

## Genesis II CR (cementless)/Profix Mobile (cemented) Total Knee Investigation

Note: This analysis compares the Genesis II CR (cless)/Profix Mobile (ctd) 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 Genesis II CR (cless)/Profix Mobile (ctd) 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% CI)
Genesis II CR (cless)/Profix Mobile (ctd)	36	241	2870	1.25 (0.88, 1.74)
Other Total Knee	26061	727695	4729125	0.55 (0.54, 0.56)
<b>TOTAL</b>	<b>26097</b>	<b>727936</b>	<b>4731995</b>	<b>0.55 (0.54, 0.56)</b>

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

TABLE 2

**Yearly Cumulative Percent Revision of Primary Total Knee Replacement**

The yearly cumulative percent revision of the Genesis II CR (class)/Profix Mobile (ctd) 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
Genesis II CR (class)/Profix Mobile (ctd)	2.9 (1.4, 6.1)	5.5 (3.2, 9.3)	7.7 (4.9, 11.9)	9.4 (6.3, 14.0)	9.4 (6.3, 14.0)	11.7 (8.2, 16.6)	11.7 (8.2, 16.6)
Other Total Knee	1.0 (1.0, 1.0)	1.9 (1.9, 1.9)	2.5 (2.4, 2.5)	2.9 (2.9, 2.9)	3.2 (3.2, 3.3)	3.6 (3.5, 3.6)	3.9 (3.8, 3.9)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Genesis II CR (class)/Profix Mobile (ctd)	12.2 (8.6, 17.2)	12.2 (8.6, 17.2)	14.5 (10.4, 19.9)	14.5 (10.4, 19.9)	15.1 (11.0, 20.7)	15.9 (11.6, 21.7)	17.7 (12.9, 23.9)
Other Total Knee	4.2 (4.1, 4.2)	4.5 (4.4, 4.5)	4.8 (4.7, 4.8)	5.1 (5.0, 5.2)	5.4 (5.3, 5.5)	5.7 (5.7, 5.8)	6.1 (6.0, 6.1)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Genesis II CR (class)/Profix Mobile (ctd)	17.7 (12.9, 23.9)	17.7 (12.9, 23.9)	17.7 (12.9, 23.9)	17.7 (12.9, 23.9)	17.7 (12.9, 23.9)		
Other Total Knee	6.4 (6.3, 6.6)	6.9 (6.7, 7.0)	7.3 (7.1, 7.4)	7.6 (7.4, 7.8)	7.9 (7.7, 8.1)	8.2 (7.9, 8.4)	8.2 (8.0, 8.5)

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

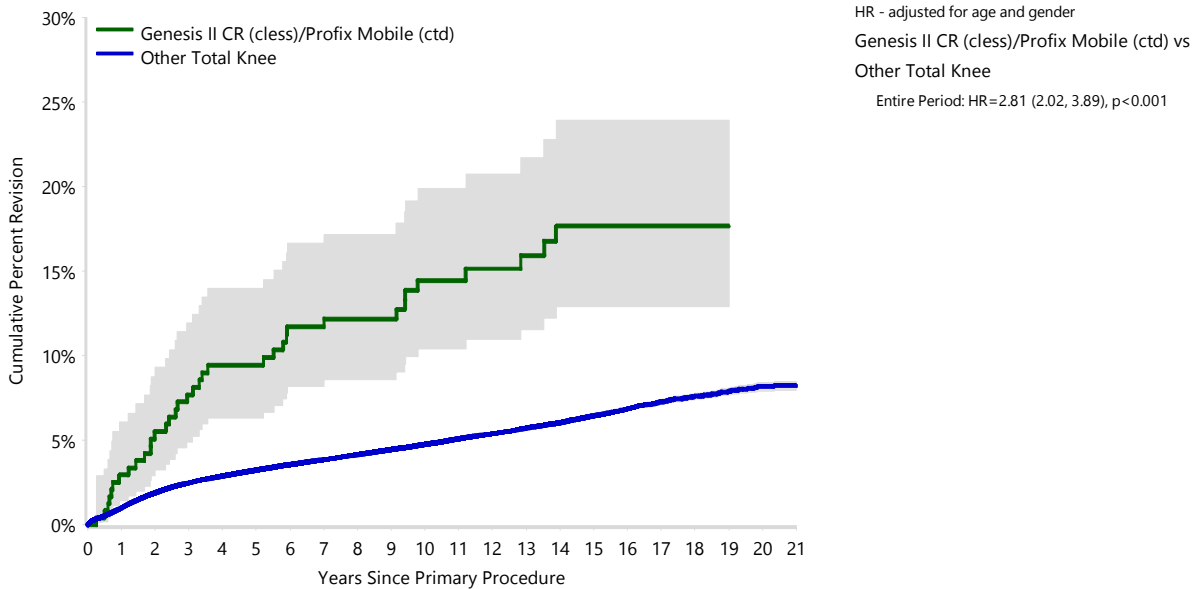
**FIGURE 1**

**Yearly Cumulative Percent Revision of Primary Total Knee Replacement**

The yearly cumulative percent revision of the Genesis II CR (cless)/Profix Mobile (ctd) 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	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Genesis II CR (cless)/Profix Mobile (ctd)	241	230	219	212	204	202	193	191	181	157	144
Other Total Knee	72769	65752	59276	52721	46404	40369	34713	29376	24575	20264	16350

