

Knee Clinical Reference Data Summary
Complete one spreadsheet per reference

Criteria - Total Knee Replacement							Optional
Criteria - A* Ratings	3A*	5A*	7A*	10A*	13A*	15A*	20A*
Minimum number of centres outside development centre(s)	3	3	3	3	3	3	3
Minimum number of surgeons outside of the development centre	3	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500	500
Minimum at risk at benchmark time	150	225	300	400	400	400	400
Maximum revision rate ‡	3.3%	3.8%	4.1%	4.6%	5.0%	5.2%	6.5%
Criteria - A Ratings	3A	5A	7A	10A	13A	15A	20A
Minimum number of centres and surgeons	3	3	3	3	3	3	3
Minimum total cohort	150	250	350	500	500	500	500
Minimum at risk at benchmark time	68	62	59	55	51	50	42
Maximum revision rate ‡	5.3%	5.8%	6.1%	6.6%	7.0%	7.2%	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	20B
Minimum number of centres and surgeons	1	1	1	1	1	1	1
Minimum total cohort	100	100	100	100	100	100	100
Minimum at risk at benchmark time	40	40	40	40	40	40	40
Maximum value of 95% lower confidence limit for revision rate	3.3%	3.8%	4.1%	4.6%	5.0%	5.2%	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.

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Orthopaedic Data
Evaluation Panel