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Medical Imaging Solutions International

CT 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 **Bayer Medrad® Stellant**. 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 100200B syringe and with **Bayer Medrad® Stellant** injectors.

REF	Product Description	Syringe Model #	Syringe Specifications
100501S	CT Angiographic Syringe	100200B	200mL Syringe
100502D	CT Angiographic Syringe	100200B	200mL Syringe
100503D	CT Angiographic Syringe	100200B	200mL Syringe

INTENDED USE

The **CT 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.
- **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

1. Ensure the pushing head of the high-pressure injection system is fully retracted.
2. Remove the imaging syringe from its packaging. Using a quick and firm motion, insert it into the mounting hole on the Stellant™ injection head. The piston will advance automatically.
    - **Note:** If insertion is too slow, the DCU screen may display an error message, and the piston rod may not advance automatically.

Contrast Media Filling Method:

Before filling, tilt the Stellant™ injection head upward to allow air to collect at the top of the syringe. Turn the tail knob to expel all air from the syringe.

1. Tube aspirator filling machine
    a. Remove the protective cap from the syringe locking fitting. Under aseptic conditions, securely connect the tube aspirator to the syringe cone tip.
    b. Insert the tube aspirator to the bottom of the contrast media bottle. Use the injection head controls to draw the required amount of media.
2. Puncture type aspirator filling medicine
    a. Remove the protective cap from the syringe locking fitting. Under aseptic conditions, securely connect the puncture-type aspirator to the syringe cone tip.
    b. Remove the metal cap from the contrast media bottle. Position the bottle so the aspirator tip is aligned and firmly insert it into the bottle. Use the injection head controls to draw the required amount of media.
3. Drain pipeline system bubbles
    a. Remove the protective cap from the luer connection tube. Connect the taper-hole connector to the syringe locking fitting, and connect the other end to the scalp needle (IV) tubing. If using a T- or Y-shaped connecting tube, ensure each taper-hole connector is properly attached to the corresponding syringes.
    b. Turn the tail knob to slowly advance the syringe piston and push contrast media through the tubing. If bubbles are present, gently shake the injection head to allow bubbles to rise and escape from the syringe and tubing.

Note: Always use the J-shape tube aspirator or puncture-type aspirator to minimize bubbles in the syringe. Using narrow-diameter tubing (e.g., catheter-over-needle) or tubing longer than 10 inches (25 cm) makes bubble removal more difficult.

4. Take out angiographic syringe
   After completing angiography, gently rotate the syringe on the injection head to unlock it. The syringe will automatically disengage. Remove it from the injection head.

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:

Repeated use of the syringe can lead to crystallization of the contrast media and partial blockage of the liquid flow path. This blockage can cause a sudden increase in pressure, which may result in leakage at the syringe tail. **To prevent this issue, do not reuse syringes**

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.

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Made in Canada

REVISION HISTORY

Rev. #	DR #	Date	Description
01	118687	08/18/2025	• New IN-100200B MR Angiographic Syringe IFU as outlined in CO #18230 / CO Task #118667.