

**LUMASON**<sup>®</sup>

(sulfur hexafluoride lipid-type A microspheres)  
for injectable suspension, for intravenous  
use or intravesical use

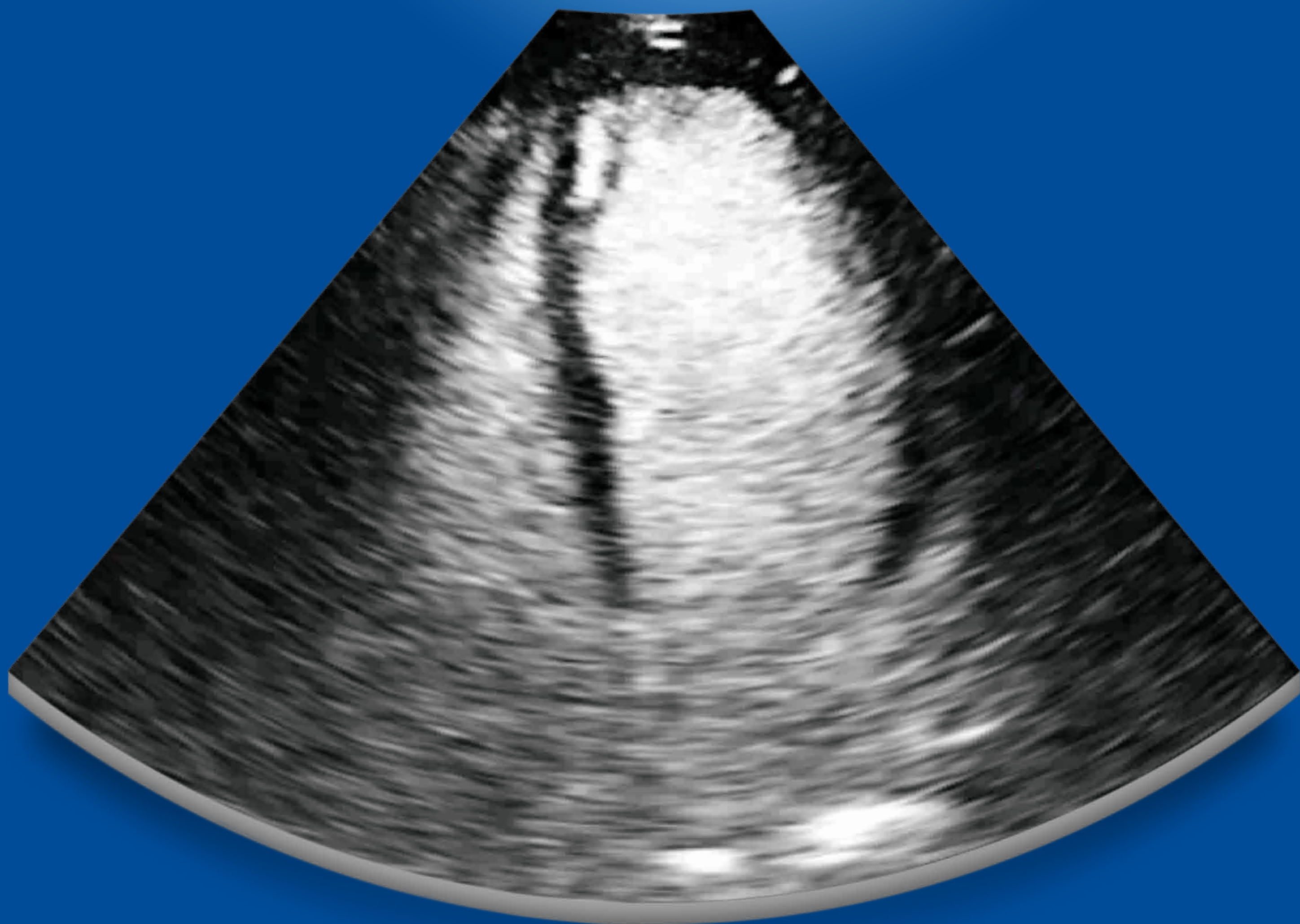


Ultrasound

Raise the standard for echocardiographic images above suboptimal<sup>1</sup>

**KNOW NOW**

with LUMASON<sup>®</sup>  
Ultrasound Contrast



The ultrasound contrast agent LUMASON helps  
improve image quality at the point of patient care.

