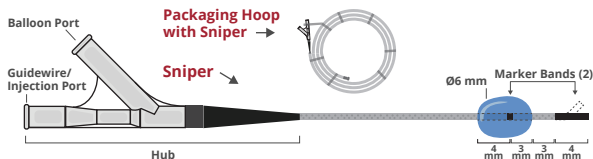


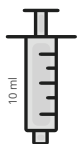
IMPORTANT! Always refer to the Sniper Balloon Occlusion Microcatheter Instructions For Use for detailed instructions.

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)



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, K™-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"

Embolic Beads‡ Up to 900 µm

Coils* Up to 0.018"

Embolic Agents* Lipiodol[®], EtOH, DMSO, Y-90, Gelfoam, Glue (n-bCA)

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.
- ▶ Wait 10-15 seconds before removing syringe.



C. Test Balloon Prime

- ▶ Follow the steps under "Use" to inflate and deflate balloon.
- ▶ To inflate balloon, use the .25 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.
- ▶ Wait 10-15 seconds before removing syringe.
- ▶ 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.
- ▶ Recommend 75% contrast for enhanced imaging.



Use

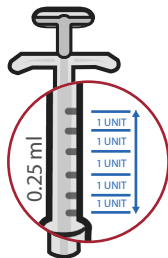
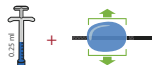
Torque Sniper Tip (applicable to K™-tip)

- ▶ Ensure the body of the Sniper is straight with no loops between hub and RHV.
- ▶ Hold the Sniper by placing one hand on the hub and the other hand on the RHV.
- ▶ Control tip torque by slowly rotating the Sniper's hub to access vessel.



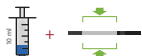
Inflate Balloon

- ▶ 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 with contrast for 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
 - Wait 10-15 seconds before removing syringe
 - Save syringe with contrast for subsequent deflation



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:

- ▶ Ensure valve is connected and sufficiently tightened to the balloon port.
- ▶ 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. Wait 10-15 seconds before removing syringe. Then reconnect 0.25 ml syringe to re-inflate balloon.
- ▶ 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. Wait 10-15 seconds before removing syringe. Then reconnect 0.25 ml syringe to re-inflate balloon.

*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® Emboshere® 700-900 µm, S810GH. Data on file.

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