

## Profix/Profix Mobile Total Knee Investigation

Note: This analysis compares the Profix/Profix Mobile 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-2023>.

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

### TABLE 1

#### Revision Rate of Primary Total Knee Replacement

The revision rate of the Profix/Profix Mobile 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)
Profix/Profix Mobile	114	1005	12924	0.88 (0.73, 1.06)
Other Total Knee	26836	757949	5069780	0.53 (0.52, 0.54)
<b>TOTAL</b>	<b>26950</b>	<b>758954</b>	<b>5082704</b>	<b>0.53 (0.52, 0.54)</b>

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

TABLE 2

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

The yearly cumulative percent revision of the Profix/Profix Mobile 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	8 Yrs
Profix/Profix Mobile	2.3 (1.5, 3.4)	5.0 (3.8, 6.6)	6.5 (5.1, 8.2)	7.3 (5.8, 9.1)	8.2 (6.6, 10.1)	8.7 (7.1, 10.7)	9.4 (7.7, 11.4)	9.6 (7.9, 11.7)
Other Total Knee	1.0 (1.0, 1.0)	1.8 (1.8, 1.9)	2.4 (2.4, 2.4)	2.8 (2.8, 2.9)	3.1 (3.1, 3.2)	3.5 (3.4, 3.5)	3.8 (3.7, 3.8)	4.0 (4.0, 4.1)

CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Profix/Profix Mobile	9.8 (8.0, 11.8)	10.0 (8.3, 12.1)	10.6 (8.8, 12.7)	11.1 (9.3, 13.3)	11.3 (9.4, 13.5)	11.7 (9.8, 14.0)	12.1 (10.1, 14.4)
Other Total Knee	4.3 (4.3, 4.4)	4.6 (4.6, 4.7)	4.9 (4.9, 5.0)	5.2 (5.2, 5.3)	5.6 (5.5, 5.6)	5.9 (5.8, 5.9)	6.2 (6.1, 6.3)

CPR	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs	22 Yrs
Profix/Profix Mobile	12.3 (10.3, 14.6)	12.5 (10.4, 14.9)	12.8 (10.7, 15.3)	13.3 (11.0, 15.9)	13.3 (11.0, 15.9)		
Other Total Knee	6.6 (6.5, 6.8)	7.0 (6.9, 7.2)	7.3 (7.2, 7.5)	7.6 (7.4, 7.8)	7.8 (7.6, 8.0)	8.0 (7.8, 8.2)	8.2 (7.9, 8.6)

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

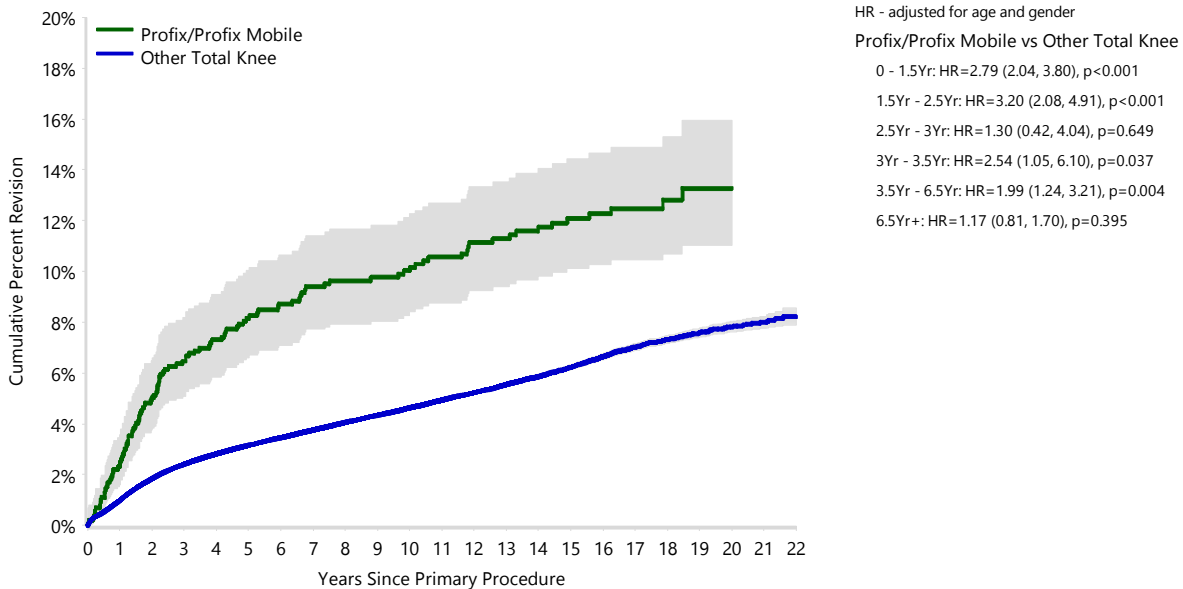
FIGURE 1

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

The yearly cumulative percent revision of the Profix/Profix Mobile 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	11 Yrs
Profix/Profix Mobile	1005	969	932	906	877	846	812	774	742	712	686	656
Other Total Knee	757949	689882	619616	556833	492801	431130	372737	318126	267229	221560	180409	143443

