

# Bracco Shapes the Future of Radiology at RSNA 2025 Annual Meeting

Integrating Innovation, Education, Sustainability, and Trust to Transform Radiology

**10 NOVEMBER 2025, PRINCETON, NJ** – Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., a leading global company in the diagnostic imaging business, will showcase a bold vision for radiology at the Radiological Society of North America (RSNA) 2025 Annual Meeting, to be held November 30 – December 4 in Chicago, Illinois. Guided by its four core pillars—innovation, education, sustainability, and trust—Bracco will highlight its purpose-driven approach and latest advances across imaging modalities. This year's theme, "Our journey to the future continues today, together, for a sustainable tomorrow," reflects Bracco's commitment to partnering with customers and the radiology community to advance patient care while protecting the planet.

# **Bracco Champions Next-Gen Radiology Education**

For more than two decades, Bracco has made education a cornerstone of progress in radiology. In 2024 alone, Bracco's educational programs reached over 100,000 healthcare professionals worldwide, supported by over 80 active accredited programs and more than \$1.4 million in medical education grants.<sup>1,2,3</sup>

This year, Bracco will introduce *Exploring the Future of MRI Innovation*, an immersive and interactive booth learning activity that guides radiologists, technologists, and administrators through a virtual four-room journey spanning the entire Magnetic Resonance Imaging (MRI) experience, beginning in the waiting room and concluding with sustainability. The platform will offer peer-reviewed insights and knowledge checks that simulate real-world decision-making scenarios. As part of Bracco's commitment to advancing education and environmental responsibility, Bracco will make a corporate donation to independent charitable organizations focused on radiology education and sustainability initiatives. Upon completing the journey, participants will have the opportunity to help determine how Bracco allocates this donation among the selected charitable organizations.

"At RSNA 2025, we're not just showcasing our vision, we're inviting the radiology community to step into it," said Noelle Heber, Executive Director, Radiology Platform, Bracco Americas. "Exploring the Future of MRI Innovation is a hands-on extension of our belief that advancing MR innovation means investing in how we learn, teach, and grow together. It reflects Bracco's role as a champion of education, a driver of innovation, and a trusted partner in the imaging community."

Bracco will highlight the expanding role of Contrast-Enhanced Ultrasound (CEUS) in radiology. CEUS offers real-time diagnostic insights without ionizing radiation, making it an increasingly valuable tool. At RSNA 2025, Bracco will underscore CEUS's importance by convening leading experts to share evolving evidence, best practices, and new frontiers for the technology. In addition to advancing education and innovation, a commitment reinforced by <a href="Hexagon">Hexagon</a>, Bracco's new state-of-the-art Research, Development, and expanded production facility, Bracco is pioneering microbubble technology and accelerating progress in precision imaging.<sup>4</sup>

During RSNA, Bracco will also celebrate the winners of the <u>Leaders on the Horizon Residents' Program</u>, honoring six residents selected for publication in *Applied Radiology*.

# **Driving Innovation Sustainably**

Bracco is advancing healthcare innovation while reducing its environmental footprint. Cutting-edge sustainability practices include implementing reverse osmosis and energy efficiency upgrades at manufacturing sites, as well as partnering with customers for responsible stewardship of iodine.<sup>1</sup>



A <u>Platinum Medal from EcoVadis</u> in 2025 places Bracco among the top 1% most sustainable companies worldwide. As a member of the United Nations Global Compact, the company upholds high standards of ecological and operational excellence.<sup>1</sup>

As part of this commitment, Bracco will host a symposium at RSNA 2025: "The Power of Sustainable Innovation in MRI: Combining AI with Low-Dose GBCA and Rapid-Exchange Contrast Delivery System" on December 1 from 10:30-11:30 AM CST in booth 2387 (South Hall). This one-hour session will feature three leading imaging experts discussing practical strategies for elevating sustainability in the MR suite through advanced contrast delivery, low-dose agents, and AI-powered imaging.