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

Committed to Science,  
Committed to You.™



LIFE FROM INSIDE

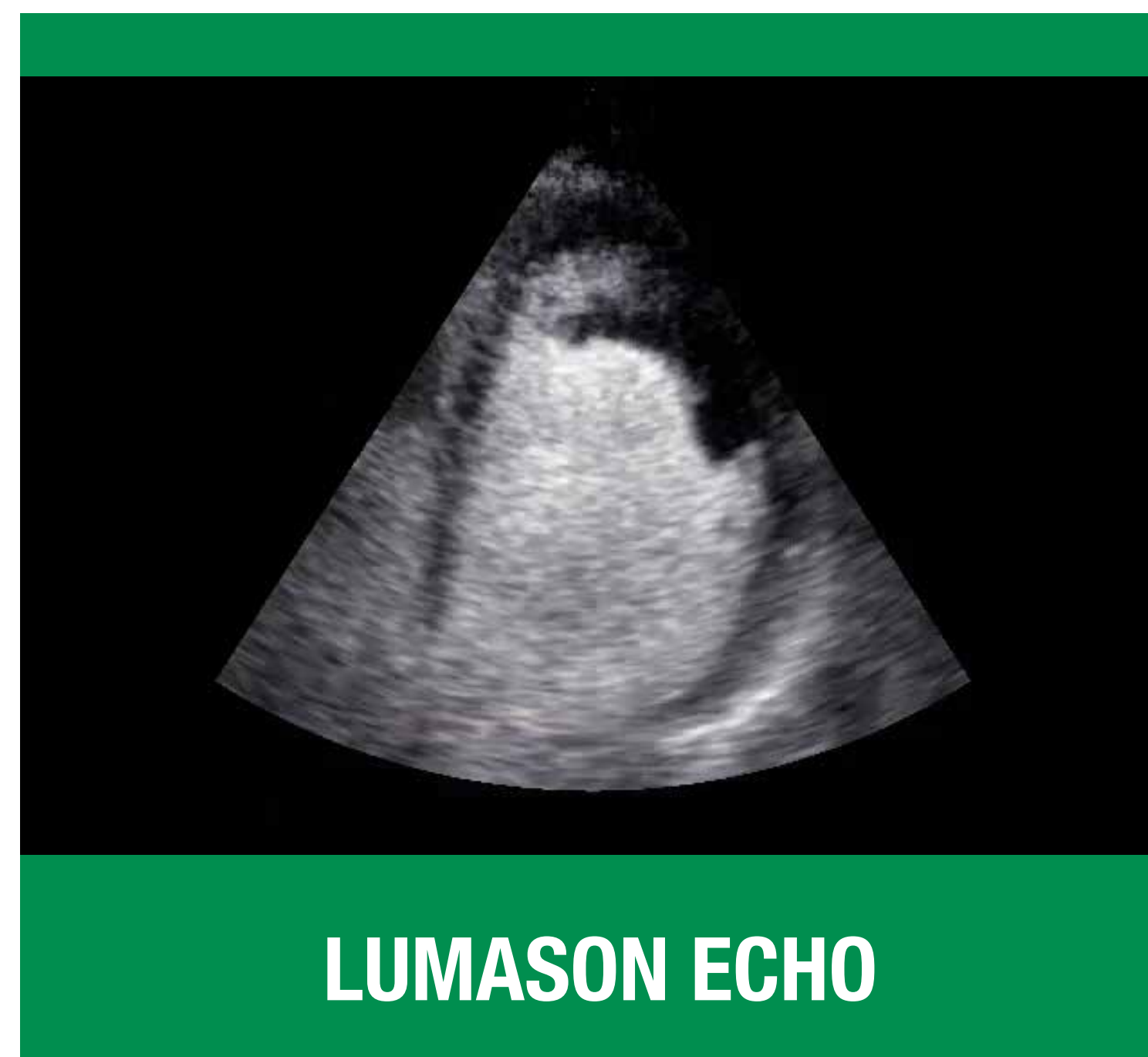
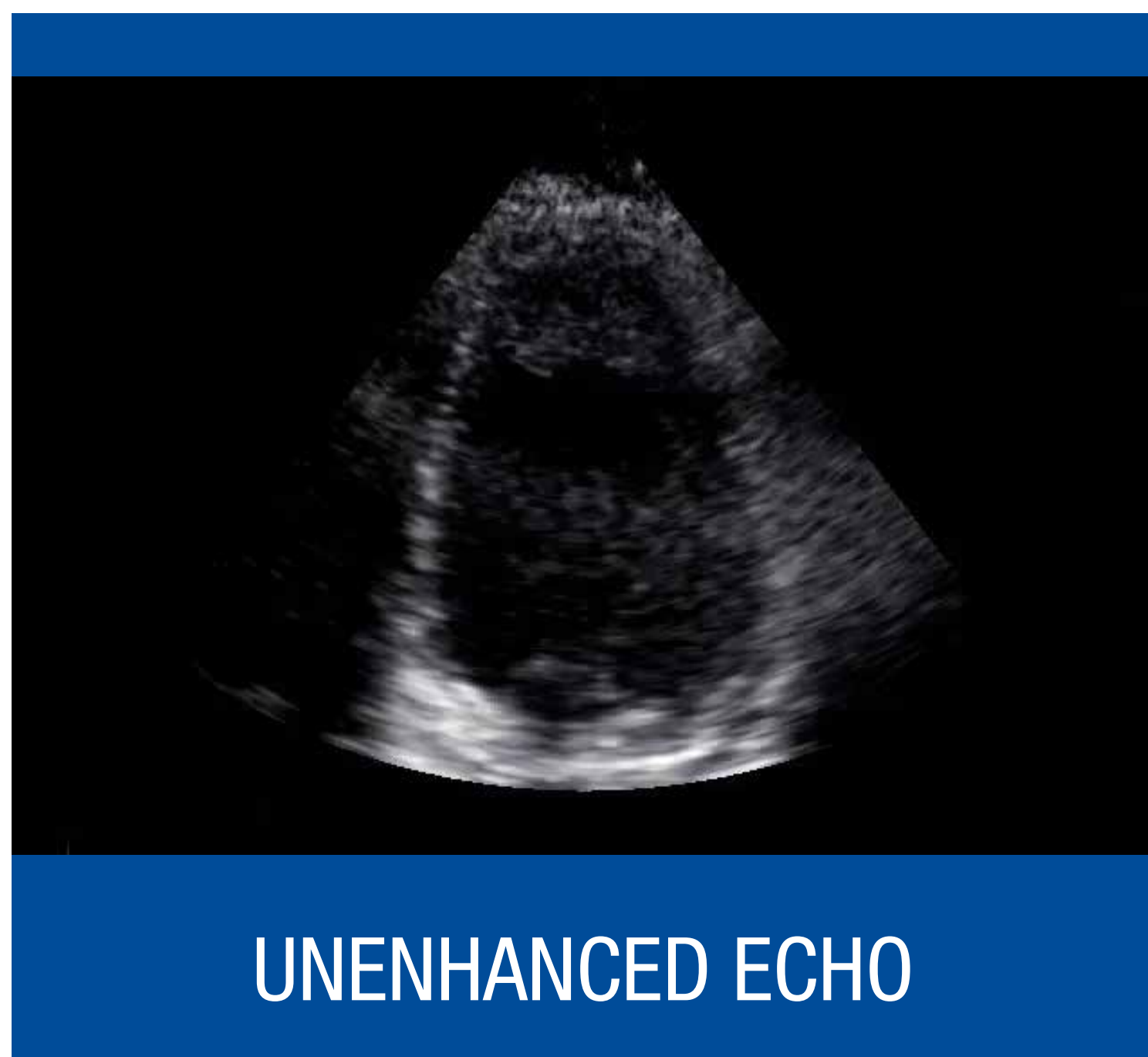
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## RESPOND NOW TO SUBOPTIMAL IMAGES

