




SCORPION[®]X Portal Vein Access Set

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RxOnly    

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

The symbols glossary is located electronically at
www.argonmedical.com/symbols

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Intended Use

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

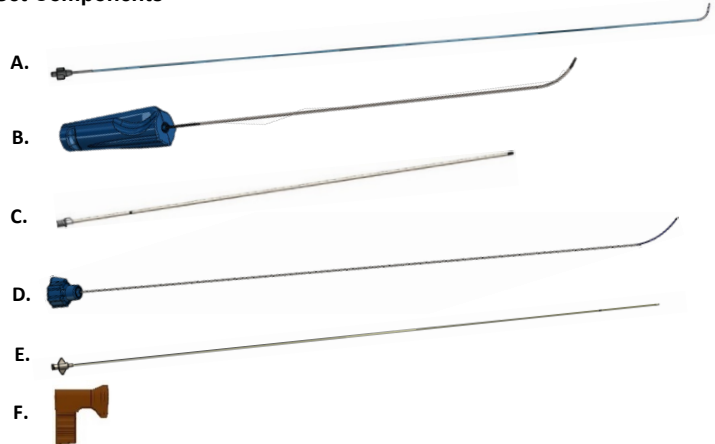
Device Description

The SCORPION[®]X Portal Vein Access Set contains a 5F MPA Catheter, a 13ga Stiffening Cannula, 17ga Nitinol Needle, a 6.2F PEEK Catheter, and an 8F Cannula Sheath. The 13ga stiffening cannula with cannula sheath has a directional handle that indicates the direction of the curve. The 17ga Nitinol Needle 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[®]X Needle Portal Vein Access Set is used to gain access to the hepatic vein and guide a sharp puncture tool (17ga Needle) through the parenchyma. The puncture tool (Needle) 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[®]X Portal Vein Access Set components are removed.

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

The SCORPION[®]X 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. 13ga x 52cm Scorpion Stiffening Cannula
- C. 8F x 52cm Cannula Sheath
- D. 17ga x 73cm Scorpion Nitinol Needle
- E. 6.2F x 71cm Scorpion Needle PEEK Catheter
- F. Spacer Clip

Contraindications

None known

Warnings

- Do not attempt to modify the 13ga Scorpion Stiffening Cannula bend angle
- 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®X 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

- Intraoperative 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 8F Cannula Sheath over the 13ga Stiffening Cannula, then place the safety clip.
5. Assemble the Needle PEEK Catheter over the 17ga Nitinol Needle, then place the spacer clip in between the PEEK Catheter and the 17ga Nitinol Needle.



Figure 1: Spacer Clip in Place

6. Obtain jugular access and advance a ≤ 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 the hepatic vein and maintain access without occluding the vessel.
11. Remove the 5F MPA Catheter, leaving the guidewire in place.
12. Introduce the 8F Cannula Sheath/13ga Stiffening Cannula assembly through the Introducer Sheath into the hepatic vein. Be careful to maintain hepatic access with the 13ga Stiffening Cannula while removing the guidewire.
13. Insert the 17ga Needle / Needle PEEK Catheter assembly until the black line on the Needle PEEK Catheter aligns with the end of the safety funnel on the 13ga Stiffening Cannula. The 17ga Needle tip should not be advanced past the Needle PEEK Catheter.
14. Orient the 13ga Stiffening Cannula toward the portal vein.
15. Remove the spacer clip from the 17ga Nitinol Needle / Needle PEEK Catheter assembly and retract the Needle PEEK Catheter until the hub is locked with the handle on the 17ga Nitinol Needle to expose the stylet tip.
16. Wedging the 13ga Stiffening Cannula against the vein wall and orienting the 17ga Nitinol Needle towards the portal vein, advance the 17ga Nitinol Needle forward through the parenchyma and toward the portal vein.
17. Remove 17ga Nitinol Needle from the Needle PEEK Catheter and confirm access to the portal vein.
18. Introduce a guidewire through the Needle PEEK Catheter into the portal vein.
19. If necessary, dilate the parenchymal tract to accommodate the 10F Introducer Sheath.

20. Advance the 10F Introducer Sheath across the parenchymal tract until the tip of the 10F Introducer Sheath is in the portal vein. Be careful to avoid occluding the portal vein with the Introducer Sheath.
21. Remove the SCORPION®X Needle PEEK Catheter, 13ga SCORPION®X Stiffening Cannula, the 8F Cannula Sheath, leaving the 10F Introducer Sheath in place.
22. Proceed with any indicated diagnostic or interventional procedures through the 10F Introducer Sheath.

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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