



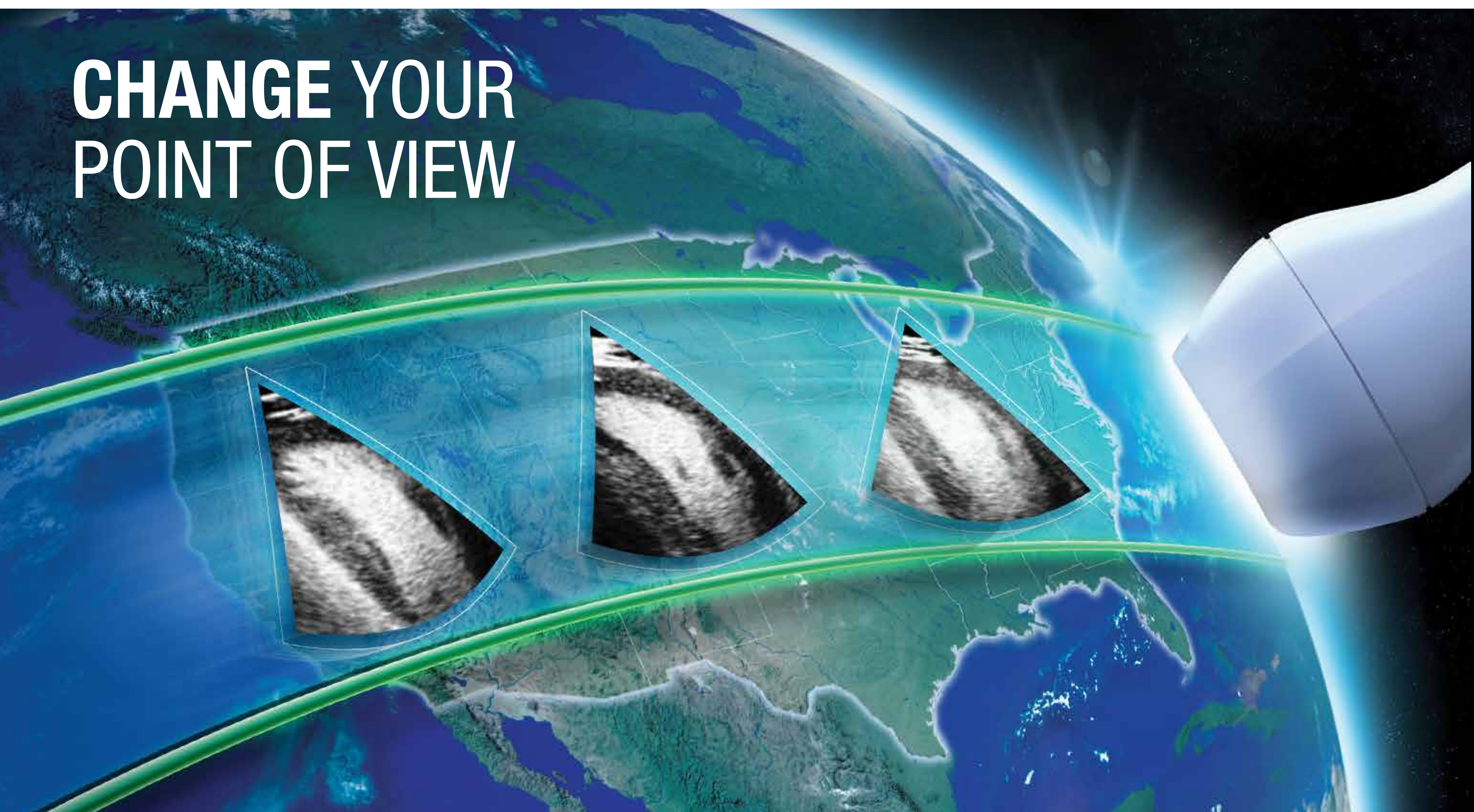
LUMASON™

(sulfur hexafluoride lipid-type A microspheres)
for injectable suspension

From Bracco Diagnostics Inc.—

A GLOBAL LEADER IN ENHANCED ECHOCARDIOGRAPHY

**CHANGE YOUR
POINT OF VIEW**



Committed to Science,
Committed to You.™



IT'S TIME TO CHANGE THE WAY YOU VIEW ECHOCARDIOGRAPHY

Bracco Diagnostics Inc. is committed to delivering high-quality products while supporting the global echocardiography community. As a global market leader in contrast imaging solutions, we use our industry expertise, resources, and educational programs to support our customers—and the patients that you serve.

Now, we bring more than a decade of experience with proven safety and efficacy in enhanced echocardiography to the United States with Lumason. Known around the world as SonoVue®, Lumason is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.¹

Lumason, in a step-saving procedural kit, helps you obtain optimal quality images.



INDICATIONS AND USAGE

Lumason is an ultrasound contrast agent indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

CONTRAINDICATIONS

Lumason is contraindicated in patients with:

- known or suspected right-to-left, bi-directional, or transient right-to-left cardiac shunts
- history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in Lumason

Do not administer by intra-arterial injection.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS CARDIOPULMONARY REACTIONS

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following the injection of ultrasound contrast agents, including sulfur hexafluoride lipid microspheres [see Warnings and Precautions (5.1)]. Most serious reactions occur within 30 minutes of administration [see Warnings and Precautions (5.1)].

