CONSUMABLES FOR INJECTORS AND CONTRAST DELIVERY SYSTEMS

MR Suite

Max 3™

Max 3™ Saline Spike

SKU 019733

Quantity 30/CS

Description of Product Use Designed for administration of saline for use in Max 3 MR Injector. Includes a saline tag for multidose use.

Max 3™ Contrast Media Spike (Two sizes available)

SKU **Large:** 019734 **Small:** 019735

Quantity 30/CS

Description of Product Use Designed for administration of MR contrast media for use in Max 3 MR Injector.

Max 3™ Patient Tubing (Two sizes available)

SKU **98 in:** 019738 **126 in:** 019739

Quantity 100/CS

Description of Product Use Single use patient tubing with double check valves. Available in 250 cm or 320 cm length. For use in Max 3 MR Injector.

Max 3™ Easy-Click-Cassette (Approved for 24-hour use)

SKU 019713

Quantity 10/CS

Description of Product Use A 24-hour, or 96 injections, day set with RFID chip that ensures it cannot be used again after the period has expired. Includes three direct media connection points – 2 for contrast and 1 for saline. For use in Max 3 MR Injector.

Max 3™ Adapter

SKU 19877

Quantity 100/CS

Description of Product Use For use with small contrast media vials.

EmpowerMR® Injector System

FastLoad™ MR Syringe Pack

SKU 017356

Quantity 50/CS

Description of Product Use Syringe tray includes: 2 100 mL syringes, 1 MR connecting tube w/ bifurcated “Y” one-way check valve, 2 vented spikes for contrast & saline. For use w/ EmpowerMR® Injector System.

CT Suite

EmpowerCTA®+ Injector System

FastLoad™ CTA Dual Syringe Pack

SKU 017354

Quantity 20/CS

Description of Product Use Syringe tray includes: 2 Disposable 200 mL syringes w/ administration set, 60" low-pressure extension set, bifurcated “Y” one-way check valve and a fill tube. For use w/ EmpowerCTA®+ Injector System.

FastLoad™ CTA Dual Syringe Pack with Spikes

SKU 017355

Quantity 20/CS

Description of Product Use Syringe tray includes: (2) Disposable 200 mL syringes w/ administration set, 60” low-pressure extension set, bifurcated “Y” one-way check valve and (2) spikes. For use w/ EmpowerCTA®+ Injector System.

FastLoad™ CT Syringe Pack with Spike

SKU 017345

Quantity 50/CS

Description of Product Use Disposable 200 mL syringe w/ 60” low-pressure extension set and 1 spike. For use w/ EmpowerCTA®+ Injector System.

FastLoad™ CT Syringe Pack

SKU 017344

Quantity 50/CS

Description of Product Use Disposable 200mL syringe w/ 60” low-pressure extension set and a fill tube. For use w/EmpowerCTA®+ Injector System.

EmpowerCTA®+ “Y” Connecting Tubing

SKU 100114

Quantity 100/CS

Description of Product Use Administration Set for use w/ EmpowerCTA®+ Injector System. Useful when utilizing two single syringes on procedures requiring saline delivery.

Imaging Bulk Pack Transfer Set

SKU 017349

Quantity 100/CS

Description of Product Use For use with ISOVUE® (Iopamidol Injection) Imaging Bulk Package to transfer contrast into empty syringes in the CT Suite.

60” Coiled Connector Tube

SKU 100113

Quantity 100/CS

Description of Product Use For use in procedures requiring an extension tubing set. Includes 100 60” low-pressure single use sets.

Fluid Transfer Set

SKU 100115

Quantity 100/CS

Description of Product Use Used for transferring contrast and saline from bottles/bags to Empower branded syringes. Includes 100 20” single use sets.

To learn more about how you can place an order, how we can help you, or how you may obtain additional information about our products, please select one of the following:

Telephone: 1-877-BRACCO 9 (1-877-272-2269)
Fax: 1-866-272-1619
Email: BRACCOOTC@diag.bracco.com
Hours of Operation: M-F 8:30 AM - 6:00 PM (EST), excluding holidays

UNLOCKING THE INVISIBLE

BRACCO
LIFE FROM INSIDE

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.

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/

EmpowerCTA®+ Injector System

Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS:
The EmpowerCTA®+ Injector System is indicated for the vascular administration of contrast and flushing media in conjunction with computed tomography (CT) scanning of the body with an optional interface to a CT scanner and an optional calculator for glomerular filtration rate (GFR).

