CONSERVATION AND STORAGE:

The QuadraSphere Q2 Microspheres solution is sensitive to temperature and must be stored at approximately 35° F to 46° F (2° C to 8° C). The reconstituted solution should be used immediately. If the procedure is not performed immediately, store it in the original vial, protected from light, at 35° F to 46° F (2° C to 8° C) for a maximum of 4 hours. Store the catheter containing the reconstituted solution at 35° F to 46° F (2° C to 8° C) until use, but discard it after 4 hours of storage.

DELIVERY INSTRUCTIONS:

1. For reconstitution, use a 1 mL syringe to aspirate the contents of the vial. If aspiration of air from the vial is performed prior to reconstitution, use a 1 mL syringe containing air to aspirate the contents of the vial. Use a 30 mL syringe and 20 gauge or larger needle to aspirate the contents of the vial. Use the aspiration syringe to draw 100% NaCl 0.9% aqueous solution or non-ionic contrast medium (or 50% NaCl 0.9% aqueous solution and 50% non-ionic contrast medium). QuadraSphere Q2 Microspheres can be injected with microcatheters with a size range of 0.020” (0.508 mm) or larger. For visualization under fluoroscopy, note that the microspheres swell approximately 4X their original dry diameter in approximately 10 seconds. The magnitude of swelling depends on the ionic concentration of the solution. The microspheres are supplied as dry particles, and are available in a dry size range of 3.5 to 4.5 microns. The solution will be evident prior to embolization can lead to mistargeted embolization and should be avoided. Note: if the syringe contains NaCl 0.9% aqueous solution or non-ionic contrast medium, the solution will swell as you withdraw it from the vial. If non-ionic contrast medium is used, wait a minimum of 5 minutes then perform a selective angiographic run to confirm microspheres are present in the desired location.

2. Apply a gentle force to the needle in the opposite direction to the upper-facing surface of the rubber cap with the heel of the needle tip. Carefully remove the syringe with the needle attached. Be sure the needle is directed toward the catheter tip as close as possible to the embolization target. The physician should be sure to carefully select QuadraSphere Q2 Microspheres that are the appropriate size. The microspheres swell approximately 4X their original dry diameter in approximately 10 seconds. The magnitude of swelling depends on the ionic concentration of the solution. The microspheres are supplied as dry particles, and are available in a dry size range of 3.5 to 4.5 microns. The solution will be evident prior to embolization can lead to mistargeted embolization and should be avoided. Note: if the syringe contains NaCl 0.9% aqueous solution or non-ionic contrast medium, the solution will swell as you withdraw it from the vial. If non-ionic contrast medium is used, wait a minimum of 5 minutes then perform a selective angiographic run to confirm microspheres are present in the desired location.

3. After preparation, carefully examine the solution to determine if until the heel of the needle tip. Be sure the needle is directed toward the catheter tip as close as possible to the embolization target. The physician should be sure to carefully select QuadraSphere Q2 Microspheres that are the appropriate size. The microspheres swell approximately 4X their original dry diameter in approximately 10 seconds. The magnitude of swelling depends on the ionic concentration of the solution. The microspheres are supplied as dry particles, and are available in a dry size range of 3.5 to 4.5 microns. The solution will be evident prior to embolization can lead to mistargeted embolization and should be avoided. Note: if the syringe contains NaCl 0.9% aqueous solution or non-ionic contrast medium, the solution will swell as you withdraw it from the vial. If non-ionic contrast medium is used, wait a minimum of 5 minutes then perform a selective angiographic run to confirm microspheres are present in the desired location.

4) After preparation, carefully examine the solution to determine if until the heel of the needle tip. Be sure the needle is directed toward the catheter tip as close as possible to the embolization target. The physician should be sure to carefully select QuadraSphere Q2 Microspheres that are the appropriate size. The microspheres swell approximately 4X their original dry diameter in approximately 10 seconds. The magnitude of swelling depends on the ionic concentration of the solution. The microspheres are supplied as dry particles, and are available in a dry size range of 3.5 to 4.5 microns. The solution will be evident prior to embolization can lead to mistargeted embolization and should be avoided. Note: if the syringe contains NaCl 0.9% aqueous solution or non-ionic contrast medium, the solution will swell as you withdraw it from the vial. If non-ionic contrast medium is used, wait a minimum of 5 minutes then perform a selective angiographic run to confirm microspheres are present in the desired location.