COOK MEDICAL

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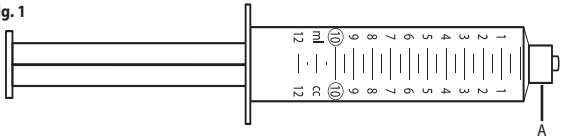
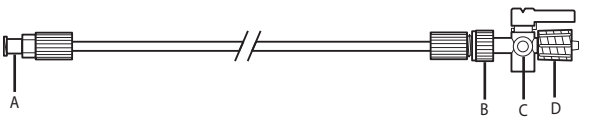
EchoTip® Insight™ Portosystemic Pressure Gradient Measurement System
Instructions for Use

Fig. 1



A. Male Luer

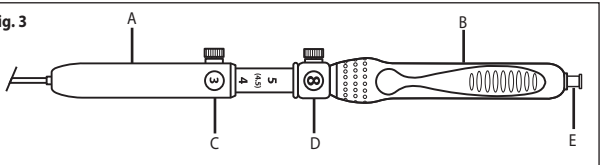
Fig. 2



A. Connecting Tube Female Luer B. Connecting Tube Male Luer C. Stopcock Sideport

D. Stopcock Male Luer

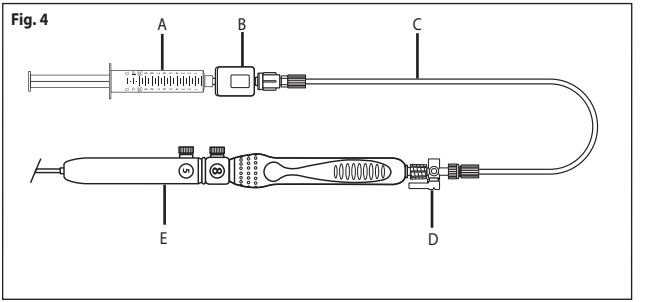
Fig. 3



A. Sliding Sheath Adjuster B. Needle Handle C. Sheath Reference Mark

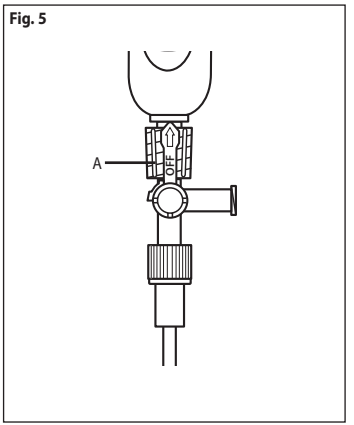
D. Safety Ring E. Female Luer

Fig. 4

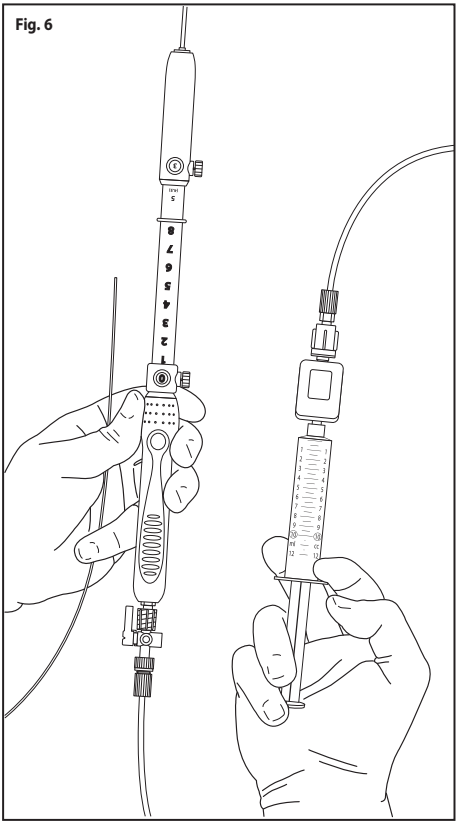


A. Syringe
B. Compass CT Transducer
C. Connecting Tube
D. 3-Way Stopcock
E. EchoTip Insight Needle

Fig. 5

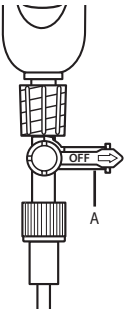


A. Stopcock 'OFF' position while priming connecting tube



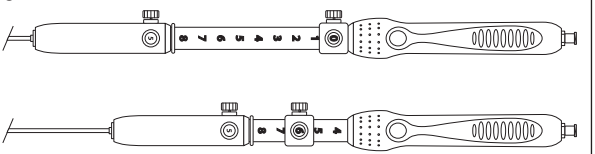
Vertical device orientation while priming system