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
Profix/Profix Mobile	615	582	543	498	444	383	247	130	72	11	0
Other Total Knee	111922	85787	65049	47997	34991	24735	16433	9944	5486	2318	538

Note: Prostheses no longer used in 2022 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	Prefix/Prefix Mobile		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	111	97.4	26004	96.9
Rheumatoid Arthritis			342	1.3
Tumour			162	0.6
Other Inflammatory Arthritis	2	1.8	160	0.6
Osteonecrosis	1	0.9	101	0.4
Fracture			48	0.2
Other			18	0.1
Chondrocalcinosis			1	0.0
<b>TOTAL</b>	<b>114</b>	<b>100.0</b>	<b>26836</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 Total Knee Replacement - Reason for Revision

Revision Diagnosis	Profix/Profix Mobile			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	6	0.6	5.3	7356	1.0	27.4
Loosening	42	4.2	36.8	6021	0.8	22.4
Instability	9	0.9	7.9	2610	0.3	9.7
Pain	13	1.3	11.4	2037	0.3	7.6
Patellofemoral Pain	9	0.9	7.9	1933	0.3	7.2
Patella Erosion	2	0.2	1.8	1785	0.2	6.7
Arthrofibrosis	5	0.5	4.4	1035	0.1	3.9
Fracture	7	0.7	6.1	1023	0.1	3.8
Malalignment	1	0.1	0.9	602	0.1	2.2
Wear Tibial Insert	2	0.2	1.8	368	0.0	1.4
Lysis	7	0.7	6.1	331	0.0	1.2
Incorrect Sizing	2	0.2	1.8	262	0.0	1.0
Patella Maltracking				186	0.0	0.7
Implant Breakage Tibial Insert	4	0.4	3.5	174	0.0	0.6
Bearing Dislocation	4	0.4	3.5	151	0.0	0.6
Implant Breakage Patella				140	0.0	0.5
Metal Related Pathology				107	0.0	0.4
Prosthesis Dislocation				84	0.0	0.3
Synovitis				75	0.0	0.3
Osteonecrosis				55	0.0	0.2
Implant Breakage Tibial				42	0.0	0.2
Implant Breakage Femoral				39	0.0	0.1
Wear Patella				36	0.0	0.1
Tumour				34	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Wear Tibial				9	0.0	0.0
Progression Of Disease				7	0.0	0.0
Patella Dislocation				2	0.0	0.0
Incorrect Side				1	0.0	0.0
Wear Femoral				1	0.0	0.0
Other	1	0.1	0.9	316	0.0	1.2
<b>N Revision</b>	<b>114</b>	<b>11.3</b>	<b>100.0</b>	<b>26836</b>	<b>3.5</b>	<b>100.0</b>
<b>N Primary</b>	<b>1005</b>			<b>757949</b>		

Note: Prostheses no longer used in 2022 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 Profix/Profix Mobile 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

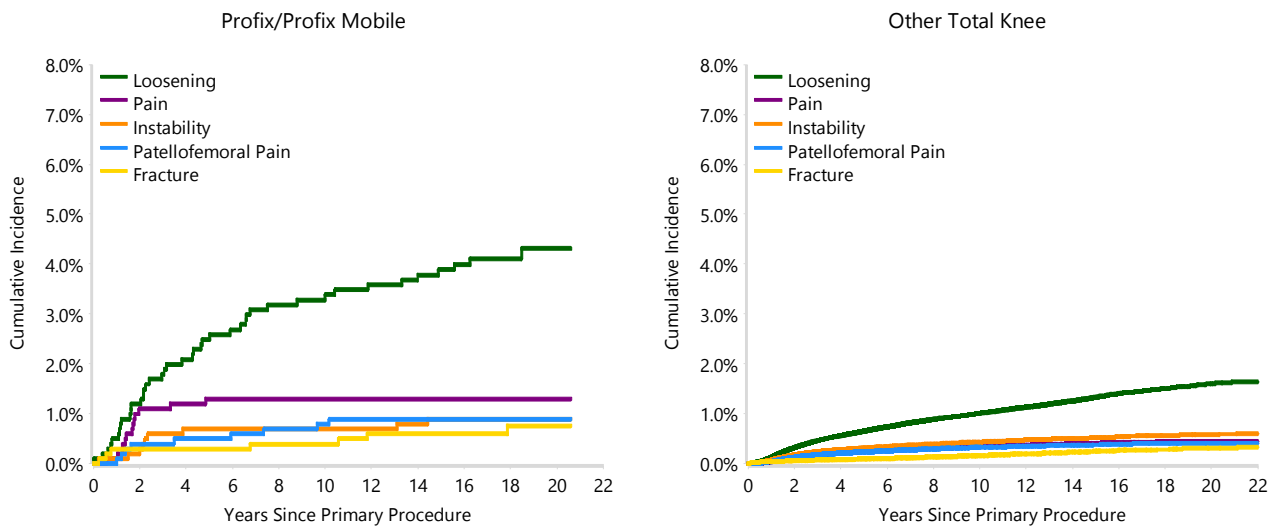


TABLE 5

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

This analysis identifies the components used in the revision of the Profix/Profix Mobile 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 Profix/Profix Mobile total knee combination compared to all other total knee prostheses.

