FDA Approves Expanded Indication for Max 3™ Syringeless MR Injector from Bracco

FDA Approval of VUEWAY® (gadopiclenol) injection Imaging Bulk Package (IBP) Enhances Options for Efficient, Sustainable MRI Contrast Delivery

25 NOVEMBER 2025, PRINCETON, NJ – Bracco Diagnostics Inc., the U.S. subsidiary of Bracco Imaging S.p.A., a global leader in diagnostic imaging, announced today that the U.S. Food and Drug Administration (FDA) has expanded the indication for the Bracco-branded Max 3™, a Rapid Exchange and Syringeless Injector for use in magnetic resonance imaging (MRI) procedures. In addition to single-dose and multi-dose vials, the Max 3™ system is now indicated for use with the newly approved VUEWAY® (gadopiclenol) injection Imaging Bulk Package (IBP) in 30 mL and 50 mL formats.

The Max 3™ injector is the first and only syringeless MRI injector available on the U.S. market. It is engineered for precise, efficient, and hygienic contrast delivery. The system simplifies MRI contrast administration with intuitive, step-by-step guidance via its user interface, helping technologists perform procedures quickly, confidently, and consistently. Its flexible design accommodates both single-use vials and multi-dose IBPs, allowing hospitals to tailor contrast delivery to their workflow, patient volume, and sustainability goals.

The FDA approval of Bracco's VUEWAY® IBP provides a new option for hospitals seeking to improve workflow and reduce waste when using an FDA-Cleared automated contrast injection system, such as the Max 3™. With its multi-dose packaging design, VUEWAY® IBP enables the delivery of multiple single doses of contrast from one container, ensuring aseptic handling, reduced material waste, and more efficient use of contrast agents.

VUEWAY® (gadopiclenol) solution for injection, intravenous use provides effective contrast enhancement at half the gadolinium dose compared to other macrocyclic GBCAs for approved indications in the U.S., offering an additional layer of patient and environmental benefit.[1,2] To date, more than three million[3] VUEWAY® injections have been administered at over 902 customer sites,[4] underscoring its growing role in high-quality MR imaging.

"This expanded presentation to our VUEWAY® product line and the Bracco MR family of MRI solutions underscores Bracco's ongoing commitment to advancing performance, efficiency, and sustainability in MRI contrast delivery," said Gary Ray, Associate Director, MR Marketing, Bracco Americas. "These innovations reflect our mission to empower hospitals with flexible solutions that reduce waste, streamline workflow, and uphold the highest standards of quality and sterility across the imaging suite."

This milestone also reinforces Bracco's longstanding commitment to driving innovation while supporting environmental stewardship. The company has implemented sustainable manufacturing practices—including reverse osmosis and energy efficiency upgrades—and continues to develop products that reduce gadolinium exposure, plastic waste, and environmental burden.[5]

To learn more about VUEWAY® IBP or the Max 3™ injector, and how Bracco is advancing precision dosing and sustainable imaging, visit https://braccomr.com/.

Please see Important Safety Information below.

VUEWAY® (gadopiclenol) injection for intravenous use

Dosage Forms

VUEWAY® is available in single-dose vials, single-dose prefilled syringes, and an imaging bulk package.

The VUEWAY Imaging Bulk Package is used for dispensing multiple single doses of gadopiclenol injection for multiple patients, using an automated contrast injection system, or contrast management system approved or cleared for use with this contrast agent in this Imaging Bulk Package. See drug and device labeling for information on devices indicated for use with this Imaging Bulk Package and techniques to help assure safe 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 www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full Prescribing Information for VUEWAY (gadopiclenol) solution for injection 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™ (the Bracco-branded Max 3™, a Rapid Exchange and Syringeless MR Injector System) is distributed by Bracco Diagnostics Inc.

Indications for use

ulrich**easy**INJECT Max 3 (XD 10180) is a contrast media 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.

ulricheasyINJECT Max 3 (XD 10180) is specifically indicated for use in MRI procedures for the delivery of the following contrast media:

• Gadobutrol Injection in single-dose (SD) container or Imaging Bulk Package (IBP)

• Gadopiclenol Injection in SD container or IBP

• Gadobenate dimeglumine Injection in SD container

• Gadoterate meglumine Injection in SD container

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 SD container is a maximum of four (4) hours, unless otherwise stated by the contrast media labeling.

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

The ulrich**easy**INJECT Max 3 (XD 10180) is not intended for injection of contrast media (CM) for high-pressure angiography.

Contraindications

The ulricheasyINJECT 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 ulrich**easy**INJECT Max 3 injector.

Do not add any disposables (i.e. connector tubing or valves) to the ulricheasyINJECT Max 3 disposables or in conjunction 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 this 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).

ulrich**easy**INJECT Max 3 is manufactured by ulrich GmbH & Co. KG.

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

ulrich**easy**INJECT 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: https://smartinject.com/max3/

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

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[1] VUEWAY® (gadopiclenol) solution for injection, intravenous use. Full Prescribing Information and Patient Medication Guide. Princeton, NJ: Bracco Diagnostics Inc.; March 2025.
[2] Loevner LA, Kolumban B, Hutóczki G, et al. Efficacy and safety of gadopiclenol for contrast-enhanced MRI of the central nervous system: the PICTURE randomized clinical trial. *Invest Radiol*. 2023 May;58(5):307-313.
[3] Data on file. Three Million Doses. Bracco Diagnostics Inc.; September 2025.
[4] Data on file. No. of Accounts. Bracco Diagnostics Inc.; September 2025.
[5] Bracco 2024 Sustainability Report.

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Kimberly Gerweck
Media Relations (USA)
Sr. Compliance & Communications Manager
Bracco Diagnostics Inc.

T +1 609.524.2777
BDIMediaContact@diag.bracco.com

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Bracco Imaging is a global leader in diagnostic imaging, dedicated to improving people's lives by shaping the future of prevention and precision medicine. With a strong passion for innovation, the company develops and provides a broad portfolio of pharmaceutical products for diagnostic imaging: contrast agents for X-ray, Computed Tomography (CT), and Magnetic Resonance Imaging (MRI), as well microbubbles for Contrast Enhanced Ultrasound (CEUS), and Molecular Imaging through radioactive tracers and novel PET imaging agents, alongside specialized medical devices and related services.

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.

Discover Bracco Imaging at www.bracco.com