# TLAB®
# Transvenous Liver Biopsy System

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## Device Description
The TLAB® Transvenous Liver Biopsy System is intended to be used for percutaneous transjugular and transfemoral venous liver access during diagnostic and interventional procedures. The device is a single use, disposable sterile device.

## Intended Purpose/Intended Use
Intended for use in obtaining liver histology samples via transjugular and transfemoral venous approaches.

## Intended Patient Population
Adult patients to include elderly adults, any gender, race, or ethnicity.

## Indication for Use
The TLAB® Transvenous Liver Biopsy System is intended to be used for percutaneous transjugular and transfemoral venous liver access during diagnostic and interventional procedures.

## Intended Users
The product is intended for use by medical professionals trained in interventional procedures and must only be used by qualified personnel who are familiar with the applicable technique.

## Duration/Lifetime
The TLAB® Transvenous Liver Biopsy System is intended for continuous use less than 1 hour.

## Clinical Benefits
The TLAB® Transvenous Liver Biopsy System presents a direct benefit to the patient by obtaining histological sample of liver tissue which allows diagnosis, prognosis, and/or treatment by the clinician.

## Risks and Side Effects
• Arteriovenous/arteriobiliary fistulas
• Hemobilia
• Puncture site hematoma
• Intraperitoneal hemorrhage
• Cardiac arrhythmias
• Myocardial infarction
• Plaque dislodgement
• Perforation of the vessel wall
• Vascular occlusion
• Pneumothorax
• Stroke or death
• Air embolism
• Infection
• Vascular spasm
• Allergic reaction to contrast
• Hepatic artery damage
• Injury or puncture of other organs

## Contraindications
None Known.
Sound professional judgement should be used to determine if use of this product is inadvisable due to specific patient characteristics, including, but not limited to occluded IVC, occluded femoral vein, occluded internal jugular vein and possibly a short length of the intrahepatic IVC.

## Warnings
- Contents are supplied sterile and are intended for single use only. Do not re-sterilize.
- 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 continue to use if any of the component are damaged during the procedure.
- Cross sectional imaging should be consulted prior to use of this device to confirm feasibility of the procedure and correct location for biopsy.
- Fluoroscopic visualization is required to ensure accurate placement.
- Selection of appropriate device should be based on patient anatomy.
- Sound professional judgement should be used when performing procedures on patients who are using anticoagulant therapy and/or patients with known coagulopathy.
- The device should be inserted over a guidewire to prevent accidental perforation of vessel walls during navigation.
- Continuous cardiac monitoring is suggested as negotiating devices into the right atrium may cause cardiac arrhythmias. This is especially important if portal pressures will be taken during the procedure and passage into the right atrium is a possibility.

## Precautions
- Do not continue to use if any of the components are damaged during the procedure. When used repeatedly in the same patient, the biopsy instrument should be inspected for damage or wear after each sample is taken.
- When bending the 7 Fr Introducer, use the associated bending tool and refer to included diagram to prevent kinking of the introducer. After bending, verify the ability to pass the biopsy needle through the introducer before inserting the device into the vasculature.
- Manipulation of radiopaque or other tips, reformation of devices or harsh handling may adversely impact performance or result in damage including, but not limited to, device fragmentation or tip detachment.
- Use of a catheter that is not supplied in the kit could lead to incompatibility, delays, or complications.

## Recommended Procedure for Liver Biopsy via Transfemoral Access

### Pre-Procedure Preparation
1. Prepare the patient for transfemoral vein access per standard clinical protocol.
2. Remove components of the TLAB® Transvenous Liver Biopsy System from the package using sterile technique.
3. Flush the components with heparinized saline or other isotonic solution before use.
4. Charge the Needle (Figure 1) by pulling back on the Plunger (A) (Figure 6 and 7)

### Directions for Use
1. Obtain femoral venous access.
2. Introduce and seat a guidewire into the inferior vena cava (IVC) using a wire introducing means, such as the 5 Fr Curved Catheter (Figure 4).
   Note: Guidewire is not included in the kit. Follow manufacturer's instructions for use.
3. Remove the wire introducing means.

