FOUNTAIN®

INSTRUCTIONS FOR USE

INFUSION SYSTEM WITH SQUIRT®- 5 FRENCH

MERIT MEDICAL®

INFUSION SYSTEM - 5 FRENCH

Intended Use of Product

A. Indications

The Fountain Infusion System with Squirt is intended to administer infusions of various therapeutic solutions into the peripheral vasculature of a patient.

B. Contraindications

The Fountain Infusion System with Squirt is contraindicated for use in the coronary vasculature.

The Fountain Infusion System with Squirt is contraindicated for use during magnetic resonance imaging.

C. Cautions

Do not use the Fountain Infusion System with a power injector. Damage to the catheter or hemostasis valve may occur.

Do not infuse solution through the Fountain Infusion System without the Merit Occluding Wire in place. Failure to use the Merit Occluding Wire will result in the majority of therapeutic solution infusing only from the end of the catheter and not through the side ports.

Do not infuse into the Fountain Infusion Catheter with any wire in place other than the Merit Occluding Wire. Using a standard guide wire or another manufacturer's occluding wire could result in potential catheter damage and/or patient injury.

The Fountain Infusion System with Squirt should be used only by physicians who have a thorough understanding of infusion therapies and the associated complications of those infusion therapies.

Do not substitute or modify any components of the system with a component manufactured by any other manufacturer. Merit Medical cannot guarantee the proper function of another manufacturer's components. Use only the Merit Access Plus™ hemostasis valve with this Fountain Infusion Catheter.

When introducing the Fountain Infusion Catheter through a synthetic graft, an introducer sheath should be used. Damage to the infusion catheter may occur if no introducer sheath is used.

D. Warning

A guide wire should never be advanced or withdrawn against resistance. If a guide wire is advanced where there is resistance, it could cause vessel trauma and/or wire damage. The cause of the resistance should be determined utilizing fluoroscopy.

All components must be adequately flushed with heparinized saline to displace air prior to insertion into the body. Complications may occur if air has not been displaced. Correct placement of the guiding wire, catheter, and occluding wire should be verified by fluoroscopy. Failure to use fluoroscopy could result in incorrect placement resulting in patient injury or death.

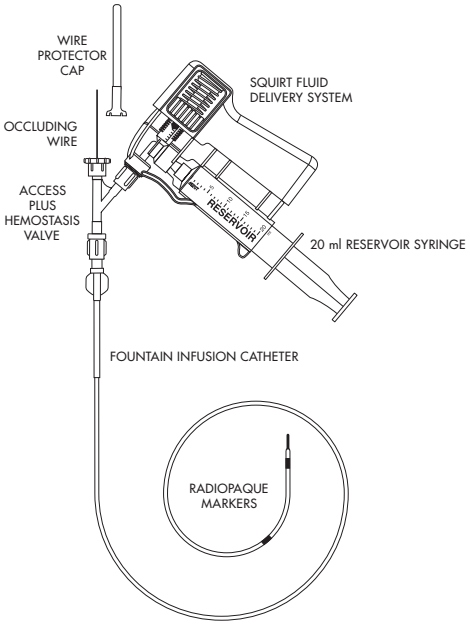
Ensure that all connections are secure before use. Do not over tighten as excessive force may damage the product.

All therapeutic agents to be infused must be used according to the manufacturer's instructions for use.

This device is intended for single use only.

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

Store in a cool dry place.



Description of Device

The Fountain Infusion System with Squirt consists of the following components:

One (1) Fountain Infusion Catheter with infusion holes at the distal section of the catheter.

One (1) Occluding Wire which occludes the distal end of the Fountain Infusion Catheter.

One (1) Access Plus hemostasis valve

One (1) 20 ml Medallion® Reservoir syringe

One (1) Squirt Fluid Delivery System

One (1) Wire Protector Cap

The above components may be packaged in a single tray or may be packaged separately.

INSTRUCTIONS FOR USE

Flushing and Debubbling the System

1. Flush the Fountain Infusion Catheter with sterile, heparinized normal saline so that all the air has been completely removed.

Warning: Complications may occur if all the air has not been removed prior to insertion into the body.

2. Place the Fountain Infusion Catheter into position under fluoroscopic guidance following standard hospital protocol. The Fountain Infusion Catheter will pass through a standard 5F introducer sheath and over a 0.035" (0.89 mm) guide wire. The two radiopaque marker bands on the Fountain Infusion Catheter indicate the infusion segment where side hole infusion occurs. (See Figure 1)

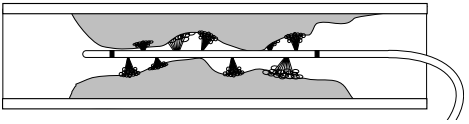


Figure 1

3. Remove the 0.035" placing guide wire and position the Occluding Wire so that the distal tip of the catheter is occluded by the guide wire. (See Figure 2)

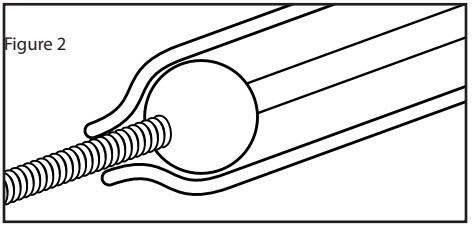


Figure 2

Warning: A guide wire should never be advanced or removed if resistance is present. If the guide wire is advanced against resistance, it could potentially create vessel trauma and/or wire damage. The cause of the resistance should be determined under fluoroscopy. Take any necessary actions to correct the problem.

