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Medical Imaging Solutions International

MR ANGIOGRAPHIC SYRINGE

INSTRUCTIONS FOR USE

Please read the product instructions carefully to ensure safe and proper operation of this product.

Important safety precautions: This appliance is intended for use by personnel with experience in diagnostic angiographic procedures who have received appropriate training.

Compatible injector models:

This product is designed for use in contrast media injection procedures. It is compatible **only** with the contrast media injection systems from **Bracco Empower MR®**. This appliance is **intended for single use only**.

CONTRAINDICATIONS

This product is not intended for multiple purposes. It must not be used for drug injection, chemical treatment, or any other application not explicitly specified in the product instructions.

Compatibility: Equipment models Compatible with 101100A and with **Bracco Empower MR®** injectors.

REF	Product Description	Syringe Model #	Syringe Specifications
400302D	MR Angiographic Syringe	101100A	100mL Syringe

INTENDED USE

The **MR Angiographic Syringe** is intended for the injection of contrast media or physiological saline. This syringe is for **single use only** and is designed to be used with angiographic injectors that are legally marketed in the United States.

The syringe seal and connecting tubing are designed to withstand up to 350 psi of pressure without leaking when used with high-pressure injection equipment

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed physician.

WARNINGS

- Do **not** use a standard (common) intravenous needle. It is strongly recommended to use a **19G to 22G** high-pressure-resistant intravenous needle or a high-pressure-resistant central venous catheter. Failure to do so may result in bursting or leakage during injection.
- Risk of Air Embolism:** Air bubbles (air emboli) can cause serious injury or death. To minimize the risk, all air must be fully expelled from the syringe and connected tubing before injection.
- Single Use Only: Do not reuse** disposable products. Reuse or failure to follow proper aseptic technique may lead to **biological contamination** and pose serious risks to patient safety. **Discard the product immediately after use.**
- Risk of Contamination: Do not remove the piston** from the syringe. Doing so may lead to bacterial contamination of the injector, increasing the risk of patient infection. Always fill the syringe **according to the instructions for use**, without removing the piston.
- Do Not Store Filled Syringes:** Using the syringe to store contrast media may result in **bacterial contamination**. After filling, the syringe must be **used immediately**. Do **not** store a pre-filled syringe for later use. Any filled but unused syringe must be **discarded**.
- Do Not Use Damaged Packaging or Components:** If the packaging is **opened, damaged**, or if any component is **broken**, use of the product may result in injury to the **patient or operator**. Always **visually inspect** the packaging and contents **prior to each use** to ensure integrity.
- If a syringe is not well-sealed, it may lead patient's injury. Unless the syringe is well sealed, otherwise please do not fill or take injection. Please make sure the alignment marks on the injector and injection head are matched-up, the piston and the plunger has been inter-locked. Bad sealing will cause thrombosis bubbles or injection dose reducing.

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- **Ensure Proper Sealing:** If the syringe is not properly sealed, it may cause injury to the patient. Do **not** fill or inject unless the syringe is fully sealed. Before use, ensure that the **alignment marks on the injector and injection head are properly matched** and that the **piston and plunger are securely interlocked**. Improper sealing can lead to air bubbles (thrombosis risk) or reduced injection dosage.
- **Risk of Leakage and Tube Damage:** Contrast media leakage or connecting tube breakage may cause injury to the patient or operator. Ensure the tubing is **clear and unobstructed** before use. Do **not exceed** the pressure limit specified on the package. Excessive pressure or a blocked tubing line can result in connector failure, leakage, or tube rupture.
- **Sharp Needle Hazard:** Using sharp needles may cause injury to the operator. Handle and insert the needle into the bottle with care to avoid accidental injury

CAUTIONS

- Familiarize yourself with and fully understand the product specifications before use.
- Do not use products beyond their designated expiration dating.
- After opening the package, inspect for content accuracy, and verify there is no damage or missing parts.
- Check the connection tubing to ensure it is free from twists, kinks, or blockages before injection.
- Improper installation of components may cause damage. Ensure all fittings are secure but not over-tightened to minimize the risk of leakage, breakage, or component failure.

