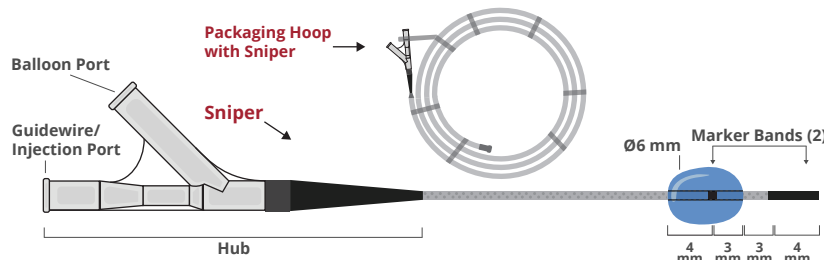


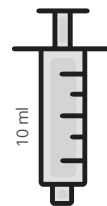
IMPORTANT! Always refer to the Sniper Balloon Occlusion Microcatheter Instructions For Use for detailed instructions.

Contents

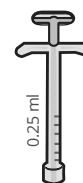
Sniper Balloon Occlusion Microcatheter (QTY 1)



10 ml Flush, priming and deflation syringe (QTY 1)



0.25 ml Inflation syringe (QTY 1)

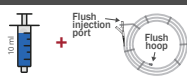


Valve (QTY 1)



Set-up

A Saline Flush



- ▶ Flush inside end of hoop with 10 ml syringe filled with saline.
- ▶ Flush injection port with 10 ml syringe filled with saline.
- ▶ Remove Sniper from packaging hoop.

B Prime Balloon



- ▶ Submerge distal tip in saline bath. Place wet gauze on top to keep distal balloon tip submerged.
- ▶ Fill 10 ml syringe with 2 ml of 50% contrast.
- ▶ Connect 10 ml syringe to the balloon port. Pull syringe plunger to top lock position. Tap hub with finger until no bubbles are seen rising in contrast. Release the plunger slowly down onto contrast.
- ▶ Remove syringe from balloon port. Exhaust air from syringe so only contrast remains.
- ▶ Connect valve to the balloon port.
- ▶ Connect 10 ml syringe filled with 2 ml of 50% contrast to the valve on balloon port.
- ▶ Pull syringe plunger to top lock position and place with Sniper in saline bath. Let sit for at least 5 minutes.
- ▶ Move plunger slowly down onto contrast.
- ▶ Remove 10 ml syringe from valve.



C Test Balloon Prime



- ▶ Follow the steps under “Use” to inflate and deflate balloon.
- ▶ To inflate balloon, use the .025 ml syringe to inject two units (0.1 ml) and confirm balloon is completely filled with contrast.
- ▶ To deflate balloon, use the 10 ml syringe and confirm all contrast has been removed.
- ▶ Save syringes filled with contrast for future use.

D Maintain Catheter Hydration



- ▶ Keep Sniper's hydrophilic coating activated.
- ▶ Return Sniper to saline bath when not in use.

E Set Power Injector



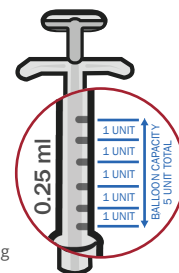
- ▶ Limit input to no greater than 900 psi and 2 ml/second.

Use

Inflate Balloon



- ▶ Use 0.25 ml syringe filled with 0.25 ml (5 units) of 50% contrast.
- ▶ Connect syringe to the valve on balloon port.
- ▶ To inflate balloon:
 - Inject one unit (0.05 ml)
 - Under fluoroscopy, watch for balloon inflation. **IMPORTANT!** There will be a delay between injection and inflation
 - Incrementally add additional units until the balloon is visualized as contouring the vessel wall. **IMPORTANT!** If unable to visualize balloon, refer to troubleshooting
 - Remove syringe from valve
 - Save syringe filled with contrast (subsequent inflation)



Deflate Balloon



- ▶ Use 10 ml syringe filled with 2 ml of 50% contrast.
- ▶ Connect syringe to the valve on the balloon port.
- ▶ To deflate and prime balloon for next use:
 - Pull plunger to syringe top until balloon is completely deflated. **IMPORTANT!** May take up to 40 seconds for balloon to completely deflate
 - Hold syringe vertical
 - Move plunger slowly down onto contrast
 - Remove syringe from valve
 - Save syringe filled with contrast for future use (subsequent deflation)

Best Practices



Imaging Before Embolization to Confirm Flow Redistribution

- ▶ When the catheter tip is at the desired location, complete an angiogram with the balloon down and with the balloon up.
- ▶ **IMPORTANT!** When the balloon is up, blood flow is slow and contrast will take longer to reach the tumor or prostate. Therefore, fluoroscopy timing will be longer for contrast visualization as compared to the balloon down configuration.