4. The 20ml reservoir syringe is filled with heparinized saline and debubbled using standard hospital protocol. This may include tapping the syringe with a hemostat or similar device.

Attach reservoir syringe to Squirt. (See Figure 3) Make sure that the syringe connection is air-tight. [The syringe rotator should be tightened by hand if using a syringe with a rotating adapter.]

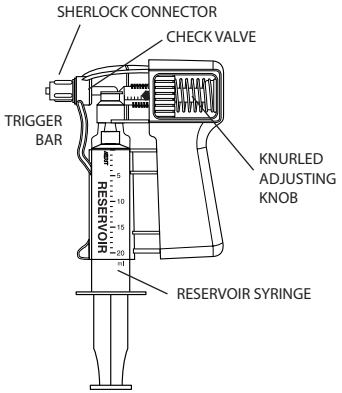


Figure 3

Holding the Squirt in an upright position activate the trigger bar repeatedly until all air bubbles are out of the check valve area of the Squirt. (See Figure 3) This may include tapping the Squirt fluid path with a hemostat or similar device. [Note: Clinician should attach a small piece of tubing if concerned about fluid dripping out of the end of the Squirt during the priming process.]

Turn Squirt such that the Sherlock connector is pointing up. Activate the trigger bar until all air bubbles are out of fluid path. (See Figure 4) This may include tapping with a hemostat or similar device. This step may have to be repeated several times to fully debubble the system.

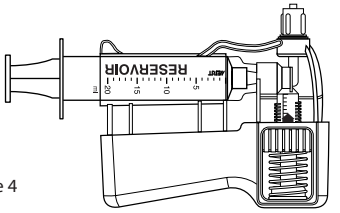


Figure 4

5. Attach the Squirt to the hemostasis valve as shown in Figure 5. Prime the hemostasis valve by placing a gloved thumb over the rotating adapter located on the hemostasis valve while activating the Squirt. This will force saline out of the back end cap of the hemostasis valve. Close the back end cap by twisting it in a clockwise direction. (See Figure 6) Continue to activate the Squirt to debubble the distal segment of the hemostasis valve.

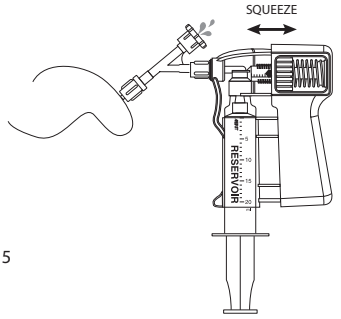


Figure 5

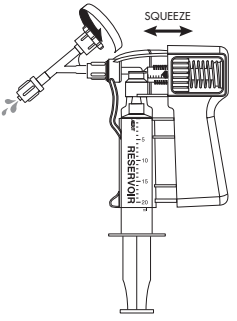


Figure 6

6. While holding the hemostasis valve in a level position, loosen the back end cap on the hemostasis valve and slide it over the proximal end of the matched Occluding Wire.

Do not connect the rotating adapter assembly to the Fountain Infusion Catheter at this time. If it is connected at this time, an air embolism could occur potentially causing injury or death to the patient.

7. The Squirt should be activated so heparinized saline from the 20 ml reservoir syringe comes through the back end cap of the hemostasis valve. (See Figure 7) When all the air has been displaced, the back end cap should be tightened onto the proximal end of the occluding wire, such that the wire will slide through it.

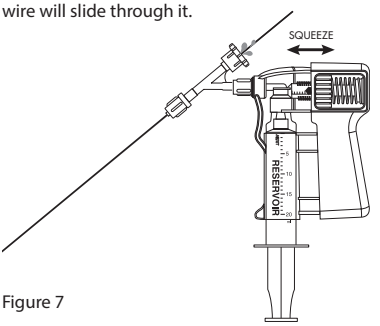


Figure 7

8. Continue to activate the Squirt. This will ensure that a liquid meniscus is at the distal segment of the hemostasis valve. Attach the rotating adapter of the hemostasis valve to the luer lock connector on the Fountain Infusion Catheter, making sure that a liquid-to-liquid connection is established. (See Figure 8)

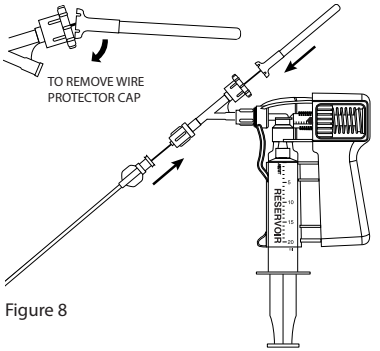


Figure 8

When the connection is completed, tighten the back end cap of the hemostasis valve onto the proximal end of the occluding wire.