Protocols have been independently developed and are not intended as medical advice. Bracco and Bracco Injeneering S.A. shall not be responsible for any physicians' reliance on these or any other products.

CONTRAINDICATIONS:
The EmpowerCTA®+ Injector System is not intended for use as a long-term infusion pump, nor is it intended to be used to inject any agents other than contrast or flushing media. Do not attempt to use the injector for any other purpose (such as chemotherapy or drug infusion). The EmpowerCTA+ Injector System should not be used to inject substances into nonvascular body cavities. Any applications of the EmpowerCTA+ Injector System other than those described in its Operator Manual are inappropriate and should not be attempted.

Not all products are available in all global markets.

EmpowerCTA+ is distributed 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); EmpowerCTA+ Email: empowerinfo@diag.bracco.com; Website: https://smartinject.com/ct-solutions/

EmpowerCTA+ is manufactured by Bracco Injeneering S.A., Avenue de Sevelin 46, CH – 1004 Lausanne, Switzerland.
https://www.bracco.com/

The Bracco Injeneering Transfer Set is a component of a contrast management system and is indicated for the transfer of ISOVUE® (iopamidol injection) contrast media as supplied in an Imaging Bulk Package to empty sterile syringes on single-use only syringe-based contrast injection systems indicated for the controlled, automatic administration on the venous side, of contrast agents for CT procedures. The Transfer Set is to be discarded after the contrast media container has been depleted or 10 hours have elapsed since the container was penetrated, whichever occurs first.

EmpowerMR® Injector System

Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS:
The EmpowerMR® Injector System is indicated for vascular administration of contrast media and flushing media in conjunction with magnetic resonance imaging (MRI).

Protocols have been independently developed and are not intended as medical advice, and Bracco shall not be responsible for any physicians' reliance on these or any other protocols.

Bracco Injeneering S.A. reserves the right at any time and without notice, to change the specifications and features described herein, or to change the production or adjust the product described.

Not all products are available in all global markets.

EmpowerMR is distributed 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/mr-solutions/

EmpowerMR is manufactured for Bracco Injeneering S.A., Avenue de Sevelin 46 CH – 1004 Lausanne, Switzerland.
https://www.bracco.com/

About Bracco Injeneering S.A.
Bracco Injeneering S.A., located in Lausanne, Switzerland, is the most recently added Business Unit of Bracco Imaging. Bracco Injeneering is committed to developing the best-in-class integrated injection solutions with a strong heritage in research and innovation. It provides quality solutions for state-of-the-art radiology centers, offering proven injection technology built on Bracco Imaging's expertise.

Thanks to this strengthened product portfolio, including the CT Exprès 3D Contrast Media Delivery System, EmpowerCTA+ Injector System, EmpowerMR® Injector System, and NEXO® Contrast Management System, Bracco Imaging will be able to focus on constant innovation, not only for devices but also for software development and data management.

CT Exprès, EmpowerCTA, EmpowerMR, IRiSCT, IRiSMR, and NEXO are registered trademarks of ACIST Medical Systems, Inc.

FastLoad is a trademark of ACIST Medical Systems, Inc.

ISOVUE®-300, -370 (Iopamidol Injection) Imaging Bulk Package

INDICATION:
ISOVUE®-300, -370 (Iopamidol Injection) Imaging Bulk Package is indicated for:

- angiography in adults throughout the cardiovascular system including cerebral and peripheral arteriography, coronary arteriography and ventriculography, selective visceral arteriography and aortography, peripheral venography (phlebography),
- in pediatric patients for angiocardiography
- in adult and pediatric intravenous excretory urography and contrast enhancement of computed tomographic (CECT) head and body imaging.
  - CT Head Imaging (to refine diagnostic precision in areas of the brain which may not have been satisfactorily visualized)
  - CT Body Imaging (enhancement of computed tomographic images for detection and evaluation of lesions in the liver, pancreas, kidneys, aorta, mediastinum, abdominal cavity, pelvis and retroperitoneal space).

For use only with an automated contrast injection system, contrast management system, or contrast media transfer set approved or cleared for use with ISOVUE-300, -370 Imaging Bulk Package.

ISOVUE-300, -370 Imaging Bulk Package is NOT FOR INTRATHECAL USE.

IMPORTANT SAFETY INFORMATION:

WARNINGS AND PRECAUTIONS
Severe Adverse Events-Inadvertent Intrathecal Administration
Serious adverse reactions including: death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema have been reported due to the inadvertent intrathecal administrations of iodinated contrast media that are not indicated for intrathecal use.

