**SUPPLEMENTAL DIGITAL CONTENT**

**Table, Supplemental Digital Content 1, Main study eligibility criteria**

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| **Key Inclusion Criteria** |
| * Skeletally mature adults aged 18 to 60 years
* Radiographic evidence of lumbar DDD, based on identification of any of the following characteristics by MRI scan:
	+ instability (≥3mm translation or ≥5° angulation)
	+ osteophyte formation of facet joints or vertebral endplates
	+ decreased disc height (>2mm compared to the adjacent level)
	+ scarring/thickening of ligamentum flavum, annulus fibrosis, or facet joint capsule
	+ herniated nucleus pulposus
	+ facet joint degeneration
	+ vacuum phenomenon
* Single-level symptomatic disease at L4/L5 or L5/S1
* Minimum of 6 months of unsuccessful conservative treatment
* Minimum Oswestry Disability Index score of 40/100
* Minimum VAS back pain score of 40/100 mm
* Surgical candidate for an anterior approach to the lumbar spine
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| **Key Exclusion Criteria** |
| * Previous surgery at any lumbar level, other than IDET, percutaneous nucleoplasty, microdiscectomy, hemilaminectomy, or laminotomy
* Chronic radiculopathy, defined as unremitting pain with a predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least 1 year
* Anatomically unsuitable for TDR based on preoperative radiographic assessment
* Index level disc height < 3 mm
* Myelopathy
* Previous compression or burst fracture at index level
* Sequestered herniated nucleus pulposus with migration
* Mid-sagittal stenosis <8mm (by MRI)
* Spondylolysis.
* Lumbar scoliosis (>11 degrees sagittal plane deformity)
* Spinal tumor
* Active systemic infection or infection at the site of surgery
* Facet ankylosis or severe facet degeneration
* Continuing steroid use or prior use for more than 2 months
* Pregnancy or planning to become pregnant within the next 2 years
* Morbid obesity (BMI >35)
* Osteoporosis, osteopenia, or metabolic bone disease
* History of rheumatoid arthritis, lupus, or other autoimmune disorder
* Ankylosing spondylitis
* Abdominal pathology that would preclude the abdominal surgical approach
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**Table, Supplemental Digital Content 2, Patient characteristics and outcomes in Control group**

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|  **Characteristic** | **ProDisc-L****(n=64)** | **Charité****(n=41)** |
| **Demographics** |  |  |
|  Age, years | 41±9 | 40±9 |
|  Male gender, n (%) | 32 (50) | 20 (49) |
|  Body mass index, kg/m2 | 27±5 | 27±4 |
| **Medical history, n (%)** |  |  |
|  Current narcotic use | 57 (89) | 39 (95) |
|  Smoking history | 31 (48) | 12 (29) |
|  Previous lumbar surgery | 18 (28) | 12 (29) |
| **Main outcomes** |  |  |
|  ODI success | 43 (67) | 26 (63) |
|  Neurological success | 48 (75) | 32 (78) |
|  Radiographic success | 28 (44) | 16 (39) |
|  Device success | 54 (84) | 35 (85) |
|  Freedom from serious device-related AEs | 48 (75) | 26 (63) |

One patient (ProDisc-L) excluded from Control group comparisons due to implant failure.

**Figure, Supplemental Digital Content 1, CONSORT flow diagram.**



ITT: intent-to-treat; SDRE: serious device-related event