

Profix Oxinium (cemented)/Profix (cementless) Total Knee Investigation

Note: This analysis compares the Profix Oxinium (ctd)/Profix (cless) 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 Profix Oxinium (ctd)/Profix (cless) 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 Oxinium (ctd)/Profix (cless)	14	100	1246	1.12 (0.61, 1.89)
Other Total Knee	26061	727695	4729125	0.55 (0.54, 0.56)
TOTAL	26075	727795	4730370	0.55 (0.54, 0.56)

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 Profix Oxinium (ctd)/Profix (class) 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
Profix Oxinium (ctd)/Profix (class)	4.0 (1.5, 10.3)	7.0 (3.4, 14.1)	8.0 (4.1, 15.4)	8.0 (4.1, 15.4)	9.0 (4.8, 16.6)	9.0 (4.8, 16.6)	9.0 (4.8, 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
Profix Oxinium (ctd)/Profix (class)	10.1 (5.6, 17.9)	11.2 (6.4, 19.4)	11.2 (6.4, 19.4)	13.8 (8.2, 22.6)	13.8 (8.2, 22.6)	13.8 (8.2, 22.6)	15.3 (9.3, 24.7)
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
Profix Oxinium (ctd)/Profix (class)	15.3 (9.3, 24.7)	15.3 (9.3, 24.7)	15.3 (9.3, 24.7)				
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.

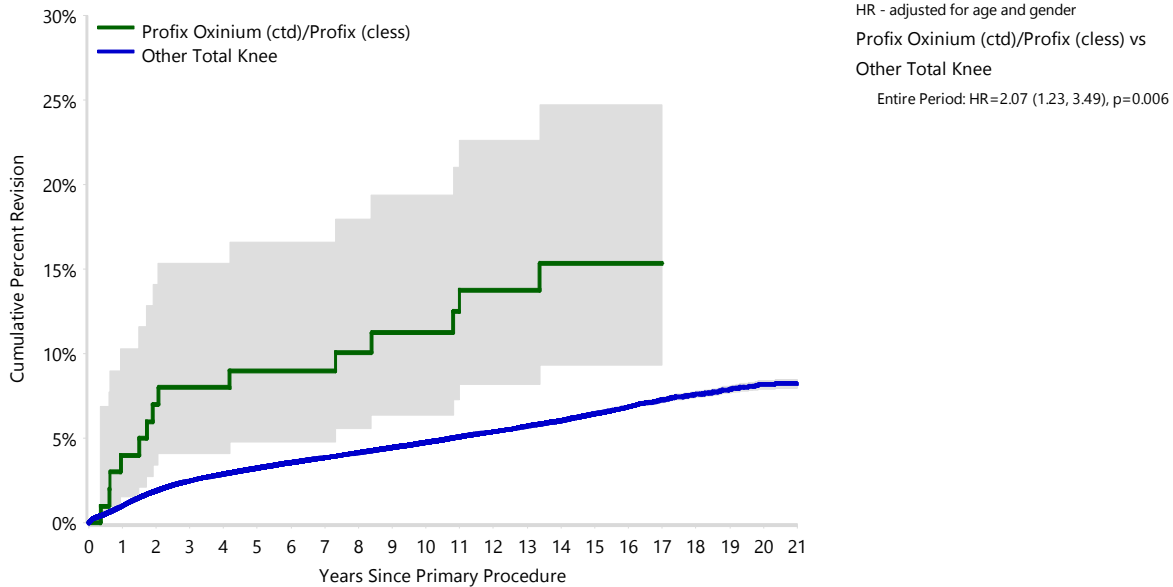
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Profix Oxinium (ctd)/Profix (cless) 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
Profix Oxinium (ctd)/Profix (cless)	100	96	93	91	91	90	86	85	80	75	74
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
Profix Oxinium (ctd)/Profix (cless)	68	65	60	47	38	28	20	4	2	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	Prefix Oxinium (ctd)/Prefix (class)		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	14	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
TOTAL	14	100.0	26061	100.0

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 20 Years)

Revision Diagnosis	Profix Oxinium (ctd)/Profix (class)			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	1	1.0	7.1	6981	1.0	26.8
Loosening	4	4.0	28.6	5841	0.8	22.4
Instability	1	1.0	7.1	2488	0.3	9.5
Pain	1	1.0	7.1	2064	0.3	7.9
Patellofemoral Pain	2	2.0	14.3	2048	0.3	7.9
Patella Erosion	4	4.0	28.6	1693	0.2	6.5
Arthrofibrosis				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				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	1	1.0	7.1	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
N Revision	14	14.0	100.0	26059	3.6	100.0
N Primary	100			727695		

Note: This table is restricted to revisions within 20 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 Profix Oxinium (ctd)/Profix (cless) 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