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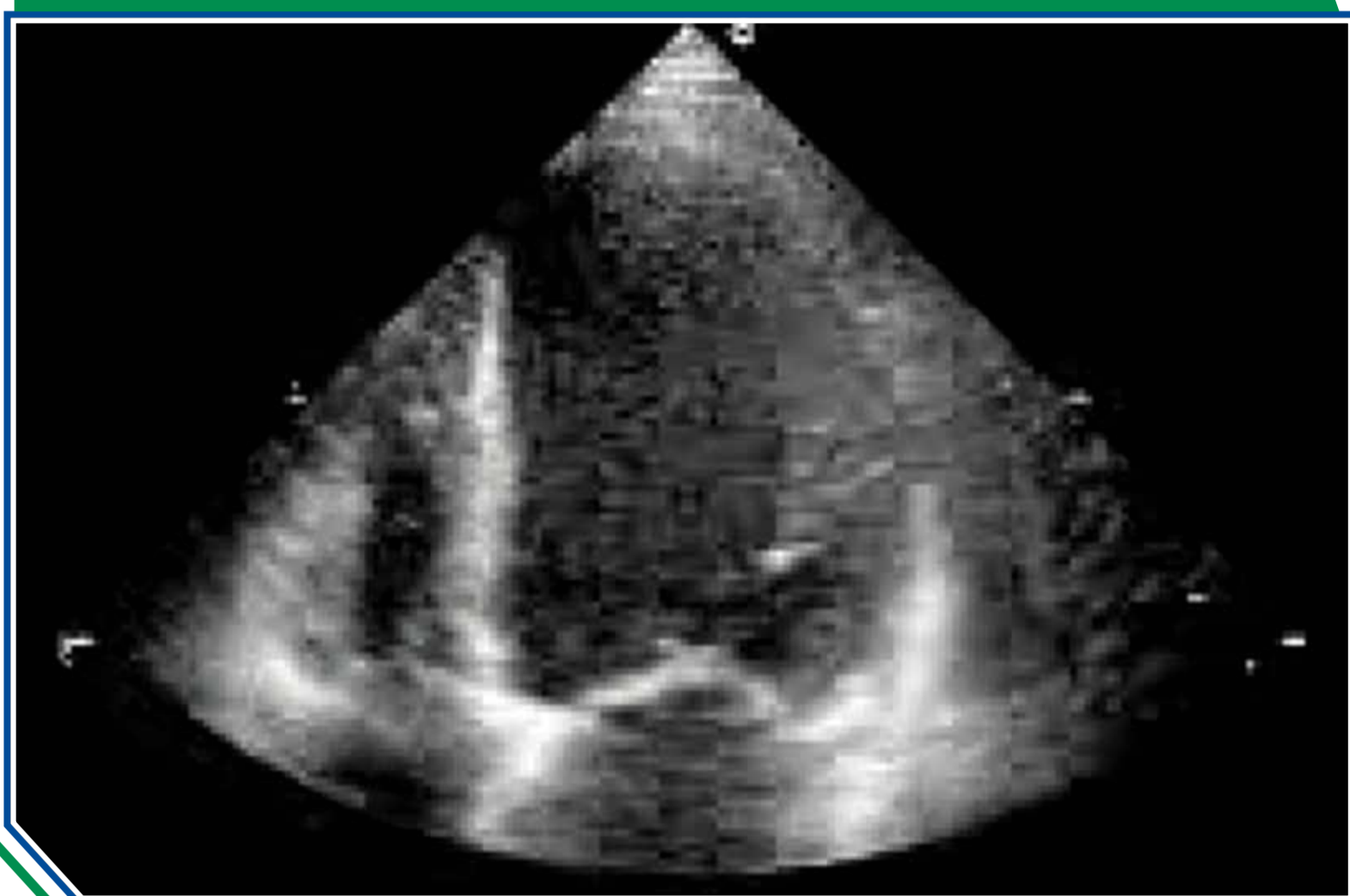
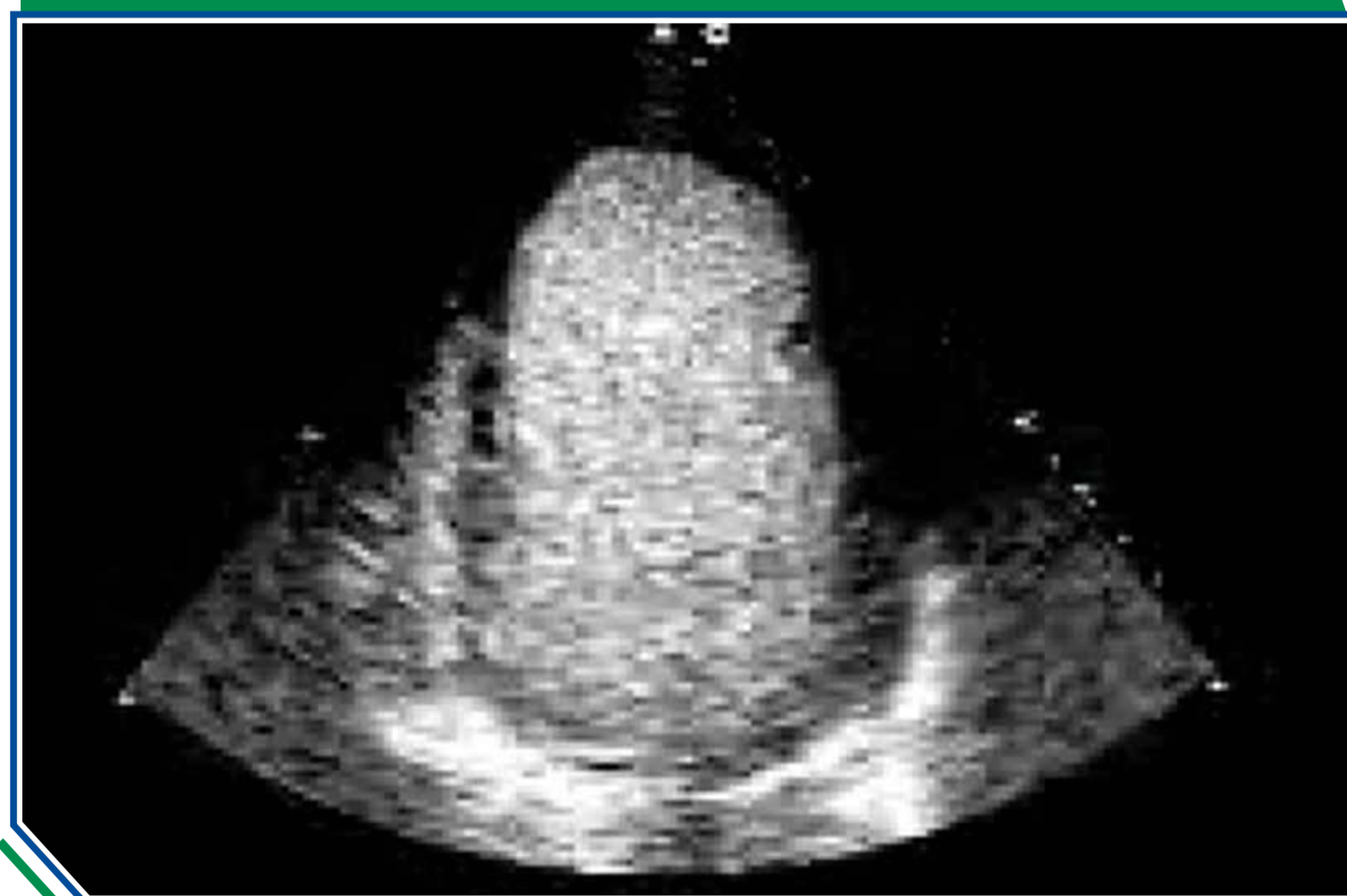
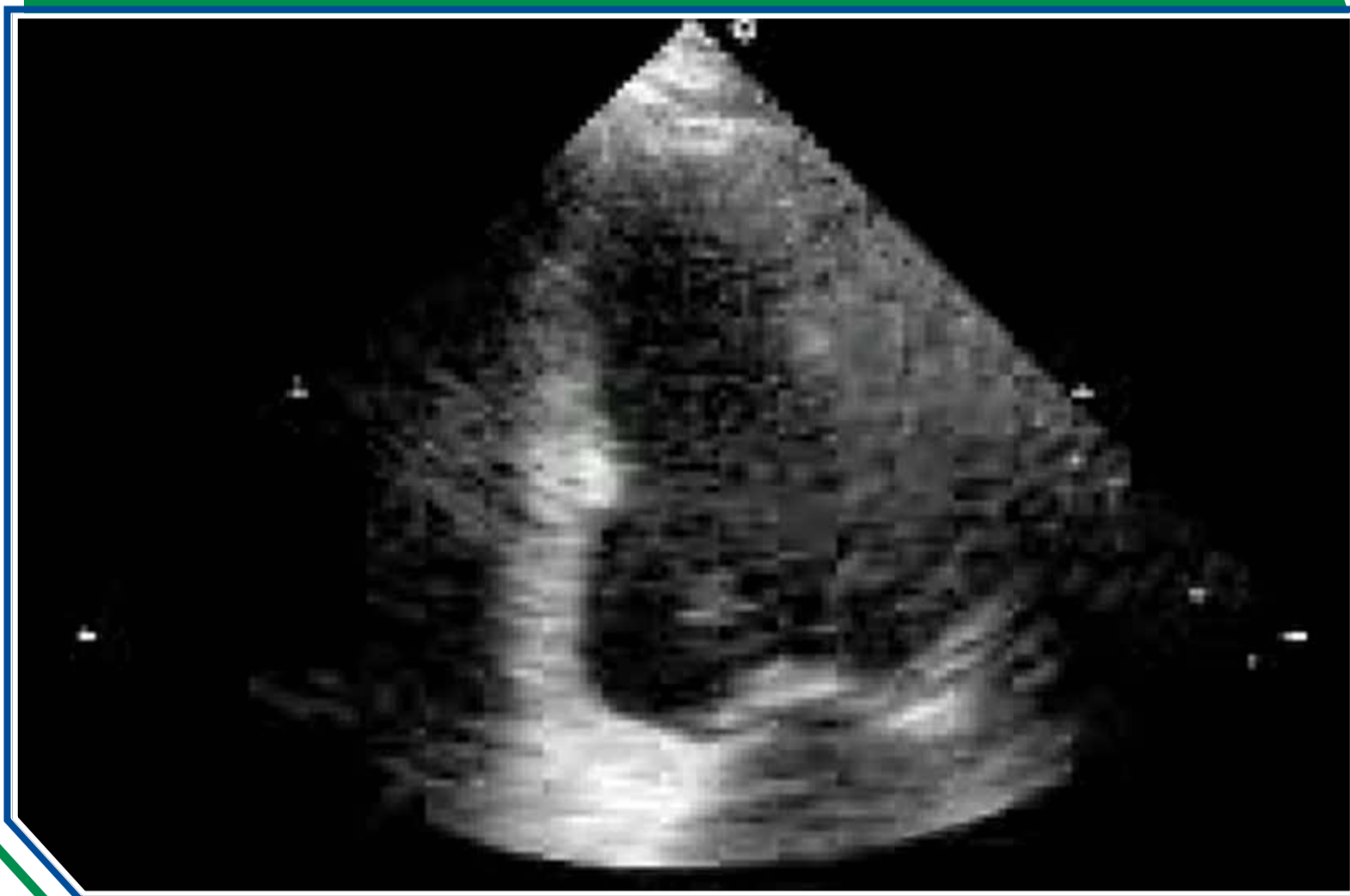
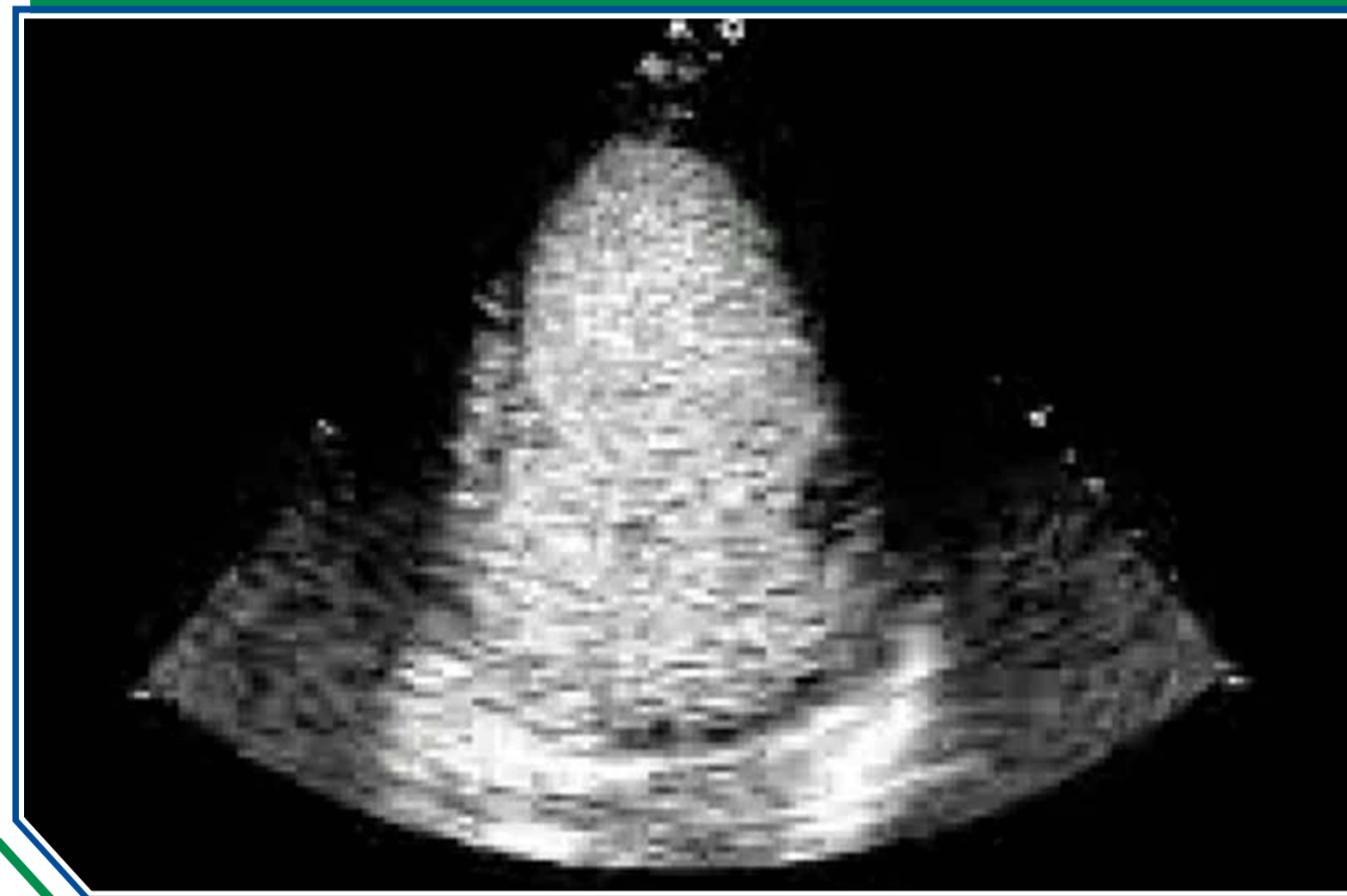
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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by Bracco Suisse SA, Plan-les-Ouates Geneve, Switzerland (Lumason lyophilized powder vial-25 mg lipid-type A/60.7 sulfur hexafluoride gas); Vetter Pharma-Fertigung GmbH & Co. KG, 88212 Ravensburg, Germany (Sodium Chloride 0.9% Injection, USP); B. Braun Melsungen AG, 34212 Melsungen, Germany (Mini-Spike).

