



# Traveler™38 Portal Vein Access Set



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20-2007-44/1121D

## Intended Use

The Traveler™38 Portal Vein Access Set is intended for transjugular liver access in diagnostic and interventional procedures.

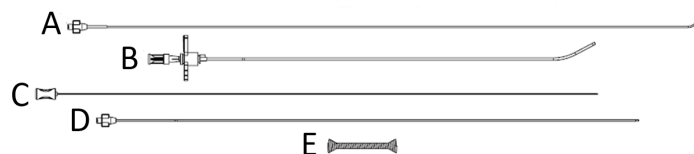
## Device Description

The Portal Vein Access Set contains a 5F MPA catheter, a 14ga Stiffening Cannula with a 7F Cannula Sheath, a 0.038" Stylet with a 5Fr Stylet Catheter (separated with a removable spacer clip), and a bending tool. 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 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™38 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 Stiffening Cannula / 7F x 52cm Cannula Sheath
- C. 0.038" x 69cm Stylet
- D. 5F x 66cm Stylet Catheter
- E. 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™38 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

- Intraabdominal 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 14ga Stiffening Cannula with the 7F Cannula Sheath.
5. If necessary, apply the Bending Tool over the 14ga Stiffening Cannula and 7Fr Cannula Sheath and adjust the angle of the cannula/sheath assembly.
6. Obtain jugular access and advance a  $\leq 0.038$ " 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 10F Introducer Sheath to the hepatic vein and maintain access without occluding the vessel.
11. Remove the 5F MPA Catheter, leaving the guidewire in place.
12. Introduce the 14ga Stiffening Cannula/7F Cannula Sheath assembly into the hepatic vein and remove the guidewire from the 14ga Stiffening Cannula. Be careful to maintain hepatic access with the 14ga Stiffening Cannula and Introducer Sheath while removing the guidewire.
13. Insert 0.038" Stylet/5F Stylet Catheter assembly into 14ga Stiffening Cannula until the black line on the Stylet Catheter aligns with the end of the safety funnel on the 14ga Stiffening Cannula. The 0.038" Stylet tip should not be advanced past the catheter or cannula tip.
14. Remove the spacer clip from the stylet/catheter assembly and retract the 5F Stylet Catheter until the hub is locked with the stylet handle to expose the stylet tip. Ensure the 0.038" Stylet tip does not advance past the distal tip of the 14ga Stiffening Cannula.
15. Orient the 14ga Stiffening Cannula toward the portal vein (the directional handle on stiffening cannula indicates the direction of the cannula curve).
16. Wedging the 14ga Stiffening Cannula against the vein wall, advance the 0.038" Stylet forward through the parenchyma and toward the portal vein. If the 0.038" Stylet is advanced beyond the portal vein, retract it until the tip of the catheter is within the portal vein.
17. Remove the 0.038" Stylet from the 5F Stylet Catheter.
18. Confirm access to the portal vein.
19. Introduce a guidewire (not supplied) through the 5F Stylet 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 until the tip of the Introducer Sheath is in the portal vein. Be careful to avoid occluding the portal vein with the Introducer Sheath.
22. Remove the 5F Stylet Catheter, 14ga Stiffening Cannula, and 7F Cannula Sheath, leaving the Introducer Sheath in place.
23. Proceed with any indicated diagnostic and interventional procedures through the 10F 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.