

**PRESTIGE<sup>®</sup> Cervical Disc  
Proposed Post-Approval Study**

# Study Design

- Investigational & control patients from original IDE clinical trial and Continued Access arm
  - Minimum of 200 patients
  - 100 patients from each group
- Postoperative data collection periods
  - 60 months (5 years)
  - 84 months (7 years)

# Primary Objective

Overall success rate in investigational treatment group statistically non-inferior to success rate in control group at 7 years postoperative

# Study Variables

- Overall Success
  - NDI improvement of  $\geq 15$  points from preop
  - Maintenance or improvement in neurological status
  - No serious implant- or implant/surgical procedure-related adverse event
  - No second surgical procedure classified as failure
- Other clinical and radiographic outcomes will be measured as defined in IDE protocol
- Continued Access metal ion study patients will be asked to provide additional blood samples in post-approval study