

# Disc Arthroplasty Study for the Lumbar Spine

## Bellin Hospital

in conjunction with Gundersen Lutheran Hospital

### Bellin Hospital Study Investigator:



#### **Dr. Andrew R. Greene**

*NeuroScience Group of NE WI*

For Appointments Call: 920-725-9373

Bellin Location: 1630 Commanche Ave.  
Green Bay, WI 54313

#### **STUDY TYPE**

This study is a multi-center, prospective, comparative effectiveness evaluation of single-level, stand-alone ALIF versus single-level ProDisc-L (PD-L) Artificial Disc in comparable patient cohorts utilizing a new outcome metric based on the pre and post-operative performance of standard physical tasks.

#### **PURPOSE**

The purpose of this study is to compare the physical capability outcomes of patients who undergo single-level ProDisc-L (PD-L) disc replacement with those of patients who undergo stand-alone, single-level anterior lumbar interbody fusion (ALIF). To date, single-level lumbar disc arthroplasty and single-level ALIF outcomes have been evaluated using subjective methods that may not accurately reflect improvement in physical performance. To our knowledge, no prospective, multi-center clinical trial has been conducted that compares lumbar disc arthroplasty outcomes with fusion outcomes in equivalently indicated patients using the quantitative data collected from physical capability outcomes testing. The magnitude of improvement in physical capability that may be expected as a result of either surgery is unknown, as is whether arthroplasty or ALIF produces the greater improvement. This study was initiated because of large improvements of over 200% in many of the physical capability tasks noted one year after PD-L in a preliminary study. These improvements exceeded any improvements ever observed at Gundersen Lutheran following fusion or medical management of patients with severe intractable low back pain secondary to degenerative disc disease. These results are important in obtaining a favorable coverage decision for arthroplasty from our own health plan.



Synthes ProDisc Lumbar  
Artificial Disc

#### Device Information:

- 1) Both devices are FDA approved and commonly used.
- 2) Both devices will restore height and eliminate discogenic pain.
- 3) ProDisc-L will maintain the motion that you already have at the affected level.
- 4) SynFix will eliminate motion at the affected level.
- 5) The operation is nearly identical for both devices.



Synthes SynFix:  
Stand Alone Anterior  
Lumbar Fusion Device