

Angiographic Syringes

INTENDED USE

Angiographic syringe is intended to deliver contrast media, which is compatible with high-pressure injection equipment during CT, DSA and MRI.

CONTRAINDICATIONS

None know

STORAGE AND TRANSPORT

1. Store in a cool, dry, clean, well ventilated place and protect from corrosive gas.
2. Keep away from sunlight, rain, snow and water. Avoid bearing heavy weight during transport.

PRECAUTIONS AND WARNINGS

READ INSTRUCTIONS PRIOR TO USE.

DO NOT USE IF THE UNIT PACKAGING OR THE PRODUCT HAVE BEEN DAMAGED OR SOILED.

1. The operator must be trained in the practice and be familiar with the operation procedure for using angiographic syringe.
2. Ensure that one operator is designated as being responsible for filling and refilling the syringe. Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that the fluid path is purged of air.
3. Visually inspect contents and package before each use and do not use if package is opened or damaged.
4. For single patient use only. Don't reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
5. To ensure that the operation procedure is under clean conditions to avoid infection.
6. When connecting tubing and syringes, steps should be taken to ensure that no air is introduced into the system.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following:

1. Allergic reactions (including anaphylaxis)
2. Arterial/venous thrombosis
3. Embolism
4. Exposure to biohazards
5. Hemorrhage
6. Infection

INSTRUCTIONS FOR USE

Syringe Installation

Install a Syringe (or Syringes) according to the power injector operation manual which the syringe fits.

1. Insert the end of the syringe in the horizontal cutouts in the injector head.

2. Advance the piston until it is past the plunger feet and the piston and plunger interlock.
3. Install the syringe according to the power injector operation manual which the syringe fits, until the syringe locks and alignment marks are positioned.

Syringe Filling

1. Tilt the injector head (or the syringe interface module) up.
2. Advance the plunger to full forward position.
3. Remove the protective cover from the syringe luer tip and attach a sterile filling device onto the tip of the syringe. "J" Fill Tube, or Vented Spike.
4. Transfer the contrast media into the syringe by one of following methods:
 - "J" Fill Tube: raise the contrast bottle until the "J" Fill Tube is fully inserted. The end of the "J" Fill Tube should be near the bottom of the contrast bottle.
 - Vented Spike: prepare the bottle or container of contrast and/or saline solution. Push the bottle or bag onto the Filling Device until the seal is punctured.

NOTE: Use "J" Fill Tube could reduce the volume and size of air bubbles drawn into the syringe during filling. It is more difficult to remove the air bubbles if you use smaller diameter tubes, such as catheter-over-needle, or a tube longer than 10 inch (25cm).

5. Aspirate contrast media into the syringe.

NOTE: If required, use your free hand to gently tap the syringe to facilitate migration of air bubbles remaining within the syringe and on the syringe plunger to the syringe tip.

Expelling Air & Attaching the Connecting Tubing

After you fill the syringe, you must expel all air from the syringe and then attach the connecting tubing. To do so:

1. Remove the filling device and expel air from the syringe. Do not hit the syringe to remove air bubbles. Reverse the plunger 3 to 5 ml, then, if applicable, rock the injector head on the pivot to dislodge the bubbles. Expel the remaining air.
2. If you are using a Y connecting tubing, attach shorter side of the Y to the contrast syringe and the longer side of the Y to the saline syringe. Do not reverse the piston plunger after you have attached the tubing.
3. Verify that the tubing is not kinked or obstructed.
4. Use the manual knob or forward button on injector head to advance the syringe plunger to provide a slow flow of contrast media through the connecting tubing. An absence of flow is an obvious indication of air in the fluid path.
5. Prime the connector tubing and make certain that the air is expelled.
6. Verify that all the air has been expelled from the syringe and fluid path.
7. Attach the connecting tube to the vascular entry device.
8. Tilt the injector head (or syringe interface module) down.

Removing the Syringe

To detach the syringe when the procedure has been completed, Remove it from the injector head. Discard all used components.

Note: After use, the angiographic syringe may be a potential bio hazard. Handle and dispose of in accordance with accepted hospital procedures.

MAINTENANCE

1. To keep the clear of angiographic syringe.
2. The operation should according to the principle of aseptic strictly.

3. To observe whether there is abnormal situation or not.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING



Keep dry



Do not use if
package is
damaged



Consult operating
instructions



Keep away
from sunlight



Date of
Manufacture



Sterilized using
ethylene oxide



Lot number



Do not reuse



Do not resterilize



Attention, see
instructions for use



Catalog number



Use by



CE Mark



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