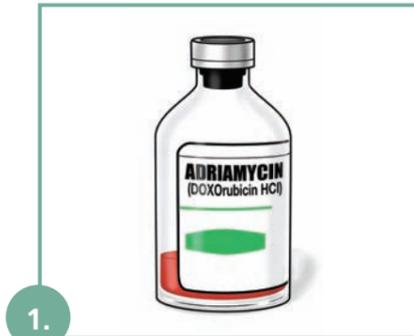


Reconstituting HepaSphere Microspheres

A Step-by-Step Reference for Clinicians

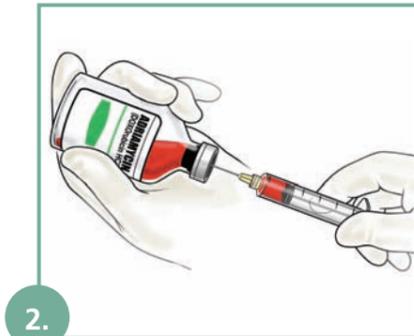
Rehydrating (or reconstituting) HepaSphere Microspheres prior to positioning the infusion catheter is highly recommended. As a Drug-loaded Embolic, HepaSphere Microspheres must be reconstituted with solubilized Doxorubicin (dissolved) in saline (0.9% NaCl solution for injection); PURE WATER MUST NEVER BE USED.

Refer to the IFU for product selection, expansion rates, reconstitution times, detailed instructions, and warnings and cautions.



1.

Dissolve lyophilized Doxorubicin-HCl in 10ml saline (0.9% NaCl solution for injection). FOR THIS APPLICATION NEVER USE PURE WATER.



2.

Aspirate the 10ml of Doxorubicin-HCl into a 10cc (or larger) syringe. Connect the syringe to a 20 gauge (or larger) needle.



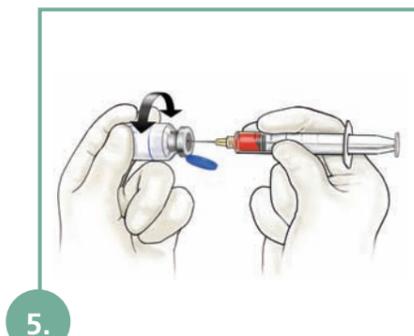
3.

Flip up plastic cap on the HepaSphere vial. Do not remove.



4.

Rotate HepaSphere vial several times to disperse microspheres.



5.

Continue to roll vial. Insert needle through HepaSphere stopper and inject full amount of Doxorubicin-HCl. Carefully remove the syringe and needle.



6.

Gently invert the vial back and forth so that the liquid contacts the stopper 5-10 times.



7.

NOTE: Let vial stand for a minimum of 60 minutes for full reconstitution.



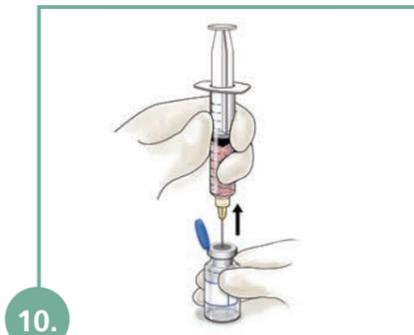
8.

Proper aspiration and/or venting techniques, as approved by the healthcare facility, may be used. If aspiration of air is performed, take care not to remove spheres from vial.



9.

Using a 20cc syringe and 20 gauge (or larger) needle, invert vial, pull needle back close to stopper, and aspirate contents.



10.

Return vial to upright position and extract needle.



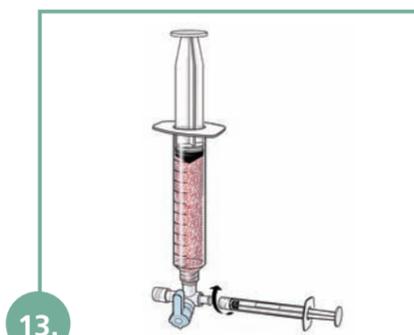
11.

Complete the syringe with 10ml non-ionic contrast media. Gently invert 2-3 times to mix.



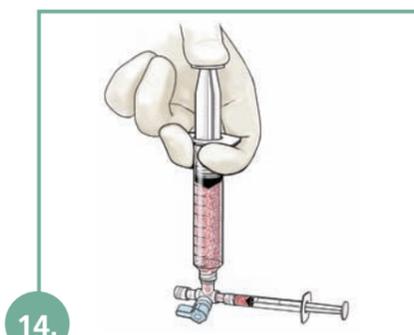
12.

Remove needle from syringe and attach syringe to 3-way stopcock so that syringe is perpendicular to male luer port.



13.

Attach 1cc injection syringe to remaining male port.



14.

Gently fill injection syringe. Repeat 2-3 times to ensure a homogenous mixture.



15.

Attach injection syringe to infusion catheter.