At RSNA 2025, Bracco will highlight its MR portfolio with products designed to reduce waste, lower gadolinium exposure, and lessen environmental impact:

- VUEWAY® (gadopiclenol) solution for injection, intravenous use, a macrocyclic gadolinium-based contrast agent (GBCA), has achieved 3 million doses. VUEWAY injection offers effective contrast enhancement at half the gadolinium (Gd) dose (0.05 mmol/kg) vs. a macrocyclic GBCA at a dose of 0.1 mmol/kg of other similar contrast media for approved indications in the U.S., which can help address the unmet medical need to minimize Gd exposure per MRI procedure, and Gd excretion into the environment, without compromising image quality. The procedure is a macrocyclic gadolinium-based contrast agent (GBCA), has achieved 3 million doses. VUEWAY injection offers effective contrast enhancement at half the gadolinium (Gd) dose (0.05 mmol/kg) vs. a macrocyclic gadolinium-based contrast agent (GBCA), has achieved 3 million doses. VUEWAY injection offers effective contrast enhancement at half the gadolinium (Gd) dose (0.05 mmol/kg) vs. a macrocyclic GBCA at a dose of 0.1 mmol/kg of other similar contrast media for approved indications in the U.S., which can help address the unmet medical need to minimize Gd exposure per MRI procedure, and Gd excretion into the environment, without compromising image quality. The procedure is a macrocyclic gadolinium of the unit of the unit
- Beyond VUEWAY injection, Bracco is proud to offer the **Max 3™**, a Rapid Exchange and Syringeless MR Injector that is a first of its kind in the MRI space, empowering intuitive, efficient, and easy-to-manage workflow and supporting best practices in radiology sustainability. This injector will strengthen green efforts in radiology suites because it will help contribute less plastic to healthcare facilities' disposable process and costs.¹
- AiMIFY<sup>TM</sup> Software is the solution for Al-powered contrast enhancement in MR imaging in the U.S. exclusively from Bracco and Subtle Medical. FDA cleared as a class II software medical device; it is intended for image enhancement in brain MRI. AiMIFY software amplifies image contrast enhancement up to two times the level obtained with a labeled dose of a GBCA, significantly improving the visibility of small and large lesions compared to standard post-contrast images. AiMIFY software can support Neuroradiologists' diagnostic confidence and offers a potentially safer alternative to increasing contrast beyond FDA-approved dosing. For more information, visit the Bracco booth #1911 and the Subtle Medical booth #4724, South Hall, Level 3.

"At this year's RSNA, we are proud to highlight how Bracco's commitment to education and sustainability go hand in hand to drive meaningful progress," said Cosimo De Pinto, Executive Vice President, Marketing & Commercial Operations, Bracco Americas. "By advancing solutions that reduce environmental impact, we are ensuring that innovation benefits both patients and the planet. Together with our partners, we are shaping a healthier, more sustainable future for radiology."

Visit Bracco at RSNA in booth #1911, South Hall, Level 3. Follow #BraccoImaging on LinkedIn for the latest updates.

# Please see Important Safety Information below.

# VUEWAY® (gadopiclenol) solution for injection, intravenous use

#### **Indications**

VUEWAY injection is indicated in adults and children aged 2 years and older for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in:

- the central nervous system (brain, spine, and associated tissues),
- the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).



# IMPORTANT SAFETY INFORMATION WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

# **Risk Associated with Intrathecal Use**

Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. VUEWAY is not approved for intrathecal use.

# **NEPHROGENIC SYSTEMIC FIBROSIS**

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

- The risk for NSF appears highest among patients with:
- Chronic, severe kidney disease (GFR < 30 mL/min/1.73 m2), or
- Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For
  patients at risk for chronically reduced renal function (e.g., age > 60 years, hypertension, diabetes),
  estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended VUEWAY dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

#### **Contraindications**

VUEWAY injection is contraindicated in patients with history of hypersensitivity reactions to VUEWAY.

#### **Warnings and Precautions**

There are **risks associated with intrathecal use** of GBCAs that can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of VUEWAY have not been established with intrathecal use and VUEWAY is not approved for intrathecal use.

Risk of **nephrogenic systemic fibrosis** is increased in patients using GBCA agents that have impaired elimination of the drugs, with the highest risk in patients with chronic, severe kidney disease as well as patients with acute kidney injury. Avoid use of GBCAs among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities.