COMPARISON OF UNENHANCED ECHO VS LUMASON ECHO

Lumason improves echo quality by enhancing the delineation of the endocardial border and opacifying the left ventricular chamber.

Unenhanced Echo**Lumason Echo****Unenhanced Echo****Lumason Echo**

Echocardiography images shown are representative images from reference studies. Individual results may vary.

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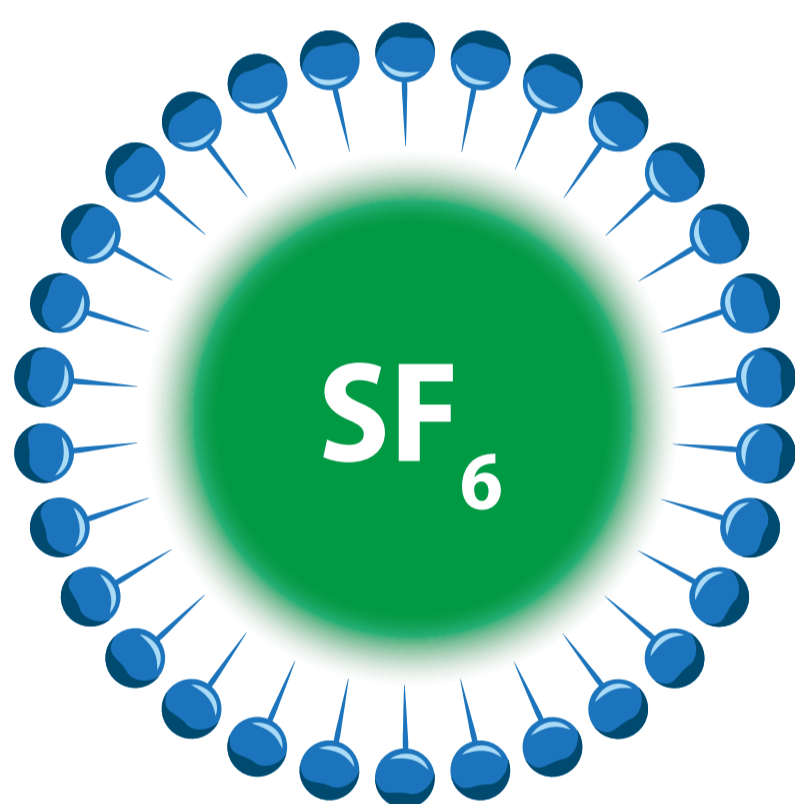
SMALL SPHERES WITH A BIG IMPACT

A microsphere's ultrasonic characteristics depend on its size, the composition of the bubble's outer shell, and the properties of the encapsulated gas. The more elastic the shell, the more easily it will be compressed and the better it will resonate.²

Lumason is constructed of sulfur hexafluoride gas and highly elastic shell.³

- ▶ Designed to be stable and resist pressure changes³
- ▶ Acoustic properties are constant over the entire range of frequencies used in clinical settings³

Schematic Representation and Characteristics of Lumason Microsphere¹



Mean diameter range	1.5–2.5 μm
Percentage of microspheres $\leq 10 \mu\text{m}$	$\geq 99\%$
Upper size limit	100% $\leq 20 \mu\text{m}$

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SAFETY AND EFFICACY YOU CAN COUNT ON

