

## **Supplement 1**

### Full Definition of DDD

DDD is defined as back pain and/or radicular pain with degeneration of the disc as confirmed by history and radiographic studies with one or more of the following factors (as measured radiographically, either by computed tomography (CT) scans, magnetic resonance imaging (MRI), myelography, discography, or plain film): 1) instability as defined by  $\geq 3$ mm translation or a  $\geq 5^\circ$  angulation; 2) osteophyte formation of facet joints or vertebral endplates; 3) decreased disc height by an average of  $\geq 2$ mm but dependent upon spinal level; 4) scarring/thickening of ligamentum flavum, annulus fibrosis, or facet joint capsule; 5) herniated nucleus pulposus; 6) and/or facet joint degeneration/changes.

## **Supplement 2**

### Full Inclusion Criteria

Inclusion criteria for the study were: 1) age 18-70 years; 2) failed extensive conservative treatment measures for at least six months; 3) DDD between L2 and S1, with at least one of the pathologies listed (a. intractable low back and lower limb discogenic or facet joint pain; b. central disc herniation requiring the bilateral approach; c. intraforaminal disc herniation that requires removal of most of the facet joint; d. symptomatic grade I spondylolysis ; e. two or three contiguous lumbar disc herniations; f. persistent or recurrent symptoms after having undergone previous lumbar discectomy).

### Full Exclusion Criteria

Exclusion criteria for the study were: 1) had previous attempts at interbody fusion at the same level; 2) had spondylolisthesis of grade II or higher; 3) had DDD of three or more non-continuous spine segments; 4) osteoporosis; 5) were in poor general health (e.g. significant circulatory or cardiac disease); 6) had a systemic infection at the site of the surgery; 7) had non-discogenic cause of symptoms; 8) had an allergy to any component of the investigational devices proposed for use in the study; 9) were pregnant or interested in becoming pregnant during the course of their involvement; 10) had severe peripheral neuropathy; 11) had multiple problematic psychosocial factors; 12) had a history of substance abuse; or 13) were a prisoner.

### Supplement 3

#### Surgical Procedure

Prior to the surgical procedure the surgeon determined the size of cage to be used by analyzing the patient's MRI films. For the ABCS device, either a 25mm cage (diameters greater than 35mm) or a 21mm cage (diameters smaller than 35mm) was used. Similar procedures were used for the MSDIFD device size. The final decision regarding cage diameter was made intraoperatively.

The patient is positioned prone on the operative table, with care taken to avoid pressure over the abdomen in order to decrease intraoperative epidural bleeding. Intraoperative fluoroscopy in the lateral plane was used to localize and verify the correct level(s) and guide the location of the skin incision. For a single level fusion, a vertical incision (~5 cm) was made through the skin, the subcutaneous tissue and the muscle fascia. The paraspinal muscles were then separated with a McCullough retractor applied from the spinous process and lamina of the two vertebrae to be fused to maintain the opening. A Midas Rex and Kerrison rongeurs were used to remove part of the lamina and medial half of the facet joint on the right side. All bone material was preserved including bone dust to later fill the devices and the space between the spinous processes. The ligamentum flavum was incised as lateral as possible to minimize exposure of the dura, protect the dural sac, and decrease post-operative epidural fibrosis.

Foraminotomy was then carried out with the amount of facet joint removed dependent on the exposure needed to minimize dural retraction. Nerve root retractors were used to retract the nerve root and dural sac medially. Disc space material was then removed in order to create space for the disc space distractor. The distractor was inserted into the disc space to a depth of 25-30 mm and rotated 90° to create space between the vertebrae followed by removal of the handle. The appropriate sized cage was then selected such that the diameter of the cage would be 6mm larger than the size of the distractor.

With the right side stabilized attention was next focused to the left side. As with the right side, portions of the lamina, facet joint, and ligamentum flavum were removed with exposure of the dura limited by maintenance of the ligamentum flavum. The amount of lamina and facet joint removed was limited to the amount sufficient to accommodate the appropriate drill guide. Nerve root retractors were then used to retract the dural sac, traversing nerve root, exiting nerve root, and epidural vessels in order to expose the disc space. The drill guide was then angled 5° manually with a similar direction in the vertical plane

as the disc space distractor. At L5-S1 the angle was usually directed caudally (at L4-5 the angle is usually down) and at L3-4 the angle was usually directed cephalad. A centering punch was used to verify the position of the drill guide with the drill guide perfectly centered around the centering punch. While drilling, the nerve root retractors were left in place along with the drill guide to further provide protection of the neural and vascular structures. Once the disc space was entered, an aggressive discectomy was not required, as the drill removed most of the disc material. An inner cannula was then inserted into the drill guide with the cannula 2 mm smaller in diameter than the diameter of the cage that was to be implanted.

The set-screw on the drill was then set so that it would advance approximately 4mm beyond the length of the cage. The disc space was subsequently extracted, beginning with a 6mm drill and advanced to the largest size drill that would fit into the inner cannula. The drill was rotated in a clockwise fashion so that during withdrawal of the drill all disc material and bone would be removed. Following the completion of drilling, the inner cannula was removed. Using a microscope, the disc space was inspected and all residual disc material was removed. After discectomy was complete, the selected cage (previously packed with the autogenous bone preserved from the laminae and facet joints) was inserted into the disc space. The cage inserter was then used to advance the cage until the distal marking on the shaft was flush with the top surface of the drill guide, thus countersinking the cage 4-5mm. The cage was then closed by inserting the threaded end cap using the end cap screwdriver. Once the devices were closed, the drill guide, nerve root retractors, and disc space distractor were all removed from the left side. An x-ray was then taken to check the position of the cage. The exact procedure was followed as described above to complete the right side of device placement. Once implanted, a final x-ray was taken to again verify cage placement. The wound was subsequently closed by re-approximation of the muscle fascia with 0 PDS, the subcutaneous tissue with 3-0 PDS, and the skin with 4-0 Vicryl. On the day following surgery the patient was ambulated with a Warm 'N' Form lumbar brace for a minimum of 6 weeks.

#### **Supplement 4**

Additional information on the surgical procedure can be found through this link:

<http://medicaldesignsllc.com/wp-content/themes/medicaldesignstheme/images/ABCManual.pdf>