FOUNTAIN®

INSTRUCTIONS FOR USE

INFUSION SYSTEM - 5 FRENCH

MERIT MEDICAL®

English

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INSTRUCTIONS FOR USE

Intended Use of Product

A. Indications

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

B. Contraindications

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

The Fountain Infusion System 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 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A guide wire should never be advanced or withdrawn against resistance.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.

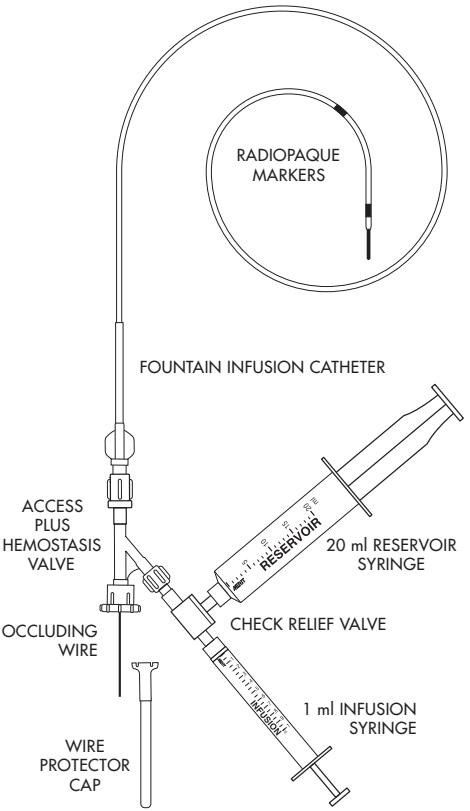
All components must be adequately flushed with heparinized saline to displace air prior to insertion into the body. Complications may occur if air has not been displaced. Correct placement of the guiding wire, catheter, and occluding wire should be verified by fluoroscopy. Failure to use fluoroscopy 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 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) Check Relief Valve (CRV)

One (1) Access Plus hemostasis valve

One (1) 1 ml Medallion® Infusion syringe

One (1) 20 ml Medallion Reservoir syringe

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. (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 wire. (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.

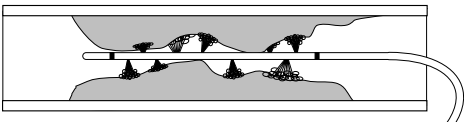


Figure 1

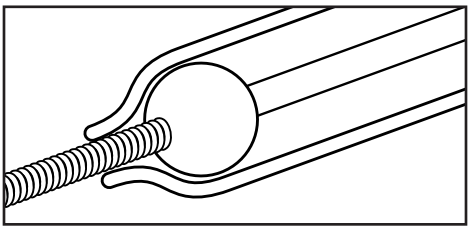


Figure 2

4. The 1 ml infusion syringe is pre-attached to the infusion port. The 20 ml reservoir syringe is filled with heparinzed saline and attached to the inlet side-port of the check valve. (Figure 3)

5. Prime the hemostasis and check valves by placing a gloved thumb over the rotating adapter located on the hemostasis valve while activating the 1 ml infusion syringe (Figure 4). 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 (Figure 5). Continue to activate the infusion syringe to debubble the distal segment of the hemostasis valve.

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.

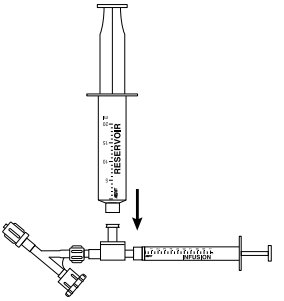


Figure 3

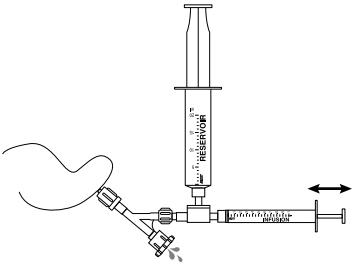


Figure 4

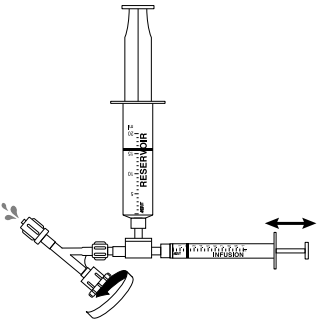


Figure 5

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 1 ml infusion syringe should be activated so heparinized saline from the 20 ml reservoir syringe comes through the back end cap of the hemostasis valve (Figure 6). 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.

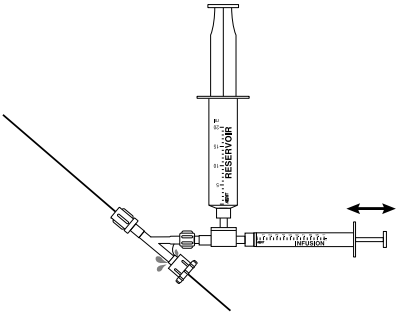


Figure 6

8. Continue to activate the infusion syringe. 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. (Figure 7)

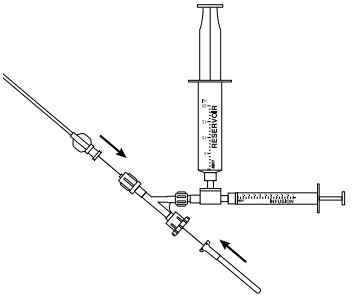
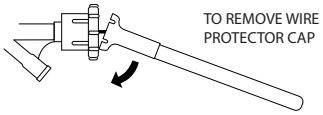


Figure 7

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 7)



Priming the System with Therapeutic Solution

9. The reservoir syringe containing saline is removed from the inlet port of the check valve. Replace it with a reservoir syringe containing the desired therapeutic solution (Figure 8). Drip a tiny volume of therapeutic solution into the input port luer lock to raise a meniscus as the connection is made (Figure 9), thereby preventing the introduction of air bubbles into the system.

10. Aspirate 1 ml of therapeutic solution into the infusion syringe. Prime the entire system with therapeutic solution by depressing the plunger of the 1 ml infusion syringe. 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

11. Aspirate the desired volume of therapeutic solution into the 1 ml infusion syringe. To infuse the therapeutic solution, depress the plunger on the 1 ml infusion syringe as needed. This procedure should be repeated for the duration of therapy as directed by the physician.

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.

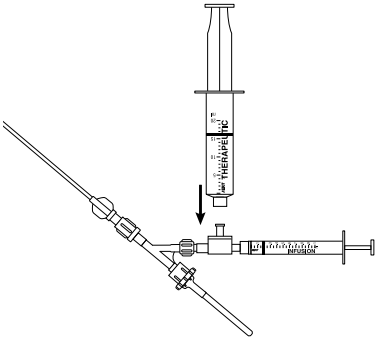


Figure 8

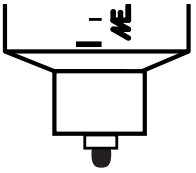


Figure 9

SYMBOL	DESIGNATION
	Caution
	Consult Instructions for Use. For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U. Customer Service.
	Do not use if package is damaged and consult instructions for use.
	Single Use
	Non-pyrogenic
	Manufacturer
	Sterile Using Ethylene Oxide
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