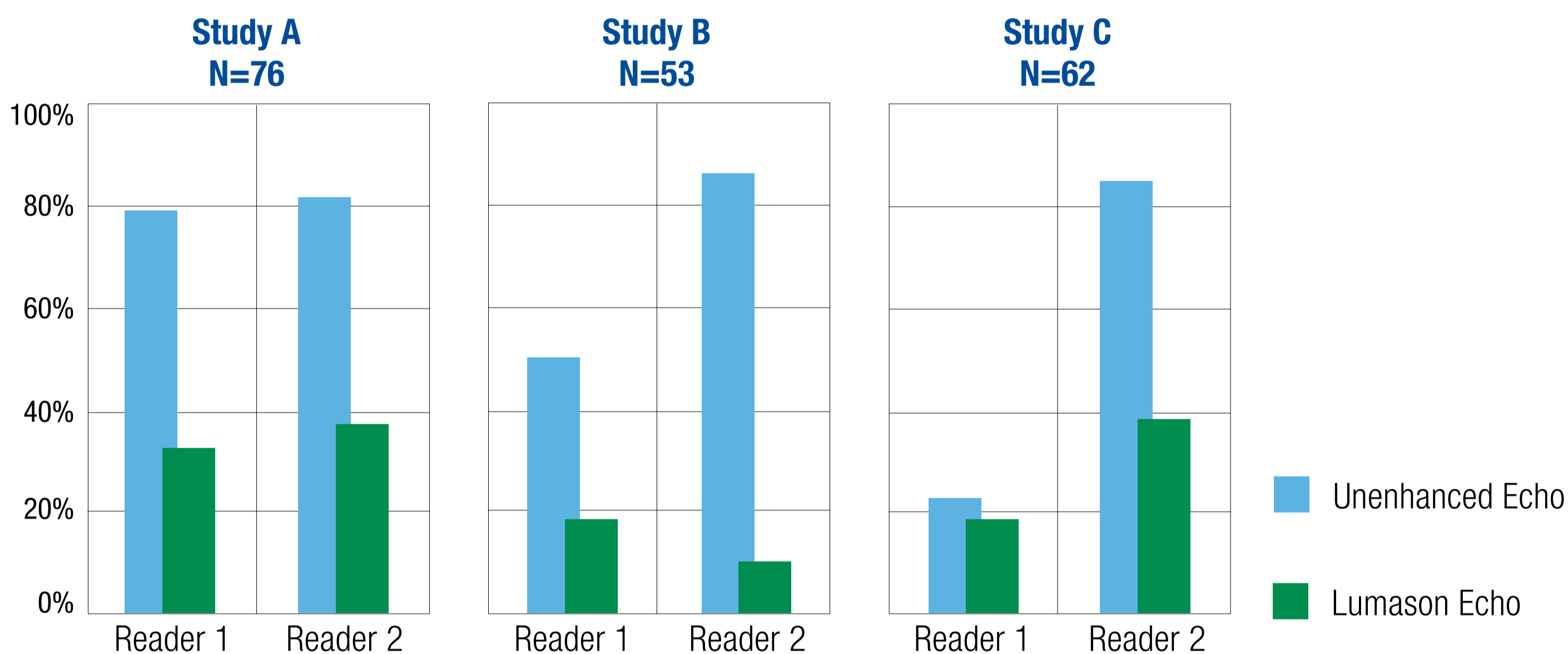
Lumason, known globally as SonoVue, has a proven safety profile.

- ▶ Adverse reactions occurred in less than 5% of patients in clinical trials (n=6179).¹
- ▶ The most commonly reported adverse reactions were headache and nausea, which were mild to moderate in intensity and spontaneously resolved.¹

Lumason Helps Improve Echo Quality

Efficacy was established in 3 multicenter, controlled clinical trials evaluating endocardial border delineation and duration of useful contrast effect in patients with suspected cardiac disease and suboptimal noncontrast echocardiograms. Lumason reduced the percentage of inadequate border delineation.¹

Reduction in Percentage of Patients with Inadequate Border Delineation



In all 3 multicenter, controlled clinical trials with Lumason, complete left ventricular opacification was observed in 52% to 80% of patients.¹

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EVERY PATIENT DESERVES A QUALITY DIAGNOSIS

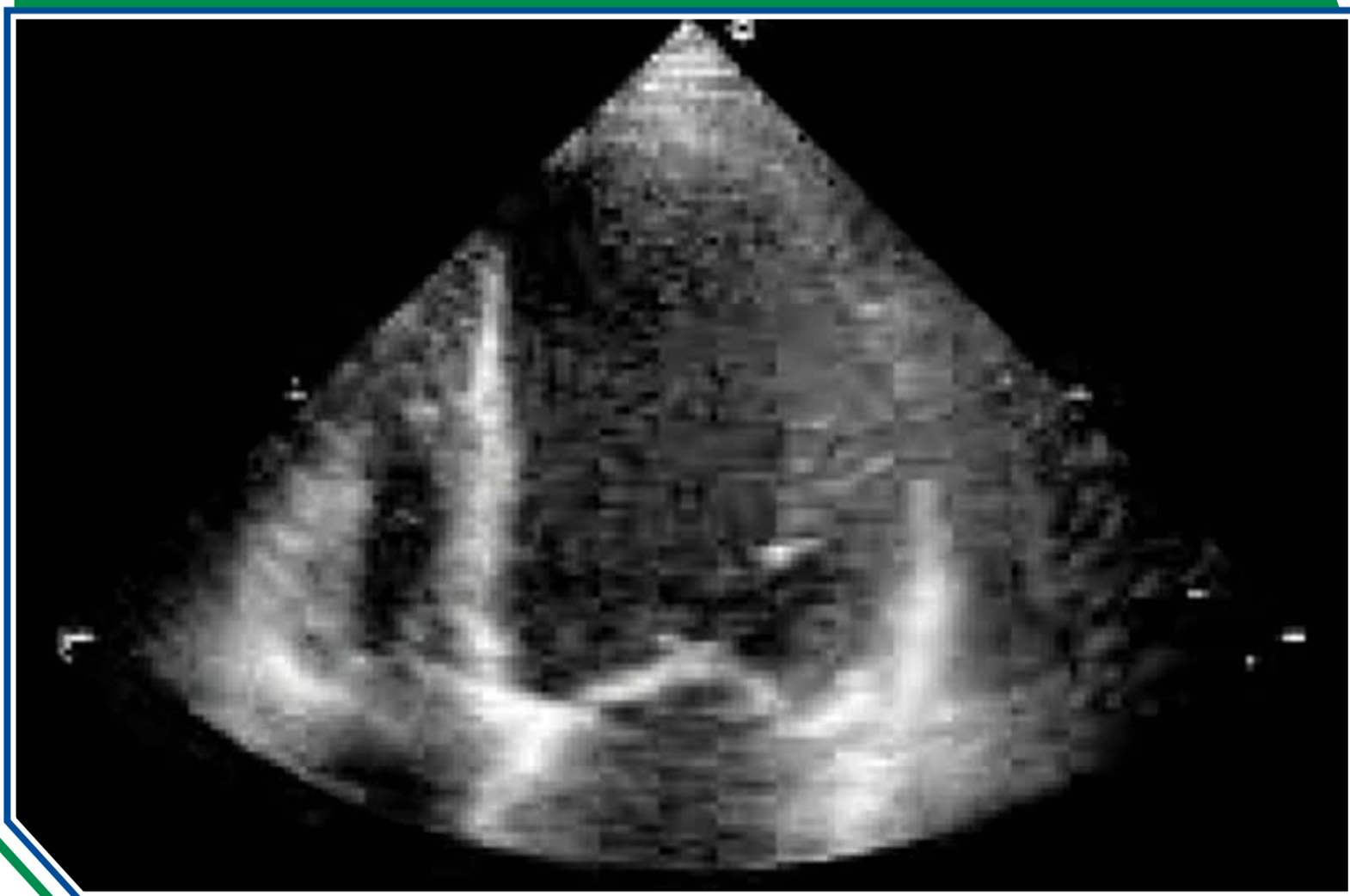
Lumason effectively converts suboptimal echocardiographic images into images of optimal quality in a wide range of patients, including the elderly.¹



