data on file. Embolx does not make any claims. For informational purposes only.

3 Boston Scientific Embozene™ 900 µmum, 19020-S1. Merit Medical® Emboshere® 700-900 µm, S810GH. Data on file.

4 Optiray® 320 (ioversol injection 68%; Guerbet LLC) contrast solution.

**Note:* A 65 cm diagnostic catheter is recommended for use with the 110 cm Sniper catheter.

- (1) Flush, priming, deflation syringe (10 ml)
- (1) Inflation syringe (0.25 ml)
- (1) Flow-switch

Indications for Use

Sniper balloon occlusion microcatheter is intended for use in the blood vessels of the peripheral vasculature where temporary occlusion is desired and offers a vessel selective technique of temporary vascular occlusion for selectively stopping or controlling blood flow. The Sniper balloon occlusion microcatheter is also intended to assist in the delivery of diagnostic agents such as contrast media and therapeutic agents into the peripheral vasculature.

Contraindications

Not intended for use in embolectomy or angioplasty procedures. Not intended for use in coronary vessels. Not intended for use in neurovasculature.

Adverse Events

Possible adverse effects include but are not limited to, the following: death, acute vessel closure, vessel perforation, vessel dissection, ischemia, hemorrhage or hematoma, drug reactions (allergic reaction to contrast medium), hypotension, hypertension, infection, arteriovenous fistula, vasospasm, stroke (air embolism and embolization or fragmentation of thrombotic or atherosclerotic material).

Warnings

- The Sniper balloon occlusion microcatheter is intended for SINGLE USE ONLY; DO NOT RE-STERILIZE; DO NOT REUSE.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Presence of calcifications or irregularities may damage the balloon or prevent its entry or removal.
- Balloon volume should not exceed the rated burst volume. The rated burst volume is based on the results of *in vitro* testing. The use of a volumetric monitoring device is recommended to prevent over-filling.
- Do not exceed the maximum recommended inflation volume of 0.25ml (after priming catheter) as balloon rupture may occur.
- To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Careful fluoroscopic observation of the catheter balloon inflation and deflation in-vivo is essential for patient safety.
- Do not attach a high-pressure device onto the balloon inflation port as this may rupture the balloon.
- Pressure in the guidewire/injection lumen should not exceed the maximum pressure rating of 900 psi (6205 kPa). Excessive pressure may cause leakage or rupture of the catheter.
- Do not over-tighten the RHV around the catheter. This could affect balloon performance and/or catheter friction during manipulation.
- Do not advance the catheter against resistance. If slight resistance is felt, pull back slightly and assess source of resistance using visual and fluoroscopic means.
- Careful fluoroscopic observation of the catheter inflation and deflation in-vivo is essential for patient safety.
- Do not use a catheter if the device or packaging has been damaged.
- Do not torque the catheter if impinged. Deformation, kink, bend, or loss of functionality could develop with excessive twisting of the catheter.

Precautions

- Use the catheter prior to the "Expiration date" specified on the package.
- Carefully inspect all devices before use to confirm the size, shape, length, and condition are appropriate for the specific procedure and compatible with accessory devices.
- Verify the size of the vessel under fluoroscopy. Ensure that the balloon diameter is appropriately sized for the diameter of the vessel.
- Once the catheter is hydrated, do not allow it to dry.
- Once removed, do not re-insert a hydrated catheter into its packaging.
- Higher viscosity and/or concentration of the contrast solution can increase balloon inflation and deflation times.

- If backloading the catheter over a guidewire, ensure the distal tip of the catheter is not damaged.
- Make sure the flow-switch remains snugly attached to the balloon inflation port.
- The catheter should only be advanced, withdrawn, or manipulated with a guidewire in place.
- When using with a Power Injector, limit input to no greater than 900 psi.
- This balloon is not intended for the expansion or delivery of a stent.
- This balloon is not intended for the treatment of in-stent restenosis (ISR).
- The catheter system should be used only by physicians trained in the use of infusion catheters for balloon occlusion in the peripheral vasculature

Chemical Compatibility

Lipiodol® (Guerbet LLC): The Sniper balloon occlusion microcatheter is compatible with Lipiodol.

Power Injection

Do not exceed 900 psi (6205 kPa). Flow rates at 900 psi based on usable length of the device using 100% contrast[5] solution at 37º C are at least: 165cm: 0.7ml/s |150cm: 0.8ml/s | 130cm: 0.9ml/s | 110cm: 1.0ml/s. Flow rates are impacted by pressure & viscosity, as such the parameters used, temperature, and concentration of contrast may give different results. When using the angled tip, prevent clogging by injecting slowly.