Fig. 7



A. Stopcock 'OFF' position while priming needle

Fig. 8



ECHOTIP® INSIGHT™ PORTOSYSTEMIC PRESSURE GRADIENT MEASUREMENT SYSTEM

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

INDICATIONS FOR USE

The EchoTip Insight Portosystemic Pressure Gradient Measurement System is indicated to directly measure pressures in the hepatic and portal venous vasculatures and is used in conjunction with an ultrasound endoscope.

DEVICE DESCRIPTION

The EchoTip Insight Portosystemic Pressure Gradient Measurement System comprises the EchoTip Insight Needle, Connecting Tube, and Compass CT transducer. Once assembled (Fig. 4), these devices are used with an ultrasound endoscope in patients with known or suspected portal hypertension.

The EchoTip Insight Needle is a device consisting of a handle with adjustable components to allow the user to adjust the extension of the needle and sheath. The device has a 5.2 Fr (1.73 mm) outer sheath for protection of the 25 ga (0.56 mm) needle and is attached to the accessory channel of an endoscope. The device has a female Luer fitting on the needle handle to allow for the connection of the stopcock. The device is supplied with a 10 ml syringe that is attached to a Compass CT transducer that is connected to both the needle and connecting tube when assembled. The device is used to access the venous vasculature related to the portal circulation and hepatic outflow through the accessory channel of an ultrasound endoscope to allow for direct measurement and monitoring of physiological pressure within this circulation.

The connecting tube consists of a 90 cm tube, a female Luer fitting, a male Luer fitting and a stopcock. The connecting tube is used to attach the transducer to the needle handle. The stopcock is used to aid priming of the assembled components. The device is used for the transfer of liquids between the EchoTip Insight components.

The Compass CT is a self-calibrating disposable pressure transducer with integrated digital display.

CONTRAINDICATIONS

Those specific to the primary endoscopic procedure to be performed in gaining access to desired target.

This device should only be used to access the hepatic vein or portal vein or their branches. Any other use is contraindicated.

POTENTIAL ADVERSE EVENTS

Those associated with an endoscopic ultrasound procedure include, but are not limited to: allergic reaction to medication, aspiration, cardiac arrhythmia or arrest, death, fever, hypotension, infection, pain/discomfort, perforation and respiratory depression or arrest.

Those associated with the device include, but are not limited to: arteriovenous fistula, cholangitis, damage to blood vessels, embolism, fever, hemorrhage, hypotension, infection, inflammation, nerve damage, pain/discomfort, perforation, pneumoperitoneum, sepsis, septicemia/bacteremia, thrombosis, vessel occlusion and vessel trauma.

WARNINGS

The tip of the needle is sharp and could cause injury to the patient or user if not used with caution.

This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.

This device contains nickel, which may cause allergic reaction in individuals with nickel sensitivity.

Product is sterile if package is unopened or undamaged. Do not use the product if the peel-open packages, or the box they are supplied in, are damaged. Do not use the product if there is doubt as to whether the product is sterile.

Visually inspect the packaging and device. If the packaging is opened or damaged when received, do not use. Visually inspect the device with particular attention to kinks, bends, or breaks. If a device abnormality is detected that would prohibit proper working condition, do not use. Please notify Cook for return authorization.

Ensure both vessels are visible and accessible prior to initiating procedure. Access to the vasculature should be approached through the liver parenchyma to reduce risk of bleeding.

The risks and potential adverse effects of the procedure in patients with pre-existing conditions (such as those listed below) must be considered relative to the potential benefits of this procedure:

- Patients with active gastrointestinal bleeding which is not controlled by medical intervention.
- Patients with known infection which is not controlled by medical intervention.
- Patients with known portal vein thrombosis.
- Patients with known heparin induced thrombocytopenia.

