

## Freedom PKR Active/Freedom PKR Active Unicompartmental Knee Investigation

Note: This analysis compares the Freedom PKR Active/Freedom PKR Active femoral/tibial combination with all other unicompartmental 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-2023>.

Note: Procedures using prostheses with no recorded use in 2022 are excluded from the comparator.

### TABLE 1

#### Revision Rate of Primary Unicompartmental Knee Replacement

The revision rate of the Freedom PKR Active/Freedom PKR Active unicompartmental knee combination is compared to all other unicompartmental knee prostheses.

**Table 1: Revision Rates of Primary Unicompartmental Knee Replacement**

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Freedom PKR Active/Freedom PKR Active	491	1505	15889	3.09 (2.82, 3.38)
Other Unicompartmental Knee	4860	48950	350591	1.39 (1.35, 1.43)
<b>TOTAL</b>	<b>5351</b>	<b>50455</b>	<b>366481</b>	<b>1.46 (1.42, 1.50)</b>

Note: Prostheses no longer used in 2022 are excluded from the comparator.

TABLE 2

### Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement

The yearly cumulative percent revision of the Freedom PKR Active/Freedom PKR Active unicompartmental knee combination is compared to all other unicompartmental knee prostheses.

**Table 2: Yearly Cumulative Percent Revision of Primary Unicompartmental Knee Replacement**

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Freedom PKR Active/Freedom PKR Active	1.8 (1.2, 2.6)	5.1 (4.1, 6.3)	7.9 (6.6, 9.4)	10.3 (8.9, 12.0)	13.7 (12.0, 15.6)	16.2 (14.4, 18.2)	18.8 (16.8, 20.9)	20.6 (18.6, 22.8)
Other Unicompartmental Knee	1.9 (1.8, 2.1)	3.5 (3.3, 3.7)	4.5 (4.4, 4.7)	5.5 (5.3, 5.7)	6.3 (6.1, 6.6)	7.2 (7.0, 7.5)	8.3 (8.0, 8.6)	9.4 (9.0, 9.7)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Freedom PKR Active/Freedom PKR Active	24.2 (22.0, 26.5)	27.5 (25.2, 29.9)	29.8 (27.4, 32.3)	31.9 (29.5, 34.5)	33.4 (30.9, 36.1)	35.1 (32.5, 37.8)	37.5 (34.7, 40.4)
Other Unicompartmental Knee	10.6 (10.2, 10.9)	11.7 (11.3, 12.1)	13.1 (12.7, 13.5)	14.4 (14.0, 14.9)	15.8 (15.3, 16.3)	17.4 (16.9, 18.0)	18.8 (18.2, 19.4)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Freedom PKR Active/Freedom PKR Active	39.7 (36.7, 42.8)	40.5 (37.3, 43.7)					
Other Unicompartmental Knee	20.4 (19.7, 21.1)	22.1 (21.4, 22.9)	24.0 (23.2, 24.9)	25.7 (24.7, 26.7)	27.8 (26.6, 29.0)	29.7 (28.3, 31.2)	30.4 (28.7, 32.3)

Note: Prostheses no longer used in 2022 are excluded from the comparator.

