

Legion Oxinium FS Total Knee Investigation

Note: This analysis compares the Legion Oxinium FS 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-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 Legion Oxinium FS 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)
Legion Oxinium FS	39	472	2568	1.52 (1.08, 2.08)
Other Total Knee	26797	757477	5067212	0.53 (0.52, 0.54)
TOTAL	26836	757949	5069780	0.53 (0.52, 0.54)

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 Legion Oxinium FS 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	8 Yrs
Legion Oxinium FS	4.8 (3.2, 7.2)	6.6 (4.6, 9.4)	6.9 (4.9, 9.7)	7.9 (5.7, 11.0)	8.3 (6.0, 11.5)	8.8 (6.3, 12.1)	9.3 (6.7, 12.9)	10.6 (7.6, 14.7)
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
Legion Oxinium FS	10.6 (7.6, 14.7)	10.6 (7.6, 14.7)	10.6 (7.6, 14.7)	12.1 (8.3, 17.4)			
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)	5.5 (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
Legion Oxinium FS							
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 (7.7, 8.2)	8.2 (7.9, 8.6)

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

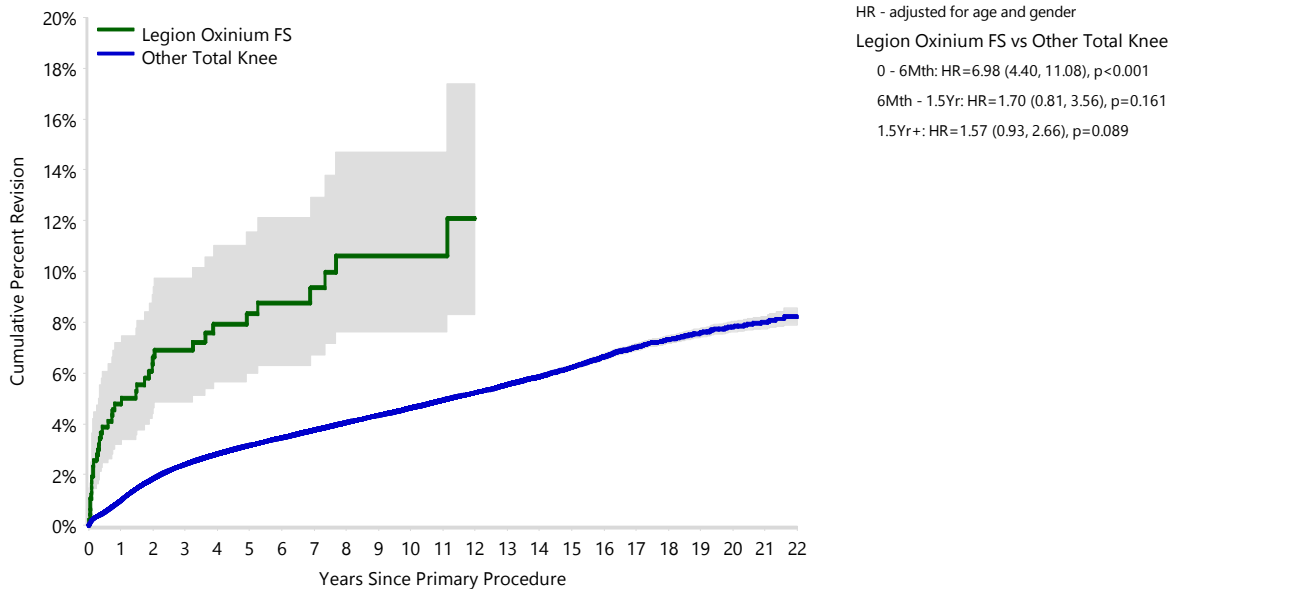
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Knee Replacement

The yearly cumulative percent revision of the Legion Oxinium FS 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	11 Yrs
Legion Oxinium FS	472	408	338	297	255	217	186	155	130	107	83	62
Other Total Knee	757477	689474	619278	556536	492546	430913	372551	317971	267099	221453	180326	143381

