



## **International Contrast Ultrasound Society (ICUS) Policy Statement Supporting Established Safety Record of Ultrasound Contrast Agents and Continued Use Where Medically Appropriate**

**Unanimously Approved April 23, 2021**

The International Contrast Ultrasound Society (ICUS) supports the well-established safety record and favorable risk-benefit profile of ultrasound contrast agents (UCAs), based on the extensive body of published safety data and favorable clinical experiences worldwide.

ICUS also encourages the use of UCAs (sometimes also known as “ultrasound enhancing agents”) to improve the quality and functionality of ultrasound images where medically appropriate, with customary safeguards in place to address any rare allergic reaction that may occur in one out of ten thousand doses.

ICUS appreciates the recent Food and Drug Administration determination that UCAs should not be used in patients who are sensitive to polyethylene glycol (PEG), a component of numerous consumer and medical products and an inactive ingredient in two UCAs approved for use in the United States and other countries throughout the world. ICUS recognizes the important role of product labels in communicating risk and protecting patient safety, and the organization supports appropriate warnings and contraindications that call attention to the potential, however rare, for an adverse event including an allergic reaction.

Physicians are called upon daily to evaluate potential benefits and risks of any diagnostic procedure or therapy. ICUS encourages physicians to carefully weigh the benefits and risks of using UCAs to enhance diagnostic ultrasound exams, along with the risks associated with alternate diagnostic imaging or foregoing diagnostic imaging.

When adverse reactions occur, as with other medical products, physicians should follow protocols established under applicable professional guidelines and administer appropriate therapy to reverse the event.

In addition, ICUS encourages a thorough evaluation of each affected patient’s underlying medical history, condition, co-morbidities and exposures in order to assess whether other factors may have contributed to the reaction.

Millions of doses of UCAs have been safely administered worldwide for decades, offering important benefits for the overwhelming number of our patients.

Based on the totality of UCA safety data now available, we conclude that UCAs have proven to be safe and beneficial for most patients and the potential for rare reactions, while serious, may be addressed with standard medical precautions.