**Hypersensitivity reactions**, including serious hypersensitivity reactions, could occur during use or shortly following VUEWAY administration. Assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders, administer VUEWAY only in situations where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions, and observe patients for signs and symptoms of hypersensitivity reactions after administration.

**Gadolinium retention** can be for months or years in several organs after administration. The highest concentrations (nanomoles per gram of tissue) have been identified in the bone, followed by other organs (brain, skin, kidney, liver and spleen). Minimize repetitive GBCA imaging studies, particularly closely spaced studies, when possible.

**Acute kidney injury** requiring dialysis has occurred with the use of GBCAs in patients with chronically reduced renal function. The risk of acute kidney injury may increase with increasing dose of the contrast agent.



**Extravasation and injection site reactions** can occur with administration of VUEWAY. Ensure catheter and venous patency before the injection of VUEWAY.

VUEWAY may **impair the visualization of lesions** seen on non-contrast MRI. Therefore, caution should be exercised when VUEWAY MRI scans are interpreted without a companion non-contrast MRI scan.

The most common adverse reactions (incidence ≥ 0.5%) are injection site pain (0.7%), and headache (0.7%).

#### **POST-MARKETING EVENTS**

The following adverse reactions have been identified during postmarketing use of GBCAs.

Gastrointestinal Disorders: Acute pancreatitis with onset within 48 hours after GBCA administration.

Respiratory, Thoracic and Mediastinal Disorders: Acute respiratory distress syndrome, pulmonary edema.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

Please click <u>here</u> for full Prescribing Information for VUEWAY (gadopiclenol) solution for injection, intravenous use, including BOXED WARNING on Nephrogenic Systemic Fibrosis.

Manufactured for Bracco Diagnostics Inc. by Liebel-Flarsheim Company LLC - Raleigh, NC, USA 27616.

VUEWAY is a registered trademark of Bracco Imaging S.p.A.

ulricheasyINJECT Max 3<sup>™</sup> (the Bracco-branded Max 3<sup>™</sup>, a Rapid Exchange and Syringeless MR Injector System) is distributed by Bracco Diagnostics Inc.

#### Indications for use

ulrich**easy**INJECT Max 3 is a contrast media (CM) management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in magnetic resonance (MR) applications.

ulrich**easy**INJECT Max 3 (XD 10180) is specifically indicated for use in MRI procedures for the delivery of VUEWAY® (gadopiclenol) solution for injection – Bracco Diagnostics Inc., MultiHance® (gadobenate dimeglumine) injection – Bracco Diagnostics Inc., Clariscan™ (gadoterate meglumine) injection – GE Healthcare Inc., DOTAREM® (gadoterate meglumine) Injection – Guerbet, LLC, Gadavist® (gadobutrol) injection – Bayer HealthCare Pharmaceuticals Inc., and Gadobutrol Injection – Fresenius Kabi AG, contrast media as supplied in approved single dose vials and Gadavist (gadobutrol) Injection – Bayer HealthCare Pharmaceuticals Inc. and Gadobutrol Injection – Fresenius Kabi AG, contrast media as supplied in approved Imaging Bulk Packages (IBPs).

The ulricheasyINJECT Max 3 is not intended for injection of contrast media for high-pressure angiography.

Easy-Click-Cassette – flex Max 3 is used for a maximum time of twenty-four (24) hours or a maximum of 96 bottles of contrast media, whichever comes first.

Use time expiration per single dose contrast media container is a maximum of four (4) hours per contrast media container, unless otherwise stated by the contrast media labeling.

Use time expiration per IBP contrast media container is a maximum of twenty-four (24) hours per contrast media container, unless otherwise stated by the contrast media labeling.

Spike for MRI disposable is for single-bottle use only and must be discarded with the media container. The Patient tubing must be discarded after each patient procedure.



ulrich**easy**INJECT Max 3 (XD 10180) is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.

# **Contraindications**

ulrich**easy**INJECT Max 3 injectors are not intended for the administration of contrast medium during high-pressure angiography or other applications that do not comply with the intended use.

