Overview

The ClarVein® Infusion Catheter (ClarVein®-IC) is an infusion catheter system designed to introduce physician-specified medicaments into the peripheral vasculature. Infusion is through an opening at the distal end of the catheter and fluid delivery is enhanced by the use of a rotating dispersion wire to mix and disperse the infused fluid in the blood stream and on the vessel wall. The dispersion wire extends through the catheter lumen (Figure 1, Item 4). It is connected to an interface Cartridge Unit for connection to the 9V DC battery motorized Handle Unit (Figure 2; Figure 4) on the proximal end, which controls wire rotation. The Handle Unit also provides a grip and syringe holder to facilitate physician-controlled infusion. Prior to drug infusion, the wire plus catheter sheath is inserted into the vasculature and once positioned at the treatment site, the catheter sheath is retracted to expose the dispersion tip.

Indication

The ClarVein®-IC is intended for infusion of physician-selected agents into the peripheral vasculature.

Product Components

1 – ClarVein® Catheter Cartridge – Refer to Figure 1
   - 45cm, Diameter 2 2/3 Fr. (0.035”), Part Number VC01-05-018-E2S or
   - 65cm, Diameter 2 2/3 Fr. (0.035”), Part Number VC01-05-018-E4S
1 - ClarVein® Handle Drive Unit, Part Number VC01-05-047-01 – Refer to Figure 2
1 – Syringe, 5 ml, Part Number VC01-01-015-01 – Refer to Figure 3
1 – Check Valve, Part Number VC01-01-014-02 – Refer to Figure 3

Figure 1: Cartridge Unit (Catheter)

1. Cartridge  2. Luer Injection Port  3. Cartridge Grip/Guide Wing  4. Catheter, 45 or 65 cm working length

Figure 2: Handle Unit (Motor Drive)

Figure 3: Cartridge Unit with Check Valve and Syringe

9. Check Valve
10. Syringe, 5 ml

Figure 4: Connecting Cartridge Unit to the Handle Unit

Step 1 - Remove Battery Terminal Insulator Tab (Figure 2, Item 10).
Step 2 - Before connecting the Cartridge Unit to the Handle check to ensure the green indicator light (LED) (Figure 2, Item 11) is on by pulling the Trigger.
Step 3 - Slide the Handle Unit onto the Cartridge Unit until the first stop
Step 4 - Push the Handle on the Cartridge Grip/Guide Wing ensuring the Handle Mating Alignment Slot is in the most proximal position and apply slight rotation pressure in the direction of the syringe holder to snap the Guide Wing into the Guide Wing Alignment Slot.
Step 5 - Snap the 5 ml Syringe into the Syringe Locking Support on the Handle Unit
Step 6 - Cartridge Unit and Handle Unit are assembled

Figure 5: Re-sheathing the Dispersion Tip

Step 1 - Unsnap the Syringe barrel from the Syringe Locking Support
Step 2 - Rotate the Cartridge Grip/Guide Wing away from the syringe holder
Step 3 - Push the Cartridge Unit distally
Step 4 - Continue to push to the most distal position/until it stops
Operation

The Clarivein®-IC is a percutaneous, 2 2/3 Fr infusion catheter, which is compatible for access with a Short Peripheral Catheter, 18G or larger, or 4-6 Fr introducer sheath, for the delivery of physician-selected medicaments into the peripheral vasculature. The Cartridge Unit plus Handle Unit is a single use, sterile disposable device.

To facilitate Catheter placement by the physician as well as ease of handling, the device is initially in two parts: the Cartridge Unit (Catheter) (Figure 1); and the hand-held 9V DC battery-operated Motor Drive Unit (Handle Unit, Figure 2). Attached to the Cartridge Unit is a Catheter with a wire passing through its center (Figure 1, Item 4). The wire has a dispersion tip at its distal end and is connected to a locking coupling at its proximal end. Dispersion wire rotation enhances fluid dispersion and is controlled by the 9V DC motorized Handle Unit (Figure 2). The dispersion wire tip is sheathed in the Catheter (Figure 1, Item 4) until device is assembled and ready to use.

The wire that passes through the Catheter is to be selected by the physician: The material can be selected as 304V Stainless Steel or Nitinol; the dispersion tip of the wire can be one of five different configurations. The available dispersion wire tip configurations include Wires A (3 bends, flat tip), B (3 bends, hemispherical tip), C (1 bend, hemispherical tip), E (1 bend, spherical tip), and G (2 bends, spherical tip).

A Check Valve and 5 ml Syringe are provided for connection to the Luer Injection Port on the Cartridge (Figure 1, Item 2; Figure 3) for delivery of the physician-selected medicament. The Handle has a Syringe Locking Support (Figure 2, Item 7) for holding the syringe in place during a procedure to facilitate single-handed operation of the device. Fluid delivery from the distal tip of the Catheter into the patient peripheral vasculature is through the annular space between the outside diameter of the wire and the internal diameter of the Catheter.