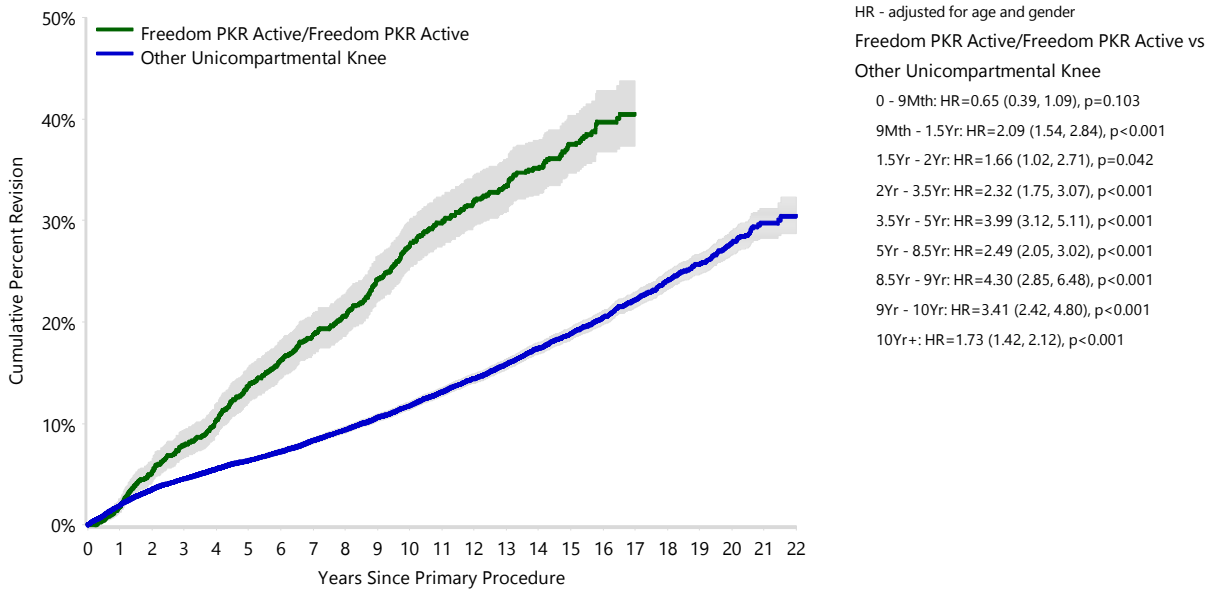
**FIGURE 1**

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

The yearly cumulative percent revision of the Freedom PKR Active/Freedom PKR Active unicompartmental knee combination is compared to all other unicompartmental 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 Unicompartmental 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	11 Yrs
Freedom PKR Active/Freedom PKR Active	1505	1474	1415	1362	1316	1250	1197	1134	1061	954	845	755
Other Unicompartmental Knee	48950	44516	40112	35992	31823	27703	23844	20641	18032	15724	13691	11855

Number at Risk	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Freedom PKR Active/Freedom PKR Active	668	575	471	348	219	102	3	0	0	0	0
Other Unicompartmental Knee	10031	8297	6758	5393	4149	3116	2243	1555	920	393	88

Note: Prostheses no longer used in 2022 are excluded from the comparator.

**TABLE 3****Primary Diagnosis for Revised Primary Unicompartamental 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 unicompartamental knee prostheses.

**Table 3: Primary Diagnosis for Revised Primary Unicompartamental Knee Replacement**

Primary Diagnosis	Freedom PKR Active/Freedom PKR Active		Other Unicompartamental Knee	
	Number	Percent	Number	Percent
Osteoarthritis	484	98.6	4813	99.0
Osteonecrosis	7	1.4	27	0.6
Rheumatoid Arthritis			12	0.2
Other Inflammatory Arthritis			6	0.1
Fracture			1	0.0
Tumour			1	0.0
<b>TOTAL</b>	<b>491</b>	<b>100.0</b>	<b>4860</b>	<b>100.0</b>

Note: Prostheses no longer used in 2022 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 Unicompartmental Knee Replacement - Reason for Revision (Follow-up Limited to 18.4 Years)

Revision Diagnosis	Freedom PKR Active/Freedom PKR Active			Other Unicompartmental Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Progression Of Disease	187	12.4	38.1	1744	3.6	36.4
Loosening	194	12.9	39.5	1540	3.1	32.2
Pain	33	2.2	6.7	360	0.7	7.5
Infection	8	0.5	1.6	256	0.5	5.3
Bearing Dislocation				180	0.4	3.8
Fracture	7	0.5	1.4	141	0.3	2.9
Instability	3	0.2	0.6	89	0.2	1.9
Lysis	38	2.5	7.7	84	0.2	1.8
Wear Tibial Insert	9	0.6	1.8	71	0.1	1.5
Malalignment	2	0.1	0.4	60	0.1	1.3
Implant Breakage Tibial Insert				40	0.1	0.8
Patellofemoral Pain	2	0.1	0.4	31	0.1	0.6
Incorrect Sizing	1	0.1	0.2	28	0.1	0.6
Prosthesis Dislocation				28	0.1	0.6
Implant Breakage Tibial	2	0.1	0.4	24	0.0	0.5
Osteonecrosis				15	0.0	0.3
Wear Tibial	2	0.1	0.4	15	0.0	0.3
Metal Related Pathology				12	0.0	0.3
Synovitis				10	0.0	0.2
Arthrofibrosis	1	0.1	0.2	9	0.0	0.2
Implant Breakage Femoral				5	0.0	0.1
Wear Femoral				4	0.0	0.1
Patella Erosion				3	0.0	0.1
Other	2	0.1	0.4	37	0.1	0.8
<b>N Revision</b>	<b>491</b>	<b>32.6</b>	<b>100.0</b>	<b>4786</b>	<b>9.8</b>	<b>100.0</b>
<b>N Primary</b>	<b>1505</b>			<b>48950</b>		

Note: This table is restricted to revisions within 18.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 are excluded from the comparator.

