

MISI

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 **Mallinckrodt®/Liebel-Flarsheim® Angiomat 6000, Illumena™**. 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 200150A syringe and with **Mallinckrodt®/Liebel-Flarsheim® Angiomat 6000, Illumena™** injectors.

REF	Product Description	Syringe Model #	Syringe Specifications
200201	CT Angiographic Syringe	200150A	150mL 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 1200 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

- **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.
- **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.

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- **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.

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 that the high-pressure injector drive head is fully retracted.
2. Remove the high-pressure syringe. Take off the front protective cap and insert the syringe into the protective sleeve.
 - Note: If the syringe is not in the correct position, it cannot be fully inserted into the sleeve.
3. Rotate the base of the protective sleeve clockwise until aligned, then lock it securely.

Contrast Media Filling Method:

1. Push the syringe plunger fully forward to expel as much air from the syringe as possible.
2. Under sterile conditions, firmly connect the J-shaped tube aspirator to the syringe cone tip.
3. Insert the J-shaped tube aspirator into the bottom of the contrast media bottle and aspirate the required volume.
4. Remove the J-shaped aspirator. Firmly connect the high-pressure tubing fitting to the syringe cone tip, and attach the other end of the high-pressure tubing to the angiographic catheter.
5. If dilution is required, add the appropriate volume of normal saline into the syringe to achieve the desired ratio.
6. Slowly advance the syringe plunger by rotating the injector tail knob, allowing the contrast media to flow forward.
 - *If the contrast media does not reach the connection point, air bubbles may be present in the tubing. In this case, continue rotating the injector tail knob clockwise to expel air bubbles from the system.*

TROUBLESHOOTING

Issue:

The piston rod of the high-pressure injector cannot be rotated, or the handle can be rotated but no liquid is dispensed.

Corrective Action:

1. Turn off the power supply.
2. Rotate the injector handle in the reverse direction.
3. Open the base cover of the syringe protective sleeve and remove the syringe from the injector.
4. Inspect the injector and syringe separately to determine if either component is malfunctioning.

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	121647	10/17/2025	• New IN-200150A.01 Disposable High Pressure Injection Syringe (CO 18461/CO Task 121473).