

Spines

Cervical Interbody Fusion Cages (1 or 2 levels) Criteria

Criteria - A* Ratings	Bronze	Silver	Gold	Platinum
Minimum number of centres outside development centre(s)	3	3	3	3
Minimum total number of patients at 2 years	100	150	200	300
Maximum revision rate at index level/s (replacement with another implant, removal of the implant, removal of the implant leaving the space empty, front or back fusion at the same level with the implant being left in place, revision decompression)	10%	5%	2%	1%
Maximum failed fusion rates at 2 years from index operation	10%	5%	2%	1%
Maximum implant related adverse events rate	10%	5%	2%	1%
Mandatory linked PROMS response numbers	25	50	100	200
Criteria - A Ratings	Bronze	Silver	Gold	Platinum
Minimum number of centres outside development centre(s)	3	3	3	3
Minimum total number of patients at 2 years	100	150	200	250
Maximum revision rate at index level/s (replacement with another implant, removal of the implant, removal of the implant leaving the space empty, front or back fusion at the same level with the implant being left in place, revision decompression)	10%	5%	2%	1%
Maximum failed fusion rates at 2 years from index operation	10%	5%	2%	1%
Maximum implant related adverse events rate	10%	5%	2%	1%
Voluntary linked PROMS response numbers - no minimum				
Criteria - B Ratings	Bronze	Silver	Gold	Platinum
Minimum number of centres outside development centre(s)	1	1	1	1
Minimum total number of patients at 2 years	30	50	70	100
Maximum revision rate at index level/s (replacement with another implant, removal of the implant, removal of the implant leaving the space empty, front or back fusion at the same level with the implant being left in place, revision decompression)	10%	5%	2%	1%
Maximum failed fusion rates at 2 years from index operation	10%	5%	2%	1%
Maximum implant related adverse events rate	10%	5%	2%	1%
Voluntary linked PROMS response numbers - no minimum				
Pre-Entry A*	Pre-Entry			
Product launched under Beyond Compliance		Products details provided to ODEP		

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Orthopaedic Data
Evaluation Panel