**FIGURE 2**

**Cumulative Incidence Revision Diagnosis of Primary Unicompartmental 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 Freedom PKR Active/Freedom PKR Active unicompartmental knee combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other unicompartmental knee prostheses.

**Figure 2: Cumulative Incidence Revision Diagnosis for Primary Unicompartmental Knee Replacement**

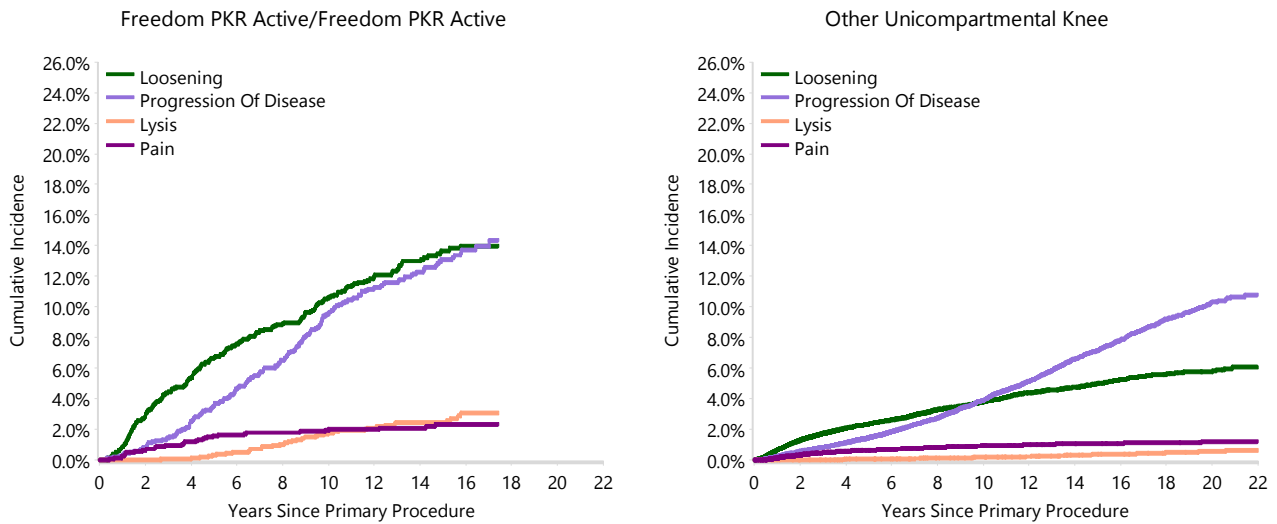


TABLE 5

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

This analysis identifies the components used in the revision of the Freedom PKR Active/Freedom PKR Active unicompartmental knee combination and compares it to the components used in the revision of all other unicompartmental 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 unicompartmental knee prostheses i.e. is there a difference in the type of revision undertaken for the Freedom PKR Active/Freedom PKR Active unicompartmental knee combination compared to all other unicompartmental knee prostheses.

**Table 5: Primary Unicompartmental Knee Replacement - Type of Revision (Follow-up Limited to 18.4 Years)**

Type of Revision	Freedom PKR Active/Freedom PKR Active		Other Unicompartmental Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	469	95.5	4033	84.3
Uni Tibial Component	15	3.1	99	2.1
Uni Femoral Component	1	0.2	51	1.1
Cement Spacer	2	0.4	39	0.8
UKR (Uni Tibial/Uni Femoral)	3	0.6	35	0.7
Patella/Trochlear Resurfacing	1	0.2	17	0.4
Removal of Prostheses			5	0.1
Femoral Component			4	0.1
Reinsertion of Components			4	0.1
Tibial Component			2	0.0
<b>N Major</b>	<b>491</b>	<b>100.0</b>	<b>4289</b>	<b>89.6</b>
Uni Insert Only			496	10.4
Patella Only			1	0.0
<b>N Minor</b>			<b>497</b>	<b>10.4</b>
<b>TOTAL</b>	<b>491</b>	<b>100.0</b>	<b>4786</b>	<b>100.0</b>

Note: This table is restricted to revisions within 18.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2022 are excluded from the comparator.