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
Legion Oxinium FS	47	32	19	12	1	0	0	0	0	0	0
Other Total Knee	111875	85755	65030	47985	34990	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	Legion Oxinium FS		Other Total Knee	
	Number	Percent	Number	Percent
Osteoarthritis	33	84.6	25971	96.9
Rheumatoid Arthritis			342	1.3
Tumour			162	0.6
Other Inflammatory Arthritis			160	0.6
Osteonecrosis	3	7.7	98	0.4
Fracture			48	0.2
Other	3	7.7	15	0.1
Chondrocalcinosis			1	0.0
TOTAL	39	100.0	26797	100.0

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 (Follow-up Limited to 16.6 Years)

Revision Diagnosis	Legion Oxinium FS			Other Total Knee		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	14	3.0	35.9	7316	1.0	27.5
Loosening	7	1.5	17.9	5953	0.8	22.4
Instability	3	0.6	7.7	2593	0.3	9.7
Pain	3	0.6	7.7	2028	0.3	7.6
Patellofemoral Pain	2	0.4	5.1	1926	0.3	7.2
Patella Erosion	1	0.2	2.6	1771	0.2	6.7
Arthrofibrosis	2	0.4	5.1	1032	0.1	3.9
Fracture	2	0.4	5.1	1007	0.1	3.8
Malalignment				601	0.1	2.3
Wear Tibial Insert				359	0.0	1.3
Lysis				320	0.0	1.2
Incorrect Sizing				261	0.0	1.0
Patella Maltracking	1	0.2	2.6	185	0.0	0.7
Implant Breakage Tibial Insert				170	0.0	0.6
Bearing Dislocation	3	0.6	7.7	148	0.0	0.6
Implant Breakage Patella				139	0.0	0.5
Metal Related Pathology	1	0.2	2.6	105	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				34	0.0	0.1
Tumour				33	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Wear Tibial				9	0.0	0.0
Progression Of Disease				6	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				316	0.0	1.2
N Revision	39	8.3	100.0	26625	3.5	100.0
N Primary	472			757477		

Note: This table is restricted to revisions within 16.6 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 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 Legion Oxinium FS 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

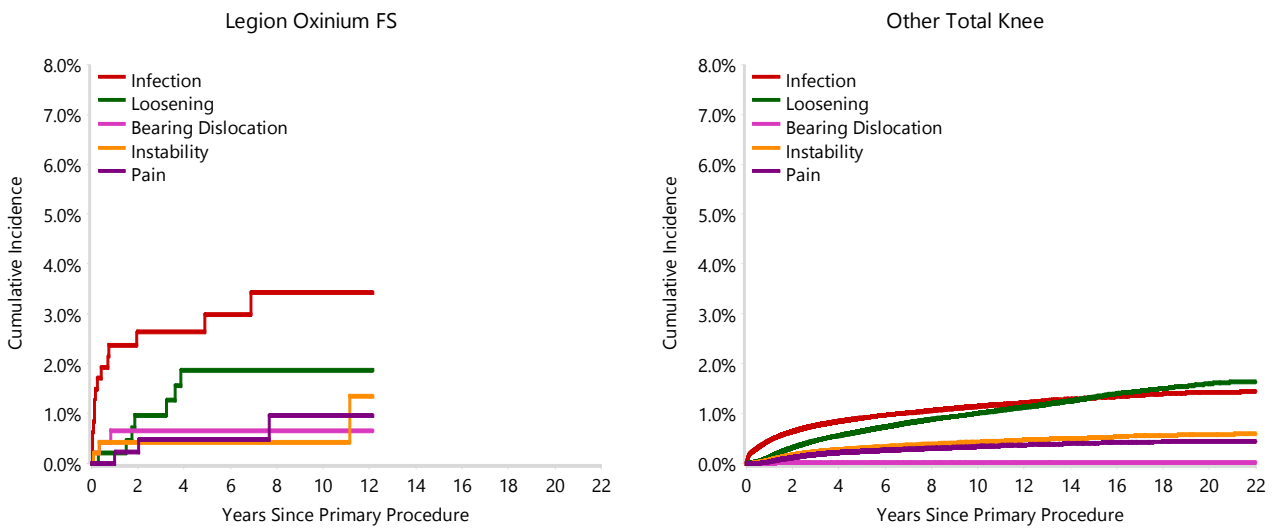


TABLE 5

Type of Revision Performed for Primary Total Knee Replacement

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

Table 5: Primary Total Knee Replacement - Type of Revision (Follow-up Limited to 16.6 Years)

