Scorpio NRG PS (cementless)/Series 7000 (cementless) Total Knee Investigation

Note: This analysis compares the Scorpio NRG PS (cless)/Series 7000 (cless) femoral/tibial combination with all other total knee prostheses.

This combination has been identified as having a significantly higher rate of revision. For a detailed explanation of the process used by the Registry that results in identification of prostheses that have a higher than anticipated rate of revision please refer to the Prostheses with Higher than Anticipated Rates of Revision chapter of the most recent AOANJRR Annual Report, https://aoanjrr.sahmri.com/annual-reports-2022.

Note: Procedures using prostheses with no recorded use in 2021 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Knee Replacement

The revision rate of the Scorpio NRG PS (cless)/Series 7000 (cless) total knee combination is compared to all other total knee prostheses.

Table 1: Revision Rates of Primary Total Knee Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% Cl)
Scorpio NRG PS (cless)/Series 7000 (cless)	84	1172	10491	0.80 (0.64, 0.99)
Other Total Knee	26061	727695	4729125	0.55 (0.54, 0.56)
TOTAL	26145	728867	4739615	0.55 (0.54, 0.56)

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Scorpio NRG PS (cless)/Series 7000 (cless) total knee combination is compared to all other total knee prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Knee Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Scorpio NRG PS (cless)/Series 7000 (cless)	1.2 (0.7,	3.4 (2.5,	4.9 (3.8,	5.6 (4.5,	6.1 (4.9,	6.5 (5.2,	6.5 (5.2,
	2.0)	4.6)	6.3)	7.1)	7.7)	8.1)	8.1)
Other Total Knee	1.0 (1.0,	1.9 (1.9,	2.5 (2.4,	2.9 (2.9,	3.2 (3.2,	3.6 (3.5,	3.9 (3.8,
	1.0)	1.9)	2.5)	2.9)	3.3)	3.6)	3.9)
CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Scorpio NRG PS (cless)/Series 7000 (cless)	6.6 (5.3,	6.9 (5.6,	7.4 (6.0,	7.9 (6.4,	8.2 (6.6,	8.2 (6.6,	8.2 (6.6,
	8.3)	8.6)	9.2)	9.8)	10.2)	10.2)	10.2)
Other Total Knee	4.2 (4.1,	4.5 (4.4,	4.8 (4.7,	5.1 (5.0,	5.4 (5.3,	5.7 (5.7,	6.1 (6.0,
	4.2)	4.5)	4.8)	5.2)	5.5)	5.8)	6.1)
CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Scorpio NRG PS (cless)/Series 7000 (cless)							
Other Total Knee	6.4 (6.3,	6.9 (6.7,	7.3 (7.1,	7.6 (7.4,	7.9 (7.7,	8.2 (7.9,	8.2 (8.0,
	6.6)	7.0)	7.4)	7.8)	8.1)	8.4)	8.5)

FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Scorpio NRG PS (cless)/Series 7000 (cless) total knee combination is compared to all other total knee prostheses. In addition, hazard ratios are reported.

Hazard ratios are reported for specific time periods during which the hazard ratio is constant. This is done to enable more specific and valid comparisons of the risk of revision over time. The pattern of variation in risk has important implications with respect to the underlying reasons for any difference.

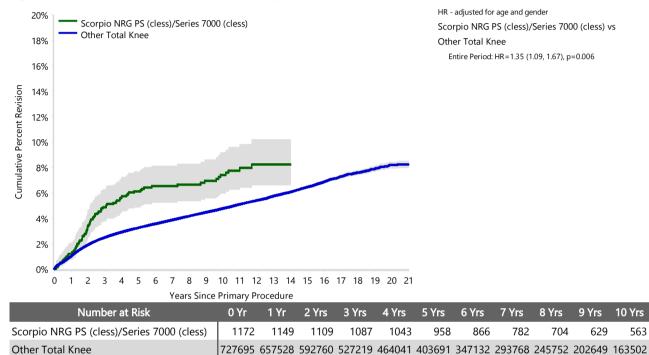


Figure 1: Cumulative Percent Revision of Primary Total Knee Replacement

Number at Risk	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Scorpio NRG PS (cless)/Series 7000 (cless)	455	314	182	47	0	0	0	0	0	0	0
Other Total Knee	128843	99109	75527	56481	41660	29601	19593	11953	6490	2687	605

Note: Prostheses no longer used in 2021 are excluded from the comparator.