**Prior to inserting the 7Fr sheath, the 5 Fr curved catheter can be used to obtain hepatic venous pressures.**

**Caution: The 5 Fr Curved Catheter (Figure 4) is not designed to be re-formed, straightened or used through the 7 Fr Introducer (Figure 8). Doing so can lead to tip failure or detachment.**

4. Optional: Insert the 5 Fr Straight Catheter (Figure 5) (provided in some sets) coaxially within the 7 Fr Introducer.

**Caution: The 7 Fr Introducer (Figure 2) is stiffened. Flexing or other manipulation of the tip of the 5 Fr Straight Catheter (Figure 5) while inserted inside the 7 Fr Introducer or other extreme handling can lead to tip failure or detachment.**

Note: Temporarily disconnecting the Valve Assembly (E) on the 7 Fr Introducer (Figure 2) may Facilitate loading the 5 Fr Straight Catheter (Figure 5) into the 7 Fr Introducer. The Valve Assembly may be disconnected by grasping the two transparent portions (G) on the Valve Assembly (E) and rotating one portion versus the other.

**Caution: The Valve Assembly (E) must be fully connected as in Figure 2 before the Needle is inserted to avoid increasing the risk of over penetration.**

5. Insert a sheath and dilator assembly (large enough to accept a 7 Fr device) over the guidewire, following manufacturer's instructions.
   Note: Sheath/dilator not included in kit.
6. Advance the sheath over the wire into the IVC
7. Leaving the sheath in place, remove the dilator.
8. Under fluoroscopic imaging, estimate the diameter of the patient's IVC.
9. Using the bending tool (Figure 13) included in the kit, put a curve in the metal stiffening cannula such that the tenting of the caval wall will occur when the cannula is inserted to the intrahepatic region of the IVC.
   Note: Be sure the curve in the cannula is within the acceptable range shown in Figure 14. A bend radius that is too small may prevent the biopsy needle from tissue sample acquisition.
10. After making the bend, insert the needle into the 7 Fr introducer, verifying that it can pass through entirely without impediment. If the needle is unable to navigate the curve, return to step 9 and increase the radius of the bend. If needle passes successfully, proceed to step 11.
11. Remove the needle from the 7Fr Introducer.
12. Confirm that the Protective Sheath (J) on the 7 Fr Introducer is securely connected to avoid puncture. Insert the 7 Fr Introducer through the previously placed sheath, over the previously placed guidewire, carefully navigating the vasculature until reaching the intrahepatic region of the IVC.
13. Remove the guidewire, and 5 Fr Straight Catheter (Figure 5) if used, when the desired position has been achieved.
14. Under fluoroscopic imaging, verify that the Introducer curve abuts the wall of the IVC by injecting a small amount of contrast. If curve is not appropriate, remove the Introducer and adjust the bend. Once bend is correct, continue to step 15.

15. Remove the guidewire, and 5 Fr Straight Catheter (Figure 5) if used, when the desired position has been achieved.
16. Confirm that the needle is charged (Figure 7). If it is not charged, charge the needle by pulling back on the plunger until a firm click is felt and heard (Figure 6).

**Caution: Functional tests are performed during manufacture. "Test firing" the device is not necessary and strongly discouraged as the cutting edge may be damaged if not supported by surrounding tissue.**

