Ultrasonography of the Liver in Adults: After reconstitution, administer 2 mL administered as an intravenous bolus injection during a 15-second period. If injection is not completed within 15 seconds, the injection should be interrupted and restarted. If injection is not completed within 15 seconds, the injection should be interrupted and restarted. If injection is not completed within 15 seconds, the injection should be interrupted and restarted. If injection is not completed within 15 seconds, the injection should be interrupted and restarted.

Echocardiography: To opacify the left ventricular endocardial border, administer 2.4 mL as an intravenous injection into the left ventricle. Follow Lumason injection with an intravenous flush using 0.9% Sodium Chloride Injection. Use a 20 gauge or larger needle. Ensure that the injection is given slowly to avoid the risk of embolization. If adequate opacification is not achieved, re-inject 0.5 mL of the reconstituted suspension. May repeat dose one time during a single examination.

DOSAGE FORMS AND STRENGTHS
- 3 mL vial containing 25 mg of lipid-type A microspheres (10 mL reconstituted suspension).
- One prefilled syringe containing 5 mL Sodium Chloride 0.9% Injection, USP (Diluent).

Lumason Administration
1. To reconstitute, insert the needle of a 5 mL Luer-Lok syringe into the reconstitution port of the vial and withdraw 2 mL of the reconstituted suspension into the 5 mL syringe (see Figure 4). Screw the Mini-Spike onto the 5 mL syringe by screwing it into clock-wise until it stops. The 5 mL syringe and Mini-Spike are not intended to be used beyond the 15-second interval for single use. Using a 5 mL syringe does not preclude the use of various diluents or amounts of Lumason, and therefore dilution may be advised. Using a 5 mL syringe does not preclude the use of various diluents or amounts of Lumason, and therefore dilution may be advised. Using a 5 mL syringe does not preclude the use of various diluents or amounts of Lumason, and therefore dilution may be advised. Using a 5 mL syringe does not preclude the use of various diluents or amounts of Lumason, and therefore dilution may be advised. Using a 5 mL syringe does not preclude the use of various diluents or amounts of Lumason, and therefore dilution may be advised. Using a 5 mL syringe does not preclude the use of various diluents or amounts of Lumason, and therefore dilution may be advised. Using a 5 mL syringe does not preclude the use of various diluents or amounts of Lumason, and therefore dilution may be advised. Using a 5 mL syringe does not preclude the use of various diluents or amounts of Lumason, and therefore dilution may be advised.
In a study of patients with pulmonary impairment, blood concentrations of SF₆ peaked at 1 to 4 minutes following injection. Lumason ultrasound images were compared to CT, MRI or histology. Specificity was 98% (43/44 patients).

**12 CLINICAL PHARMACOLOGY**

**12.1 Pharmacodynamics**

Lumason is a ultrasonic contrast agent that accesses the microvasculature, providing useful echocardiographic signal intensity for two minutes after the injection. Lumason microspheres are responsible for these values.

**12.2 Pharmacokinetics**

12.2.1 Distribution

The effect of Lumason on pulmonary hemodynamics was studied in a prospective, open-label study of 36 patients with suspected cardiac disease and a suboptimal non-contrast echocardiography result. Lumason ultrasound images were compared to CT, MRI or histology. Specificity was 98% (43/44 patients).

**12.3 Pharmacokinetics**

• One prefilled syringe containing 5mL of Sodium Chloride 0.9% Injection, USP (Diluent)

**14.3 Pulmonary Hemodynamic Effects**

A total of 191 patients with suspected cardiac disease and suboptimal non-contrast echocardiography received Lumason. The effect of Lumason on pulmonary hemodynamics was studied in a prospective, open-label study of 36 patients with suspected cardiac disease and a suboptimal non-contrast echocardiography result.

**14.4 Echocardiographic Assessment**

In one published study, 44 patients with an indeterminate focal liver lesion (23 males, 21 females, age range: 4-18 years, 34% Hispanic, 18% Caucasian, 5% Asian, and 1% other racial or ethnic groups. The mean weight was 80 kg (range 44 to 173 kg).

**16.2 Storage and Handling**

- One clear glass 10 mL vial containing 25 mg of lyophilized powder lipid-type A, 60.7 mg of sulfur hexafluoride gas (SF₆), and 0.04 mg of palmitic acid. The headspace of each vial contains 6.07 mg/mL (± 2 %) sulfur hexafluoride, SF₆, as a gas.

- One Mini-Spike syringe containing 1 mL of Sodium Chloride 0.9% Injection, USP (Diluent)

**16.4 Compatibility**

- One prefilled syringe containing 5mL of Sodium Chloride 0.9% Injection, USP (Diluent)

**17 PATIENT COUNSELING INFORMATION**

- One clear glass 10 mL vial containing 25 mg of lyophilized powder lipid-type A, 60.7 mg of sulfur hexafluoride gas (SF₆), and 0.04 mg of palmitic acid. The headspace of each vial contains 6.07 mg/mL (± 2 %) sulfur hexafluoride, SF₆, as a gas.

- One Mini-Spike syringe containing 1 mL of Sodium Chloride 0.9% Injection, USP (Diluent)

**18 ADVERSE REACTIONS**

**18.1 General**

- One clear glass 10 mL vial containing 25 mg of lyophilized powder lipid-type A, 60.7 mg of sulfur hexafluoride gas (SF₆), and 0.04 mg of palmitic acid. The headspace of each vial contains 6.07 mg/mL (± 2 %) sulfur hexafluoride, SF₆, as a gas.

- One Mini-Spike syringe containing 1 mL of Sodium Chloride 0.9% Injection, USP (Diluent)