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
Genesis II CR (cless)/Profix Mobile (ctd)	126	115	105	94	84	79	74	58	47	27	5
Other Total Knee	12884	99109	75527	56481	41660	29601	19593	11953	6490	2687	605

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

**TABLE 3****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**

Primary Diagnosis	Genesis II CR (class)/Profix Mobile (ctd)		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	36	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
<b>TOTAL</b>	<b>36</b>	<b>100.0</b>	<b>26061</b>	<b>100.0</b>

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

TABLE 4

## 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: Primary Total Knee Replacement - Reason for Revision

Revision Diagnosis	Genesis II CR (class)/Profix Mobile (ctd)			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	8	3.3	22.2	6981	1.0	26.8
Loosening	18	7.5	50.0	5841	0.8	22.4
Instability	1	0.4	2.8	2490	0.3	9.6
Pain	3	1.2	8.3	2064	0.3	7.9
Patellofemoral Pain	2	0.8	5.6	2048	0.3	7.9
Patella Erosion	2	0.8	5.6	1693	0.2	6.5
Arthrofibrosis	1	0.4	2.8	997	0.1	3.8
Fracture				944	0.1	3.6
Malalignment				603	0.1	2.3
Wear Tibial Insert				364	0.1	1.4
Lysis				345	0.0	1.3
Incorrect Sizing				259	0.0	1.0
Patella Maltracking	1	0.4	2.8	181	0.0	0.7
Bearing Dislocation				153	0.0	0.6
Implant Breakage Tibial Insert				150	0.0	0.6
Implant Breakage Patella				134	0.0	0.5
Metal Related Pathology				117	0.0	0.4
Prosthesis Dislocation				80	0.0	0.3
Synovitis				78	0.0	0.3
Osteonecrosis				58	0.0	0.2
Implant Breakage Tibial				42	0.0	0.2
Implant Breakage Femoral				38	0.0	0.1
Wear Patella				33	0.0	0.1
Tumour				28	0.0	0.1
Heterotopic Bone				15	0.0	0.1
Wear Tibial				12	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				302	0.0	1.2
<b>N Revision</b>	<b>36</b>	<b>14.9</b>	<b>100.0</b>	<b>26061</b>	<b>3.6</b>	<b>100.0</b>
<b>N Primary</b>	<b>241</b>			<b>727695</b>		

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 Genesis II CR (cless)/Profix Mobile (ctd) total knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total knee prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Knee Replacement

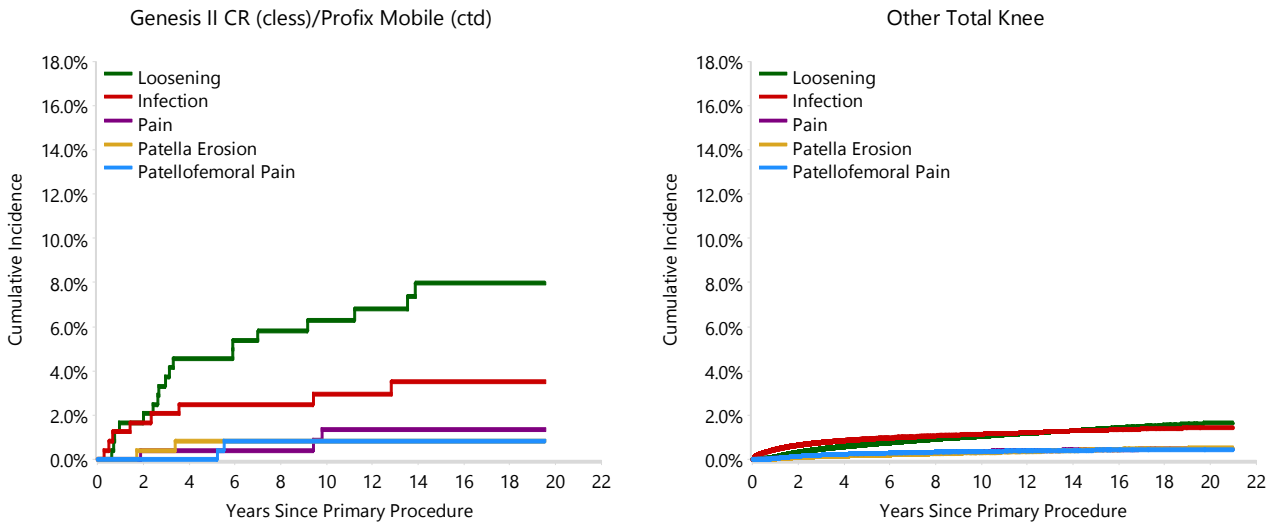


TABLE 5

**Type of Revision Performed for Primary Total Knee Replacement**

This analysis identifies the components used in the revision of the Genesis II CR (class)/Profix Mobile (ctd) 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 Genesis II CR (class)/Profix Mobile (ctd) total knee combination compared to all other total knee prostheses.

