Traveler™16
Portal Vein Access Set

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The symbols glossary is located electronically at
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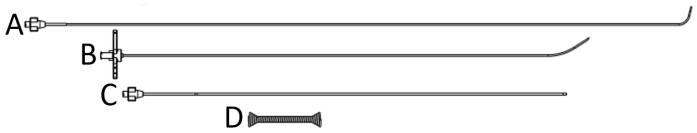
Intended Use
The Traveler™16 Portal Vein Access Set is intended for transjugular liver access in diagnostic and interventional procedures.

Device Description
The Portal Vein Access Set contains a 5F MPA catheter, a 16ga Curved Needle with a 7Fr Needle Catheter (separated with a removable spacer clip), and a bending tool. The 16ga Curved Needle has a directional handle that indicates the direction of the curve and the orientation of the bevel.

These components are used to create a pathway through vascular access to the liver parenchyma through which an endoprosthetic can be delivered. The Portal Vein Access Set is used to gain access to the hepatic vein and guide a sharp puncture tool toward the parenchyma. The puncture tool 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 Portal Vein Access Set components are removed. The Portal Vein Access Set is typically in use in procedures up to 4 hours.

The Traveler™16 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. 16ga x 57cm Curved Needle
C. 7F x 51cm Needle Catheter
D. Bending Tool

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 and if the expiry date has been exceeded.
- 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 a guidewire when advancing or manipulating kit components and accessories in the vasculature.
- Do not bend the needle/catheter assembly more than 40° at any single point, as this might cause kinking of the needle/catheter.
- Tested capability of Traveler™16 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 package integrity before use.
- Inspect all set components prior to use
- For use by physicians trained in vascular diagnostic and interventional techniques only
- Use fluoroscopic guidance when advancing, retracting, or manipulating kit components and accessories in the vasculature.
- The patient should be monitored (EKG, oximetry, blood pressure, pulse) during the procedure.
- Use of power injection of contrast media to verify access to the portal vein may cause a loss of access.

Potential Complications
- Intraperitoneal hemorrhage
- Puncture site hematoma
- Cardiac arrhythmia
- Arteriovenous fistula

Instructions for Use

1. Remove all components from packaging using sterile technique.
2. Flush components with saline (not supplied).
3. Assemble the 10F Introducer Sheath (not supplied) with the 10F Dilator (not supplied).
4. Assemble the 7F Needle Catheter with the 16ga Curved Needle. (needle should not be advanced past the 7F Needle Catheter tip)
5. If necessary, apply the Bending Tool over the 7Fr Needle Catheter and 16ga Needle and adjust the angle of the needle/catheter assembly.
6. Obtain jugular access and advance a ≤0.038" guidewire through the jugular vein, into the inferior vena cava.
7. Advance a compatible 10F Introducer Sheath/Dilator assembly 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 5Fr MPA Catheter over the guidewire into the hepatic vein.
11. Advance the 10F Introducer Sheath to the hepatic vein and maintain access without occluding the vessel.
12. Carefully remove the 5F MPA Catheter.
13. Introduce the 16ga Curved Needle/7F Needle Catheter assembly through the 10F Introducer Sheath. When the black line on the 7F Needle Catheter is aligned with the proximal end of the Introducer Sheath hemostasis valve, the 7FNeedle Catheter tip will be aligned with the distal tip of the Introducer Sheath. The needle should not be advanced past the catheter tip during insertion.
14. Carefully remove the guidewire.
15. Remove the spacer clip from the needle/catheter assembly and retract the 7F Needle Catheter until the hub is locked with the needle handle to expose the needle tip.
16. Advance the needle/catheter assembly into the hepatic vein.
17. Orient the needle/catheter assembly toward the portal vein (the directional handle on needle indicates the direction of the needle bevel and curve).
18. Advance the needle into the parenchyma and toward the portal vein. If the needle is advanced beyond the portal vein, retract it until the tip of the needle is within the portal vein.
19. Confirm access to the portal vein.
20. Introduce a guidewire (not supplied) through the needle to maintain access to the portal vein.
21. Remove the 16ga Needle and Needle Catheter. Be careful to maintain hepatic access with the guidewire while removing the 16ga Needle and Needle Catheter.
22. Dilate the parenchymal tract to accommodate the 10F Introducer Sheath.
23. Advance the 10F Introducer Sheath across the parenchymal tract until the tip of the Introducer Sheath is in the portal vein. Be careful to avoid occluding the portal vein with the 10F Introducer Sheath.
24. Proceed with any indicated diagnostic or interventional procedures through a 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.