Make a visible difference with LUMASON.<sup>1</sup>



Echocardiographic images are courtesy of Stephen Glen, Forth Valley Royal Hospital, Larbert, United Kingdom.  
Individual results may vary.

### INDICATIONS AND USAGE<sup>1</sup>

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- in echocardiography to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border in adult patients with suboptimal echocardiograms
- in ultrasonography of the liver for characterization of focal liver lesions in adult and pediatric patients
- in ultrasonography of the urinary tract for the evaluation of suspected or known vesicoureteral reflux in pediatric patients

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LUMASON is contraindicated in patients with:

- history of hypersensitivity reactions to sulfur hexafluoride lipid microsphere components or to any of the inactive ingredients in LUMASON

### IMPORTANT SAFETY INFORMATION<sup>1</sup>

#### 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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**You are encouraged to report negative side effects of prescription drugs to the FDA.**  
Visit <https://www.fda.gov/Safety/MedWatch/default.htm> or call 1-800-FDA-1088.

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## ENHANCE

LUMASON improves echo quality by **delineating the endocardial border**<sup>1</sup>

## OPACIFY

LUMASON improves echo quality by **opacifying the left ventricular chamber**<sup>1</sup>

# KNOW NOW

**At Bracco, we are committed to raising the standard for echocardiographic images above suboptimal.<sup>1</sup>**

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**BRACCO**  
LIFE FROM INSIDE

