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-2025.

Note: Procedures using prostheses with no recorded use in 2024 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	48	545	3268	1.47 (1.08, 1.95)
Other Total Knee	24659	720516	4532270	0.54 (0.54, 0.55)
TOTAL	24707	721061	4535539	0.54 (0.54, 0.55)

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 Cumula	ative Percent	: Revision (9	5% CI) of Pr	imary Total	Knee Repla	cement		
CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs	8 Yrs
Legion Oxinium FS	5.1 (3.5, 7.3)	6.6 (4.7, 9.1)	7.0 (5.1, 9.6)	7.8 (5.8, 10.6)	8.5 (6.3, 11.4)	9.2 (6.8, 12.3)	9.7 (7.2, 12.9)	10.7 (7.9, 14.3)
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, 2.8)	3.1 (3.1, 3.2)	3.5 (3.4, 3.5)	3.8 (3.7, 3.8)	4.1 (4.0, 4.1)
CPR	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs	16 Yrs
Legion Oxinium FS	10.7 (7.9, 14.3)	10.7 (7.9, 14.3)	11.5 (8.5, 15.6)	12.5 (9.1, 17.1)	12.5 (9.1, 17.1)	12.5 (9.1, 17.1)		
Other Total Knee	4.4 (4.3, 4.5)	4.7 (4.7, 4.8)	5.1 (5.0, 5.1)	5.4 (5.3, 5.5)	5.7 (5.6, 5.8)	6.0 (5.9, 6.1)	6.4 (6.3, 6.5)	6.8 (6.7, 7.0)
CPR	17 Yrs	18 Yrs	19 Yr	s 20	Yrs 2	1 Yrs	22 Yrs	23 Yrs
Legion Oxinium FS								
Other Total Knee	7.3 (7.1, 7.4	1) 7.6 (7.4, 7	7.8) 7.9 (7.7	7, 8.1) 8.1 (7	7.9, 8.3) 8.4	(8.1, 8.6)	3.5 (8.2, 8.8)	8.6 (8.3, 8.9)

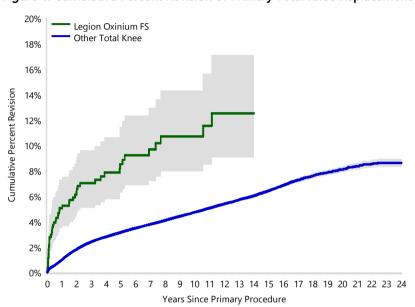
FIGURE 1

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



HR - adjusted for age and gender

Legion Oxinium FS vs Other Total Knee

0 - 3Mth: HR=7.24 (95% CI 4.36, 12.01), p<0.001

3Mth - 6Mth: HR=5.99 (95% CI 2.68, 13.35), p<0.001

6Mth - 1.5Yr: HR=1.92 (95% CI 1.00, 3.69), p=0.050

1.5Yr+: HR=1.55 (95% CI 0.97, 2.46), p=0.064

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	545	480	422	371	309	270	231	192	164	136	110	96
Other Total Knee	720516	640248	561613	497821	435016	379944	326044	276288	231313	191038	154472	123772
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	23 Yrs
Legion Oxinium FS	78	57	43	27	16	10	1	0	0	0	0	0
Other Total Knee	97910	75164	56506	41481	29987	21213	14966	10421	6807	4051	2359	1090

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

	Legion Oxinium FS		Other To	tal Knee
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	40	83.3	23850	96.7
Rheumatoid Arthritis	1	2.1	300	1.2
Tumour			192	0.8
Other Inflammatory Arthritis			158	0.6
Osteonecrosis	4	8.3	86	0.3
Fracture			50	0.2
Other	3	6.3	22	0.1
Chondrocalcinosis			1	0.0
TOTAL	48	100.0	24659	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 Total Knee Replacement - Reason for Revision (Follow-up Limited to 18.6 Years)

