

Criteria - Total Ankle Replacement / Total Talus Replacement			
Criteria - A* Ratings	3A*	5A*	7A*
Minimum number of centres outside development centre(s)	3	3	3
Minimum total cohort	100	125	150
Minimum at risk at benchmark time	50	75	100
Maximum revision rate ‡	5.0%	7.0%	10.0%
Mandatory linked PROMS score (any validated score on at least 50% of minimum at risk patients)			
‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level			
Criteria - A Ratings	3A	5A	7A
Minimum number of centres and surgeons	3	3	3
Minimum total cohort	100	125	150
Minimum at risk at benchmark time	50	75	100
Maximum revision rate ‡	5.0%	7.0%	10.0%
‡ The upper 95% confidence interval for KM revision rate (1 - Survival) must be lower than the specified level			
Criteria - B Ratings	3B	5B	7B
Minimum number of centres and surgeons	1	1	1
Minimum total cohort	30	30	30
Minimum at risk at benchmark time	10	10	10
Maximum value of 95% lower CI for revision rate	5.0%	7.0%	10.0%
Pre-Entry A*	Pre-Entry		
Product launched under Beyond Compliance		Products details provided to ODEP	

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Published 16 September 2024



Orthopaedic Data  
Evaluation Panel