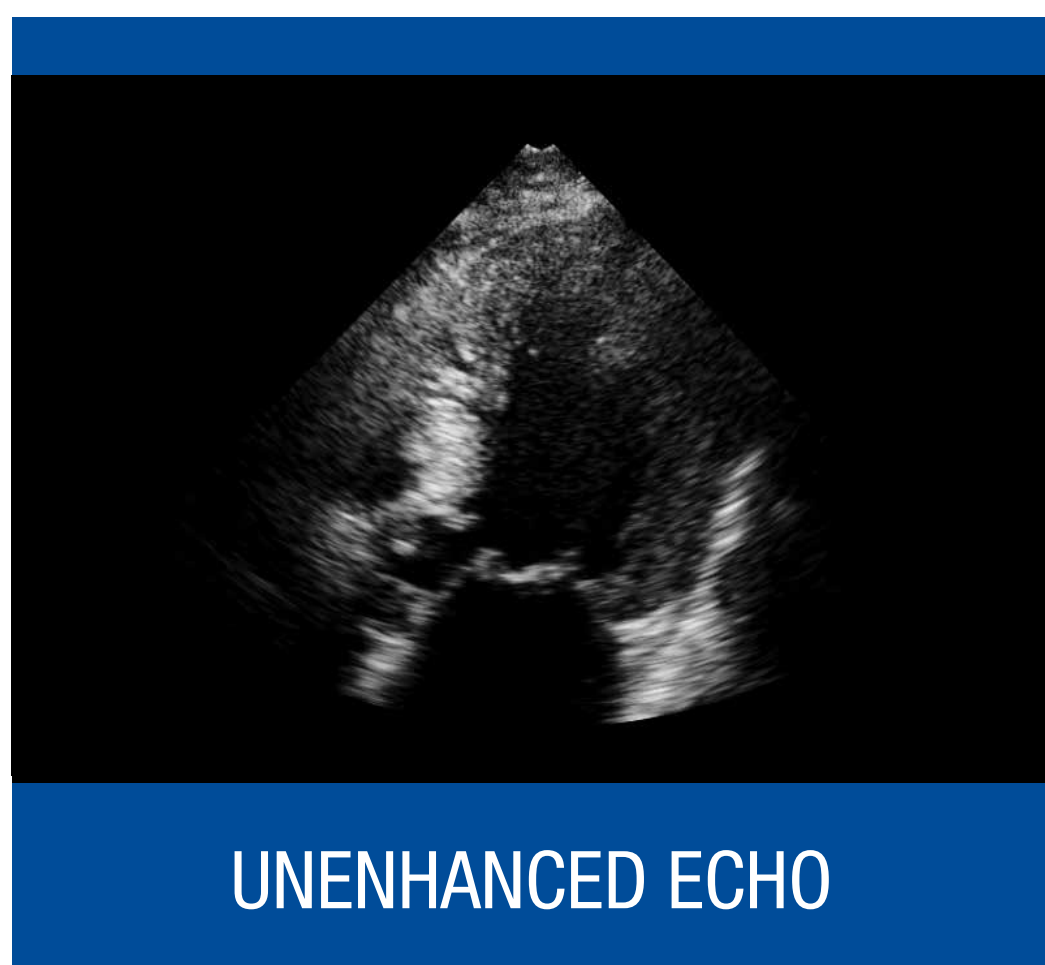
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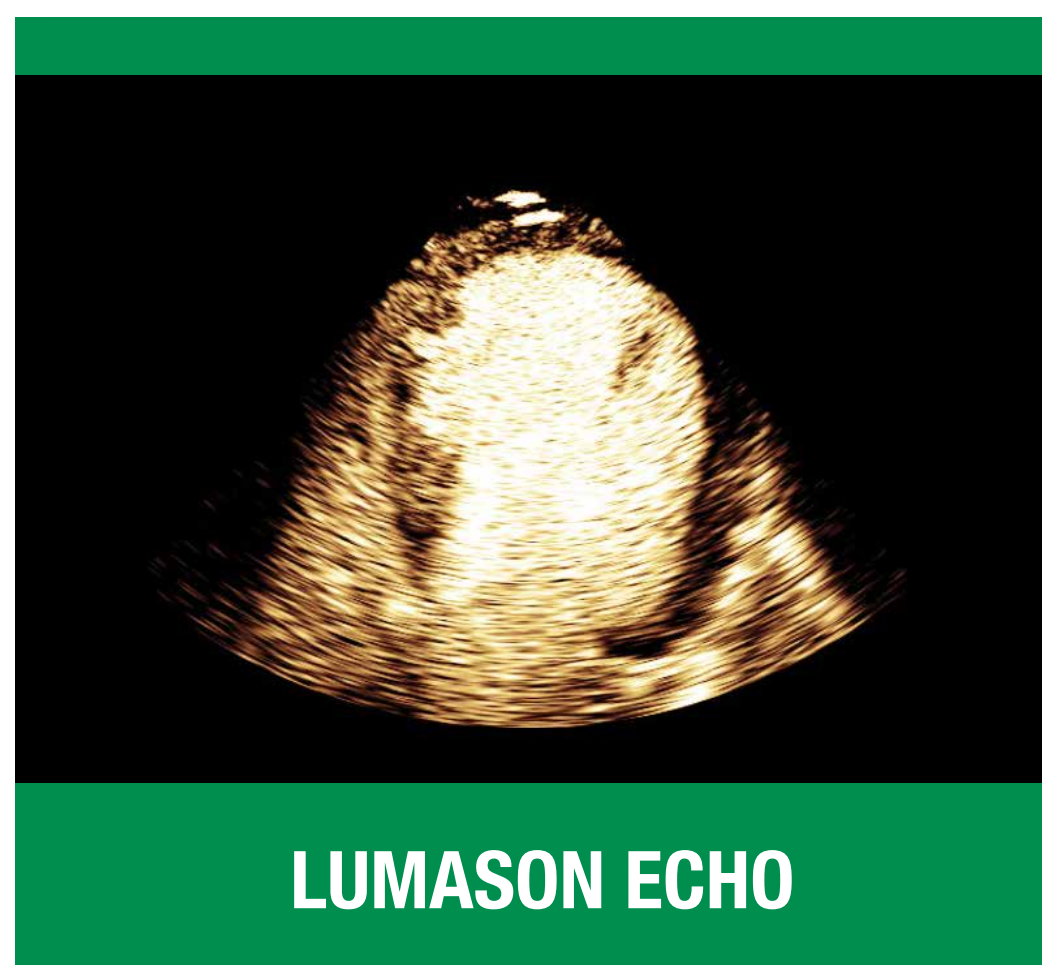