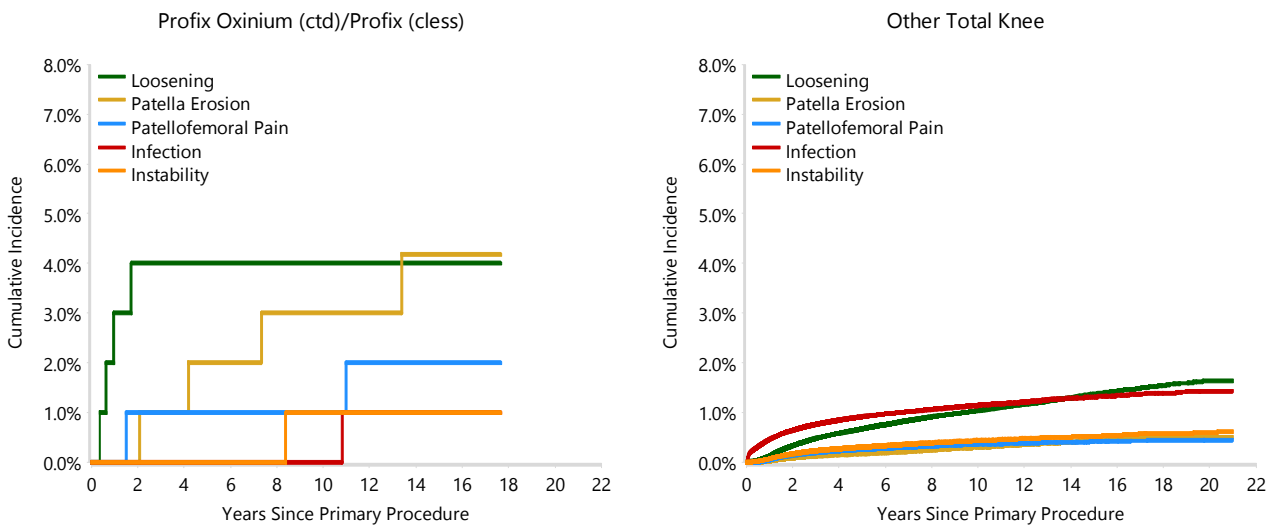


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

This analysis identifies the components used in the revision of the Profix Oxinium (ctd)/Profix (cless) 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 Oxinium (ctd)/Profix (cless) total knee combination compared to all other total knee prostheses.

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 20 Years)

Type of Revision	Profix Oxinium (ctd)/Profix (cless)		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)			6418	24.6
Tibial Component	3	21.4	2100	8.1
Cement Spacer	1	7.1	1360	5.2
Femoral Component	1	7.1	1311	5.0
Removal of Prostheses			150	0.6
Total Femoral			21	0.1
Reinsertion of Components			11	0.0
N Major	5	35.7	11371	43.6
Insert Only	2	14.3	7122	27.3
Patella Only	4	28.6	4783	18.4
Insert/Patella	3	21.4	2710	10.4
Minor Components			59	0.2
Cement Only			14	0.1
N Minor	9	64.3	14688	56.4
TOTAL	14	100.0	26059	100.0

Note: This table is restricted to revisions within 20 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 Profix Oxinium (ctd)/Profix (cless) 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 Oxinium (ctd)/Profix (cless) Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	1	11
Hybrid (Tibial Cementless)	13	89
TOTAL	14	100

TABLE 7**Revision Rates of Profix Oxinium (ctd)/Profix (cless) 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 Oxinium (ctd)/Profix (cless) Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	14	100
TOTAL	14	100

TABLE 8**Revision Rates of Profix Oxinium (ctd)/Profix (cless) 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 Oxinium (ctd)/Profix (cless) Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	14	100
TOTAL	14	100

TABLE 9**Revision Rates of Profix Oxinium (ctd)/Profix (cless) 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 Oxinium (ctd)/Profix (cless) Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Minimally Stabilised	14	100
TOTAL	14	100

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Profix Oxinium (ctd)/Profix (cless) 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 Oxinium (ctd)/Profix (cless)	NSW	6	26
	QLD	0	1
	SA	8	73
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
TOTAL		26075	727795

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

TABLE 11**Number of Revisions of Profix Oxinium (ctd)/Profix (cless) Primary Total Knee Replacement by Year of Implant**

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

Year of Implant	Number Revised	Total Number
2002	0	5
2003	0	5
2004	5	29
2005	4	17
2006	1	15
2007	1	8
2008	0	10
2009	3	8
2010	0	2
2012	0	1
TOTAL	14	100

TABLE 12

Revision Rates of Profix Oxinium (ctd)/Profix (cless) 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 Oxinium (ctd)/Profix (cless) 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
Femoral					
Profix Oxinium	71522127-71522277	NONPOROUS ZIRCONIUM OXINIUM FEMORAL COMPONENT	YES		
Tibial					
Profix	71504110-71504270	POROUS TIBIAL BASEPLATE	NO		POROUS
Profix	71504151-71504261	POROUS TIBIAL BASEPLATE W.OUT/HOLES	NO		POROUS
Profix	71505120-71505260	POROUS HA TIBIAL BASEPLATE W/HOLES	NO	HA COATED	POROUS
Profix	71505320-71505460	POROUS HA TIBIAL BASEPLATE W.OUT/HOLES	NO	HA COATED	POROUS
Profix	71926278-71926299	POROUS HA TIBIAL BASEPLATE W.OUT/HOLES	NO	HA COATED	POROUS
Profix	71930930-71930942	PROFIX POROUS HA COATED TIBIAL BASEPLATE WITH TANTALUM BEADS WITHOUT HOLES	NO	HA COATED	POROUS

Table 12: Revised Number of Profix Oxinium (ctd)/Profix (cless) Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	Tibial Range	N Revised	N Total
71522127-71522277	71504110-71504270	0	4
	71504151-71504261	0	2
	71505120-71505260	0	1
	71505320-71505460	13	82
	71926278-71926299	1	7
	71930930-71930942	0	4
TOTAL		14	100