PRECAUTIONS

Refer to package label for minimum channel size required for this device.

Do not use the device supplied for any purpose other than stated intended use.

Refer to the Compass CT Instructions for Use for technical specifications and detailed operation instructions including warnings, precautions and operating range of transducer.

Use of the devices supplied are restricted to a trained healthcare professional. The EchoTip Insight Needle should only be used by physicians trained in Endoscopic Ultrasound procedures.

The needle must be retracted into the sheath and the thumbscrew on the safety ring must be locked at the 0 cm mark to hold the needle in place prior to introduction, advancement or withdrawal of device. Failure to retract the needle may result in damage to the endoscope.

The transducer must be positioned at the phlebostatic axis (fourth intercostal space at the mid anterior posterior midpoint of the chest wall) while obtaining a pressure measurement to ensure reading is accurate.

A sterile fluid (i.e. heparinized saline) is used to flush the system once all parts are assembled during system preparation. Refer to flushing solution labelling prior to use to ensure all appropriate cautions, warnings and contraindications are observed.

In a well-lit area, ensure no large air bubbles that may occlude the system are present. If air bubbles are observed, they must be removed from the system before proceeding. Air in the

system may increase the response time of the transducer to measure pressure within the portal or hepatic vein.

Once assembled, ensure the closed system remains intact and is not opened to atmospheric pressure during the procedure as doing so will affect the measurements.

Device damage such as needle kinking may result in a non-responsive/inaccurate measurement or higher forces when priming fluid. Do not continue to use the product if there is doubt as to whether the product is damaged.

Vessel penetration may lead to intrahepatic bleeding and non-responsive/inaccurate pressure measurement.

SYSTEM PREPARATION

1. Visually inspect the packaging confirming it is unopened and free from damage prior to use.
2. Visually inspect the device components confirming they are free from damage prior to use.
3. Remove all components from their individual packaging.
4. Remove the Luer cap from the transducer.
5. Switch on the transducer as outlined in the Compass CT Instructions for Use.
6. Fill 10 ml syringe (Fig. 1) with sterile fluid, ensuring that all large air bubbles are removed from the syringe.
7. Attach the prepared syringe to the female Luer fitting of the transducer.
8. Attach the male Luer lock fitting of the transducer to the white female Luer fitting of the connecting tube and secure tightly.
9. Attach the male Luer lock fitting of the connecting tube stopcock (Fig. 2) to the female Luer fitting on the needle handle (Fig. 3) and secure tightly. **Note:** The system is now fully assembled and should correspond with the image shown in Fig. 4.
10. Prime the system up to the stopcock by slowly advancing plunger into syringe ensuring no large air bubbles are present (Fig. 5 & Fig. 6). **Note:** Fluid should be visible exiting the sideport of the stopcock.
11. Adjust the stopcock to close the sideport before proceeding to prime the needle with minimum 1 ml of sterile fluid (Fig. 6 & Fig. 7). **Note:** Fluid should be visible exiting the distal tip of the sheath.
12. Inspect system to ensure all connections are tight, fully engaged and there are no large air bubbles present in the system. **Note:** If air is present in the tubing or Luer connections, repeat Steps 10–12.
13. Identify the patient's phlebostatic axis and level the transducer at this point. **Caution:** Position the transducer at this level while obtaining the pressure measurement. Any movement will change current or subsequent pressure measurements.

If a syringe exchange is required during the procedure, complete the following steps:

a. If the device is within the endoscope, remove the device by disconnecting the Luer lock fitting from the accessory channel port by rotating the device handle counter clockwise and withdraw the entire device from the endoscope.
b. Disconnect the syringe from the female Luer fitting of the transducer.
c. Fill 10 ml syringe (Fig. 1) with sterile fluid, ensuring that all large air bubbles are removed from the syringe and attach the syringe to the female Luer fitting of the transducer.
d. Repeat Steps 10 through 12 of "System Preparation".

