

## Renasis Total Knee Investigation

Note: This analysis compares the Renasis femoral prosthesis with all other total knee prostheses.

This prosthesis 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 Renasis total knee prosthesis 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)
Renasis	18	121	1453	1.24 (0.73, 1.96)
Other Total Knee	26061	727695	4729125	0.55 (0.54, 0.56)
<b>TOTAL</b>	<b>26079</b>	<b>727816</b>	<b>4730578</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 Renasys total knee prosthesis 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
Renasys	2.5 (0.8, 7.5)	2.5 (0.8, 7.5)	4.2 (1.8, 9.8)	6.7 (3.4, 13.0)	8.5 (4.6, 15.1)	9.3 (5.3, 16.2)	10.3 (6.0, 17.4)
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
Renasys	10.3 (6.0, 17.4)	11.2 (6.7, 18.5)	11.2 (6.7, 18.5)	12.3 (7.4, 19.9)	14.5 (9.1, 22.7)	14.5 (9.1, 22.7)	15.7 (10.0, 24.2)
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
Renasys	15.7 (10.0, 24.2)						
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.

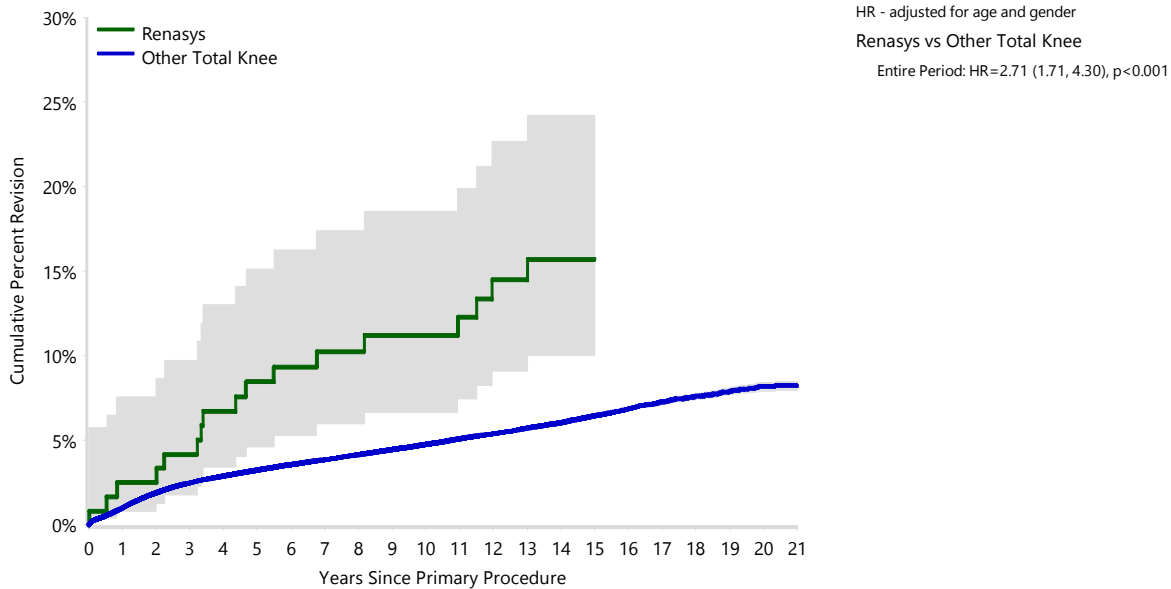
**FIGURE 1**

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

The yearly cumulative percent revision of the Renasys total knee prosthesis 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
Renasys	121	117	116	113	110	104	101	98	97	94	89
Other Total Knee	727695	657528	592760	527219	464041	403691	347132	293768	245752	202649	163502

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
Renasys	82	75	70	55	52	21	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.

