ENGLISH

FOUNTAIN ValveTip

INFUSION SYSTEM - 4 FRENCH & 5 FRENCH

INSTRUCTIONS FOR USE

INTENDED PURPOSE
The Fountain ValveTip Infusion System is intended to be used to deliver solution of thrombolytic agent to target thrombi in the peripheral vasculature.

INDICATIONS
The Fountain Valve Tip Infusion System is indicated for use in patients with peripheral vascular thrombosis.

CONTRAINDICATIONS
The Fountain ValveTip Infusion System is contraindicated for use in the coronary vasculature. The Fountain ValveTip Infusion System is contraindicated for use during magnetic resonance imaging.

CLINICAL BENEFITS
The Fountain ValveTip Infusion System provides an indirect clinical benefit of facilitating solution of thrombolytic agent infusion in patients with peripheral vascular thrombosis.

Patient Population:
The Fountain ValveTip Infusion System is intended for use in patients undergoing routine thrombolysis of the peripheral vasculature.

Intended User(s):
For use by physicians with training in percutaneous endovascular procedures.

Performance Characteristics:
The Fountain ValveTip Infusion System is designed with performance characteristics for use in patients' vascular system. See individual labels for french size, length, and infusion section.

HOW SUPPLIED
The product is supplied sterile unless the package has been opened or damaged. Sterilized using ethylene oxide. For single patient use only. Do not reuse. Do not resterilize.

CAUTIONS
- Do not use the Fountain ValveTip Infusion System with a power injector. Damage to the catheter or hemostasis valve may occur.
- Do not infuse into the Fountain ValveTip Infusion Catheter with any wire in place. Using a standard guide wire or any manufacturer's occluding wire could result in potential catheter damage and/or patient injury.
- The Fountain ValveTip 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 ValveTip Infusion Catheter.
- When introducing the Fountain ValveTip 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.

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 and catheter 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.
- In the event of a malfunction of the device and/or changes in the performance of the device, exercise caution as this may indicate a change that may affect the safety of the device.
- After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.

REUSE PRECAUTION STATEMENT
For single patient use only. Do not 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.

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable member state.
For a copy of this device's current European Summary of Safety and Clinical Performance (SSCP), please go to the European database on medical devices (Eudamed), where it is linked to the basic UDI- DI. https://ec.europa.eu/tools/eudamed.

POTENTIAL COMPLICATIONS
Damage to the catheter if an introducer sheath is not used.
Potential for embolism if the catheter is not flushed with heparinized saline.

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

Store in a cool dry place.

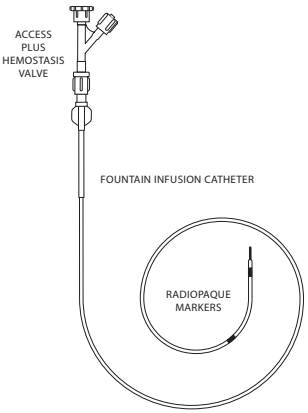
DESCRIPTION OF DEVICE

The Fountain ValveTip Infusion System consists of the following components:

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

One (1) Access Plus hemostasis valve

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



PRIMING VOLUME
The approximate system priming volume for each catheter are as follows:
- 45cm catheter – 1.0ml
- 90cm catheter – 1.5 ml
- 135cm catheter – 2.0ml

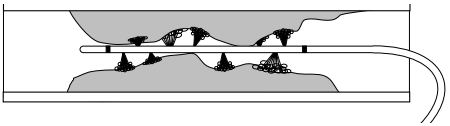
INSTRUCTIONS FOR USE

FLUSHING AND DEBUBBLING THE SYSTEM
1. Flush the Fountain ValveTip 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.

CATHETER INSERTION
2. Place the Fountain ValveTip Infusion Catheter into position under fluoroscopic guidance following standard hospital protocol. The two radiopaque marker bands on the Fountain ValveTip Infusion Catheter indicate the infusion segment where

side hole infusion occurs. (Figure 1)
Note: The Fountain ValveTip Infusion Catheter will pass through a standard 4F or 5F introducer sheath and over a 0.035" (0.89 mm) guide wire. Use a 4F introducer sheath with the corresponding 4F Fountain ValveTip Infusion System, and a 5F introducer sheath with the corresponding 5F Fountain ValveTip Infusion System.