17. Gently introduce the charged needle (Figure 7) into the Valve Assembly (E) of the 7 Fr Introducer (Figure 2).
18. Confirm that no critical structures are within the needle stroke length, or "throw", of the device. Gently advance the needle until the Indicator Mark (C) on the needle meets the Safety Guide (F) on the Valve Assembly (E). In this position, the tip of the Needle is positioned near the Distal Tip (L) of the 7 Fr Introducer.
19. Referencing the Red Directional Arrow (H) on the 7 Fr Introducer, direct the 7 Fr Introducer and apply gentle pressure to "tent" the wall of the IVC adjacent to the biopsy site. Verify under imaging that the distal tip is within the intrahepatic portion of the IVC.
20. Using clinical judgment, advance the needle into the targeted biopsy site until the Handle (B) rests against the Safety Guide (F). In this "Hub-to-Hub" position, the needle has advanced beyond the Distal Tip (L) of the 7 Fr Introducer.
    Note: For best performance, as the needle is advanced confirm that the Red Directional Arrow (H) on the 7 Fr Introducer is aligned in the same direction of the Red Cap (D) on the Handle (B) of the needle to achieve Red-to-Red Alignment. To achieve this, the needle may be gently rotated. This orientation maintains proper alignment between the direction of the Bend in the 7 Fr Introducer and Specimen Notch (N) of the needle. Maintain red-to-red alignment during the last 5 cm of insertion.
21. While applying even pressure on the needle to maintain its Hub-to-Hub position with the Safety Guide (F), gently advance the Plunger (A) to the First Stop (Figure 10). This exposes the Specimen Notch (N).
22. Confirm location and exposure of Notch under visualization
23. While maintaining Hub-to-Hub alignment, fire the needle by applying additional pressure on the Plunger (A) (Figure 11). You will feel and hear the firing of the needle.
24. While maintaining the position of the 7 Fr Introducer, remove the needle.

**An IVC gram should be performed after all samples are completed to demonstrate the intrahepatic IVC patency.**

25. Remove the specimen from the needle by pulling back on the Plunger (A) to the Charged Position (Figures 6 and 7) and gently pushing the Plunger (A) forward to the First Stop (Figure 10) to expose the Specimen Notch (N). Using the Tissue Removal Swabs (Figure 3), the specimen may be safely and gently removed from the Specimen Notch (Figure 12).
26. Process the specimen according to clinical protocols.
27. If desired, additional cores can be obtained by pulling Plunger (A) back to the charged position (Figure 7) and proceeding as described above.

## Recommended Procedure for Liver Biopsy via Transjugular Access

### Pre-Procedure Preparation

1. Prepare the patient for transjugular access per clinical protocols.
2. Remove the components of the TLAB® Transvenous Liver Biopsy System from the package using sterile technique.
3. Flush components with heparinized saline or similar isotonic solution before use.
4. Charge the Needle (Figure 1) by pulling back on the Plunger (A) (Figure 6 and 7) until a firm click is felt and heard and gently place it for later use.

### Directions for Use

1. Obtain internal jugular venous access.
2. Introduce and seat a guidewire into the right hepatic vein using a wire introducing means, such as the 5 Fr Curved Catheter (Figure 4) (provided in some sets) or by other methods. Note: Guidewire is not included in the TLAB® Transvenous Liver Biopsy System. Follow manufacturer's instructions for use.
3. Remove the wire introducing means.

**Caution: The 5 Fr Curved Catheter (Figure 4) is not designed to be re-formed, straightened or used through the 7 Fr Introducer (Figure 8). Doing so can lead to tip failure or detachment.**

4. Optional: Insert the 5 Fr Straight Catheter (Figure 5) (provided in some sets) coaxially within the 7 Fr Introducer.

**Caution: Use of a catheter that is not supplied in the kit could lead to incompatibility, delays or complications.**

**Caution: The 7 Fr Introducer (Figure 2) is stiffened, and flexing or other manipulation of the tip of the 5 Fr Straight Catheter (Figure 5) while inserted inside the 7 Fr Introducer or other extreme handling can lead to tip failure or detachment.**
Note: Temporarily disconnecting the Valve Assembly (E) on the 7 Fr Introducer (Figure 2) may Facilitate loading the 5 Fr Straight Catheter (Figure 5) into the 7 Fr Introducer. The Valve Assembly may be disconnected by grasping the two transparent portions (G) on the Valve Assembly (E) and rotating one portion versus the other. Caution: The Valve Assembly (E) must be fully connected as in Figure 2 before the Needle is inserted to avoid increasing the risk of capsular perforation.