The Handle Unit contains an internal safety switch that causes the electrical circuit to be activated only when the Handle Unit is inserted onto the Cartridge Unit and moved to its stop position (Figure 4b). The Handle Unit contains a locking coupling and the Cartridge Unit contains a mating locking coupling. Once mated the Cartridge Unit and Handle Unit cannot be separated. Positioning the Cartridge Unit at its most proximal position in the Handle Unit causes the distal end of the dispersion wire to be unsheathed to expose the dispersion tip. To deactivate the circuit and re-sheath the dispersion wire tip into the Catheter after mating, the Cartridge Unit can be moved distally in the Handle Unit to a stop position.

When the circuit is activated (i.e., the Cartridge Unit in its most proximal position in the Handle Unit), pulling the trigger (Figure 2, Item 8) causes the wire to rotate. Approximate speed of the dispersion wire is physician-selected (prior to Cartridge Unit and Handle Unit mating) using the Four Position Speed Adjustment Selector (Figure 2, Item 6), with the following approximate settings: 2,000 (labeled as “L” or low), 2,500 (labeled as “M1” or medium), 3,000 (labeled as “M2” or medium-high), and 3,500 (labeled as “H” or high) RPM. The distal tip of the Catheter is radiopaque and visualized with ultrasound.
Patient Preparation

⚠️ Use sterile techniques. Pre-medicate appropriately as per clinic or hospital protocol.

Device Performance

Remove the ClariVein®-IC from the package. Remove battery terminal insulator then verify the Motor Drive Unit function by pulling the Trigger of the Handle Unit (Figure 2, Item 8). A green indicator light (LED) will illuminate if motor drive unit is functioning properly.

⚠️ DO NOT USE if green indicator light (LED) does not illuminate.

Procedure

1. Prepare and drape the puncture site as required in general hospital procedures.
2. Select an appropriately sized access device (sheath) to accommodate the ClariVein®-IC. The minimum size access device that is compatible with ClariVein®-IC is an 18G Short Peripheral Catheter.
3. Administer local anesthetic at puncture sight if a venous sheath is selected or as per general hospital procedure if a Short Peripheral Catheter is selected.
4. Prepare and place the access device as per general hospital protocol.
5. Check the tightness of the connection between the hemostasis (cartridge) and the catheter. If it feels loose, tighten by pushing the hub in and turning clockwise. This can help prevent a catheter leak.
5b. Connect the provided Check Valve to the Luer Injection Port (Figure 1, Item 2; Figure 3) on the ClariVein®-IC Cartridge Unit. Flush ClariVein®-IC Cartridge Unit through the Check Valve and Luer Injection Port (Figure 1, Item 2) with sterile saline.
6. Fill the provided 5 ml Syringe with medicament to be infused.
7. Thread the ClariVein®-IC Catheter tip to the desired location in the peripheral vasculature using imaging guidance.
8. Attach the the provided 5 ml Syringe with medicament to be infused
9. Once the catheter tip is in the desired position, join the Handle Unit and Cartridge Unit (Figure 4) by:
   a. Remove battery terminal insulator by pulling the tab and removing it completely from the device. (Figure 2, item 10)
   b. Check that the green indicator light (LED) on the Handle Unit lights by pulling the trigger. Discard if it does not light. (Figure 2, item 11)
   c. Select and set the desired dispersion wire tip speed using the Four Position Speed Adjustment Selector (Figure 2, Item 6) on the Handle Unit. The four speed positions are labeled as L, M1, M2, and H, and represent the following:
      1) L – low, approximately 2,000 RPM (minimum speed)
      2) M1 – medium, approximately 2,500 RPM
      3) M2 – medium high, approximately 3,000 RPM
      4) H – high, approximately 3,500 RPM (maximum speed)
   d. Slide the Mating Alignment Slot (Figure 2, Item 5) of the Handle Unit onto the Cartridge Unit to the first stop (Figure 4, Step 3).
   e. Push the Handle Unit until the Cartridge Grip/Guide Wing (Figure 1, Item 3) is in its most proximal position and apply slight pressure towards the syringe holder to snap the Guide Wing into the Guide Wing Alignment Slot (Figure 2, item 9; Figure 4B, Step 4).
   f. Snap the Syringe into Syringe Locking Support (Figure 2, Item 7).

⚠️ Note: The electrical circuit is not yet armed.
Procedure (Cont)

- The electrical circuit is now armed and the dispersion wire tip is now deployed.

⚠ Note: Provided Syringe may be safely disconnected and reconnected from the Check Valve and refilled if additional medicants are required.

