

Elbow Clinical Reference Data Summary

Criteria - Total Elbow Replacement				
Criteria - A* Ratings	3A*	5A*	7A*	10A*
Minimum number of centres outside development centre(s)	3	3	3	3
Minimum total cohort	40	60	80	100
Minimum at risk at benchmark time	20	20	20	20
Maximum revision rate ‡	7.0%	10.0%	12.0%	15.0%
PROMs score (any validated score), minimum number of patients	20	20	20	20
‡ 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	40	60	80	100
Minimum at risk at benchmark time	20	20	20	20
Maximum revision rate ‡	7.0%	10.0%	12.0%	15.0%
PROMs score (if 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	40	40	40	40
Minimum at risk at benchmark time	10	10	10	10
Maximum value of 95% lower confidence limit for revision rate	10.0%	12.0%	15.0%	20.0%
Pre-Entry A*	Pre-Entry			
Product launched under Beyond Compliance	Product details provided to ODEP			

Criteria - Radial Head Replacement				
Criteria - A* Ratings	3A*	5A*	7A*	10A*
Minimum number of centres outside development centre(s)	3	3	3	3
Minimum total cohort	40	60	80	100
Minimum at risk at benchmark time	20	20	20	20
Maximum revision rate ‡	5.0%	8.0%	10.0%	12.0%
PROMs score (any validated score), minimum number of patients	20	20	20	20
‡ 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	40	60	80	100
Minimum at risk at benchmark time	20	20	20	20
Maximum revision rate ‡	5.0%	8.0%	10.0%	12.0%
PROMs score (if 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	40	40	40	40
Minimum at risk at benchmark time	10	10	10	10
Maximum value of 95% lower confidence limit for revision rate	8.0%	10.0%	12.0%	15.0%
Pre-Entry A*	Pre-Entry			
Product launched under Beyond Compliance	Product details provided to ODEP			

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Orthopaedic Data
Evaluation Panel