5. Confirm that the Protective Sheath (J) on the 7 Fr Introducer is securely connected to avoid puncture and insert the 7 Fr Introducer over the guidewire. A 9 Fr sheath (not included) can provide access for the 7 Fr Introducer and may be placed prior to inserting the 7 Fr Introducer.

**Caution: The 7 Fr Introducer is not intended to be re-formed or manipulated. Doing so may lead to damage of the device, affect product performance, or cause other complications.**

Note: If preferred, the guidewire may be more easily "back loaded" into the 7 Fr Introducer while the Valve Assembly (E) is temporarily disconnected.

**Caution: The Valve Assembly (E) must be fully connected as in Figure 2 before the Needle is inserted to avoid the risk of capsular perforation.**

6. Make any appropriate adjustments to avoid capsular perforation using clinical judgment. Contrast material may be injected through the Side Port (I) in the Valve Assembly (E) of the 7 Fr Introducer.
7. Remove the guidewire, and 5 Fr Straight Catheter (Figure 5) if used, when the desired position has been achieved.
8. Confirm that the Needle is charged (Figure 7). If it is not charged, charge the Needle by pulling back on the Plunger until a firm click is felt and heard (Figure 6).

**Caution: Functional tests are performed during manufacture. "Test firing" the device is not necessary and strongly discouraged as the cutting edge may be damaged if not supported by surrounding tissue.**

9. Gently introduce the charged Needle (Figure 7) into the Valve Assembly (E) of the 7 Fr Introducer (Figure 2).

**Caution: If the Valve Assembly (E) has been disconnected (Figure 9), do not insert the Needle until the Valve Assembly has been reconnected.**

10. Confirm that no critical structures are within the needle stroke length, or "throw", of the device. Gently advance the Needle until the Indicator Mark (C) on the Needle meets the Safety Guide (F) on the Valve Assembly (E). In this position, the tip of the Needle is positioned near the Distal Tip (L) of the 7 Fr Introducer.
11. Referencing the Red Directional Arrow (H) on the 7 Fr Introducer, direct the 7 Fr Introducer and, if desired, apply gentle forward pressure to "tent" the wall of the hepatic vein adjacent to the biopsy site.
12. Using clinical judgment, advance the Needle into the targeted biopsy site until the Handle (B) rests against the Safety Guide (F). In this "Hub-to-Hub" position, the Needlehas advanced beyond the Distal Tip (L) of the 7 Fr Introducer.

Note: For best performance, as the Needle is advanced confirm that the Red Directional Arrow (H) on the 7 Fr Introducer is aligned in the same direction of the Red Cap (D) on the Handle (B) of the Needle to achieve Red-to-Red Alignment. To achieve this, the Needle may be gently rotated. This orientation maintains proper alignment between the direction of the Bend in the 7 Fr Introducer and Specimen Notch (N) of the Needle. Maintain Red-to-Red alignment during the last 5 cm of insertion.

13. While applying even pressure on the Needle to maintain its Hub-to-Hub position with the Safety Guide (F), gently advance the Plunger (A) to the First Stop (Figure 10). This exposes the Specimen Notch (N).
14. Confirm location and exposure of Notch under visualization.
15. While maintaining Hub-to-Hub alignment, fire the Needle by applying additional pressure on the Plunger (A) (Figure 11). You will feel and hear the firing of the Needle.
16. While maintaining the position of the 7 Fr Introducer, remove the Needle. Caution: It is very important to inject contrast medium immediately following each firing of the needle to assess the puncture and rule out capsular perforation and extravasation.
17. Remove the specimen from the Needle by pulling back on the Plunger (A) to the Charged Position (Figures 6 and 7) and gently pushing the Plunger (A) forward to the First Stop (Figure 10) to expose the Specimen Notch (N). Using the Tissue Removal Swabs (Figure 3), the specimen may be safely and gently removed from the Specimen Notch (Figure 12).
18. Process the specimen according to clinical protocols.
19. If desired, additional cores can be obtained by pulling Plunger (A) back to the charged position (Figure 7) and proceeding as described above

### Disposal

After use, handle and dispose in accordance with hospitals policies and procedures concerning biohazard materials and waste.