10 Yrs

563

Primary Diagnosis for Revised Primary Total Knee Replacement

This table identifies the diagnosis of the primary procedure which was subsequently revised. This information is provided as there is a variation on outcome depending on the primary diagnosis. It is therefore important when considering the reasons for a higher than anticipated rate of revision that there is identification of the primary diagnosis. This information should be compared to the primary diagnosis for the revisions of all other total knee prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Knee Replacement

	Scorpio NRG PS (cles	s)/Series 7000 (cless)	Other To	otal Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	84	100.0	25251	96.9
Rheumatoid Arthritis			331	1.3
Other Inflammatory Arthritis			161	0.6
Tumour			151	0.6
Osteonecrosis			98	0.4
Fracture			49	0.2
Other			19	0.1
Chondrocalcinosis			1	0.0
TOTAL	84	100.0	26061	100.0

Reasons for Revision

This is reported in two ways: a percentage of primary procedures revised and as a percentage of all revision procedures.

% Primaries Revised: This shows the proportional contribution of each revision diagnosis as a percentage of the total number of primary procedures. This percentage can be used to approximate the risk of being revised for that diagnosis. Differing percentages between groups, with the same distribution of follow up time, may identify problems of concern.

% Revisions: The number of revisions for each diagnosis is expressed as a percentage of the total number of revisions. This shows the distribution of reasons for revision within a group but cannot be used as a comparison between groups.

Table 4: Primar	v Total Knee Replacement	- Reason for Revision (Follow-u	b Limited to 14.8 Years)

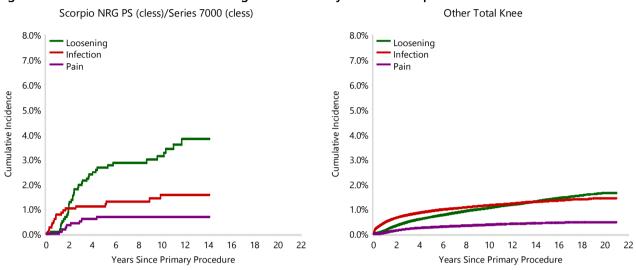
	Scorpio NR	G PS (cless)/Series	7000 (cless)		Other Total Knee	
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	17	1.5	20.2	6930	1.0	27.0
Loosening	39	3.3	46.4	5728	0.8	22.3
Instability	4	0.3	4.8	2456	0.3	9.6
Pain	8	0.7	9.5	2046	0.3	8.0
Patellofemoral Pain	1	0.1	1.2	2034	0.3	7.9
Patella Erosion	2	0.2	2.4	1653	0.2	6.4
Arthrofibrosis	3	0.3	3.6	995	0.1	3.9
Fracture	2	0.2	2.4	916	0.1	3.6
Malalignment	1	0.1	1.2	599	0.1	2.3
Wear Tibial Insert	1	0.1	1.2	330	0.0	1.3
Lysis				321	0.0	1.3
Incorrect Sizing	1	0.1	1.2	258	0.0	1.0
Patella Maltracking				181	0.0	0.7
Bearing Dislocation				152	0.0	0.6
Implant Breakage Tibial Insert	3	0.3	3.6	142	0.0	0.6
Implant Breakage Patella				133	0.0	0.5
Metal Related Pathology				113	0.0	0.4
Prosthesis Dislocation				79	0.0	0.3
Synovitis				76	0.0	0.3
Osteonecrosis				58	0.0	0.2
Implant Breakage Tibial				40	0.0	0.2
Implant Breakage Femoral				35	0.0	0.1
Wear Patella	1	0.1	1.2	29	0.0	0.1
Tumour				27	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Wear Tibial				11	0.0	0.0
Progression Of Disease				6	0.0	0.0
Patella Dislocation				2	0.0	0.0
Wear Femoral				2	0.0	0.0
Incorrect Side				1	0.0	0.0
Other	1	0.1	1.2	301	0.0	1.2
N Revision	84	7.2	100.0	25668	3.5	100.0
N Primary	1172			727695		

Note: This table is restricted to revisions within 14.8 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2021 are excluded from the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement

This figure details the cumulative incidence of the most common reasons for revision. The five most common reasons for revision are included as long as each of these reasons account for more than 10 procedures or at least 5% of all revisions for the Scorpio NRG PS (cless)/Series 7000 (cless) total knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total knee prostheses.





Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Scorpio NRG PS (cless)/Series 7000 (cless) total knee combination and compares it to the components used in the revision of all other total knee prostheses.

The reason this analysis is undertaken is to identify whether there is one or more components which are being replaced that differ from the components replaced for revisions of all other total knee prostheses i.e. is there a difference in the type of revision undertaken for the Scorpio NRG PS (cless)/Series 7000 (cless) total knee combination compared to all other total knee prostheses.