INSTRUCTIONS FOR USE

1. Identify desired vasculature by endoscopic ultrasound where a triplicate pressure measurement will be taken. **Note:** Ensure both vessels are visible and accessible through the liver parenchyma prior to proceeding with the following steps.
2. With the needle retracted into the sheath and the thumbscrew on the safety ring locked at the 0 cm mark to hold the needle in place, introduce the device into the accessory channel of the endoscope. **Caution:** If resistance is encountered on device introduction, reduce angulation of scope until smooth passage is allowed.
3. Advance the device, in small increments, until the Luer lock fitting at the base of the sliding sheath adjuster meets the Luer fitting of the accessory channel port.
4. Attach the device to the endoscope accessory channel port by rotating the device handle clockwise until the fittings are connected.
5. Adjust the sheath to the desired position, ensuring that it is endoscopically visible, confirming that the sheath has emerged from the working channel of the scope. To adjust sheath length, loosen the thumbscrew lock on the sliding sheath adjuster and slide until the preferred length is attained. **Note:** The reference mark for the sheath length will appear in the sliding sheath adjuster window (Fig. 3). Tighten thumbscrew on the sliding sheath adjuster to maintain the preferred sheath length.
6. While maintaining position of the ultrasound endoscope, set the needle to the desired length by loosening the thumbscrew on the safety ring, and advancing it until the desired reference mark for needle advancement appears in the window of safety ring (Fig. 8). Tighten thumbscrew to lock the safety ring in place. **Note:** The number in the safety lock ring window indicates the extension of the needle in centimeters. **Caution:** During needle adjustment or extension, ensure the device has been attached to the accessory channel of the endoscope. Failure to attach the device prior to the needle adjustment or extension may result in damage to the endoscope.
7. Extend the needle by advancing the needle handle to the pre-positioned safety ring into desired vessel under ultrasound guidance, either hepatic or portal vein, or their branches. **Caution:** If excessive resistance is encountered on needle advancement, retract the needle into the sheath with the thumbscrew locked at 0 cm mark, reposition the scope and attempt needle advancement from another angle. Failure to do so may result in needle breakage, device damage or malfunction. **Note:** Following puncture continue to visualize puncture site to ensure no leakage and continuously observe throughout the procedure.
8. Using the prepared syringe, instill up to 0.5 ml of sterile fluid while observing the ultrasound view. Confirm location within the vessel and ensure that the needle tip is not against the vessel wall as this may alter pressure readings.
9. While maintaining position of both the needle tip and the transducer, allow time for pressure reading to equilibrate. Record the pressure reading displayed on the transducer. **Caution:** Ensure sufficient time is given (minimum 60 seconds) to the device to allow it to stabilize before recording the measurement from the attached transducer. **Note:** For subsequent measurements instill up to 0.5 ml of sterile fluid to flush the system for the next measurement.
10. Without retracting the needle, repeat Step 9 to obtain triplicate measurements while maintaining this position in the vessel. **Note:** Measurements in the portal and hepatic vein are completed in triplicate to ensure values obtained are reproducible and to record the average of the three values. If they are not reproducible, additional measurements should be obtained. If the additional measurements are still not reproducible or

additional sterile fluid is required, follow Steps a–d of "System Preparation" before obtaining additional measurements.

11. Retract the needle completely into the sheath by pulling back on the needle handle and lock the thumbscrew on the safety ring at the 0 cm mark to hold the needle in place. (Fig. 8)
12. Reposition the endoscope and identify the second vessel to be accessed (opposite of the vessel accessed in Step 7). Obtain triplicate measurements in this vessel by repeating Steps 6 through 10 of the "Instructions for Use".
13. Upon completion of the procedure, retract the needle completely into the sheath by pulling back on the needle handle and lock the thumbscrew on the safety ring at the 0 cm mark to hold the needle in place.
14. To remove the device from the endoscope, disconnect the Luer lock fitting from the accessory channel port by rotating the device handle counter clockwise and withdraw the entire device from the endoscope.
15. Calculate and record the portal pressure gradient (the difference between the average hepatic vein and average portal vein measurements).

Upon completion of procedure, dispose of device per institutional guidelines for biohazardous medical waste.

HOW SUPPLIED

Supplied together in non-sterile box. Individual devices supplied sterilized by ethylene oxide gas in peel-open packages. Only devices supplied should be used for procedure. Store in a dark, dry, cool place. Avoid extended exposure to light.

Rx ONLY

STERILE | EO

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