FUNCTIONAL ANAESTHETIC DISCOGRAPHY™
PROCEDURE OVERVIEW

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

Under fluoroscopic image guidance, the DISCYPHOR DIRECT™ Outer Needle is introduced through the skin via a posterolateral approach. The DISCYPHOR DIRECT™ Inner Needle is inserted through the DISCYPHOR DIRECT™ Outer Needle into the nucleus of the target disc. The catheter is then inserted through the inner needle and into the disc. The outer and inner needles are then removed simultaneously, leaving the catheter in the disc nucleus. The balloon, located at the distal tip of the catheter, is inflated using a contrast medium to anchor the catheter within the disc nucleus during the functional testing process. The proximal end of the catheter is capped and secured to the patient with anchoring devices and/or sterile tape, and the 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 performing activities such as sitting, walking or bending. The patient is asked to rate this pain using the Visual Analog Pain Scale (VAS) or the Numeric Pain Rating Scale (NPRS). If applicable, patient's range of motion is also noted. Patient is then injected with 0.5 - 0.7 cc of anesthetic, and upon anesthetic onset, asked again to rate pain level (and applicable range of motion). Comparison pain scores and range of motion 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. Medtronic Spine LLC 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™ (F.A.D.™) Procedure has associated risks, including serious complications. For complete information regarding indications for use, contraindications, warnings, precautions, adverse events and methods of use, please reference the devices' Instructions for Use.