

Criteria - Spine

Criteria - A* Ratings	3A*	5A*	7A*	10A*
Minimum number of centres outside development centre(s)	3	3	3	3
Minimum total cohort	100	150	200	250
Minimum at risk at benchmark time	100	125	150	175
Maximum revision rate (to include interbody fusions, removal and replacement. fusion with replacement left in situ)	3.0%	5.0%	7.0%	10.0%
Percentage of patients who have undergone adjacent segment surgery	3.0%	5.0%	7.0%	10.0%
Linked PROMS score (any validated score on at least 50 patients) available				
The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level				
Criteria - A Ratings	3A	5A	7A	10A
Minimum number of centres and surgeons	3	3	3	3
Minimum total cohort	100	150	200	250
Minimum at risk at benchmark time	40	40	40	40
Maximum revision rate (to include interbody fusions, removal and replacement. fusion with replacement left in situ)	3.0%	5.0%	7.0%	10.0%
Percentage of patients who have undergone adjacent segment surgery	3.0%	5.0%	7.0%	10.0%
Voluntary linked PROMS score (any validated score on at least 50 patients) not available				
The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level				
Criteria - B Ratings	3B	5B	7B	10B
Minimum number of centres and surgeons	1	1	1	1
Minimum total cohort	50	50	50	50
Minimum at risk at benchmark time	10	10	10	10
Maximum value of 95% lower confidence limit for revision rate. (Revisions to include Removal. replacement and fusion)	3.0%	5.0%	7.0%	10.0%
Percentage of patients who have undergone adjacent segment surgery	3.0%	5.0%	7.0%	10.0%
Voluntary linked PROMS score (any validated score on at least 50 patients) Available / Not available				
Pre-Entry A*	Pre-Entry			
Product launched under Beyond Compliance	Products details provided to ODEP			

FOR PUBLIC RELEASE

26 May 2022



Orthopaedic Data
Evaluation Panel