

Knee Clinical Reference Data Summary

Criteria - Total Knee Replacement						
Criteria - A* Ratings	3A*	5A*	7A*	10A*	13A*	15A*
Minimum number of centres outside development centre(s)	3	3	3	3	3	3
Minimum number of surgeons outside of the development centre	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	150	225	300	400	400	400
Maximum revision rate ‡	3.5%	4.0%	4.5%	5.0%	6.0%	6.5%
Criteria - A Ratings	3A	5A	7A	10A	13A	15A
Minimum number of centres and surgeons	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500
Minimum at risk at benchmark time	66	60	55	51	45	42
Maximum revision rate ‡	5.5%	6.0%	6.5%	7.0%	8.0%	8.5%
‡ 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	13B	15B
Minimum number of centres and surgeons	1	1	1	1	1	1
Minimum total cohort	100	100	100	100	100	100
Minimum at risk at benchmark time	40	40	40	40	40	40
Maximum value of 95% lower confidence limit for revision rate	3.5%	4.0%	4.5%	5.0%	6.0%	6.5%
Pre-Entry A*	Pre-Entry					
Product launched under Beyond Compliance	Product details supplied to ODEP					

Combining data sets:

Please note, that where any combination of volumes across 2 constructs is included in a submission (e.g. for constructs with or without patellae), a minimum number of 100 implants must be available for each construct. In addition, at least one construct must have the minimum volume past the benchmark being applied for.

FOR PUBLIC RELEASE

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Orthopaedic Data
Evaluation Panel