




## SCORPION® Portal Vein Access Set

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 <https://www.argonmedical.com/resources/product-information>

The symbols glossary is located electronically at  
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### Intended Use

The SCORPION® Portal Vein Access Set is intended for transjugular liver access in diagnostic and interventional procedures.

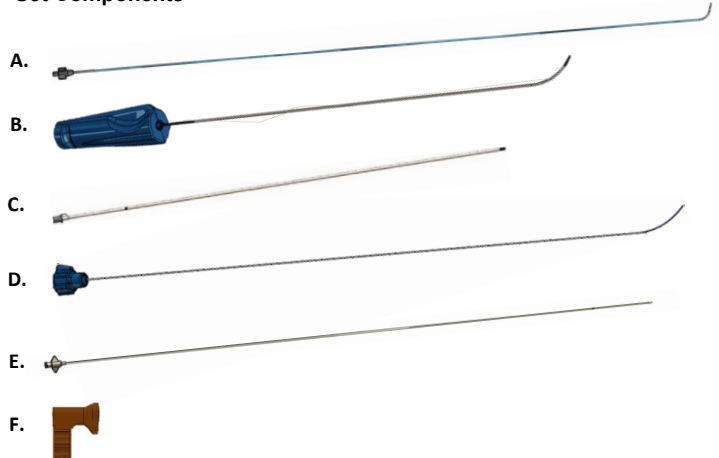
### Device Description

The SCORPION® Portal Vein Access Set contains a 5F MPA catheter, a 14ga Stiffening Cannula, a 0.040" Nitinol Stylet with a 5F PEEK Catheter, and a 7F Cannula Sheath. The 14ga stiffening cannula with cannula sheath has a directional handle that indicates the direction of the curve. These components are used to create a pathway through the liver parenchyma through which an endoprosthesis can be delivered. The SCORPION® Portal Vein Access Set is used to gain access to the hepatic vein and guide a sharp puncture tool (0.040" Stylet) through the parenchyma. The puncture tool (Stylet) is used to make a pathway from the hepatic vein to the portal vein, and then the pathway is dilated to provide access for a larger sheath. The shunt is inserted through the sheath and deployed through the pathway. Then, all of the SCORPION® Portal Vein Access Set components are removed.

The SCORPION® Portal Vein Access Set is typically in use in procedures up to 4 hours

The SCORPION® Portal Vein Access Set is compatible with the 10F Flexor® Check-Flo® Introducer Set (KCFW-10.0-38-40-RB, G32233) manufactured by Cook Medical.

### Set Components



- A. 5F x 80cm MPA Catheter
- B. 14ga x 52cm Scorpion Stiffening Cannula
- C. 7F x 52cm Cannula Sheath
- D. 0.040" x 73cm Scorpion Nitinol Stylet
- E. 5F x 71cm Scorpion PEEK Catheter
- F. Spacer Clip

### Contraindications

None known

### Warnings

- Do not use the device or accessories after the expiration date.
- Contents are supplied sterile and are intended for single use only. Do not re-sterilize. Do not use if sterile barrier is damaged.
- Reuse or reprocessing has not been evaluated and may lead to its failure and subsequent patient illness, infection or other injury.
- Do not use if package is open or damaged.
- Do not use excessive force when advancing, retracting, or manipulating kit components and accessories.
- Do not overtighten hub connections.
- A patient may experience a negative reaction to angiography if the patient is allergic to contrast media or has compromised renal function.
- Risks and benefits should be carefully assessed in pregnant patients as radiation from fluoroscopic imaging may endanger the fetus.
- Use fluoroscopic guidance when advancing, retracting, or manipulating kit components and accessories in the vasculature.
- Use a guidewire when advancing or manipulating kit components and accessories in the vasculature.
- Use of power injection of contrast media to verify access to the portal vein may cause a loss of access.
- After use, the portal access kit components may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.
- Do not continue to use any component damaged during the procedure.
- Tested capability of SCORPION® Portal Vein Access Set has been tested solely with the 10F Flexor® Check-Flo® Introducer Set (KCFW-10.0-38-40-RB, G32233) manufactured by Cook Medical. Use of alternative introducer sets is not recommended.

### Precautions

- Inspect all set components prior to use.
- For use by physicians trained in vascular diagnostic and interventional techniques only.
- Vascular access is necessary to use the SCORPION® Portal Vein Access Set to access the portal vein through the liver parenchyma.
- A patient may experience a negative reaction to angiography if the patient is allergic to contrast media or has compromised renal function.
- The patient should be monitored (EKG, oximetry, blood pressure, pulse) during the procedure.

### Potential Adverse Events

- Intraperitoneal hemorrhage
- Puncture site hematoma
- Gall bladder puncture
- Cardiac arrhythmia
- Cardiac tamponade
- Arteriovenous fistula
- Arterio-biliary fistula
- Death

### Instructions for Use

1. Remove all components from packaging using sterile technique.
2. Flush components with saline (not supplied).
3. Prepare the 10F Introducer Sheath with the 10F Dilator.
4. Assemble 7F Cannula Sheath over the 14ga Stiffening Cannula.
5. Assemble the PEEK Catheter over the 0.040" Nitinol Stylet, then place the spacer clip in between the PEEK Catheter and 0.040" Nitinol Stylet.



**Figure 1: Spacer Clip in Place**

6. Obtain jugular access and advance a  $\leq 0.035$ " guidewire (not supplied) through the jugular vein, into the inferior vena cava.
7. Advance a compatible 10F Introducer Sheath and 10F Dilator (not supplied) over the guidewire into the IVC.
8. Remove the 10F Dilator.
9. Insert the 5F MPA Catheter over the guidewire into the hepatic vein. Advance the guidewire into the hepatic vein.
10. Advance the 10F Introducer Sheath to the hepatic vein.
11. Remove the 5F MPA Catheter, leaving the guidewire in place.
12. Introduce the 7F Cannula Sheath /14ga Stiffening Cannula assembly through the Introducer Sheath into the hepatic vein. Then remove guidewire. Be careful to maintain hepatic access with the 14ga Stiffening cannula and Introducer Sheath while removing the guidewire.
13. Insert the 0.040" Nitinol Stylet / PEEK Catheter assembly until the black line on the PEEK Catheter aligns with the end of the safety funnel on the 14ga Stiffening Cannula. The 0.040" Stylet tip should not be advanced past the PEEK Catheter.
14. Orient the 14ga Stiffening Cannula toward the portal vein.
15. Remove the spacer clip from the 0.040" Nitinol Stylet / PEEK Catheter assembly and retract the PEEK Catheter until the hub is locked with the handle on the 0.040" Nitinol Stylet to expose the stylet tip.
16. Wedging the 14ga Stiffening Cannula against the vein wall and orienting the 0.040" Nitinol Stylet towards the portal vein, advance the 0.040" Stylet forward through the parenchyma and toward the portal vein.
17. Remove the 0.040" Nitinol Stylet from the PEEK Catheter.
18. Confirm access to the portal vein.
19. Introduce a guidewire through the PEEK Catheter into the portal vein.
20. If necessary, dilate the parenchymal tract to accommodate the 10F Introducer Sheath.

21. Advance the 10F Introducer Sheath across the parenchymal tract and into the portal vein.
22. Remove the PEEK Catheter, 14ga Stiffening Cannula, and SCORPION® Cannula Sheath leaving the 10F Introducer Sheath in place.
23. Proceed with any indicated interventional procedures.

### Disposal

After use, this product may be a potential biohazard. Dispose in accordance with applicable laws and regulations.

### Storage

Store at controlled room temperature.

### CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.

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