## 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-2025.

Note: Procedures using prostheses with no recorded use in 2024 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	531	1505	17214	3.08 (2.83, 3.36)
Other Unicompartmental Knee	5258	50910	389433	1.35 (1.31, 1.39)
TOTAL	5789	52415	406647	1.42 (1.39, 1.46)

TABLE 2

Other Unicompartmental Knee

## 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 (95% CI) 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	1.9 (1.3, 2.7)	5.1 (4.1, 6.4)	8.0 (6.7, 9.5)	10.4 (9.0, 12.1)	13.8 (12.1, 15.6)	16.3 (14.5, 18.3)	18.8 (16.9, 20.9)	20.6 (18.6, 22.8)
Other Unicompartmental Knee	1.9 (1.8, 2.0)	3.4 (3.2, 3.6)	4.4 (4.2, 4.6)	5.3 (5.1, 5.5)	, .	7.0 (6.8, 7.3)	8.1 (7.8, 8.3)	9.1 (8.8, 9.4)
CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
CPR			29.5 (27.2,					
Freedom PKR Active/Freedom PKR Active	26.3)	29.6)	32.0)	34.3)	36.2)	38.0)	40.8)	42.9)

CPR	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs	23 Yrs
Freedom PKR Active/Freedom PKR Active	40.9 (38.1, 43.9)	42.8 (39.8, 46.0)	43.2 (40.2, 46.5)				
Other Unicompartmental Knee	21.4 (20.7, 22.1)	23.0 (22.3, 23.8)	24.8 (23.9, 25.6)	26.7 (25.7, 27.7)	28.7 (27.6, 29.8)	30.4 (29.1, 31.7)	31.2 (29.7, 32.6)

12.9)

11.7)

10.2 (9.9, 11.3 (11.0, 12.5 (12.2, 13.8 (13.4, 15.2 (14.8, 16.8 (16.3, 18.2 (17.7, 19.7 (19.1,

17.3)

20.3)

14.3)

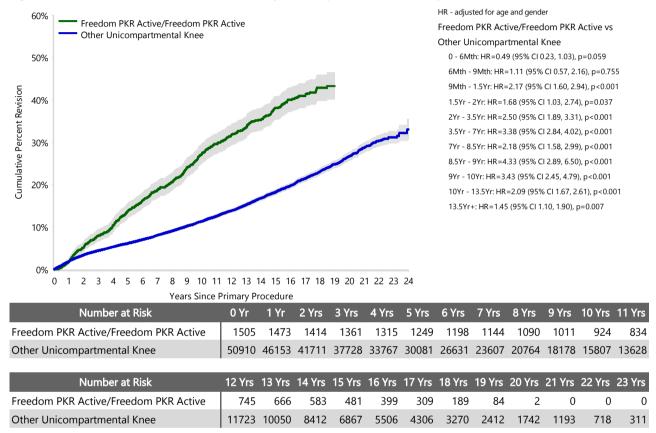
#### FIGURE 1

### 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



## Primary Diagnosis for Revised Primary Unicompartmental 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 unicompartmental knee prostheses.

Table 3: Primary Diagnosis for Revised Primary Unicompartmental Knee Replacement

	Freedom PKR Active/Freedom PKR Active		Other Unicomp	artmental Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	524	98.7	5206	99.0
Osteonecrosis	7	1.3	30	0.6
Rheumatoid Arthritis			14	0.3
Other Inflammatory Arthritis			5	0.1
Fracture			2	0.0
Tumour			1	0.0
TOTAL	531	100.0	5258	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: Primary Unicompartmental Knee Replacement - Reason for Revision (Follow-up Limited to 20.4 Years)