The injector is not protected against the effects of defibrillation. Before a defibrillator is used, the patient must be disconnected from the ulricheasyINJECT Max 3 injector.

Do not add any disposables (i.e. connector tubing or valves) to the ulrich **easy**INJECT Max 3 with the patient tubing that are not provided by ulrich medical. No valves or other connectors may be placed in-line between the patient tubing and the patient cannula. The disposables identified in this IFU are designed, manufactured, and tested for connection with cannulas for pressure injections.

Do not use ulrich**easy**INJECT Max 3 injectors with any other contrast media (other than those described in the IFU). Any other contrast media are inappropriate and should not be used. Do not operate the injector and terminal, including any accessories, in potentially explosive atmospheres or in the vicinity of combustible materials (especially anesthetic drugs, detergents, and oxygen-enriched environments).

ulricheasyINJECT Max 3 is manufactured by ulrich GmbH & Co. KG.

ulrich medical is a registered trademark of ulrich GmbH & Co. KG.

ulricheasyINJECT Max 3 is a trademark of ulrich GmbH & Co. KG.

ulrich**easy**INJECT Max 3 is distributed as the Bracco-branded Max 3, a Rapid Exchange and Syringeless MR Injector System, by Bracco Diagnostics Inc.; 510 Carnegie Center, Suite 300, Princeton, NJ 08540 USA; Phone: (800) 631-5245; Fax: (609) 514-2424; Customer Service: 1-877-BRACCO 9 (1-877-272-2269); Scientific Information: 1-800-257-5181 (Option 2); Website: <a href="https://smartinject.com/max3/">https://smartinject.com/max3/</a>

#### AiMIFY™ Software

# **Indications for Use**

AiMIFY is an image processing software that can be used for image enhancement in MRI images. It can be used to increase contrast-to-noise ratio (CNR), contrast enhancement (CEP), and lesion-to-brain ratio (LBR) of enhancing tissue in brain MRI images acquired with a gadolinium-based contrast agent. It is intended to enhance MRI images acquired using standard approved dosage per the contrast agent's instructions for use.

#### **Cautions**

AiMIFY-enhanced images should not be used alone to assist patient diagnosis. The standard post-contrast image must always be reviewed first before using AiMIFY-enhanced images for patient diagnosis.

Please be aware that AiMIFY is not intended for artifact reduction, such as metal artifact and motion artifact. Enhanced images may have similar artifacts as input images.

AiMIFY may enhance intensity differences between pre-and post-contrast images that are caused by 1) registration errors between the sequences or 2) image artifacts in either sequence.



AiMIFY may enhance vessel conspicuity more than standard acquired post-contrast images. In cases where vessel conspicuity interferes with or delays diagnosis, the standard post-contrast image should be used for adjudication.

AiMIFY-enhanced images may contain false lesions due to enhancement of image quality issues in either input sequences, due to being introduced by the AiMIFY algorithm, or both. The standard post-contrast image should be used to rule out false lesions.

Please be aware that AiMIFY has only been trained and tested on head MRI for contrast enhancement. Using the AiMIFY software in other anatomies or use cases not defined in this user manual could result in unknown image enhancement performance.

The internal morphology of tissue in input sequences have been tested to be moderately preserved by AiMIFY processing both for lesion tissue and parenchyma tissue. Internal morphology may appear to be missing due to window leveling of the image, and can be obtained by adjusting the window levels.

Please be aware that AiMIFY is intended for use only with standard of care quality images. Standard approved dose contrast images should be acquired per the contrast agent's instructions for use. The standard of care should not be adjusted in preparation for using AiMIFY.

Please be aware that AiMIFY should not be used for acquiring stat scans or emergent scans, as image processing time may delay diagnosis.

Standard approved dose contrast images should be acquired per the contrast agent's instructions for use. AiMIFY-enhanced images are not fully equivalent to post-contrast images acquired with a higher than recommended actual dosage of contrast. However, the high-dose-like appearance of AiMIFY-enhanced images offers a potentially safer alternative to actually acquiring post-contrast images beyond standard dosing.

