CONSERVATION AND STORAGE:

CAUTION:

Microspheres that may still be in the catheter lumen. Discard the catheter after

• When stasis in the feeding pedicle occurs while delivering the QuadraSphere

Note:

Microspheres in a slow, nonforceful, pulsatile manner over a time period of

• Two methods for embolic aliquot sequestering for injection may be used:

•  Aspirate the QuadraSphere Microspheres mixture into the injection syringe.

Microspheres. Use of a 1 mL injection syringe is recommended.

•  Additional 1 mL syringe volumes may be used for smaller volumes

of reconstitution, exercise caution not to remove the spheres from the vial.

Techniques, as approved by the healthcare facility, may be used for easier injection of

Microspheres are compressible and can be injected easily through

solution and non-ionic contrast media, as compared to their initial dry diameter.

microspheres swell to approximately four times their diameter in 0.9% NaCl aqueous

The external surface of the vial is sterile.

•  Inspect the packaging to confirm that it is intact. Remove the vial from the pouch.

•  Invert the vial back and forth so that the liquid contacts the stopper 5-10 times.

•  Additional information is found in the Warnings section

•  Allergic reaction to non-ionic contrast media or embolic material

•  Allergic reaction to medications (e.g. analgesics)

•  Infection necessitating medical intervention

•  Blinding, hearing loss, and loss of smell

•  Ischemia at an undesired location, including ischemic stroke, ischemic infarction

•  Pulmonary embolism due to arteriovenous shunting

during or after the procedure, and may include, but are not limited to, the following:

Care for patients with the following conditions:

Additional evaluations or precautions may be necessary in managing periprocedural

Warnings about use of small microspheres:

• Consider upsizing the Microspheres if angiographic evidence of embolization does

• Vascular anatomy or blood flow precluding correct catheter placement or embolic

•  Some of the QuadraSphere Microspheres may be slightly outside of the range,

•  High flow arteriovenous shunts or fistulae with luminal diameter greater than the

•  Presence of collateral vessel pathways potentially endangering normal territories

•  Feeding arteries too small to accept the selected QuadraSphere Microspheres

•  Presence ofMarcaed invasion vessels entering from outside the target area

•  Post embolization swelling may result in ischemia to tissue adjacent to target area.

•  Potential complications in patients with arteriovenous malformations

Potential consequences include swelling, necrosis, paralysis, abscess and/or stronger

ischemic injury results from use of smaller sized microspheres

In consideration of the arteriovenous

occlusion in the vasculature and after consideration of the arteriovenous

proper radiation dose is applied for each specific type of procedure performed.

and death.

• Because of the significant complications of misembolization, extreme caution should

angiographic appearance.

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