**Table 5: Primary Total Knee Replacement - Type of Revision**

Type of Revision	Genesis II CR (class)/Profix Mobile (ctd)		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	13	36.1	6419	24.6
Tibial Component	2	5.6	2100	8.1
Cement Spacer	3	8.3	1360	5.2
Femoral Component	5	13.9	1311	5.0
Removal of Prostheses	1	2.8	150	0.6
Total Femoral			21	0.1
Reinsertion of Components	1	2.8	11	0.0
<b>N Major</b>	<b>25</b>	<b>69.4</b>	<b>11372</b>	<b>43.6</b>
Insert Only	2	5.6	7123	27.3
Patella Only	5	13.9	4783	18.4
Insert/Patella	4	11.1	2710	10.4
Minor Components			59	0.2
Cement Only			14	0.1
<b>N Minor</b>	<b>11</b>	<b>30.6</b>	<b>14689</b>	<b>56.4</b>
<b>TOTAL</b>	<b>36</b>	<b>100.0</b>	<b>26061</b>	<b>100.0</b>

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

TABLE 6

**Revision Rates of Genesis II CR (class)/Profix Mobile (ctd) 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 Genesis II CR (class)/Profix Mobile (ctd) Primary Total Knee Replacement by Fixation**

Fixation	N Revised	N Total
Cemented	0	1
Hybrid (Tibial Cemented)	36	240
<b>TOTAL</b>	<b>36</b>	<b>241</b>

TABLE 7

**Revision Rates of Genesis II CR (class)/Profix Mobile (ctd) 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 Genesis II CR (class)/Profix Mobile (ctd) Primary Total Knee Replacement by Bearing Surface**

Bearing Surface	N Revised	N Total
Non XLPE	36	241
<b>TOTAL</b>	<b>36</b>	<b>241</b>



**TABLE 8****Revision Rates of Genesis II CR (class)/Profix Mobile (ctd) 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 Genesis II CR (class)/Profix Mobile (ctd) Primary Total Knee Replacement by Bearing Mobility**

Bearing Mobility	N Revised	N Total
Rotating	36	241
<b>TOTAL</b>	<b>36</b>	<b>241</b>

**TABLE 9****Revision Rates of Genesis II CR (class)/Profix Mobile (ctd) 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 Genesis II CR (class)/Profix Mobile (ctd) Primary Total Knee Replacement by Stability**

Stability	N Revised	N Total
Minimally Stabilised	36	241
<b>TOTAL</b>	<b>36</b>	<b>241</b>

TABLE 10

**Revision Rates of Primary Total Knee Replacement by State**

This enables a state by state variation to be identified for the Genesis II CR (cless)/Profix Mobile (ctd) 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.

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

Component	State	N Revised	N Total
Genesis II CR (cless)/Profix Mobile (ctd)	NSW	6	46
	VIC	20	119
	QLD	2	10
	WA	8	65
	SA	0	1
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
<b>TOTAL</b>		<b>26097</b>	<b>727936</b>

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

**TABLE 11****Number of Revisions of Genesis II CR (cless)/Profix Mobile (ctd) Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Genesis II CR (cless)/Profix Mobile (ctd) 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 Genesis II CR (cless)/Profix Mobile (ctd) Primary Total Knee Replacement by Year of Implant**

Year of Implant	Number Revised	Total Number
2000	2	20
2001	8	54
2002	9	52
2003	4	26
2004	1	10
2005	1	4
2006	0	2
2007	2	5
2008	3	12
2009	0	6
2010	1	9
2011	2	17
2012	0	2
2013	3	22
<b>TOTAL</b>	<b>36</b>	<b>241</b>

TABLE 12

### Revision Rates of Genesis II CR (class)/Profix Mobile (ctd) 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 Genesis II CR (class)/Profix Mobile (ctd) 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
<b>Femoral</b>					
Genesis II CR	71420032-71420062	POROUS CR FEMORAL COMPONENT	NO		BEADED
Genesis II CR	71422024-71422052	POROUS HA CR FEMORAL COMPONENT	NO	HA COATED	BEADED
Genesis II CR	71928325-71928338	HA COATED CR FEMORAL COMPONENT	NO	HA COATED	BEADED
<b>Tibial</b>					
Profix Mobile	71549101-71549208	NONPOROUS TIBIAL BASEPLATE	YES		

**Table 12: Revised Number of Genesis II CR (class)/Profix Mobile (ctd) Primary Total Knee Replacement by Catalogue Number Range**

Femoral Range	Tibial Range	N Revised	N Total
71420032-71420062	71549101-71549208	20	134
71422024-71422052	71549101-71549208	12	93
71928325-71928338	71549101-71549208	4	14
<b>TOTAL</b>		<b>36</b>	<b>241</b>