- Dispersion wire rotation will not occur until the Trigger (Figure 2, Item 8) on the Handle Unit is pulled. Motor Drive Unit function/dispersion wire rotation will be indicated by illumination of green indicator light (LED) on the Handle Unit.

- Once joined, the Cartridge Unit assembly is not removable from the Handle Unit.

10. Before activating the device (pulling the Trigger) verify the wire tip is in the desired location in the peripheral vasculature using imaging guidance.

11. Activate dispersion wire rotation by pulling the Trigger (Figure 2, Item 8) and slowly draw the device through the treatment area while simultaneously infusing the fluid by pressing the Syringe plunger with the thumb of the same hand (Figure 6). A withdrawal rate of 1-2 mm/second is recommended.

12. Do not operate the rotating tip in the access device.

   Note: The exact infusion procedure is to be determined by the physician.

13. After completion of the infusion procedure (i.e., the rotating dispersion tip has passed through the treatment area and the therapeutic fluid simultaneously dispersed), and before removal from patient re-sheath the dispersion tip and disable the motor by the following:
   a. Unsnap the Syringe barrel from the Syringe Locking Support on the Handle Unit (Figure 5, Step 1).
   b. Rotate the Cartridge Unit away from the syringe holder (Figure 5, Step 2).
   c. Push Cartridge Unit to its most distal position until it stops (Figure 5, Step 3).

14. Dispose per hospital protocol.

⚠ Contraindications

The ClariVein®-IC is contraindicated for use in the coronary and cerebral vasculature

The ClariVein®-IC is contraindicated for use in the pulmonary vasculature

The ClariVein®-IC is contraindicated for use in diseased and atherosclerotic arteries

The ClariVein®-IC is not intended for infusion of blood or blood products.

⚠ Do not use the ClariVein®-IC in patients contraindicated for endovascular procedures.

The user of ClariVein®-IC should refer to the product insert of the therapeutic solution for contraindications, indications, warnings and side effects.
### Warnings and Precautions

- Prior to use of device, remove the battery terminal insulator by pulling insert tab away from device.
- This product should be used by physicians that have a thorough understanding of Intravascular ultrasound, angiographic and ultrasound procedures and peripheral vascular anatomy.
- Modification of this equipment is not allowed.
- Contains no medications.
- Internally powered device.
- Prior to use carefully examine the ClariVein®-IC components including the Cartridge Unit/ Catheter, the Handle Unit, the Check Valve, and Syringe and verify they have not been damaged during shipment. If the components show any sign of damage DO NOT USE.
- Due to the risk of exposure to HIV or other blood borne pathogens, health care workers should always use standard blood and body fluid precautions in the care of all patients. Sterile techniques should be strictly adhered to during any handling of the device.
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Before using ClariVein®-IC, verify proper function and integrity of the device.
- Do not kink the catheter. Do not use catheter if kinked.
- Use an introducer sheath or a short peripheral catheter for access to the peripheral vasculature. Failure to use a catheter or sheath for access may result in damage to the tip of the device.
- Injection of fluid should be done using the syringe provided or other 5 ml syringe.
- Injection of fluid may be made with a suitable infusion pump.
- Manipulate the catheter only under imaging guidance.
- Never move an intravascular device against resistance.
- Confirm position of the catheter and wire tip in the desired location by ultrasound imaging or angiography before activation of the device.
- Potential fatigue failure of the ClariVein®-IC dispersion wire may occur with prolonged activation of the device. A withdrawal rate (i.e., through the treatment area) of 1-2 mm/second is recommended.
- Do not remove the catheter from patient with motor running and/or dispersion tip extended.

### Adverse Effects

Potential adverse effects that might be associated with ClariVein®-IC are similar to those associated with any interventional procedure and include the following:

1. Abrupt thrombosis and occlusion of the treated vessel.
2. Bleeding from the site of access.
3. Vascular rupture and perforation.
5. Hemolysis.
6. Hematoma.
7. Embolization
8. Reaction to contrast medium.
11. Hypotension, Hypertension.
12. Infection at the access site.
13. Neurological deficits including stroke and death.
Definitions of Symbols

⚠️ "Do not reuse"

🚫 "Do not re-sterilize"

ATYPE BF APPLIED PART

⚠️ "Caution"

ℹ️ “Follow instructions for use"

REF Catalog/Reorder Number

STERILIZED Sterilization using ethylene oxide

LOT Manufacturer's Lot Number

📅 Date of Manufacture

_expiry Expiration Date

🚫 Not made with natural rubber latex

🛡️ The product contains batteries which must be disposed of properly

/import Manufacturer

💧 Device should be kept dry

🌡️ Upper limit of temperature

💧, Humidity limitation

🚫 “Do not use if package damaged”

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

Glass Fragile, handle with care