The wire protector cap can then be placed over the proximal portion of the occluding wire and snapped into the back end cap of the hemostasis valve (See Figure 8).

Priming the System with Therapeutic Solution

9. If the clinician wishes to conserve thrombolytic medication, the Squirt should be primed as instructed previously.

Turn the Squirt until the syringe is pointing down. (See Figure 9) Remove the priming reservoir syringe that is loaded with sterile saline. Fill a syringe with thrombolytic solution.

Using the thrombolytic solution syringe, place a small amount of thrombolytic solution into the female luer connector of the Squirt. This will cause a small meniscus of therapeutic solution to be placed on the female luer connector. (See Figure 10)

Attach the syringe loaded with therapeutic solution. (See Figure 10) Make sure that the connection is air-tight. If any bubbles inadvertently enter the system they may be removed by activating the trigger bar until all air bubbles are out of the fluid path. (The dead space volume is approximately 0.5 ml.)

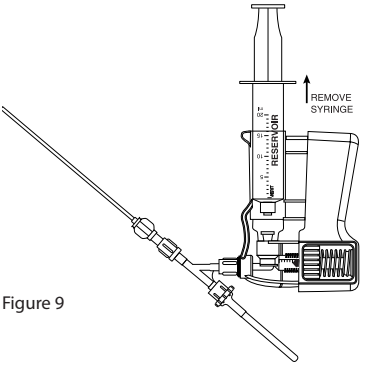


Figure 9

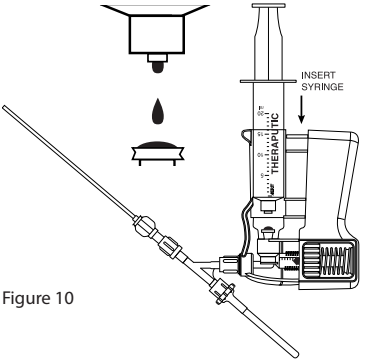


Figure 10

10. Prime the entire system with therapeutic solution by depressing the Squirt. The approximate system prime volumes for each catheter are as follows:

45cm catheter - 1.0ml
90cm catheter - 1.5mls
135cm catheter - 2.0mls

Warning: All therapeutic agents to be infused must be used according to the manufacturer's instructions for use.
Administering Infusion Therapy

Administering Infusion Therapy

11. The stroke volume ejected from the Squirt can be adjusted from 0 - 1 ml of fluid by turning the knurled knob located in the handle. When holding the Squirt with the Sherlock connector pointed away from user, rotate the knob clockwise to decrease stroke volume. Rotating the knob in a counter-clockwise direction will increase the stroke volume of the device. (See Figure 11) Adjust the plunger tip to the amount of fluid to be infused with each stroke by aligning the plunger ring with the gradation marks on the Squirt's barrel. After activating the trigger once the dosage is set and will deliver the same amount of fluid each time the activation trigger is fully pulled.

To infuse the therapeutic solution, depress the Squirt as needed. This procedure should be repeated for the duration of therapy as directed by the physician.

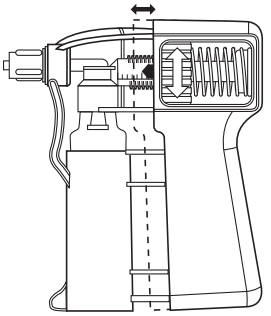


Figure 11

Instructions for Use with a Reservoir Bag or Bottle

Attach tubing connector to the female luer attachment located on the underside portion of the Squirt. Make sure the connection is air-tight so that no air can enter the system. Holding the Squirt in an upright position prime the Squirt System in a similar manner to the priming instructions as listed above. Turn Squirt such that the Sherlock connector is pointing up. Repeatedly activate the trigger bar until all air is out of fluid path. This may include tapping the Squirt with a hemostat or similar device. The device is now ready to inject fluid into the Fountain Infusion Catheter. (See Figure 12) Caution: Make sure that fluid level in reservoir bag or bottle is continuously monitored so air is not inadvertently injected.

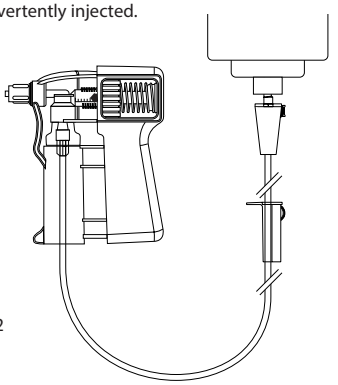


Figure 12

I.V. Pump Infusion Instructions

Prime the Fountain Infusion Catheter and hemostasis valve as described in the previous instructions. Place the catheter, hemostasis valve, and occluding wire as previously described. The occluding wire and catheter should always be placed under fluoroscopic control.

Attach the primed hemostasis valve to the I.V. line that has been primed according to the manufacturer's instructions for use. Make sure the connection is air-tight. Note: The I.V. infusion pump that is used should have the "occlusion alarm pressure limit" set at 10 psi or 517mmHg.

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