INSTALLATION AND APPLICATION

Installation Instructions

- Ensure the high-pressure injection system's pushing head is fully retracted.
- Remove the syringe from the packaging and insert it into the installation hole on the injection head.
- Install the base plate with syringes on both sides into the base installation, ensuring the syringes are securely positioned.

Contrast Media Filling Method:

Before filling the medication, tilt the injection head upward to allow air to gather at the top of the syringe. Start the injection equipment and push the piston fully to the end of the injector.

1) J shape tube aspirator filling medicine

- a. Remove the syringe locking fitting protective cap. Under aseptic conditions, securely connect the J-shaped tube aspirator to the injector cone tip.
- b. Insert the J-shaped tube aspirator to the bottom of the contrast media or physiological saline bottle. Turn on the injection equipment to begin drawing the medication.

2) Puncture type aspirator filling medicine

- a. Remove the syringe locking fitting protective cap. Under aseptic conditions, firmly connect the tube aspirator to the injector cone tip.
- b. Remove the metal cap from the medicine bottle. Hold the bottle firmly and insert the puncture tip of the aspirator into the bottle. Turn on the injection equipment to draw the medication.

Drain pipeline system bubbles:

- a. Remove the protective cap from the luer connection tube. Connect the taper hole connector to the syringe locking connector, and securely attach the other end to the scalp needle (IV), tightening it firmly. For the Y-shaped (or T-, U-shaped) connecting tubing, connect the two taper hole connectors to the respective two syringe locking fittings. Then, connect the other end to the scalp needle (IV) and tighten securely.
- b. Turn the tail knob of the high-pressure injection equipment to slowly advance the syringe piston, allowing the contrast media to move forward gradually. If bubbles are present in the tubing system, gently shake the injection head to help the bubbles rise to the top, enabling their removal from the syringe and connecting tubing.

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NOTE: Please use the J-shaped tube medicine aspirator or punctured medicine aspirator to minimize air bubbles during syringe filling. If a small-diameter tube, such as a catheter-over-needle, or tubing longer than 10 inches (25 cm) is used, it may be more difficult to remove air bubbles effectively.

TROUBLESHOOTING

Leakage at the Fitting During High-Pressure Injection:

6:100 luer seal fittings are used in the connecting tubing between the syringe and scalp needle (or IV). These fittings **must be securely tightened** during high-pressure injection to prevent minor leakage.

Leakage at High-Pressure Syringe Tail:

Leakage at the syringe tail may occur if the syringe is reused. Repeated use can lead to **contrast media crystallization** and **partial blockage** of the fluid pathway. The resulting **sudden increase in pressure** may cause leakage at the syringe tail. **Do not reuse** the syringe under any circumstances.

STORAGE CONDITIONS

Store this product in a clean, dry area with good air circulation. Make sure the humidity stays below 80%. Do not store it in places where there are corrosive gases or chemicals in the air, like strong cleaners or industrial fumes.

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Symbol	Standard Reference	Standard Title	Symbol Title	Explanation
	21 CFR Part 801.109(b)(1)	Labeling-Prescription devices	Prescription only	Indicates that the product is authorized for sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1	Medical Devices – Symbols to be used with Medical device labels, labelling and information to be supplied.	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1	Medical Devices – Symbols to be used with Medical device labels, labelling and information to be supplied.	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1	Medical Devices – Symbols to be used with Medical device labels, labelling and information to be supplied.	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1	Medical Devices – Symbols to be used with Medical device labels, labelling and information to be supplied.	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1	Medical Devices – Symbols to be used with Medical device labels, labelling and information to be supplied.	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1	Medical Devices – Symbols to be used with Medical device labels, labelling and information to be supplied.	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, but presented on the medical device itself.
	ISO 15223-1	Medical Devices – Symbols to be used with Medical device labels, labelling and information to be supplied.	Consult instructions for use	Indicates the need for the user to consult the instructions for use.

Manufactured for:

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Made in Canada

REVISION HISTORY

Rev. #	DR #	Date	Description
01	118675	08/18/2025	• New IN-101100A MR Angiographic Syringe IFU as outlined in CO #18227 / CO Task #118665.