InVera Infusion Device

The InVera Infusion Device is a minimally invasive, single-use, disposable catheter system designed for the controlled infusion of physician-specified agents into the superficial veins of the lower limb. It provides physicians with a precise and effective tool for targeted delivery.

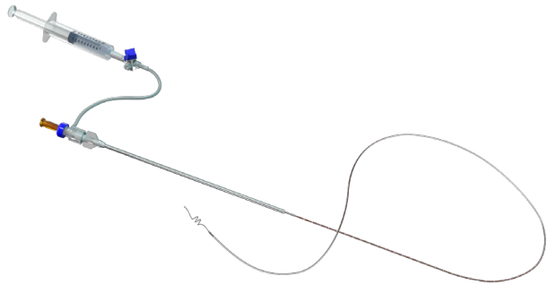

Figure 1 - InVera Infusion Device

The InVera Infusion Device (Fig. 1) has been designed for use in the peripheral vasculature, including the saphenous veins and related superficial veins of the lower limb, to ensure smooth and controlled navigation to the target site (Fig. 4). It is typically introduced at the thigh, knee or ankle level via a 5Fr Introducer sheath. The reinforced catheter design delivers excellent pushability supporting direct access, without the requirement for a guidewire, reducing procedural complexity. The echogenic distal catheter section is easily visualised by ultrasound during navigation to the target site.

The helical coil is deployed from its constrained position in the distal catheter by a simple and intuitive pin-and-pull handle mechanism. The helical coil can be easily recaptured and repositioned under direct ultrasound visualisation (see Fig. 5) to ensure ideal placement in the target vein. The radial outward force of the 6mm diameter coil and its micro-textured lumen engaging surface stimulate venospasm resulting in shrinkage of the target vein diameter (1,2). This reduces the volume of blood available to cause dilution of the infused agent.

Prior to infusion of agents, the helical coil is withdrawn in the target vein by straightforward catheter shaft withdrawal by the user. This results in localized venospasm in the target infusion area and exposure of the subendothelial layer secondary to mechanical disruption by the lumen engaging surface of the helical coil.

Infusion is performed by attachment of a syringe to the 3-way tap connected by an extension tube to the catheter handle luer hub. The infused agent is delivered through catheter for end-hole infusion to the target zone. Infusion is typically performed at intervals across the target zone depending on the clinical requirement. Following completion of infusion, the helical coil is recaptured, and the device is removed.

Key Features

Nitinol Helical Coil

Unique design with micro-textured lumen engaging outer surface and smooth inner surface (see Fig. 2). Precision laser cut textured surface disrupts the vein wall at a cellular level, without catching or snagging in vein wall valves, for a smooth and intuitive withdrawal process.

Delivery Catheter

Holds the constrained coil during navigation and delivers physician-specified agents, such as sclerosants, to the target area (see Fig.4). The catheter's distal outer section is composed of spirally cut stainless-steel, combining strength and flexibility.

Ergonomic Pin & Pull Handle

Designed for easy deployment and recapture of the helical coil. An integrated infusion port with a standard luer connector allows for seamless agent delivery via an injection extension tube.

Safety & Performance Device Benefits

- **Precise Delivery:** Engineered for targeted infusion of physician-specified agents to the vein lumen and sub-endothelial layers.
- **Intuitive Method:** The device's design prioritizes ease of use, allowing for quick integration into standard clinical practice. The procedure is straightforward and based on existing minimally invasive ultrasound-guided endovascular techniques.
- **Procedural Efficiency:** The single-use, disposable design contributes to an efficient procedure flow across a range of clinical environments. No requirement for additional consoles or equipment.
- **Minimally Invasive:** Introduced via a standard 5Fr introducer sheath. Non-thermal, Non-Tumescent technique requires only a single injection of local anesthetic at the introducer site, promoting a faster return to daily activities for patients.

Intended Use

The InVera Infusion Device is intended 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.

**The InVera Infusion device is an Investigational product and is not currently available for sale in the US, EU or any other international market. It is intended solely for investigational research use at this time. We are working towards regulatory approval in the US, EU and additional international markets.*

References:

1. Loesch A, Dashwood MR. On the sympathetic innervation of the human greater saphenous vein: relevance to clinical practice. Curr Vasc Pharmacol. 2009 Jan;7(1):58–67.

2. Mueller RL, Raines JK. ClariVein mechanochemical ablation: background and procedural details. Vasc Endovascular Surg. 2013 Apr;47(3):195–206.

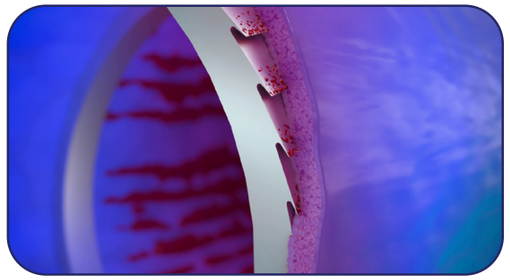

Figure 2 - Helical coil micro-abrasive features

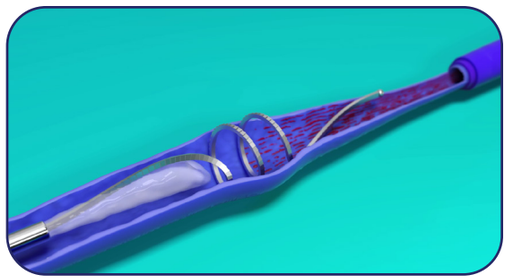

Figure 3 - Agent Infusion via catheter

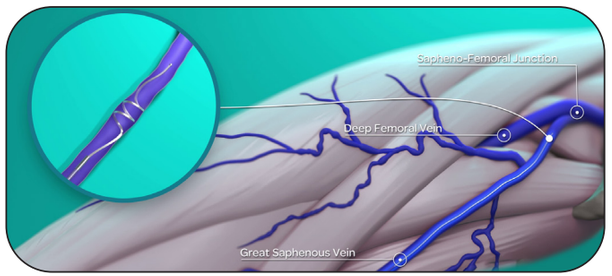

Figure 4 - Catheter access in vasculature

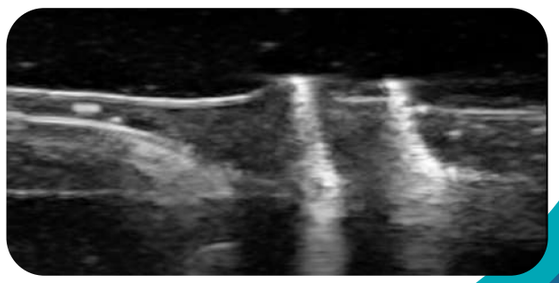

Figure 5 – Coil in contact with vessel wall on ultrasound transverse view