		Legion Oxinium FS			Other Total Knee	
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Infection	16	2.9	33.3	7068	1.0	28.7
Loosening	8	1.5	16.7	5232	0.7	21.3
Instability	4	0.7	8.3	2530	0.4	10.3
Patella Erosion	1	0.2	2.1	1810	0.3	7.4
Pain	5	0.9	10.4	1754	0.2	7.1
Patellofemoral Pain	2	0.4	4.2	1477	0.2	6.0
Arthrofibrosis	2	0.4	4.2	1045	0.1	4.2
Fracture	3	0.6	6.3	1008	0.1	4.1
Malalignment				488	0.1	2.0
Wear Tibial Insert				320	0.0	1.3
Lysis				263	0.0	1.1
Incorrect Sizing				210	0.0	0.9
Implant Breakage Tibial Insert				204	0.0	0.8
Patella Maltracking	1	0.2	2.1	174	0.0	0.7
Bearing Dislocation	5	0.9	10.4	136	0.0	0.6
Implant Breakage Patella				132	0.0	0.5
Metal Related Pathology	1	0.2	2.1	100	0.0	0.4
Prosthesis Dislocation				70	0.0	0.3
Synovitis				59	0.0	0.2
Osteonecrosis				46	0.0	0.2
Implant Breakage Femoral				43	0.0	0.2
Wear Patella				43	0.0	0.2
Implant Breakage Tibial				35	0.0	0.1
Tumour				30	0.0	0.1
Heterotopic Bone				14	0.0	0.1
Progression Of Disease				8	0.0	0.0
Wear Tibial				6	0.0	0.0
Incorrect Side				1	0.0	0.0
Patella Dislocation				1	0.0	0.0
Wear Femoral				1	0.0	0.0
Other				295	0.0	1.2
N Revision	48	8.8	100.0	24603	3.4	100.0
N Primary	545			720516		

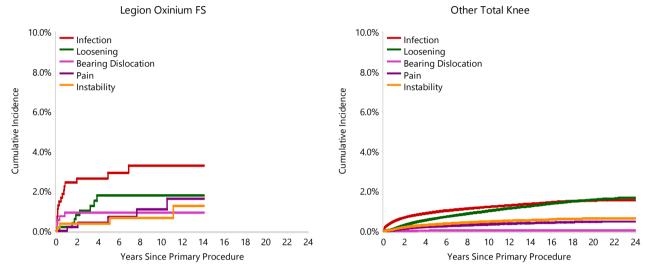
Note: This table is restricted to revisions within 18.6 years for all groups to allow a time-matched comparison of revisions.

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



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 18.6 Years)

	Legion Oxinium FS		Other To	otal Knee
Type of Revision	Number	Percent	Number	Percent
TKR (Tibial/Femoral)	7	14.6	5879	23.9
Tibial Component	1	2.1	1801	7.3
Femoral Component	2	4.2	1182	4.8
Cement Spacer	2	4.2	1079	4.4
Removal of Prostheses	1	2.1	123	0.5
Total Femoral			22	0.1
Reinsertion of Components			7	0.0
N Major	13	27.1	10093	41.0
Insert Only	25	52.1	7635	31.0
Patella Only	6	12.5	4155	16.9
Insert/Patella	3	6.3	2649	10.8
Minor Components	1	2.1	62	0.3
Cement Only			9	0.0
N Minor	35	72.9	14510	59.0
TOTAL	48	100.0	24603	100.0

Note: This table is restricted to revisions within 18.6 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 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	47	541
Hybrid (Tibial Cementless)	1	4
TOTAL	48	545

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	42	441
XLPE	6	104
TOTAL	48	545

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	48	545
TOTAL	48	545

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	32	315
Posterior Stabilised	16	230
TOTAL	48	545

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 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 10: 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	1	18
2015	2	23
2016	0	25
2017	2	24
2018	7	37
2019	1	30
2020	4	37
2021	3	53
2022	2	38
2023	3	41
2024	2	30
TOTAL	48	545

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 11: Revised Number of Legion Oxinium FS Primary Total Knee Replacement by Tibial Component

Tibial Component	N Revised	N Total
Genesis II	9	128
Legion Revision Tibial Baseplate	39	417
TOTAL	48	545