InVera medical

Device Description

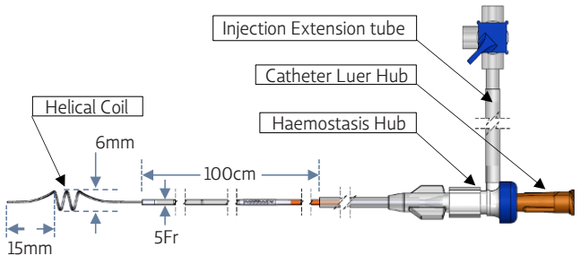

Figure 1 InVera Infusion Device

Intended Use

InVera Infusion Device is indicated for the infusion of physician-specified agents, including sclerosant, into veins of the peripheral vasculature (e.g., superficial veins, saphenous veins).

Indications for Use

The InVera Infusion Device is indicated for use in veins of the peripheral vasculature (e.g., superficial veins, saphenous veins) in adults.

Intended User

Vascular surgeons, Cardiologists, Interventional Radiologists, and physicians trained in ultrasound guided endovascular techniques.

Clinical Benefits

Minimally-invasive infusion of physician-specified agents, including sclerosant, into veins of the peripheral vasculature. Indirect clinical benefits of the InVera Infusion Device include no risk of thermal nerve or skin burn injuries, less painful procedure without requirement for multiple needlesticks to deliver tumescent anaesthesia.

Contraindications

The InVera Infusion Device is contraindicated for use in the following:

- Diseased and atherosclerotic arteries
- Pulmonary vasculature
- Coronary & cerebral vasculature
- Arterial vasculature
- Deep venous vasculature
- Patients for whom endovascular procedures are contraindicated
- Patients with a contraindication to the specific infused agent
- Patients with active thromboembolic disease
- Infusion of blood or blood products

Potential Adverse Events

Potential adverse events that may occur with use of the InVera Infusion Device include, but are not limited to the following:

- The need for additional procedures/interventions
- Vessel perforation
- Embolization
- Deep Vein Thrombosis
- Pulmonary Embolism
- Leg Edema
- Phlebitis
- Sepsis
- Allergic Reaction
- Hematoma
- Pain
- Nerve Injury
- Soft Tissue Damage
- Hemorrhage/Bleeding
- Neurological deficits
- Anaphylactic reaction to infused substances
- Renal Impairment
- Infection

Warnings and Precautions

- This product should only be used by physicians who have a thorough understanding of peripheral vascular anatomy and procedures and vascular ultrasound.
- Modification of equipment is not allowed.
- Do not kink the Catheter, if kinked do not use the device.
- Do not exert excessive force when withdrawing or advancing the Catheter.
- Use an introducer sheath to access the peripheral vasculature otherwise there is a risk of Catheter tip damage.
- Manipulate the Catheter only under imaging guidance and confirm position of the tip of the device before deployment of the helical coil.
- Inner Catheter can be rotated to adjust position of the helical coil. Do not rotate more than 2 full rotations to avoid excessive strain.
- Packaging contains no medications. Prior to the infusion of any physician-specified agent, carefully read and understand the product insert and intended use including warnings, cautions, potential side effects and contraindications.
- Use correct dosage of the physician specified agent as per manufacturer instructions. Correct priming of Catheter must be considered for achieving correct dosage. **Priming volume of InVera Infusion Device is 1.5ml.**
- Only attach syringes to the infusion port on the Injection Extension tube. Do not attach any syringes to the Catheter Luer Hub as this is not part of the infusion pathway.
- Confirm syringe and Injection Extension tube luer connections. Do not use if leakage of solution persists.
- The InVera Infusion Device is sterilised by E-beam and is supplied in a sterile condition. In the event that the packaging has been damaged or opened unintentionally dispose of the device immediately.
- Store the device at ambient temperatures.
- The InVera Infusion Device is a sterile single-use only device. Reuse of the device may result in infection and reduced technical success of the procedure.
- Following completion of the procedure dispose of the device according to local laws for biohazardous waste.
- Contains Cobalt: The stainless-steel components of this device contain >0.1% weight by weight of Cobalt (CAS No. 7440-48-4), which is defined as a 1B CMR (carcinogenic, mutagenic or toxic to reproduction) substance. The amount of cobalt in the stainless-steel components has been evaluated considering the intended used and toxicological profile of the device. The cobalt used does not cause an increased risk to carcinogenic or reproductive risks.
- Persons allergic to nickel titanium (Nitinol) may suffer an allergic response to this device.