Slow Injection of Contrast and Embolic Agent

- ▶ Flow redistribution in favor of the tumor or prostate requires that a low pressure is maintained distal to the balloon.
- ▶ Slow injection is required to maintain low pressure.
- ▶ Rapid injection will overwhelm the protective pressure gradient.
- ▶ Contrast injection rate should be between 0.5 to 1.0 ml/second.
- ▶ Embolic injection rate should be about 1.0 ml/minute with intermittent pause between injections.



Recommended Diagnostic Catheter Length with 110 cm Sniper

The use of a 65 cm diagnostic catheter is recommended for use with the Sniper 110 cm length as it maximizes the distal reach inside the patient.



Reaching Embolization Endpoint

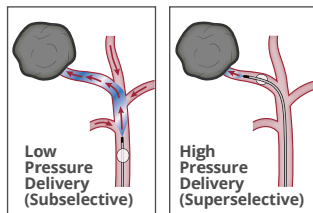
With balloon occlusion there is slow moving, forward flow around the catheter tip due to reversal of collateral arteries, capillaries and interstitial fluid. Depending on Sniper tip placement during embolization, the treatment endpoint can be visualized under fluoroscopy as follows:

Sniper tip is subselective (Low Pressure Delivery)

- ▶ Observation of contrast stasis in distal arteries.

Sniper tip is superselective (High Pressure Delivery)

- ▶ Observation of:
 - Contrast in portal vein **or**
 - Embolic reflux around the Sniper balloon **or**
 - Sniper balloon "pushing back" in the vessel.



Watershed Tumor Treatment

- ▶ Use high pressure delivery where the Sniper tip is placed superselectively or segmentally.
- ▶ Not Recommended: Low pressure delivery where the Sniper tip has a subselective or Lobar placement. In tumors that are between segments and have multiple feeders, a low pressure is maintained only in the segment with the balloon occlusion. Therefore, pressure from the feeders originating in the other segment with normal pressure can flow through the tumor and into the low pressure created by the occlusion.

Troubleshooting

Kink Prevention

Cause:

- ▶ An important part of Sniper's exceptional tracking ability is its stiff proximal catheter. The catheter can kink if the operator is not aware.
- ▶ There is a kink point at the RHV. The catheter cannot be bent sharply in this area.

Solution:

- ▶ Advance the catheter forward by holding and pushing the catheter no more than 3 cm from the RHV.



Unexpected Balloon Deflation

Cause:

- ▶ The valve is either not connected or not sufficiently tightened to the balloon port **or**
- ▶ Excess vacuum in balloon lumen.

Solution:

- ▶ When inflating balloon, connect syringe to the valve on balloon port.
- ▶ Remove and reconnect the valve on the balloon port which equilibrates the pressure.
- ▶ Re-inflate the balloon until it is seen contouring to the vessel wall under fluoroscopy.



Balloon Migration

Cause:

- ▶ A distal shift of the balloon is normal and expected and should be corrected.

Solution:

- ▶ Remove 25% of the balloon inflation volume.
- ▶ Retract the Sniper catheter, with the balloon 75% inflated, until the balloon is in the desired position.
- ▶ While holding the Sniper and diagnostic catheter in place, re-inflate the balloon until it is seen contouring to the vessel wall under fluoroscopy.



Unable to Visualize Inflated Balloon

Cause:

- ▶ Insufficient amount of contrast in balloon.

Solution:

- ▶ Take a high resolution spot image **or**
- ▶ Disconnect 0.25 ml syringe and connect 10 ml syringe filled with 2 ml of 50% contrast. Pull syringe plunger to top lock position for 2 minutes. Move plunger slowly down onto contrast. Then reconnect 0.25 ml syringe to reinflate balloon.



Specifications and Compatibilities

Specifications

Balloon Diameter	Up to 6 mm (which occludes up to 5.5 mm vessels)		
Catheter Functional Length**	110 cm	130 cm	150 cm
Tip Shape**	Straight tip		
Catheter Outer Diameter (proximal)	2.9F (0.038")		
Catheter Outer Diameter (distal)	2.2F (0.029")		
Catheter Inner Diameter (Infusion Lumen)	0.020" (0.51 mm)		
Dead Space Volume (hub + catheter)	0.32 ml (110 cm) 0.36 ml (130 cm) 0.41 ml (150 cm)		
Injection Pressure	Up to 900 psi		

Compatibilities

Guidewire	0.014" or 0.016"
Embolitic Beads‡	Up to 900 µm
Coils*	Up to 0.018"
Embolitic Agents*	Lipiodol®, EtOH, DMSO, Y-90, Gelfoam, Glue (n-bCA)

*See Sniper Chemical Compatibility Statement Letter MK-0351 at <http://embolx.com/products/>. Embolx does not make any claims; for informational purpose only.

**Consult your sales representative for local market clearance and availability.

‡Boston Scientific Embosphere™ 900 µm, 19020-S1. Merit Medical® Embosphere® 700-900 µm, S810GH. Data on file. ©Copyright 2018. Sniper is a registered trademark of Embolx. Visit embolx.com/patents for patent information. All trademarks and registered trademarks are the property of their respective owners.

