

ProDisc-L



The initial ProDisc lumbar [artificial disc](#) was developed by Thierry Marnay ¹⁾ in [1989](#), and was used clinically in the early 1990s. Subsequently, the second generation, ProDisc II was developed in [1999](#) with cobalt chrome endplates and constrained polyethylene core and approved for commercial use in Europe the same year. Two years after the publication of the Charité IDE trial in the United States, in [2007](#), the results of the ProDisc IDE trial comparing LDR to a circumferential fusion as control were published. ²⁾ Short-term studies disclosed early findings from single sites involved in the trial. ^{3) 4) 5) 6) 7)}

The completed trial at 2-yr follow-up included 161 arthroplasty and 75 fusion patients. ⁸⁾ Complication rate was noted to be at 9% at 8.7 yr follow-up, and there was a reoperation rate of 3.7%.²⁷ Overall success in the IDE trial was defined as a 15-point improvement in ODI score, no revision, improvement in Short Form 36 score, absence of neurological events, and radiographic success (no migration, subsidence, radiolucency, or loss of disk height, and maintenance of range of motion [ROM]). Trial data reported improvements in the LDR group in VAS for pain by an average of 39 points and improvement by 28 points in ODI. It is worth noting, however, that the ODI tool used in this trial was not the validated ODI ⁹⁾. Additionally, there was a clear difference in the success rate between the sponsor criteria and the FDA criteria.

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