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

Type of Revision	Profix/Profix Mobile		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	42	36.8	6657	24.8
Tibial Component	5	4.4	2136	8.0
Cement Spacer	3	2.6	1363	5.1
Femoral Component	6	5.3	1322	4.9
Removal of Prostheses	10	8.8	154	0.6
Total Femoral			24	0.1
Reinsertion of Components			13	0.0
<b>N Major</b>	<b>66</b>	<b>57.9</b>	<b>11669</b>	<b>43.5</b>
Insert Only	18	15.8	7583	28.3
Patella Only	19	16.7	4730	17.6
Insert/Patella	9	7.9	2772	10.3
Minor Components	2	1.8	64	0.2
Cement Only			18	0.1
<b>N Minor</b>	<b>48</b>	<b>42.1</b>	<b>15167</b>	<b>56.5</b>
<b>TOTAL</b>	<b>114</b>	<b>100.0</b>	<b>26836</b>	<b>100.0</b>

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

**TABLE 6****Revision Rates of Profix/Profix Mobile 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 Profix/Profix Mobile Primary Total Knee Replacement by Fixation**

Fixation	N Revised	N Total
Cemented	19	141
Cementless	35	272
Hybrid (Tibial Cemented)	59	579
Hybrid (Tibial Cementless)	1	13
<b>TOTAL</b>	<b>114</b>	<b>1005</b>

**TABLE 7****Revision Rates of Profix/Profix Mobile 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 Profix/Profix Mobile Primary Total Knee Replacement by Bearing Surface**

Bearing Surface	N Revised	N Total
Non XLPE	114	1005
<b>TOTAL</b>	<b>114</b>	<b>1005</b>



**TABLE 8****Revision Rates of Profix/Profix Mobile 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 Profix/Profix Mobile Primary Total Knee Replacement by Bearing Mobility**

Bearing Mobility	N Revised	N Total
Rotating	114	1005
<b>TOTAL</b>	<b>114</b>	<b>1005</b>

**TABLE 9****Revision Rates of Profix/Profix Mobile 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 Profix/Profix Mobile Primary Total Knee Replacement by Stability**

Stability	N Revised	N Total
Minimally Stabilised	114	1005
<b>TOTAL</b>	<b>114</b>	<b>1005</b>

TABLE 10

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

This enables a state by state variation to be identified for the Profix/Profix Mobile 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
Profix/Profix Mobile	NSW	45	218
	VIC	5	163
	QLD	1	4
	ACT/NT	63	620
Other Total Knee	NSW	7959	262433
	VIC	5825	153047
	QLD	5766	157008
	WA	3245	81139
	SA	2967	66419
	TAS	437	18133
	ACT/NT	637	19770
<b>TOTAL</b>		<b>26950</b>	<b>758954</b>

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

**TABLE 11****Number of Revisions of Profix/Profix Mobile Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Profix/Profix Mobile 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 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 11: Number of Revisions of Profix/Profix Mobile Primary Total Knee Replacement by Year of Implant**

Year of Implant	Number Revised	Total Number
2001	3	32
2002	28	165
2003	21	173
2004	32	258
2005	23	245
2006	4	51
2007	2	56
2008	0	11
2009	1	12
2010	0	2
<b>TOTAL</b>	<b>114</b>	<b>1005</b>

TABLE 12

## Revision Rates of Profix/Profix Mobile 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 Profix/Profix Mobile 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>					
Profix	71502110-71502270	PROFIX POROUS FEMORAL COMPONENT	NO		POROUS
Profix	71503120-71503270	POROUS HA CR FEMORAL COMPONENT	NO	HA COATED	POROUS
Profix	71522110-71522270	NONPOROUS CONSTRAINED FEMORAL COMPONENT	YES		
Profix	71522111-71522271	NONPOROUS FEMORAL COMPONENT W/TAPER	YES		
<b>Tibial</b>					
Profix Mobile	71540102-71540208	POROUS TIBIAL BASEPLATE	NO		POROUS
Profix Mobile	71544102-71544208	POROUS HA TIBIAL BASEPLATE	NO	HA COATED	POROUS
Profix Mobile	71549101-71549208	NONPOROUS TIBIAL BASEPLATE	YES		

Table 12: Revised Number of Profix/Profix Mobile Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
71502110-71502270	71540102-71540208	0	2
	71544102-71544208	5	42
	71549101-71549208	32	282
71503120-71503270	71544102-71544208	29	228
	71549101-71549208	27	298
71522110-71522270	71544102-71544208	1	12
	71549101-71549208	20	139
71522111-71522271	71549101-71549208	0	2
<b>TOTAL</b>		<b>114</b>	<b>1005</b>