

CLARIVEIN® OC INFUSION CATHETER

Procedural Guidance



The foregoing Procedural Checklist and other information are for the practitioner's convenience and for general information purposes only. Before using any product, refer to the Instructions for Use (IFU) for indications, contraindications, warnings, precautions, and directions for use.

ClariVein® OC recommended steps for the intended use of the infusion of physician-specified agents in the peripheral vasculature when the target vessel is a superficial, saphenous vein.

SET UP	Check
1. Review the preoperative clinical assessment (patient history and physical exam) and duplex ultrasound findings.	<input type="checkbox"/>
2. Confirm the vessel to be treated, diameter, treatment lengths and access site.	<input type="checkbox"/>
3. Identify junctions to deep system (saphenofemoral junction (SFJ), saphenopopliteal junction (SPJ), perforators).	<input type="checkbox"/>
4. Ensure that all necessary instruments and fluids are available in the procedure room.	<input type="checkbox"/>
5. Confirm the procedure bed can place patient in the supine or prone position.	<input type="checkbox"/>
6. Determine the concentration, volume and infusion rate of physician-specified fluid.	<input type="checkbox"/>
7. Rotate leg for easy access to vasculature.	<input type="checkbox"/>
8. Prepare and drape leg in sterile manner for duplex ultrasound and access.	<input type="checkbox"/>

ACCESS	Check
1. Position bed in Reverse Trendelenburg.	<input type="checkbox"/>
2. Administer local anesthetic at puncture site as needed per institutional protocol	<input type="checkbox"/>
3. Select an appropriately sized access device. Recommended access device should be equal to or greater than a 4F introducer or 18 G Short Peripheral Catheter.	<input type="checkbox"/>
4. The patient should be moved from Reverse Trendelenburg to a flat position (supine position for GSV or the prone position for SSV).	<input type="checkbox"/>

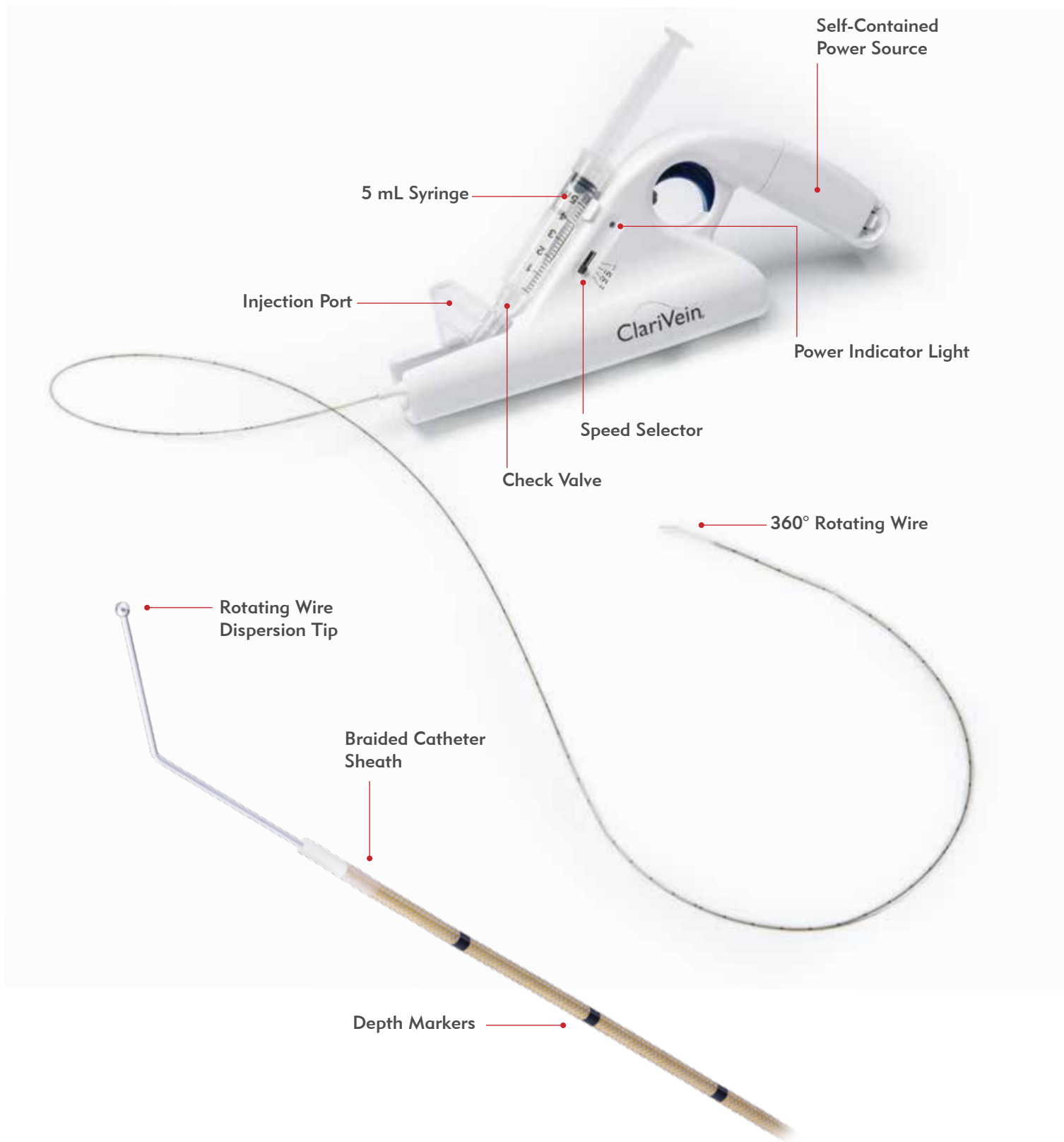
PROCEDURE	Check
1. Select appropriate length ClariVein® OC infusion catheter (45 cm, 65 cm, or 85 cm).	<input type="checkbox"/>
2. Use sterile technique to carefully remove the wrapped tray with the Cartridge Assembly and Motor Drive Unit (MDU) and pass to the sterile field.	<input type="checkbox"/>
3. Remove Battery Terminal Insulator Tab from the MDU and discard.	<input type="checkbox"/>
4. Depress trigger and note Green LED light. If Green LED light does not light, do not use. Gather all contents of the kit together and report event to Merit. Select a new kit.	<input type="checkbox"/>
5. Attach check valve to catheter assembly injection port. a. Check Valve: turn clockwise onto the Catheter Assembly injection port.	<input type="checkbox"/>
6. Flush the infusion catheter and check valve with appropriate fluid.	<input type="checkbox"/>