**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	Renasys		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	18	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>18</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 (Follow-up Limited to 16.7 Years)

Revision Diagnosis	Number	Renasys		Other Total Knee		
		% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	3	2.5	16.7	6962	1.0	26.8
Loosening	4	3.3	22.2	5797	0.8	22.4
Instability				2478	0.3	9.6
Pain	3	2.5	16.7	2059	0.3	7.9
Patellofemoral Pain				2046	0.3	7.9
Patella Erosion	1	0.8	5.6	1683	0.2	6.5
Arthrofibrosis	1	0.8	5.6	996	0.1	3.8
Fracture	1	0.8	5.6	933	0.1	3.6
Malalignment				601	0.1	2.3
Wear Tibial Insert				355	0.0	1.4
Lysis	2	1.7	11.1	338	0.0	1.3
Incorrect Sizing	1	0.8	5.6	258	0.0	1.0
Patella Maltracking				181	0.0	0.7
Bearing Dislocation				152	0.0	0.6
Implant Breakage Tibial Insert	1	0.8	5.6	148	0.0	0.6
Implant Breakage Patella				133	0.0	0.5
Metal Related Pathology				116	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	1	0.8	5.6	42	0.0	0.2
Implant Breakage Femoral				38	0.0	0.1
Wear Patella				31	0.0	0.1
Tumour				27	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>18</b>	<b>14.9</b>	<b>100.0</b>	<b>25930</b>	<b>3.6</b>	<b>100.0</b>
<b>N Primary</b>	<b>121</b>			<b>727695</b>		

Note: This table is restricted to revisions within 16.7 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 Renasys total knee prosthesis. 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**

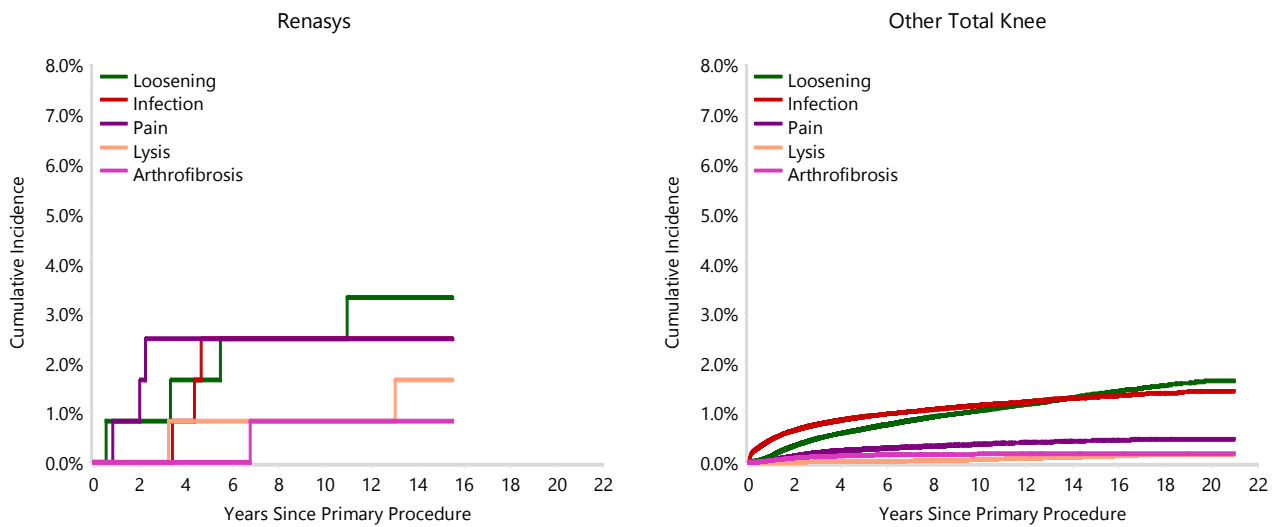


TABLE 5

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

This analysis identifies the components used in the revision of the Renasys total knee prosthesis 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 Renasys total knee prosthesis compared to all other total knee prostheses.

**Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 16.7 Years)**

Type of Revision	Renasys		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	4	22.2	6363	24.5
Tibial Component	4	22.2	2095	8.1
Cement Spacer			1357	5.2
Femoral Component			1311	5.1
Removal of Prostheses			149	0.6
Total Femoral			20	0.1
Reinsertion of Components			11	0.0
<b>N Major</b>	<b>8</b>	<b>44.4</b>	<b>11306</b>	<b>43.6</b>
Insert Only	9	50.0	7098	27.4
Patella Only			4769	18.4
Insert/Patella	1	5.6	2684	10.4
Minor Components			59	0.2
Cement Only			14	0.1
<b>N Minor</b>	<b>10</b>	<b>55.6</b>	<b>14624</b>	<b>56.4</b>
<b>TOTAL</b>	<b>18</b>	<b>100.0</b>	<b>25930</b>	<b>100.0</b>

Note: This table is restricted to revisions within 16.7 years for all groups to allow a time-matched comparison of revisions.

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

**TABLE 6****Revision Rates of Renasys 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 Renasys Primary Total Knee Replacement by Fixation**

Fixation	N Revised	N Total
Cemented	18	121
<b>TOTAL</b>	<b>18</b>	<b>121</b>

**TABLE 7****Revision Rates of Renasys 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 prosthesis are listed.

**Table 7: Revised Number of Renasys Primary Total Knee Replacement by Bearing Surface**

Bearing Surface	N Revised	N Total
Non XLPE	18	121
<b>TOTAL</b>	<b>18</b>	<b>121</b>



**TABLE 8****Revision Rates of Renasys 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 prosthesis are listed.

**Table 8: Revised Number of Renasys Primary Total Knee Replacement by Bearing Mobility**

Bearing Mobility	N Revised	N Total
Fixed	18	121
<b>TOTAL</b>	<b>18</b>	<b>121</b>

**TABLE 9****Revision Rates of Renasys 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 prosthesis are listed.

**Table 9: Revised Number of Renasys Primary Total Knee Replacement by Stability**

Stability	N Revised	N Total
Posterior Stabilised	18	121
<b>TOTAL</b>	<b>18</b>	<b>121</b>

TABLE 10

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

This enables a state by state variation to be identified for the Renasys total knee prosthesis 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
Renasys	NSW	3	14
	VIC	8	43
	QLD	6	46
	WA	0	7
	SA	0	1
	ACT/NT	1	10
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>26079</b>	<b>727816</b>

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

**TABLE 11****Number of Revisions of Renasys Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Renasys total knee prosthesis. 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 Renasys Primary Total Knee Replacement by Year of Implant**

Year of Implant	Number Revised	Total Number
2005	8	51
2006	9	53
2007	0	3
2008	1	14
<b>TOTAL</b>	<b>18</b>	<b>121</b>

TABLE 12

**Revision Rates of Renasys 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 Renasys 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
<b>Femoral</b>			
Renasys	71932011-71932018	PS OXINIUM FEMORAL COMPONENT W/ RSA BEADS	YES
Renasys	74021134-74021147	PRIMARY PS OXINIUM FEMORAL COMPONENT	YES

**Table 12: Revised Number of Renasys Primary Total Knee Replacement by Catalogue Number Range**

Femoral Range	N Revised	N Total
71932011-71932018	1	16
74021134-74021147	17	105
<b>TOTAL</b>	<b>18</b>	<b>121</b>

**TABLE 13****Revision Rates of Renasys Primary Total Knee Replacement by Component**

A prosthesis may be combined with multiple components. This analysis has been undertaken to determine if the revision rate varies according to the component with which it is combined.

**Table 13: Revised Number of Renasys Primary Total Knee Replacement by Tibial Component**

Tibial Component	N Revised	N Total
Genesis II	15	87
Journey	3	34
<b>TOTAL</b>	<b>18</b>	<b>121</b>