FIGURE 1

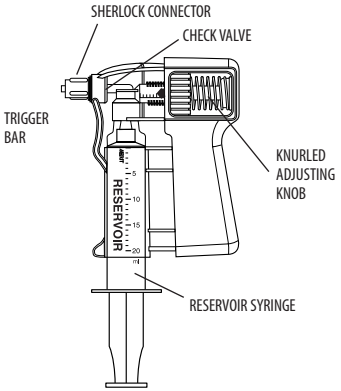


3. Remove the 0.035" placing guide wire. Proceed with infusion using standard hospital protocol, without the use of an occluding wire.
Warning: A guide wire should never be advanced or removed if resistance is present. If the guide wire is advanced against resistance, it could potentially create vessel trauma and/or wire damage. The cause of the resistance should be determined under fluoroscopy. Take any necessary actions to correct the problem.

INFUSION INSTRUCTIONS - IF USING SQUIRT DEVICE

1. Fill the 20ml reservoir syringe with heparinized saline and debubble using standard hospital protocol. This may include tapping the syringe with a hemostat or similar device.
2. Attach reservoir syringe to Squirt. (Figure 2) Make sure that the syringe connection is air-tight.
Note: The syringe rotator should be tightened by hand if using a syringe with a rotating adapter.

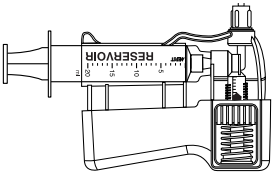
FIGURE 2



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. (Figure 2) 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.

4. Turn Squirt such that the Sherlock connector is pointing up. Activate the trigger bar until all air bubbles are out of fluid path. (Figure 3) 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 3



5. Attach the Squirt to the hemostasis valve as shown in Figure 4. 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. (Figure 5) Continue to activate the Squirt to debubble the distal segment of the hemostasis valve.
Warning: Do not connect the rotating adapter assembly to the Fountain ValveTip 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.

FIGURE 4

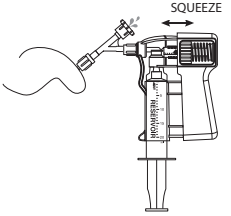
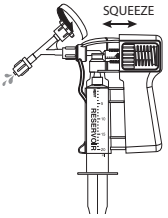
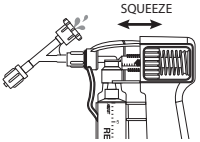


FIGURE 5

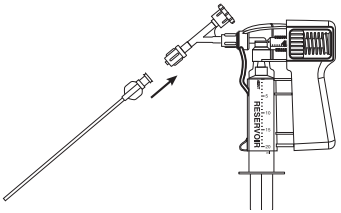


6. The Squirt should be activated so heparinized saline from the 20 ml reservoir syringe comes through the back end cap of the hemostasis valve until all the air has been displaced.



7. 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 ValveTip Infusion Catheter, making sure that a liquid-to-liquid connection is established. (Figure 6)

FIGURE 6

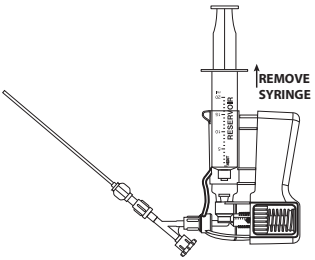


8. Complete connection.

PRIMING THE SYSTEM WITH THERAPEUTIC SOLUTION

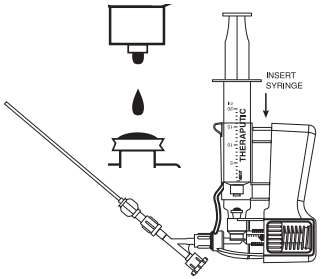
9. If the clinician wishes to conserve thrombolytic medication, the Squirt should be primed as instructed previously.
10. Turn the Squirt until the syringe is pointing down. (Figure 7) Remove the priming reservoir syringe that is loaded with sterile saline. Fill a syringe with thrombolytic solution.

FIGURE 7



11. 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. (Figure 8)
12. Attach the syringe loaded with therapeutic solution. (Figure 8)
    Warning: 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 8



13. 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

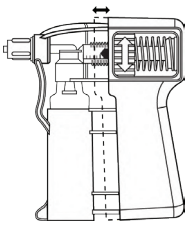
    Warning: All therapeutic agents to be infused must be used according to the manufacturer's instructions for use.

