

## Knee Clinical Reference Data Summary

<b>Criteria - Unicondylar Knee Replacement</b>						
<b>Criteria - A* Ratings</b>	<b>3A*</b>	<b>5A*</b>	<b>7A*</b>	<b>10A*</b>	<b>13A*</b>	<b>15A*</b>
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 ‡	4.5%	6.0%	7.5%	10.0%	12.0%	13.5%
<b>Criteria - A Ratings</b>	<b>3A</b>	<b>5A</b>	<b>7A</b>	<b>10A</b>	<b>13A</b>	<b>15A</b>
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	55	45	40	40	40	40
Maximum revision rate ‡	6.5%	8.0%	9.5%	12.0%	14.0%	15.5%
‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level						
<b>Criteria - B Ratings</b>	<b>3B</b>	<b>5B</b>	<b>7B</b>	<b>10B</b>	<b>13B</b>	<b>15B</b>
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	4.5%	6.0%	7.5%	10.0%	12.0%	13.5%
<b>Pre-Entry A*</b>	<b>Pre-Entry</b>					
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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