

FUNCTIONAL ANAESTHETIC DISCOGRAPHY™ **PROCEDURE OVERVIEW**

To perform the Functional Anaesthetic Discography™ (F.A.D.™) Procedure, the Discyphor™ Catheter is anchored within each suspected intervertebral disc by a balloon. Typical discography access technique is used to insert the Discyphor Catheter(s) into the disc space(s). The F.A.D. Procedure allows for both functional and anaesthetic assessment of suspected painful intervertebral discs in chronic low back pain patients.

Under fluoroscopic image guidance, the Discyphor™ Introducer Needle is docked on or in the outer annulus. The Discyphor™ Spinal Needle is inserted through the Discyphor Introducer Needle into the center of the target disc. The Discyphor™ Guidewire is inserted through the Discyphor Spinal Needle into the disc nucleus and the Discyphor Spinal Needle is removed, leaving the Discyphor Guidewire in the disc. The Discyphor Catheter is inserted over the Discyphor Guidewire into the disc through the Discyphor Introducer Needle. The Discyphor Guidewire and Discyphor Introducer Needle are then removed after the Discyphor Catheter has been inserted into the disc nucleus. The balloon anchor of the Discyphor Catheter is inflated using a contrast medium to anchor the catheter within the disc space during the functional testing process. The proximal end of the Discyphor Catheter is capped and secured to the patient with sterile tape and patient is transferred to recovery.

Upon sedation recovery, patient tries to recreate typical low back pain by loading the spine in a functional or physiological fashion during such activities such as sitting, walking or bending. The patient is asked to rate this pain using the Visual Analog Pain Scale (VAS). Patient is then injected with 0.5 - 0.7 cc of anaesthetic, and after approximately 10 minutes asked again to measure pain level. Comparison pain scores are measured for anesthetic disc improvement and additional valuable information for consideration of treatment options of discogenic back pain. A two point drop, or greater in pain score would indicate that the disc level is a pain generator.

The information provided in this notice is intended as general information only. It is not advice about how to code or complete or submit any particular claim for payment for the F.A.D. Procedure. Kyphon Inc. cannot guarantee coverage or reimbursement for the F.A.D. Procedure and makes no other representations as to selecting codes for the F.A.D. Procedure or compliance with any other billing protocols or prerequisites. As with all claims, physicians and hospitals are responsible for exercising their independent clinical judgment in selecting the codes that most accurately reflect the patient's condition and procedures furnished to a patient. Physicians and hospitals should refer to current, complete, and authoritative publications such as AMA CPT publications or insurer policies for selecting codes based on the care rendered to an individual patient, and may wish to contact individual carriers, fiscal intermediaries, or other third-party payers as needed.

As with most interventional procedures, the Functional Anaesthetic Discography procedure has associated risks, including serious complications. For complete information regarding indications for use, warnings, precautions, adverse events, and methods of use, please reference the device's Instructions for Use. *KYPHON* is a registered trademark, and *Ahead of the Curve*, *Discyphor*, and *Functional Anaesthetic Discography* are trademarks, of Kyphon Inc. ©2008 Kyphon Inc. All Rights Reserved. 16000944-01