**TABLE 6****Revision Rates of Freedom PKR Active/Freedom PKR Active Primary Unicompartmental 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 Freedom PKR Active/Freedom PKR Active Primary Unicompartmental Knee Replacement by Fixation**

Fixation	N Revised	N Total
Cemented	491	1505
<b>TOTAL</b>	<b>491</b>	<b>1505</b>



TABLE 7

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

This enables a state by state variation to be identified for the Freedom PKR Active/Freedom PKR Active unicompartmental knee combination and provides the comparative data for each of the states for all other unicompartmental 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 7: Revised Number of Primary Unicompartmental Knee Replacement by State**

Component	State	N Revised	N Total
Freedom PKR Active/Freedom PKR Active	NSW	409	1197
	VIC	64	275
	QLD	1	3
	WA	2	2
	SA	12	24
	ACT/NT	3	4
Other Unicompartmental Knee	NSW	1478	12842
	VIC	921	10727
	QLD	856	9759
	WA	580	7520
	SA	671	5120
	TAS	181	1899
	ACT/NT	173	1083
<b>TOTAL</b>		<b>5351</b>	<b>50455</b>

Note: Prostheses no longer used in 2022 are excluded from the comparator.

**TABLE 8****Number of Revisions of Freedom PKR Active/Freedom PKR Active Primary Unicompartmental Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Freedom PKR Active/Freedom PKR Active unicompartmental 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 2022 has a maximum of one year to be revised, whereas a primary procedure performed in 2020 has a maximum of three years to be revised.

**Table 8: Number of Revisions of Freedom PKR Active/Freedom PKR Active Primary Unicompartmental Knee Replacement by Year of Implant**

Year of Implant	Number Revised	Total Number
2004	8	19
2005	66	223
2006	93	281
2007	98	264
2008	47	162
2009	63	149
2010	33	102
2011	25	75
2012	21	68
2013	12	63
2014	13	51
2015	6	31
2016	3	12
2017	3	5
<b>TOTAL</b>	<b>491</b>	<b>1505</b>

TABLE 9

### Revision Rates of Freedom PKR Active/Freedom PKR Active Primary Unicompartmental 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 Freedom PKR Active/Freedom PKR Active 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	Mobility	Material	Fixation
<b>Femoral</b>						
Freedom PKR/Active	10UNF100RL-10UNF520RM	UNI FEMORAL COMPONENT	YES			POLISHED
Freedom PKR/Active	10UNF120RLN-10UNF520RMN	FREEDOM TREKKING FEMORAL COMPONENT TINBN	YES			
<b>Tibial</b>						
Freedom PKR/Active	10UNT165RL-10UNT465RM	UNICOMPARTMENTAL TIBIAL	YES	FIXED	NON CROSS-LINKED POLYETHYLENE	
Freedom PKR/Active	10UNTA65RL-10UNTF95RM	UNICOMPARTMENTAL TIBIAL	YES	FIXED	NON CROSS-LINKED POLYETHYLENE	
Freedom PKR/Active	10UNTA65RLE-10UNTF95RME	UNICOMPARTMENTAL TIBIAL	YES	FIXED	XL POLYETHYLENE + ANTIOXIDANT	

**Table 9: Revised Number of Freedom PKR Active/Freedom PKR Active Primary Unicompartmental Knee Replacement by Catalogue Number Range**

Femoral Range	Tibial Range	N Revised	N Total
10UNF100RL-10UNF520RM	10UNT165RL-10UNT465RM	8	19
	10UNTA65RL-10UNTF95RM	453	1368
	10UNTA65RLE-10UNTF95RME	21	93
10UNF120RLN-10UNF520RMN	10UNTA65RL-10UNTF95RM	1	1
	10UNTA65RLE-10UNTF95RME	8	24
<b>TOTAL</b>		<b>491</b>	<b>1505</b>