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PROCEDURE (CONTINUED)	Check
7. Advance infusion catheter through sheath under ultrasound guidance.	<input type="checkbox"/>
8. Steer the infusion catheter by turning the Catheter Assembly; do not attempt to twist or turn the infusion catheter by itself.	<input type="checkbox"/>
9. Thread the infusion catheter tip to the desired location in the peripheral vasculature using duplex ultrasound.	<input type="checkbox"/>
10. Join the catheter assembly to the MDU (Position 1, click: wire tip is sheathed; Position 2, click: angled part of wire tip is unsheathed). NOTE: The electrical circuit is now armed and the Dispersion Wire Tip is now unsheathed.	<input type="checkbox"/>
11. Confirm the location of the infusion catheter tip is in the desired location before activation of Dispersion Wire rotation. a. GSV, 2 cm distal from SFJ. b. SSV, start at the top of the fascial curve	<input type="checkbox"/>
12. Inform the patient they may feel a slight vibration.	<input type="checkbox"/>
13. Keep the infusion catheter straight between the access point and pull point at all times (the wire may break under tension).	<input type="checkbox"/>
14. Depress trigger and slowly withdraw the device without fluid infusion for 3-5 seconds; continue to slowly withdraw the spinning device through the treatment area while simultaneously infusing the physician-specified agent. NOTE: Do not follow or observe the Dispersion Wire Tip with the ultrasound probe while it is spinning. Doing so may cause the tip to catch.	<input type="checkbox"/>
15. Hold the MDU with one hand, while using the other hand to securely grasp the infusion catheter proximal to the access site, ensuring the infusion catheter does not kink or become damaged. Pull-back rate of 1 - 2 mm/second (6-7 sec/1 cm) is recommended.	<input type="checkbox"/>
16. After the first 10 cm check treated vessel under duplex ultrasound guidance, if no vein wall reaction, re-sheath the WIRE (Position 1) before re-advancing the infusion catheter and thread to an appropriate position, unsheathe and go to 15. NOTE: never advance infusion catheter in Position 2.	<input type="checkbox"/>
17. With approximately half of the vessel's targeted infusion length remaining, slide the access device to the most proximal end of the Catheter Assembly.	<input type="checkbox"/>
18. Continue until the white mark on the infusion catheter can be visualised at the access site (approximately 8 cm from the Dispersion Wire Tip when the Dispersion Wire is in Position 2); treat an additional 2-3 cm. Treatment length without a sheath depends on the skin-to-vessel depth of the patient being treated. Extravascular treatment may cause pain and is to be avoided.	<input type="checkbox"/>
19. Release the trigger to stop the MDU, re-sheath the wire tip (Position 1) and verify that the desired outcome has been achieved.	<input type="checkbox"/>
20. Remove the infusion catheter.	<input type="checkbox"/>

POST PROCEDURE	Check
1. Ask the patient to perform several (20-30) plantar flexion movements or the physician or nurse should flex the foot.	<input type="checkbox"/>
2. Apply compression stocking or wrap as per standard practice at the facility.	<input type="checkbox"/>
3. Institute appropriate post-procedural patient care.	<input type="checkbox"/>
4. Perform appropriate clinical follow-up.	<input type="checkbox"/>

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ClariVein® OC is not available in the USA

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