CLAIMS

1. A balloon-anchored, biopsy device for acquiring a biopsy sample of a target organ in a subject, the biopsy device comprising:

a first elongated tube enclosing a first lumen with a first proximal end and a distal tip, wherein a section of the first elongated tube near the distal tip comprises a balloon that when inserted into a blood vessel of a target organ of a subject and inflated, anchors the section in the blood vessel near a biopsy site in the target organ;

a second elongated tube enclosing a second lumen with a second proximal end and a second distal end coupled to a rigid contoured section comprising a beveled distal exit of the second lumen, which is positioned at the biopsy site of the target organ when the first elongated tube is anchored in the blood vessel by the inflated balloon, wherein a predefined length of the first and the second elongated tubes are longitudinally attached to one another and the rigid contoured section is positioned over the balloon such that the beveled distal exit is positioned over a proximal end of the balloon; and

a flexible biopsy needle attached to a distal end of a wire for insertion into the second lumen of the second elongated tube for navigation to the biopsy site, wherein the flexible biopsy needle is guided by the rigid contoured section and configured to exit the beveled distal exit of the second lumen for penetration into tissue of the target organ at the biopsy site at a predefined angle between a longitudinal axis of the section of the first elongated tube and a longitudinal axis of the flexible biopsy needle, and to acquire a biopsy sample of the target organ at the biopsy site.

2. The biopsy device according to claim 1, wherein the flexible biopsy needle comprises a Tru-cut biopsy needle.

3. The biopsy device according to claim 1, wherein the first elongated tube and the second elongated tube respectively comprise a balloon catheter and a guide catheter.

4. The biopsy device according to claim 1, wherein the target organ comprises a liver.

5. The biopsy device according to claim 4, wherein the blood vessel comprises a hepatic vein of the liver.

6. The biopsy device according to claim 1, further comprising a locking mechanism coupled to the second proximal end for fixing the position of the flexible biopsy needle at the distal end of the wire in the second lumen.

7. The biopsy device according to claim 6, wherein components of the locking mechanism are selected from the group consisting of a Tuohy Borst adapter, a luer lock, and a compressible clamp.

8. The biopsy device according to claim 1, wherein the flexible biopsy needle comprises a cutting cannula and a stylet.

9. The biopsy device according to claim 8, wherein the flexible biopsy needle comprises a flattened band and an alignment notch for maintaining an alignment of the cutting cannula and the stylet.

10. The biopsy device according to claim 1, wherein the first elongated tube is more flexible than the second elongated tube.

11. The biopsy device according to claim 1, further comprising an outer tube with the predefined length into which the first elongated tube and the second elongated tube are inserted so as to longitudinally attach the first elongated tube and the second elongated tube to one another.

12. The biopsy device according to claim 1, wherein the diameter of the inflated balloon is larger than the diameter of the blood vessel.

13. The biopsy device according to claim 1, wherein the diameter of the inflated balloon is no larger than 20% of the diameter of the blood vessel.

14. The biopsy device according to claim 1, wherein the predefined angle is in the range of 15-45 degrees.

15. The biopsy device according to claim 1, further comprising a connecting tube for insertion into the second lumen for guiding the flexible biopsy needle at the distal end of the wire to the biopsy site.

16. The biopsy device according to claim 1, wherein the flexible biopsy needle comprises a stylet joined to a stylet wire in an end-to-end joint.

17. The biopsy device according to claim 1, wherein the flexible biopsy needle comprises a hollow stylet and a stylet wire inserted into an overlapping joint.

18. The biopsy device according to claim 1, wherein the flexible biopsy needle comprises an inner stylet and outer stylet with a cutting edge arranged in a concentric configuration.

19. The biopsy device according to claim 18, wherein the flexible biopsy needle is configured to acquire the biopsy sample by rotating the outer stylet with the cutting edge relative to the inner stylet when the flexible biopsy needle is within the tissue of the target organ.

20. The biopsy device according to claim 19, wherein the flexible biopsy needle is configured to encapsulate the acquired biopsy sample in a specimen notch when the outer stylet remains in a rotated position substantially opposite to the inner stylet.

21. The biopsy device according to claim 1, wherein the balloon comprises a distal balloon and a proximal balloon, which are inflatable separately or together in the blood vessel.

22. The biopsy device according to claim 1, wherein the second elongated tube is coupled to a pressure transducer for measuring a hepatic venous pressure gradient (HVPG) by processing a signal from the pressure transducer in a signal processing unit.