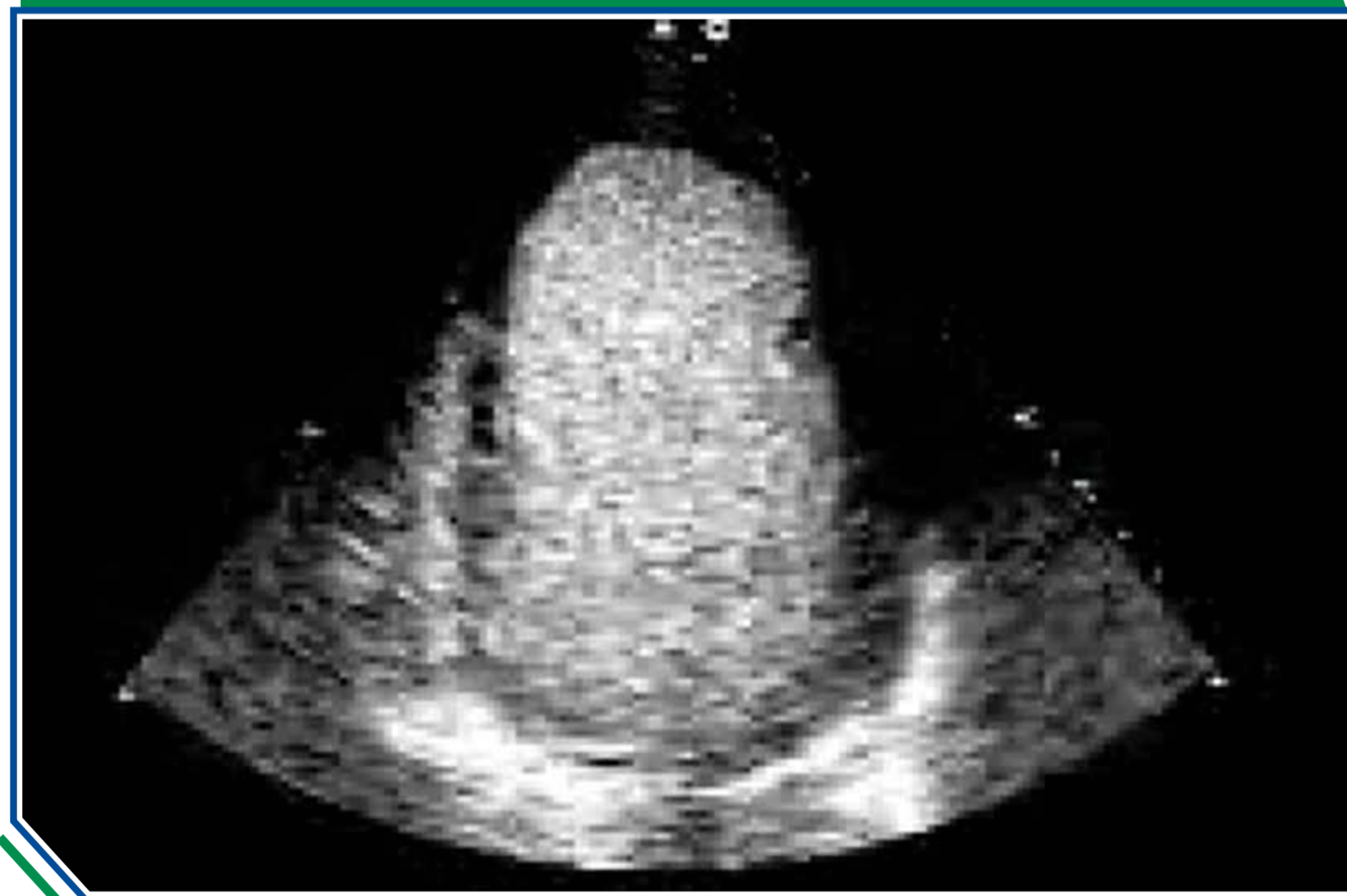
Comparison of Unenhanced Echo vs Lumason Echo

Lumason improves echo quality by enhancing the delineation of the endocardial border and opacifying the left ventricular chamber.