Preparations for Use

1. Prepare a contrast solution using sterile saline per hospital standard. The expected inflation and deflation times with recommended 50% solution are less than 20 and 40-60 seconds respectively. **Caution:** Viscosity of the contrast solution will affect inflation and deflation times.
2. With the catheter in the hoop, hydrate the catheter using the 10 ml syringe filled with 10 ml saline. Connect syringe directly to the inside end of the hoop and inject saline to flush. Refill the syringe with saline. Connect the syringe to the Sniper's injection port and inject saline to flush. **Caution:** Once the catheter is hydrated, do not allow it to dry.
3. Connect the flow-switch in the open position to the balloon inflation port.
4. Fill large syringe with 2ml of 50% contrast solution and connect to flow-switch.
5. Pull plunger to top, twist clockwise to lock in place, and **close** flow-switch.
6. Remove syringe, hold vertical, and expel air.
7. Re-attach syringe to balloon port. Pull plunger to top, twist clockwise to lock, and **open** flow-switch.
8. Keep syringe vertical. After bubbles are seen (<30 seconds) move plunger down onto contrast and **wait minimum 30 seconds.**
9. Leaving flow-switch open, remove syringe, then **close** flow-switch.
10. Advance a guidewire through the guidewire/infusion port and into the catheter. **Caution:** If backloading the catheter over a guidewire, ensure the distal tip of the catheter is not damaged.
11. Remove the catheter from the packaging hoop. **Caution:** Once removed, do not re-insert a hydrated catheter into its packaging. Inspect the Sniper catheter for physical damage.
12. Sniper is now ready to use.

[5] Optiray® 320 (ioversol injection 68%; Guerbet LLC) contrast solution

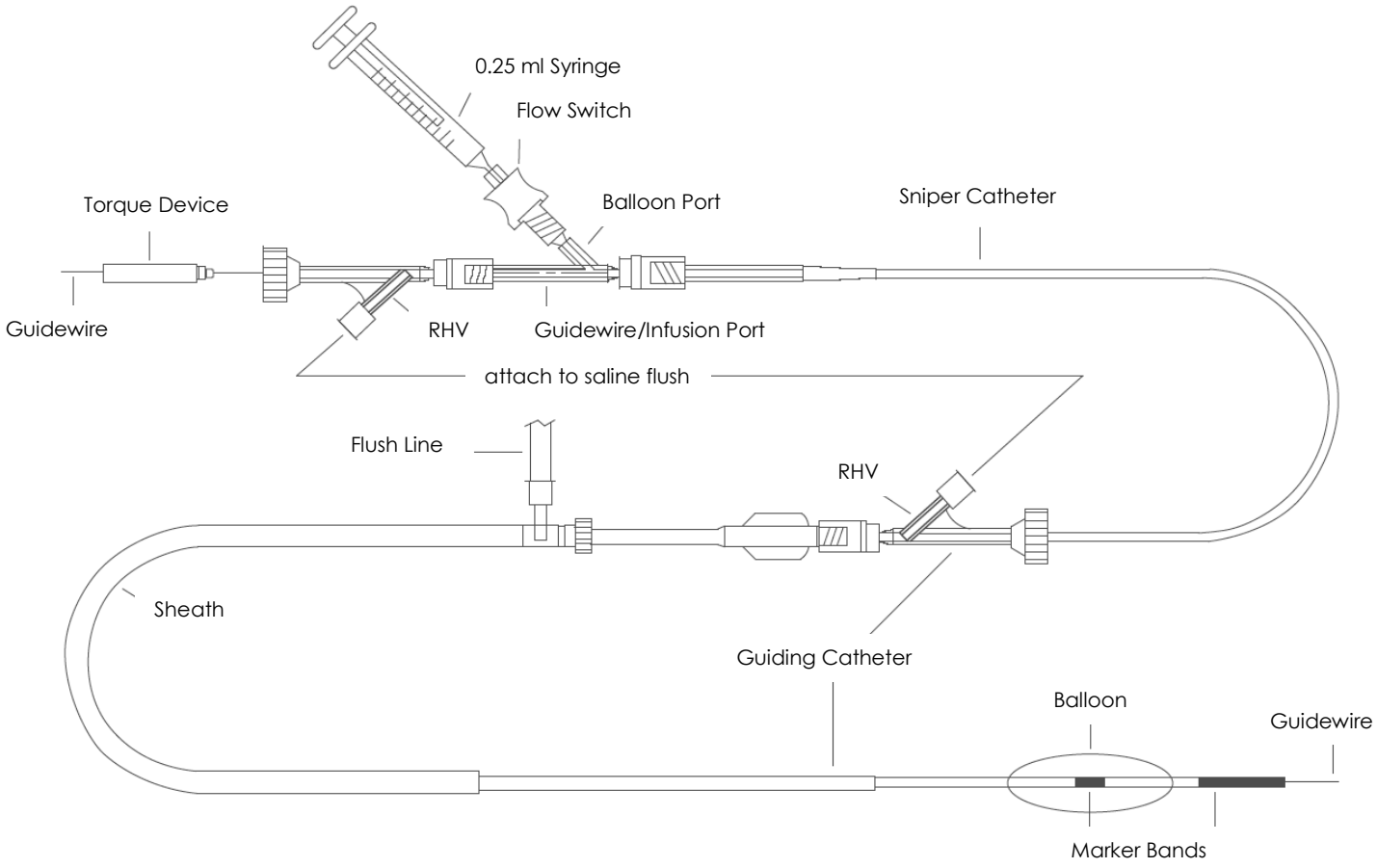

Figure 2: Procedural Setup and Configuration
(showing balloon catheter inserted into a guiding catheter and sheath)