	Scorpio NRG PS (cles	Scorpio NRG PS (cless)/Series 7000 (cless)		otal Knee
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	15	17.9	6248	24.3
Tibial Component	9	10.7	2089	8.1
Cement Spacer	8	9.5	1350	5.3
Femoral Component	3	3.6	1310	5.1
Removal of Prostheses			149	0.6
Total Femoral			20	0.1
Reinsertion of Components			11	0.0
N Major	35	41.7	11177	43.5
Insert Only	17	20.2	7052	27.5
Patella Only	10	11.9	4751	18.5
Insert/Patella	22	26.2	2615	10.2
Minor Components			59	0.2
Cement Only			14	0.1
N Minor	49	58.3	14491	56.5
TOTAL	84	100.0	25668	100.0

Note: This table is restricted to revisions within 14.8 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2021 are excluded from the comparator.

Revision Rates of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Fixation

This analysis is provided as some prostheses have more than one fixation option. Additionally there are prostheses where an alternative to the recommended approach to fixation was used e.g. a cementless prosthesis that has been cemented or vice-versa.

Table 6: Revised Number of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total	
Cemented	0	2	
Cementless	80	1141	
Hybrid (Tibial Cemented)	4	28	
Hybrid (Tibial Cementless)	0	1	
TOTAL	84	1172	

TABLE 7

Revision Rates of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Bearing Surface

This analysis is provided as some prostheses are combined with a variety of bearing surfaces. All bearing surfaces used with this combination are listed.

Table 7: Revised Number of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	8	106
XLPE	76	1066
TOTAL	84	1172

Revision Rates of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Bearing Mobility

This analysis is provided as some prostheses are combined with a variety of bearing mobilities. All bearing mobilities used with this combination are listed.

Table 8: Revised Number of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	84	1172
TOTAL	84	1172

TABLE 9

Revision Rates of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Stability

This analysis is provided as some prostheses are combined with a variety of stabilities. All stabilities used with this combination are listed.

Table 9: Revised Number of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Posterior Stabilised	84	1172
TOTAL	84	1172

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Scorpio NRG PS (cless)/Series 7000 (cless) total knee combination and provides the comparative data for each of the states for all other total knee prostheses.

The purpose of this analysis is to determine if the higher than anticipated rate of revision has widespread distribution between states. If there is widespread distribution then the reason for the higher than anticipated rate of revision is unlikely to be surgeon specific. If the prosthesis has been used in only a small number of states it is not possible to distinguish if the higher than anticipated rate of revision is related to the prosthesis, surgeon, technique or patient.

Component	State	N Revised	N Total
Scorpio NRG PS (cless)/Series 7000 (cless)	NSW	15	195
	VIC	23	642
	QLD	0	4
	WA	44	279
	TAS	2	52
Other Total Knee	NSW	7722	253121
	VIC	5553	144487
	QLD	5690	153171
	WA	3235	77905
	SA	2837	63440
	TAS	418	16885
	ACT/NT	606	18686
TOTAL		26145	728867

Table 10: Revised Number of Primary Total Knee Replacement by State

Number of Revisions of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Scorpio NRG PS (cless)/Series 7000 (cless) total knee combination. It also provides the subsequent number of revisions of the primaries reported in that year.

Primary procedures performed in later years have had less follow up time therefore the number revised is expected to be less than the number revised in earlier years. For example, a primary procedure performed in 2021 has a maximum of one year to be revised, whereas a primary procedure performed in 2019 has a maximum of three years to be revised.

Table 11: Number of Revisions of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2007	5	76
2008	19	185
2009	26	171
2010	12	166
2011	9	114
2012	1	67
2013	1	71
2014	5	76
2015	1	72
2016	3	77
2017	2	69
2018	0	28
TOTAL	84	1172

Revision Rates of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Catalogue Number Range

Many prostheses have a number of catalogue ranges. The catalogue range is specific to particular design features; more than one catalogue range usually indicates a minor difference in design in a particular Scorpio NRG PS (cless)/Series 7000 (cless) prosthesis.

This analysis has been undertaken to determine if the revision rate varies according to the catalogue number range.

Model	Catalogue Range	Catalogue Description	Cement	Coating	Fixation
Femoral					
Scorpio NRG PS	816403L-816413R	PS HA FEMORAL COMPONENT	NO	HA COATED	
Tibial					
Series 7000	71250003-71250013	SCORPIO COCR MICROSTRUCTURE BEADED TIBIAL BASEPLATE	NO		BEADED
Series 7000	71450003-71450013	SERIES 7000 STANDARD TIBIAL TRAY MICROSTRUCTURED COCR UHMWPE/PA COATED	NO	HA COATED	
Series 7000	75150003-75150013	SERIES 7000 STANDARD TIBIAL TRAY HA COATED	NO	HA COATED	

Table 12: Revised Number of Scorpio NRG PS (cless)/Series 7000 (cless) Primary Total Knee Replacement by Catalogue Number Range

Femoral Range Ti	ibial Range	N Revised	N Total	
816403L-816413R 71250	0003-71250013	1	4	
71450	0003-71450013	48	375	
75150	0003-75150013	35	793	
TOTAL		84	1172	