## IMAGE NOW WITH PROVEN EFFICACY AND SAFETY

LUMASON helped enhance image quality by improving  
**endocardial border delineation**<sup>1†</sup>



UNENHANCED ECHO



LUMASON ECHO

**LUMASON resulted in reduction in percentage of patients with inadequate border delineation.<sup>1</sup>**

Echocardiographic images are courtesy of Nicola Gaibazzi, Cardiology Department, Parma University Hospital, Parma, Italy.  
Individual results may vary.

## Administration of LUMASON improved left ventricular border delineation.<sup>1†</sup>

<sup>†</sup>Study design: 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 resulted in reduction in percentage of patients with inadequate border delineation.

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Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In the LUMASON completed clinical trials, 6856 adult patients were exposed to LUMASON; the most commonly reported adverse reactions (occurring in at least 0.2% of patients) are listed below.

**Adverse Reactions in Patients\* (n=6856)<sup>1</sup>**

Number (%) of Patients with Adverse Reactions	Headache	Nausea	Dysgeusia	Injection-site pain	Feeling hot	Chest discomfort	Chest pain	Dizziness	Injection-site warmth
340 (5%)	65 (1%)	37 (0.5%)	29 (0.4%)	23 (0.3%)	18 (0.3%)	17 (0.2%)	12 (0.2%)	11 (0.2%)	11 (0.2%)

\*occurring in at least 0.2% of patients

**Most adverse reactions were mild to moderate in intensity and resolved spontaneously.<sup>1</sup>**

LUMASON is an ultrasound contrast agent made up of SF<sub>6</sub>-filled microspheres. LUMASON is not chemically related to sulfonamide antibiotics.<sup>1</sup>

Sulfur hexafluoride gas in LUMASON is inert and undergoes little or no biotransformation<sup>1</sup>

LUMASON microspheres are constructed of sulfur hexafluoride gas in a highly elastic shell<sup>2</sup>

- ≥99% of LUMASON microspheres are ≤10 μm<sup>1</sup>
  - Upper size limit: 100% of LUMASON microspheres are ≤20 μm<sup>1</sup>
- Designed to be stable and resist pressure changes<sup>2</sup>
- Acoustic properties constant over the entire range of frequencies used in clinical settings<sup>3</sup>

Small **spheres** make a big difference



**LUMASON is known globally as SonoVue<sup>®</sup> which has been administered to millions of patients worldwide since its first approval in 2001.<sup>4</sup>**

The individuals who appear are for illustrative purposes only. All persons depicted are models and not real patients or healthcare professionals.

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## ADMINISTER—IN VARIOUS CLINICAL SETTINGS



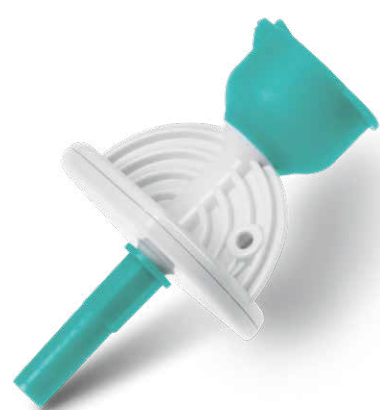
Portable kit

- Single patient-use procedural kit<sup>1</sup>
- Simple-to-use
  - Shake vigorously for 20 seconds until homogeneous white milky liquid forms
  - No activation device required