Special attention must be given to insure that this drug product is not inadvertently administered intrathecally.

Caution must be exercised in patients with severely impaired renal function, those with combined renal and hepatic disease, or anuria, particularly when larger or repeated doses are administered.

Clotting
Clotting has been reported when blood remains in contact with syringes containing nonionic contrast media. Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with both ionic and nonionic contrast media, therefore meticulous angiographic techniques are recommended in addition to minimizing the length of the procedure to help decrease in vitro clotting.

Patients with Multiple Myeloma or Paraproteinemia
Radiopaque diagnostic contrast agents are potentially hazardous in patients with multiple myeloma or other paraproteinemia, particularly in those with therapeutically resistant anuria. The risk in myelomatous patients is not a contraindication; however, special precautions are required.

Patients with Sickle Cell Disease
Contrast media may promote sickling in individuals who are homozygous for sickle cell disease when injected intravenously or intraarterially.

Patients with Pheochromocytoma
Administration of radiopaque materials to patients known or suspected of having pheochromocytoma should be performed with extreme caution. If the possible benefits of such procedures outweigh the considered risks, the procedures may be performed; however, the amount of radiopaque medium injected should be kept to an absolute minimum. The blood pressure should be assessed throughout the procedure and measures for treatment of a hypertensive crisis should be available. These patients should be monitored very closely during contrast enhanced procedures.

Thyroid Storm
The use of iodinated radiopaque diagnostic agents in patients with hyperthyroidism or with an autonomously functioning thyroid nodule suggest that this additional risk be evaluated in such patients before use of any contrast medium.

Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age
Hypothyroidism or transient thyroid suppression has been reported after both single and multiple exposures to iodinated contrast media.

Younger age, very low birth weight, prematurity, underlying medical conditions affecting thyroid function, admission to neonatal or pediatric intensive care units, and congenital cardiac conditions are associated with an increased risk of hypothyroidism after ICM exposure. Pediatric patients with congenital cardiac conditions may be at greatest risk given that they often require high doses of contrast during invasive cardiac procedures.

An underactive thyroid during early life may be harmful for cognitive and neurological development and may require thyroid hormone replacement therapy. After exposure to ICM, individualize thyroid function monitoring based on underlying risk factors, especially in term and preterm neonates.

Severe Cutaneous Adverse Reactions
Severe Cutaneous adverse reactions (SCAR) may develop from 1 hour to several weeks after intravascular contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN), acute generalized exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS). Reaction severity may increase and time to onset may decrease with repeat administration of contrast agent; prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions.

Acute Renal Impairment / Failure
Diabetic nephropathy may predispose to acute renal impairment following intravascular contrast media administration. Acute renal impairment following contrast media administration may precipitate lactic acidosis in patients who are taking biguanides.

Preparatory dehydration is dangerous and may contribute to acute renal failure in patients with advanced vascular disease, diabetic patients, and in susceptible nondiabetic patients (often elderly with preexisting renal disease). Patients should be well hydrated prior to and following iopamidol administration.

Hypersensitivity /Anaphylaxis
Patients at increased risk include those with a history of a previous reaction to a contrast medium, with a known sensitivity to iodine, with a known clinical hypersensitivity (bronchial asthma, hay fever, and food allergies). A thorough medical history with emphasis on allergy and hypersensitivity, prior to the injection of any contrast medium, may be more accurate than pretesting in predicting potential adverse reactions. Premedication with antihistamines or corticosteroids to avoid or minimize possible allergic reactions in such patients should be considered.

Patients with Congestive Heart Failure
The potential transitory increase in the circulatory osmotic load in patients with congestive heart failure requires caution during injection. These patients should be observed for several hours following the procedure to detect delayed hemodynamic disturbances.

DRUG INTERACTION
Renal toxicity has been reported in a few patients with liver dysfunction who were given oral cholecystographic agents followed by intravascular contrast agents. Postpone administration of intravascular agents in any patient with known or suspected hepatic or biliary disorder who has recently received a cholecystographic contrast agent.

ADVERSE REACTIONS
The most frequent adverse reactions are hot flashes, angina pectoris, flushing, bradycardia, hypotension, and hives.

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 ISOVUE® Imaging Bulk Package products.

ISOVUE Imaging Bulk Package is currently manufactured for Bracco Diagnostics Inc. at three locations: BIPSO GmbH, Singen (Germany), Patheon Italia S.p.A., Ferentino (Italy), and S. M. Farmaceutici SRL, Tito (Italy).

ISOVUE is a registered trademark of Bracco Diagnostics Inc.

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