#### **Contraindications**

AiMIFY is an image processing software that inherently doesn't cause harm to patients of any subpopulation. However, gadolinium-based contrast agents are associated with contraindications, precautions, and warnings for certain subpopulations. Strictly follow the gadolinium-based contrast agent's instructions for use, including but not limited to contraindicated patient populations, prior to processing with AiMIFY.

# Limitations

AiMIFY has been trained and tested using a diverse DICOM image dataset collected from different MR imaging applications at 0.3T, 1.5T, and 3.0T, including:

- TI weighted imaging for pre and post-contrast brain scans obtained with gadolinium-based contrast agents in 2D sequences, such as fluid-attenuated inversion recovery (FLAIR) and fast spin echo (FSE).
- TI weighted imaging for pre and post-contrast brain scans obtained with gadolinium-based contrast agents in 3D sequences, such as BRAin VOlume (BRAVO) inversion-recovery-prep fast split echo (SPGR) and Magnetization Prepared Rapid Gradient Echo (MPRAGE).
- Acquisition in axial, coronal, and sagittal orientations.
- Images acquired with GE Medical Systems, Philips Medical Systems, Siemens Healthineers, and Hitachi scanners (see separate Scanner List for models).
- Images (for performance testing) spanning a variety of pathologies including patients with Cerebritis, Glioma, Inflammation, Lymphoma, Meningioma, Metastatic lesions, Multiple sclerosis, Neuritis, other tumor-related lesions (e.g., resection/radiation necrosis / suspected cyst / etc.), and other abnormalities.
- Patients aged 7 to 86 years old with an even distribution of females and males in the test dataset.



Lesions in the dataset were small (<1 cc) and large (>1 cc).

Any imaging sequences/applications outside the above list may result in prolonged processing time and/or unreasonable results.

AiMIFY is manufactured for Bracco Diagnostics Inc. by Subtle Medical Inc. - Menlo Park, CA, USA 94025.

AiMIFY is a trademark of Bracco Imaging S.p.A.

All other trademarks and registered trademarks are the property of their respective owners.

For additional information about Bracco's products and for full prescribing information, please visit <a href="http://imaging.bracco.com/us-en">http://imaging.bracco.com/us-en</a>.

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- <sup>1</sup> Bracco 2024 Sustainability Report. Bracco Diagnostics Inc.; 2024.
- <sup>2</sup> Data on file. Over 80 Active Accredited Programs. Bracco Diagnostics Inc.; OCT 2024
- <sup>3</sup> Data on file. Over \$1.4M Invested in Medical Education Grants. Bracco Diagnostics Inc.; DEC. 2024.
- <sup>4</sup> <u>Hexagon: A New Era Begins</u>, Bracco Diagnostics Inc.; JAN 2025.
- <sup>5</sup> Data on file. Three Million Doses. Bracco Diagnostics Inc.; SEPT 2025.
- <sup>6</sup> VUEWAY® (gadopiclenol) solution for injection, intravenous use. Full Prescribing Information and Patient Medication Guide. Princeton, NJ: Bracco Diagnostics Inc.; March 2025.
- <sup>7</sup> Loevner LA, Kolumban B, Hutóczki G, et al. <u>Efficacy and safety of gadopiclenol for contrast-enhanced MRI of the central nervous system: the PICTURE randomized clinical trial</u>. *Invest Radiol*. 2023 May;58(5):307-313.
- <sup>8</sup> Dekker HM, Stroomberg GJ, Van der Molen AJ, Prokop M. <u>Review of strategies to reduce the contamination of the water environment by gadolinium-based contrast agents</u>. Insights Imaging. 2024 Feb 27;15(1):62. doi: 10.1186/s13244-024-01626-7. PMID: 38411847; PMCID: PMCI0899148.
- <sup>9</sup> Please refer to the AiMIFY User Manual for full safety and use information.

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The company is committed to advancing radiology by sharing knowledge to cultivate future thought leaders, linking today's practice with tomorrow's progress. Since 1927, Bracco Imaging has grown to more than 3,800 employees and now supports patients and radiology professionals in over 100 countries.

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