1

LUMASON Vial



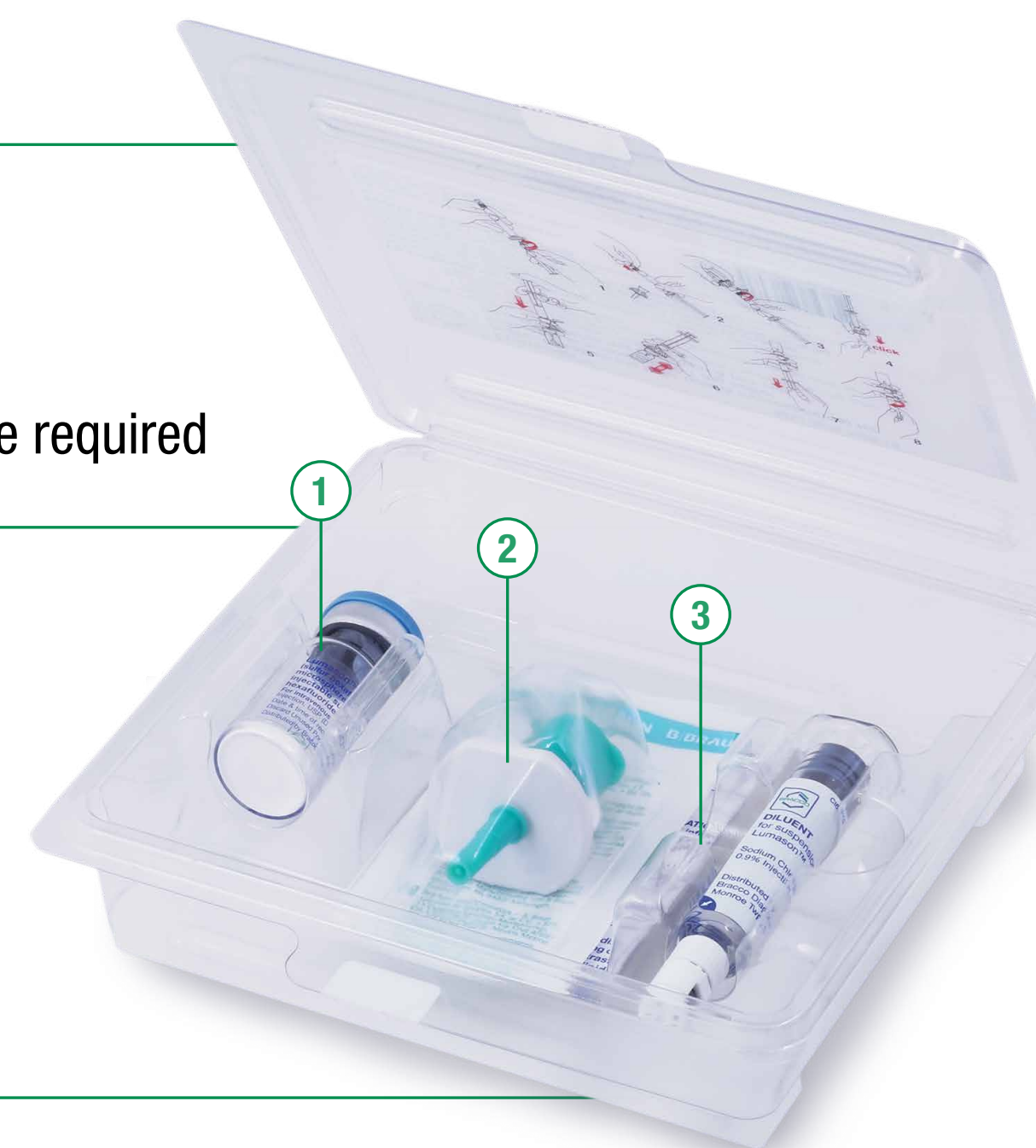
2

Mini-spike



3

Prefilled syringe containing  
5 mL Sodium Chloride 0.9%  
injection, USP (diluent)<sup>1</sup>



