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 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 ulrich**easy**INJECT 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 ulrich**easy**INJECT 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).

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

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

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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/

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