	Freedom P	edom PKR Active/Freedom PKR Active		Other	· Unicompartmenta	l Knee
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Progression Of Disease	209	13.9	39.4	1987	3.9	38.2
Loosening	206	13.7	38.8	1581	3.1	30.4
Pain	34	2.3	6.4	374	0.7	7.2
Infection	9	0.6	1.7	268	0.5	5.2
Bearing Dislocation				201	0.4	3.9
Fracture	8	0.5	1.5	160	0.3	3.1
Instability	3	0.2	0.6	109	0.2	2.1
Lysis	41	2.7	7.7	95	0.2	1.8
Wear Tibial Insert	9	0.6	1.7	82	0.2	1.6
Malalignment	2	0.1	0.4	66	0.1	1.3
Implant Breakage Tibial Insert				54	0.1	1.0
Incorrect Sizing	1	0.1	0.2	31	0.1	0.6
Patellofemoral Pain	1	0.1	0.2	30	0.1	0.6
Implant Breakage Tibial	4	0.3	0.8	28	0.1	0.5
Prosthesis Dislocation				27	0.1	0.5
Metal Related Pathology				14	0.0	0.3
Osteonecrosis				13	0.0	0.3
Wear Tibial	2	0.1	0.4	12	0.0	0.2
Arthrofibrosis	1	0.1	0.2	11	0.0	0.2
Synovitis				11	0.0	0.2
Wear Femoral				5	0.0	0.1
Implant Breakage Femoral				4	0.0	0.1
Patella Erosion				3	0.0	0.1
Other	1	0.1	0.2	33	0.1	0.6
N Revision	531	35.3	100.0	5199	10.2	100.0
N Primary	1505			50910		

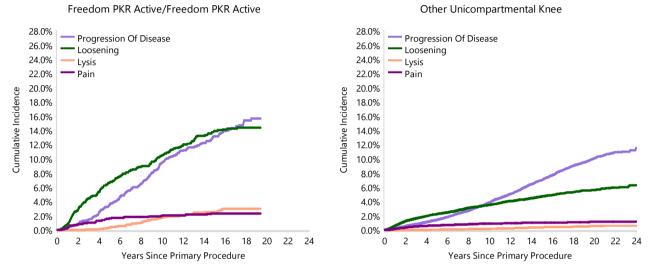
Note: This table is restricted to revisions within 20.4 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2024 are excluded from the comparator.

### 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



### 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 20.4 Years)

	Freedom PKR Active/Freedom PKR Active		Other Unicompartmental Knee	
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	508	95.7	4385	84.3
Uni Tibial Component	16	3.0	95	1.8
Uni Femoral Component	1	0.2	47	0.9
Cement Spacer	2	0.4	40	0.8
UKR (Uni Tibial/Uni Femoral)	3	0.6	35	0.7
Patella/Trochlear Resurfacing	1	0.2	16	0.3
Removal of Prostheses			5	0.1
Femoral Component			4	0.1
Reinsertion of Components			4	0.1
Tibial Component			1	0.0
N Major	531	100.0	4632	89.1
Uni Insert Only			566	10.9
Patella Only			1	0.0
N Minor			567	10.9
TOTAL	531	100.0	5199	100.0

Note: This table is restricted to revisions within 20.4 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2024 are excluded from the comparator.

# 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	531	1505
TOTAL	531	1505

## 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	442	1197
	VIC	70	275
	QLD	2	3
	WA	2	2
	SA	12	24
	ACT/NT	3	4
Other Unicompartmental Knee	NSW	1479	12313
	VIC	1049	11729
	QLD	958	10315
	WA	700	8024
	SA	729	5299
	TAS	194	2150
	ACT/NT	149	1080
TOTAL		5789	52415

# 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 2024 has a maximum of one year to be revised, whereas a primary procedure performed in 2022 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	69	223
2006	97	281
2007	103	264
2008	53	162
2009	67	149
2010	39	102
2011	30	75
2012	26	68
2013	12	63
2014	15	51
2015	6	31
2016	3	12
2017	3	5
TOTAL	531	1505

# 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
Femoral						
Freedom PKR/Active	10UNF100RL-10UNF520RM	UNI FEMORAL COMPONENT	YES			POLISHED
Freedom PKR/Active	10UNF120RLN-10UNF520RMN	FREEDOM TREKKING FEMORAL COMPONENT TINBN	YES			
Tibial						
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	491	1368
	10UNTA65RLE-10UNTF95RME	23	93
10UNF120RLN-10UNF520RMN	10UNTA65RL-10UNTF95RM	1	1
	10UNTA65RLE-10UNTF95RME	8	24
TOTAL		531	1505