### Storage

Store at controlled room temperature.

**Note:**
In the event a serious incident related to this device occurs, the event should be reported to Argon Medical at quality.regulatory@argonmedical.com as well as to the competent health authority where the user/patient resides.

**KEY**

**Figure 1:** Flexcore® Biopsy Needle
- A) Plunger
- B) Handle
- C) Indicator Mark
- D) Red Cap

**Figure 2:** 7 Fr Introducer
- E) Valve Assembly
- F) Safety Guide
- G) Two Clear Portions
- H) Red Directional Arrow
- I) Side Port
- J) Protective Sheath
- K) Bend
- L) Distal Tip

**Figure 3:** Tissue Collection Swab

**Figure 4:** 5 Fr Curved Catheter (Not Available in All Markets)

**Figure 5:** 5 Fr Straight Catheter

**Figure 6:** Charging Needle

**Figure 7:** Charged Needle

**Figure 8: DO NOT** Insert 5 Fr Curved Catheter into 7 Fr Introducer

**Figure 9: DO NOT** Insert Needle into 7 Fr Introducer if Valve Assembly is Disconnected and/or Protective Sheath is Disconnected

**Figure 10:** Plunger Advanced to First Stop Exposing Notch
- M) First Stop
- N) Specimen Notch

**Figure 11:** Fire the Needle by Advancing Plunger Beyond First Stop

**Figure 12:** Retrieving Specimen from Notch with Tissue Collection Swab

**Figure 13:** Bending Tool

**Figure 14:** Bending Diagram

Figure 1

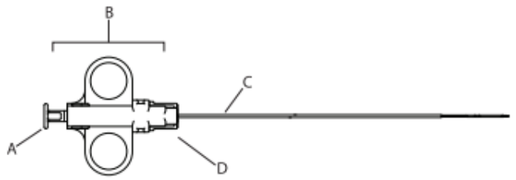


Figure 2

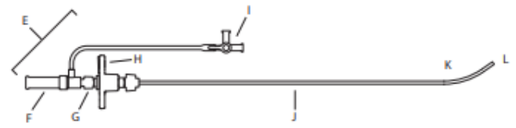


Figure 3



Figure 4

Figure 5

Figure 6

Figure 7

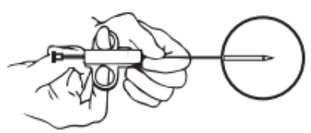

Figure 8

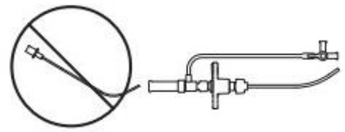

Figure 9

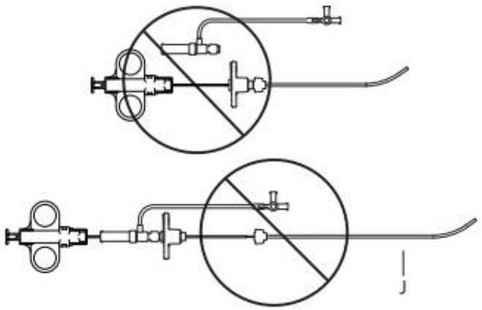


Figure 10

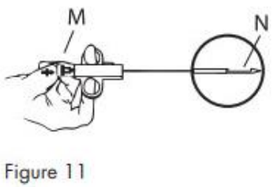


Figure 11

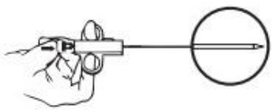

Figure 12

Figure 13

Figure 14