Safe and effective in patients like those you care for every day<sup>1</sup>



Among ultrasound contrast

**Only LUMASON does not require refrigeration**

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## BRACCO SUPPORT—YOUR INSIGHT, OUR SOLUTIONS

Products and programs from a global leader in contrast imaging solutions

### Dedicated Clinical Applications Team

Supports clinicians, educational programs, and product evaluations

### Dedicated Account Managers

Focus on the clinical and economic value of LUMASON

### Medical Education

Peer-to-peer and from internal Bracco medical staff

### Corporate Investment and Resources

Support societies and the ultrasound imaging community

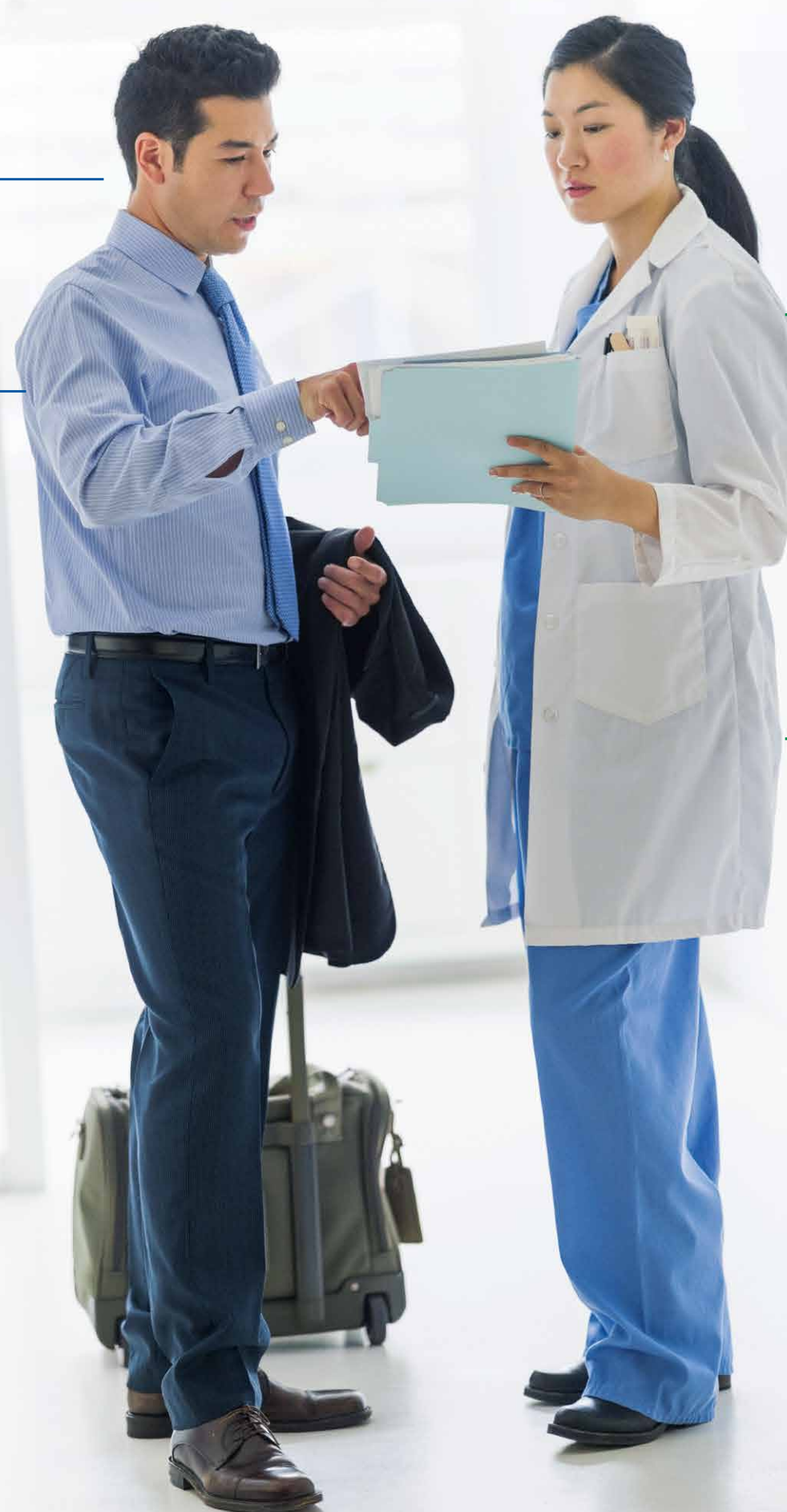
### New Technology Reimbursement

LUMASON is the only agent with a dedicated pass-through code:  
[https://www.braccoimaging.com/sites/braccoimaging.com/files/technica\\_sheet\\_pdf/us-en-2018-01-30-reimbursement-kit-lumason.pdf](https://www.braccoimaging.com/sites/braccoimaging.com/files/technica_sheet_pdf/us-en-2018-01-30-reimbursement-kit-lumason.pdf)

### Dedicated Reimbursement Hotline

For ongoing reimbursement assistance:  
Call **1-800-349-1388** or email [askbracco@reimbursement.bracco.com](mailto:askbracco@reimbursement.bracco.com)

