

dextera®

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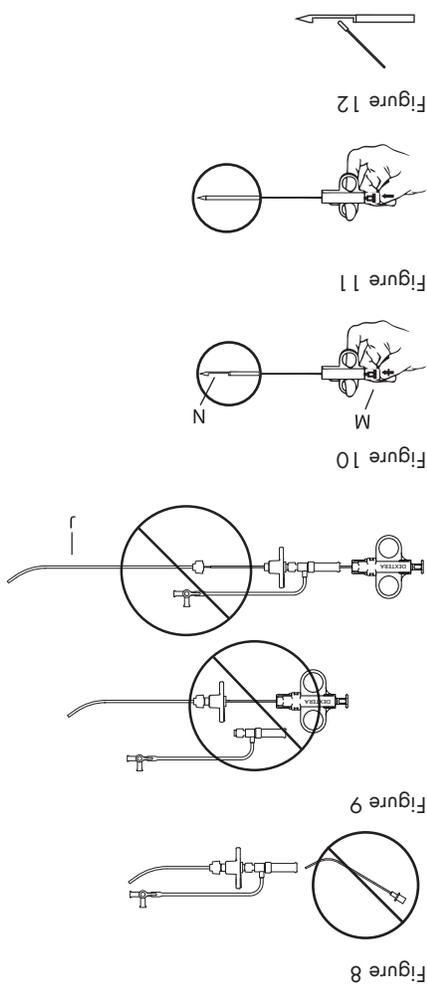
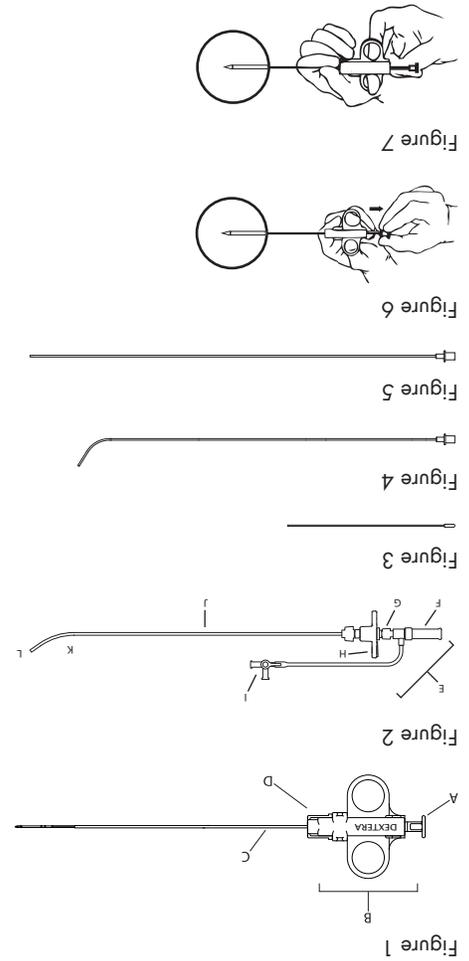
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TLAB® Patel Set®
 Transjugular Liver Biopsy System

Directions for Use

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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
 J) Protective Sheath
 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

Rx only      

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INDICATIONS FOR USE

For transjugular liver access biopsy.

CONTRAINDICATIONS

None Known.

Sound professional judgment should be used to determine if use of this product is inadvisable due to specific patient characteristics, including, but not limited to: thrombosis of the internal jugular vein, untreated infections or reaction to contrast medium. The clinician should evaluate the risks of potential complications of the procedure, including, but not limited to: arteriovenous fistulas, puncture site hematoma, intraperitoneal hemorrhage, cardiac arrhythmias, and puncture of other organs.

PRECAUTIONS

Directions for Use (“DFU”) assume clinical training in transjugular liver access biopsy procedures. This DFU is NOT intended to define or suggest any medical or surgical technique. The clinician is responsible for proper procedural technique and use of this product. Contact us and request technical assistance prior to using this product if you do not completely understand this DFU. Confirm packaging integrity for sterility, product condition and expiration dating prior to use. Contrast material, fluoroscopic and ultrasound visualization are required to ensure accurate placement.

Continuous cardiac monitoring is suggested as negotiating devices past the right atrium may cause cardiac arrhythmias. 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.

PRESENTATION

The TLAB® Patel Set® Transjugular Liver Biopsy System is presented in a Chevron Tyvek® Peel Pouch, which includes up to five sterile pouches in a master pouch. The inner pouches include:

Each TLAB® Patel Set® contains:

- Flexcore® Biopsy Needle, 18 ga or 19 ga, 68 cm overall length, 16.5 mm notch, 20 mm throw (Figure 1)
- 7 fr Introducer with Protective Sheath and Valve Assembly with Safety Guide, 60 cm overall length (Figure 2)
- Tissue Removal Swabs, 10 cm length, polyurethane foam tip, nylon handle (Figure 3)

For convenience, some Sets contain additional optional components that may be used based on clinician preference and discretion:

- 5 fr Curved Catheter, 76 cm overall length, for delivering a guidewire to the Right Hepatic Vein (Figure 4) (Not Available in All Markets)
- 5 fr Straight Catheter, 65 cm overall length for smoother transition between the 7 fr Introducer and guide wire (Figure 5)

SUGGESTED PROCEDURE

1. Prepare the patient for transjugular access per clinical protocols.
2. 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.
3. Obtain venous access.
4. Introduce and seat a guidewire into the right hepatic vein using a wire introducing means, such as the 5f Curved Catheter (Figure 3) (provided in some sets) or by other methods.
5. 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.

6. 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 7fr 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.

7. Confirm that the Protective Sheath (J) on the 7 fr Introducer is securely connected to avoid puncture and insert the 7f 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.

8. 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 7fr Introducer.
9. Remove the guidewire, and 5fr Straight Catheter (Figure 5) if used, when the desired position has been achieved.
10. 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.

11. 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.

12. 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.
13. Referencing the Red Directional Arrow (H) on the 7 fr Introducer, direct the 7 fr Introducer and, if desired, apply gentle forward pressure to “feni” the wall of the hepatic vein adjacent to the biopsy site.
14. 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.

15. 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).
16. Confirm location and exposure of Notch under visualization.
17. 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.
18. While maintaining the position of the 7fr 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.

19. 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).
20. Process the specimen according to clinical protocols.
21. If desired, additional cores can be obtained by pulling Plunger (A) back to the charged position (Figure 7) and proceeding as described above.