Recommended Accessories

The following accessories are needed to use the device to treat patients, however, they are not supplied with the device:

- 5 Fr vascular Access Kit
- Flushing syringe
- Sterile saline (USP 0.9%)
- Physician-specified agent for infusion.

Direction for Use

Device Preparation

1. Visually inspect the product package prior to opening.
   Do not use if package is opened or damaged.
2. Use sterile technique to carefully remove the tray from the pouch and the contents from the tray.
3. The device is packaged with the coil in the deployed position, exposed from the Catheter. Inspect the device to be certain there are no visible signs of damage or defects.
   Do not use if contents are damaged.
   Caution: Do not loop the device during recapture or deployment as this will increase the forces experienced. Always maintain a straight configuration.
4. Recapture the Coil into the Catheter by immobilising the Haemostasis Hub in one hand and pulling the Catheter Luer Hub back until the Coil has been fully captured inside the outer Catheter.
5. Attach a syringe filled with sterile saline to the luer on the Injection Extension tube.
6. Flush sterile saline (USP 0.9%) through the Injection Extension tube luer to prime the system until saline is observed coming out at the tip.

Catheter Positioning

1. Under ultrasound guidance advance the InVera Infusion Catheter through the access device to the desired position within the target vein in the leg.
2. Using ultrasound imaging guidance, confirm that the echogenic Catheter tip is located in the correct position in relation to the deep venous anatomy.

Deployment of the Coil

1. Under ultrasound guidance, deploy the coil by holding the Hemostasis Hub in one hand and withdrawing it over the stainless-steel tube towards the Catheter Luer Hub which is held in the other hand. Confirm the position of the coil in the target vein.
2. Recapture and repeat step 1. if adjustment to position is required.

Procedural Steps

1. Orient the Catheter to maintain a straight position and to avoid kinking or creating an acute bend between the vascular access site and the Catheter hub.
   Caution: A kink could cause damage to the device or patient injury.
   Caution: Do not exert excessive force when withdrawing or advancing the Catheter.
2. Slowly withdraw the device through the treatment area at a recommended pull-back rate of 5 seconds/cm by holding the Haemostasis Hub or outer Catheter sheath. The Catheter markings are at 1cm intervals. Increased resistance may be encountered during withdrawal as the coil passes through venous valves. The coil will automatically elongate and reduce its diameter in this scenario resulting in a slight alteration in withdrawal forces experienced by the user.
3. Check using ultrasound for signs of adequate vessel spasm and coil contact with the vein wall. It may be necessary to repeat the withdrawal process by recapturing the coil and readvancing the Catheter to repeat procedural steps 1-2.
   Caution: **Do not perform excessive deployment and recapture beyond procedural necessity as it may compromise device integrity.**
4. Mechanical disruption of the inner vessel lining is only achieved when the coil is in contact with the vessel. Mechanical disruption can be performed up to three times on a section of target vessel if required.
5. Following mechanical disruption administer the physician-specified agent via luer on the Injection Extension tube. Infuse the physician-specified agent under ultrasound guidance. The Catheter dead space is 1.5ml which should be considered during infusion of liquids. Physician-specified agents are administered per the manufacturer instructions for use.
   Caution: If excessive syringe pressures are experienced or there is failure to deliver the physician-specified agent, recapture and remove the device. Flush with saline to check fluid injection pathway.

Recapture of the Coil

1. Under ultrasound guidance recapture the coil by pulling the Catheter Luer Hub back, keeping the Hemostasis Hub stationary so the inner assembly moves back, and the helical coil has fully recaptured inside the outer Catheter.

Removal of Device

1. Under ultrasound guidance remove the InVera Catheter out through the access device.

Legend

Symbol	Title	Symbol	Title
MD	Medical Device		Date of Manufacture
LOT	Lot Number		Do not use if package is damaged and consult the Instructions for Use
	Use-by Date		Do not reuse
STERILE R	Sterile using Radiation		Sterile barrier
	Single Sterile barrier system with protective packaging outside		Manufacturer
	Consult instructions for use	Rx	Prescription Use Only
UDI	Unique Device Identifier	REF	Reference Number
	Keep away from moisture		Temperature Limit
	Contains hazardous substances (Cobalt, CAS No. 7440-48-4)		

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In the event that any serious incident occurs in relation to the device, it should be reported to InVera Medical and the competent authority of the member state in which the user is established.

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