Directions for Use

1. Confirm the flow-switch is firmly attached to the balloon port.
2. Open the RHV of the guiding catheter until it allows the introduction of the catheter and guidewire assembly. After insertion, carefully tighten the RHV around the catheter so as to prevent backflow, yet still enable catheter advancement. **WARNING:** Do not over-tighten the RHV around the catheter as damage to the balloon and/or catheter shaft may occur.
3. Advance the catheter with the guidewire in place. Use fluoroscopic visualization to reach the desired location. Radiopaque markers can be used to visualize catheter placement. **WARNING:** Do not advance the catheter against resistance. If slight resistance is felt, pull back slightly and assess the source of resistance using visual and fluoroscopic means. Slight resistance may be felt through a tight turn, if this is the case, advance slowly with small strokes until the catheter resistance minimizes or position is reached. *NOTE:* Flushing with saline will minimize resistance.
4. To inflate balloon:
    a. Use 0.25 ml syringe filled with 0.25 ml of 50% contrast. Connect the syringe to the flow-switch on the balloon port.
    b. Under fluoroscopy, watch for balloon inflation. *NOTE:* There will be a delay between injection and inflation
    c. Incrementally inject contrast until the balloon is visualized as contouring the vessel wall. A distal shift of the balloon may occur which is normal and expected. (Refer to Figure 3 for approximate balloon diameters as related to injected volumes.) **WARNING:** Do not exceed the maximum recommended inflation volume of 0.25 ml as balloon rupture may occur (see Figure 3). **WARNING:** Careful fluoroscopic observation of the catheter inflation and deflation in-vivo is essential for patient safety. **WARNING:** Do not attach a high-pressure device to the balloon inflation port as this may rupture the balloon. **WARNING:** Do not use a catheter that has been damaged. **WARNING:** Do not inflate the balloon with air or gas while in the body.

5. Confirm flow-switch is closed, then remove syringe to maintain balloon inflation. Flow-switch must remain firmly secured to balloon port.
6. Remove the guidewire and continue with the procedure as directed by the physician.
7. If an embolic agent is used, slowly inject the embolic agent into the guidewire/infusion port to maintain low pressure and slow particle flow. **WARNING:** Pressure in the guidewire/injection lumen should not exceed the maximum pressure rating of 900 psi (6205 kPa). Excessive pressure may cause leakage or rupture of the catheter. *Note:* In order to achieve optimal performance and to maintain lubricity, it is important that flush solution be maintained between the catheter and guiding catheter, and all intraluminal devices. Flushing aids in preventing contrast crystal formation and/or clotting on the intraluminal device and inside the balloon lumen.
8. Visualize under fluoroscopy to determine if the embolization endpoint has been reached.
9. At the end of the procedure, deflate the balloon. Reattach the 10 ml syringe to open flow-switch and aspirate. Use fluoroscopic visualization to confirm balloon deflation. Once deflated, safely withdraw the catheter over or with the guidewire. *Note:* If the balloon is not deflating, check to ensure that the RHV is not too tight and flow-switch is open.
10. Dispose of used devices per hospital protocol.

Balloon Inflation Parameters

Note: Balloon diameter should be monitored fluoroscopically to achieve the desired occlusion. Results can be affected by other clinical factors.

How Supplied

The Sniper balloon occlusion catheter is intended for SINGLE USE ONLY. DO NOT RE-STERILIZE. DO NOT REUSE. Discard the catheter after one procedure. Structural integrity and/or function may be impaired through reuse or cleaning. Catheters are extremely difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Embolx will not be responsible for any product that is re-sterilized. As long as the packaging is not opened or damaged, the Embolx Sniper catheter is sterile and non-pyrogenic. The product is not made from natural rubber latex.

Storage

Store in a cool, dry place.

Definition of Symbols

Symbol	Reference	Symbol Title	Explanatory Text
	ISO 15223-1 §5.1.1	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 §5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 §5.1.6	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 §5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 §5.2.3	Sterilized by ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1 §5.4.2	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	ISO 15223-1 §5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use. Available at www.embolx.com
	ISO 15223-1 §5.2.8	Do not use the product if the package is damaged.	Indicates a medical device that should not be used if the package has been damaged or opened.

	Emboly, Inc.	Recommended Guidewire	Indicates the recommended guidewire size to use with the Sniper device.
	21 CFR 801.109	Prescription-only	Requires prescription in the United States.
	ISO 80000-1 §3.1	Quantity	Quantity of package contents.
	ISO 15223-1 § 5.6.3	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.
	MDD (Medical Device Directive) 93/42/EEC	CE Marking	When labeled, cleared for sale in the EU.

Warranty

Embolx, Inc. warrants that this medical device is free from defects in both materials and workmanship. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.

Refer to the *Instructions for Use* digital version at www.embolx.com.

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