The following sample is for illustrative purposes only, and reflects one of several options that may be available in this hypothetical case

Sample Operative Report (Reference Material Only)

Patient Name: Mrs. Smith
Date June xx, 2006

Pre-op Diagnosis: Possible L4-5 and L5-S1 discogenic pain syndrome as determined by physical exam and MRI.

Post-op Diagnosis: Likely and L5- S1 discogenic pain syndrome.

Procedure: L3-4, L4-5 and L5-S1 Provocative discogram
L4-5 and L5-S1 Functional Anaesthetic Discography™ Procedure
**Total time for Discyphor Direct™ Catheter placement/removal and functional anaesthetic examination _____minutes.

Anesthesia: IV Sedation

Complications: None

INDICATIONS: Mrs. Smith is a 32 year old female who presents with chronic low back pain. The pain has been refractory at all times to conservative management. Preoperative radiological imaging studies demonstrated disc degeneration and a moderate loss of disc height at the L4-5 and L5-S1 levels, worse at the L4-5 level. MRI imaging revealed Type II Modic changes at L4-5 and L5-S1 and a High Intensity Zone in the central posterior annulus of L5-S1. No annular tears were detected in any lumbar discs.

The patient presents today for further evaluation of her pain syndrome. After explaining the risks, benefits and alternatives to the patient including the option of continued conservative care, and the risks including but not limited to such as infection, neurologic injury and persistent pain at the injection site, the patient understood these and elected to proceed with procedure.

PROCEDURE: The patient was brought to the operating room, IV sedation was obtained and 1g Ancef was given IV preoperatively. The patient was carefully positioned prone on the image table. All bony prominences were carefully padded. Using a left-sided posterolateral approach under fluoroscopic guidance, salient landmarks were marked out on the patient's skin. The needle injection site to access the L4-5 and L5-S1 disc spaces via the discogram approach was injected with 1% lidocaine.

DISCYPHOR DIRECT™ Outer Needles were placed via this posterolateral approach to the left posterolateral margin at the L4-5 and L5-S1 disc spaces. DISCYPHOR DIRECT™ Inner Needles were then placed into the center of the discs at the L4-5 and L5-S1 levels. Via AP, enface, and lateral images, placement was confirmed in the center of the disc. With the needles secure in the center of discs, contrast diluted 1:1 with sterile saline was injected into both the L4-5 and L5-S1 disc spaces under pressure. The patient reported an immediate painful and concordant severe pain response to the injection at the L4-5 level. She rated her pain as 7/10 and stated the pain was reproduction of her usual symptoms. Next, the L5-S1 disc space was injected with contrast and again the patient reported severe concordant pain response which she rated at 9/10. Total volume of injection was 1.0 ml ml into both L4-5 and L5-S1 disc spaces.

Due to both levels being positive, the L3-4 adjacent level was investigated. A DISCYPHOR DIRECT™ Outer Needle was placed via this posterolateral approach to the left posterolateral margin of the L3-4 disc. A DISCYPHOR DIRECT™ Inner Needle was then placed into the center of the disc. Via AP, enface, and lateral images, placement was confirmed in the center of the disc. With the needle secure in the center of disc, contrast diluted 1:1 with sterile saline was injected into the L3-4 disc space under pressure. The patient reported no pain upon injection. The outer and inner needles in the L3-4 disc were then removed.

DISCYPHOR DIRECT™ Catheters were inserted through the inner needles, into the L4-5 and L5-S1 disc spaces. The outer and inner needles were removed simultaneously once the radiographic marker placement was confirmed via imaging to be entirely within the disc. Stopcock assemblies were attached to the inflation lumens at the proximal end of the DISCYPHOR DIRECT™ Catheters. The balloons were inflated with omnipaque contrast at both the L4-5 and L5-S1 levels. The Stopcocks were closed off and caps were sterilely replaced to the proximal luer fittings on the Stopcocks. Injection assemblies were connected to the injection lumens of the DISCYPHOR DIRECT™ Catheters at the L4-5 and L5-S1 levels. The DISCYPHOR DIRECT™ Catheters were sterilely dressed.

The patient was brought out to the postanesthesia care unit in good condition. She was at this point told to sit up in a position that is usually painful for her and to report her typical pain. First the L4-5 level was injected in a double–blinded fashion with normal saline. The patient reported preinjection pain scale of 8/10; during the injection it increased to 9/10; at 5 minutes after, it was 8/10; followed by 10 minutes 7/10 and 20 minutes 7/10. The patient reported no significant improvement in her condition. Next, the L4-5 level was injected with 0.7ml of lidocaine 4%. During the injection her pain scale remained at 7/10; at 5 minutes after her pain was 7/10 and this was maintained at 10 and 20 minutes after. The patient reported no significant improvement in her symptoms. Next the L5-S1 level was injected in a double-blinded fashion with .06ml of normal saline into the L5-S1 disc space. The preinjection visual analog score was 8/10. During the injection the pain increased to 9/10; at 5 minutes after it was 6/10; at 10 minutes after it was 7/10; and at 20 minutes after it was 8/10. The patient again reported no significant improvement in her symptoms. Next the L5-S1 level was injected with 4% lidocaine at total volume of 0.7 ml. During the injection, the patient's pain was maintained at 8/10; at 5 minutes after the injection it was 5/10; at 10 minutes it was 5/10; and at 20 minutes it was 4/10. The patient reported that her pain with extension and some of her pain with flexion was improved. The patient reported that this was a significant improvement over her baseline level.

Conclusion: Likely L5-S1 discogenic pain syndrome

There were no complications. The catheters were then removed in their entirety.