At Bracco Diagnostics Inc.,  
**Your Insight,  
Our Solutions**



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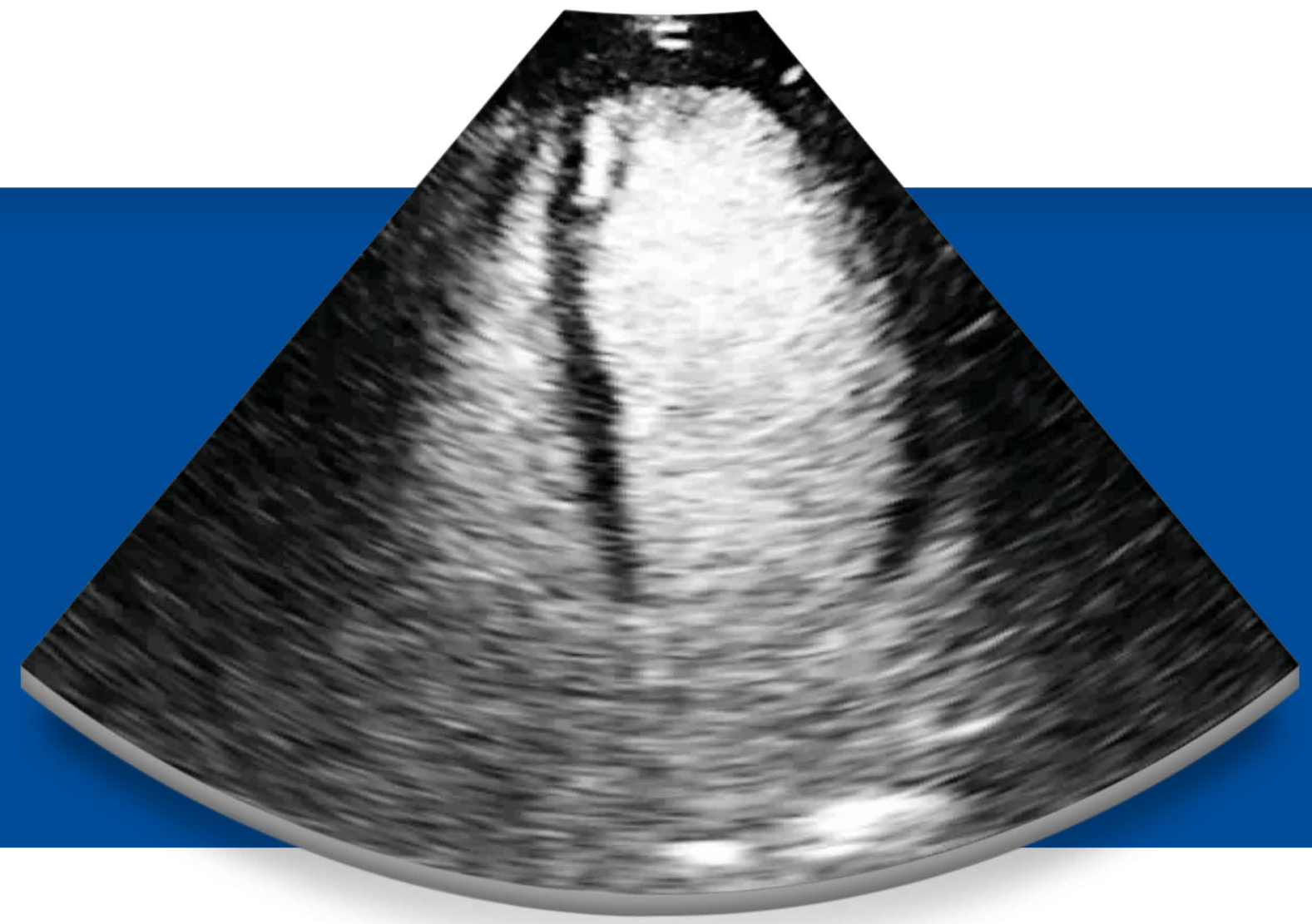
LIFE FROM INSIDE

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LUMASON helps you obtain quality diagnostic images at the point of patient care

-  Image quality<sup>1</sup>
-  Proven safety and efficacy profile<sup>1</sup>
-  Portable kit<sup>1</sup>
-  No refrigeration or activation devices required<sup>1</sup>
-  Support from Bracco Diagnostics Inc.—the company that understands your contrast imaging needs

## Ordering Information

<b>NDC#</b>	0270-7099-16
<b>Product description</b>	LUMASON (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use, 25 mg/vial
<b>Packaging</b>	5 kits per carton



Customer Service: 1-877-BRACCO 9 (1-877-272-2269)

**References:** 1. LUMASON (sulfur hexafluoride lipid-type A microspheres) for injectable suspension, for intravenous use or intravesical use full Prescribing Information. Monroe Twp., NJ: Bracco Diagnostics Inc.; December 2016. 2. Schneider M. Characteristics of SonoVue. *Echocardiography*. 1999;16(7, pt 2):743-746. 3. Schneider M, Arditi M, Barrau MB, et al. BR1: A new ultrasonographic contrast agent based on sulfur hexafluoride-filled microbubbles. *Invest Radiol*. 1995;30(8):451-457. 4. Data on file. Bracco Diagnostics Inc.

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LUMASON is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by Bracco Suisse S.A., 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).

LUMASON is a registered trademark of Bracco Diagnostics Inc. SonoVue is a registered trademark of Bracco Suisse S.A.

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