ADMINISTERING INFUSION THERAPY WITH SQUIRT DEVICE

14. 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. (Figure 9) 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 9



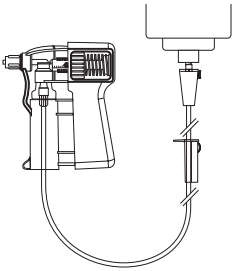
INSTRUCTIONS FOR USE WITH A RESERVOIR BAG OR BOTTLE

15. 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.
16. Holding the Squirt in an upright position prime the Squirt System in a similar manner to the priming instructions as listed above.
17. 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 ValveTip Infusion Catheter. (Figure 9)
    Caution: Make sure that fluid level in reservoir bag or bottle is continuously monitored so air is not inadvertently injected.

INFUSION INSTRUCTIONS - IF USING PULSE INFUSION KIT

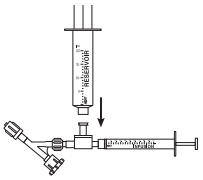
1. The 1 ml infusion syringe, CRV, and hemostasis valve are pre-assembled. Fill the 20 ml reservoir syringe with heparinized saline and attach to the inlet side-port of the check valve. (Figure 10)

FIGURE 10



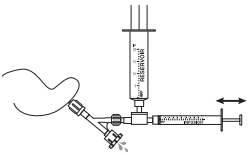
2. Prime the hemostasis and check valves by placing a gloved thumb over the rotating adapter located on the hemostasis valve while activating the 1 ml infusion syringe. (Figure 11) This will force saline out of the back end cap of the hemostasis valve. Close the back end cap by twisting it in a clockwise direction (Figure 14). Continue to activate the infusion syringe to debubble the distal segment of the hemostasis valve.

FIGURE 11



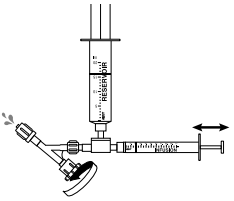
3. Prime the hemostasis and check valves by placing a gloved thumb over the rotating adapter located on the hemostasis valve while activating the 1 ml infusion syringe (Figure 12). This will force saline out of the back end cap of the hemostasis valve.

FIGURE 12



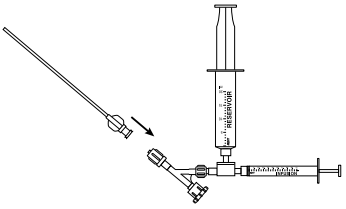
4. Close the back end cap by twisting it in a clockwise direction (Figure 13). Continue to activate the infusion syringe to debubble the distal segment of the hemostasis valve. Continue to activate the infusion syringe. This will ensure that a liquid meniscus is at the distal segment of the hemostasis valve.

FIGURE 13



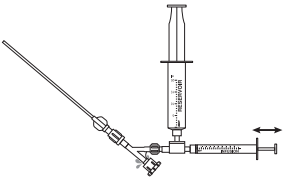
5. Attach the rotating adapter of the hemostasis valve to the luer lock connector on the Fountain Infusion Catheter, making sure that a liquid-to-liquid connection is established. (Figure 14)

FIGURE 14



6. 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 until all the air has been displaced. (Figure 15)

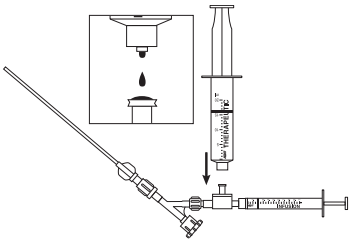
FIGURE 15



PRIMING THE SYSTEM WITH THERAPEUTIC SOLUTION

7. The reservoir syringe containing saline is removed from the inlet port of the check valve. Replace it with a syringe containing the desired therapeutic solution. Drip a tiny volume of therapeutic solution into the input port luer lock to raise a meniscus as the connection is made (Figure 16), thereby preventing the introduction of air bubbles into the system.

FIGURE 16



8. 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 WITH THE PULSE INFUSION KIT

9. 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

1. Prime the Fountain ValveTip Infusion Catheter and hemostasis valve as described in the previous instructions. Place the catheter and hemostasis valve as previously described. The catheter should always be placed under fluoroscopic control.
2. 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.

SYMBOL	DESIGNATION
	Single Use
	Caution
	Non-Pyrogenic
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Manufacturer
	Use By: YYYY-MM-DD
EC REP	Authorized Representative in European Community
REF	Catalog Number
MD	Medical Device
UDI	Unique Device Identifier
	Date of Manufacture: YYYY-MM-DD
LOT	Lot Number
	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 Re-sterilize
STERILE EO	Sterilized Using Ethylene Oxide
	Single Sterile Barrier System

CE 2797

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400660010_001 ID 2024-09-19