Unenhanced Echo



Lumason Echo



Echocardiography images shown are representative images from reference studies. Individual results may vary.

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COMPLETE PROCEDURAL KIT SAVES STEPS

Available in an easy-to-use procedural kit to eliminate the extra steps to gather supplies.



Single patient-use procedural kit

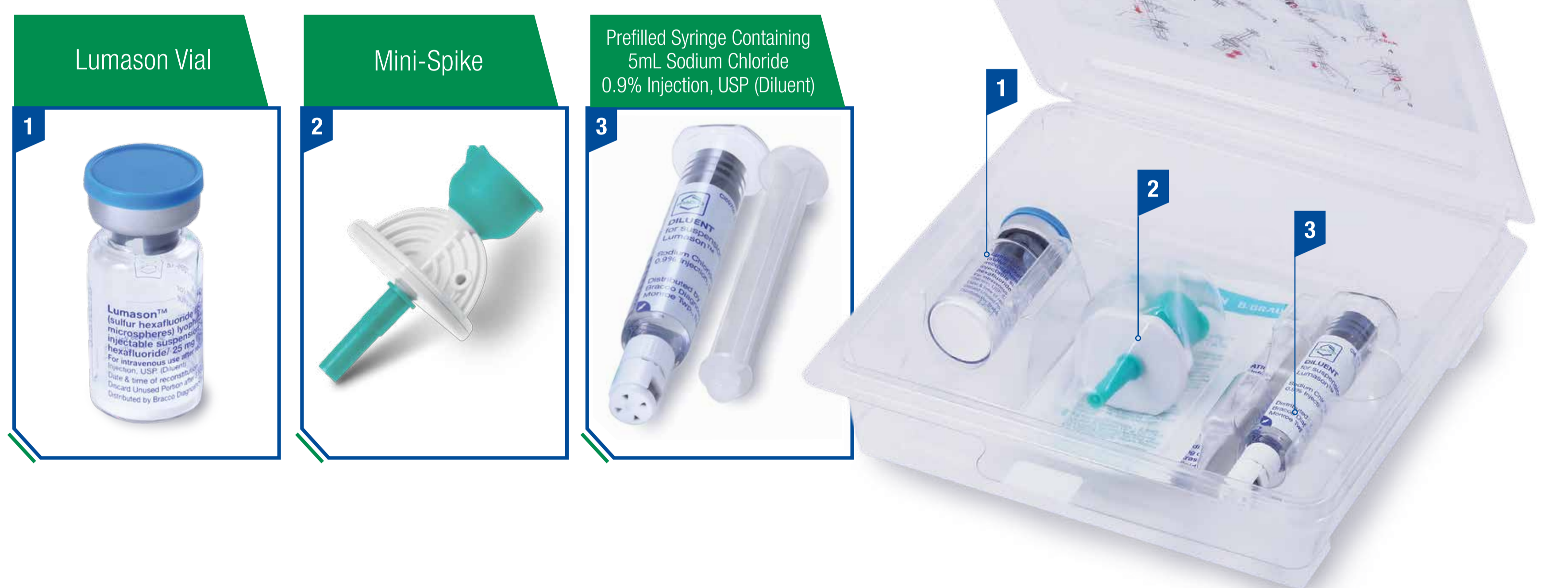


No refrigeration or activation device required



Portable kit to go wherever you go

Lumason Procedural Kit Components



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GET READY TO CHANGE THE WAY YOU VIEW ECHOCARDIOGRAPHY AGENTS WITH LUMASON

 Microspheres designed for stability, resistance to pressure, and a wide range of acoustic properties to help improve suboptimal echo image quality³

 Proven safety and efficacy profile

 Convenient, step-saving kit

Ordering Information

NDC #	Product Description	Packaging
0270-7099-16	Lumason (sulfur hexafluoride lipid-type A microspheres), 25 mg/vial	5 kits per carton

For more information about Lumason, visit imaging.bracco.com/us-en/lumason.
To speak with a Bracco representative, please contact 1-877-BRACCO-9 (1-877-272-2269)

REFERENCES: **1.** Lumason (sulfur hexafluoride lipid-type A microspheres) for injectable suspension full Prescribing Information. Monroe Township, NJ: Bracco Diagnostics Inc., October 2014. **2.** Senior R, Becher H, Monaghan M, et al. Contrast echocardiography: evidence-based recommendations by European Association of Echocardiography. *Eur J Echocardiogr.* 2009;10:194-212. **3.** Schneider M. Characteristics of SonoVue. *Echocardiography.* 1999;16(7, pt 2):743-746.
All individuals who appear in this brochure are for illustrative purposes only. All persons depicted are models and not real patients.

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Lumason is a trademark of Bracco Diagnostics Inc.
SonoVue is a registered trademark of Bracco Suisse SA.

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