Type of Revision	Legion Oxinium FS		Other Total Knee	
	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	6	15.4	6570	24.7
Tibial Component	1	2.6	2130	8.0
Cement Spacer	1	2.6	1357	5.1
Femoral Component	2	5.1	1319	5.0
Removal of Prostheses	1	2.6	150	0.6
Total Femoral			24	0.1
Reinsertion of Components			13	0.0
N Major	11	28.2	11563	43.4
Insert Only	20	51.3	7531	28.3
Patella Only	5	12.8	4707	17.7
Insert/Patella	2	5.1	2744	10.3
Minor Components	1	2.6	63	0.2
Cement Only			17	0.1
N Minor	28	71.8	15062	56.6
TOTAL	39	100.0	26625	100.0

Note: This table is restricted to revisions within 16.6 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 Legion Oxinium FS 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 Legion Oxinium FS Primary Total Knee Replacement by Fixation

Fixation	N Revised	N Total
Cemented	38	468
Hybrid (Tibial Cementless)	1	4
TOTAL	39	472

TABLE 7**Revision Rates of Legion Oxinium FS 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 Legion Oxinium FS Primary Total Knee Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Non XLPE	35	387
XLPE	4	85
TOTAL	39	472

TABLE 8**Revision Rates of Legion Oxinium FS 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 Legion Oxinium FS Primary Total Knee Replacement by Bearing Mobility

Bearing Mobility	N Revised	N Total
Fixed	39	472
TOTAL	39	472

TABLE 9**Revision Rates of Legion Oxinium FS 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 Legion Oxinium FS Primary Total Knee Replacement by Stability

Stability	N Revised	N Total
Fully Stabilised	26	261
Posterior Stabilised	13	211
TOTAL	39	472

TABLE 10

Revision Rates of Primary Total Knee Replacement by State

This enables a state by state variation to be identified for the Legion Oxinium FS 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
Legion Oxinium FS	NSW	7	79
	VIC	3	104
	QLD	20	173
	WA	7	76
	SA	1	30
	TAS	0	1
	ACT/NT	1	9
Other Total Knee	NSW	7952	262354
	VIC	5822	152943
	QLD	5746	156835
	WA	3238	81063
	SA	2966	66389
	TAS	437	18132
	ACT/NT	636	19761
TOTAL		26836	757949

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

TABLE 11**Number of Revisions of Legion Oxinium FS Primary Total Knee Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Legion Oxinium FS 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 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 Legion Oxinium FS Primary Total Knee Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2006	2	7
2007	1	22
2008	3	19
2009	2	28
2010	1	28
2011	6	24
2012	3	31
2013	3	30
2014	0	18
2015	2	23
2016	0	25
2017	2	24
2018	5	37
2019	1	30
2020	4	37
2021	2	53
2022	2	36
TOTAL	39	472

TABLE 12**Revision Rates of Legion Oxinium FS 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 Legion Oxinium FS 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
Femoral			
Legion Oxinium FS	71421162-71421178	OXINIUM CONSTRAINED FEMORAL COMPONENT	YES

Table 12: Revised Number of Legion Oxinium FS Primary Total Knee Replacement by Catalogue Number Range

Femoral Range	N Revised	N Total
71421162-71421178	39	472
TOTAL	39	472

TABLE 13**Revision Rates of Legion Oxinium FS 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 Legion Oxinium FS Primary Total Knee Replacement by Tibial Component

Tibial Component	N Revised	N Total
Genesis II	7	118
Legion Revision Tibial Baseplate	32	354
TOTAL	39	472