

## Secur-Fit Plus/PINNACLE Total Conventional Hip Investigation

Note: This analysis compares the Secur-Fit Plus/PINNACLE femoral stem/acetabular combination with all other total conventional hip 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 metal/metal prostheses with head size larger than 32mm are excluded from the comparator. Procedures using prostheses with no recorded use in 2021 are excluded from the comparator.

### TABLE 1

#### Revision Rate of Primary Total Conventional Hip Replacement

The revision rate of the Secur-Fit Plus/PINNACLE total conventional hip combination is compared to all other total conventional hip prostheses.

**Table 1: Revision Rates of Primary Total Conventional Hip Replacement**

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Secur-Fit Plus/PINNACLE	14	246	1371	1.02 (0.56, 1.71)
Other Total Conventional Hip	15845	453209	2719766	0.58 (0.57, 0.59)
<b>TOTAL</b>	<b>15859</b>	<b>453455</b>	<b>2721137</b>	<b>0.58 (0.57, 0.59)</b>

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

TABLE 2

**Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement**

The yearly cumulative percent revision of the Secur-Fit Plus/PINNACLE total conventional hip combination is compared to all other total conventional hip prostheses.

**Table 2: Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement**

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Secur-Fit Plus/PINNACLE	3.3 (1.6, 6.4)	4.1 (2.2, 7.5)	4.5 (2.5, 8.0)	5.0 (2.8, 8.6)	5.0 (2.8, 8.6)	5.6 (3.3, 9.6)	5.6 (3.3, 9.6)
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.2, 2.2)	2.5 (2.5, 2.6)	2.8 (2.8, 2.9)	3.1 (3.0, 3.2)	3.4 (3.3, 3.5)	3.7 (3.6, 3.7)

CPR	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs
Secur-Fit Plus/PINNACLE	5.6 (3.3, 9.6)						
Other Total Conventional Hip	4.0 (3.9, 4.0)	4.3 (4.2, 4.4)	4.6 (4.6, 4.7)	5.0 (4.9, 5.1)	5.4 (5.3, 5.5)	5.8 (5.7, 5.9)	6.2 (6.1, 6.4)

CPR	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs	20 Yrs	21 Yrs
Secur-Fit Plus/PINNACLE							
Other Total Conventional Hip	6.7 (6.5, 6.8)	7.1 (6.9, 7.3)	7.5 (7.3, 7.7)	7.9 (7.6, 8.1)	8.6 (8.3, 8.9)	8.9 (8.5, 9.3)	9.8 (9.0, 10.8)

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

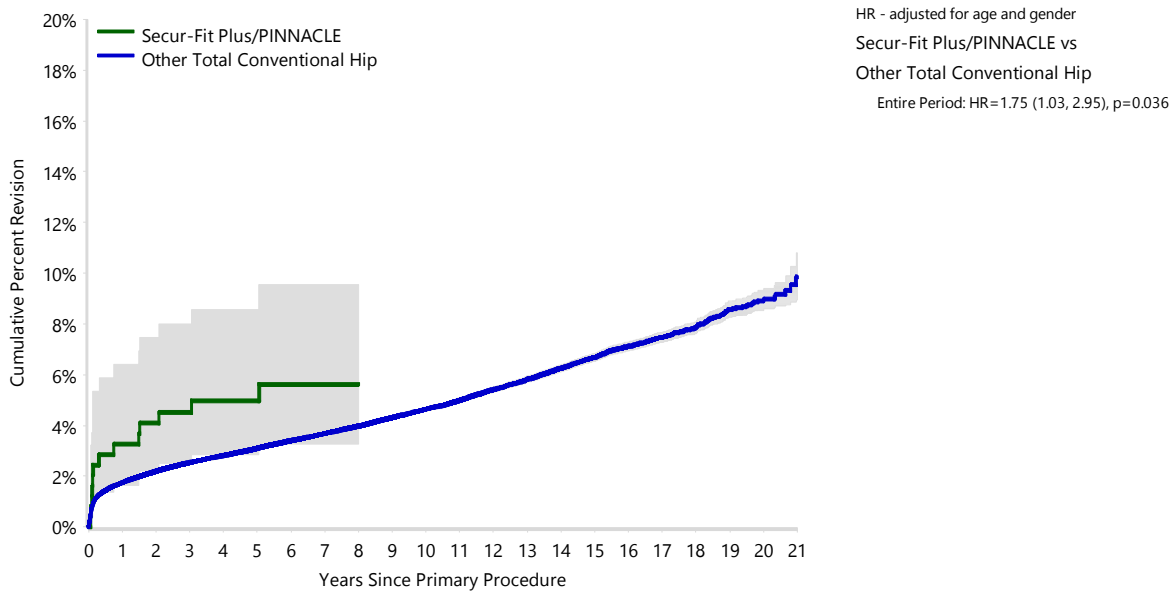
**FIGURE 1**

**Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement**

The yearly cumulative percent revision of the Secur-Fit Plus/PINNACLE total conventional hip combination is compared to all other total conventional hip 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 Conventional Hip 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
Secur-Fit Plus/PINNACLE	246	234	232	211	176	143	118	75	40	3	3
Other Total Conventional Hip	453209	398449	353821	308966	267029	227917	191469	158508	131170	108023	88152

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
Secur-Fit Plus/PINNACLE	3	3	2	2	1	1	0	0	0	0	0
Other Total Conventional Hip	70600	55340	42206	31907	24031	17718	12212	7611	4006	1573	276

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**TABLE 3****Primary Diagnosis for Revised Primary Total Conventional Hip 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 conventional hip prostheses.

**Table 3: Primary Diagnosis for Revised Primary Total Conventional Hip Replacement**

Primary Diagnosis	Secur-Fit Plus/PINNACLE		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Osteoarthritis	13	92.9	13099	82.7
Fractured Neck Of Femur			1164	7.3
Osteonecrosis			718	4.5
Developmental Dysplasia			247	1.6
Rheumatoid Arthritis	1	7.1	172	1.1
Failed Internal Fixation			140	0.9
Tumour			137	0.9
Other Inflammatory Arthritis			91	0.6
Fracture/Dislocation			47	0.3
Arthrodesis Takedown			16	0.1
Other			14	0.1
<b>TOTAL</b>	<b>14</b>	<b>100.0</b>	<b>15845</b>	<b>100.0</b>

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm 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 Conventional Hip Replacement - Reason for Revision (Follow-up Limited to 16.4 Years)

Revision Diagnosis	Secur-Fit Plus/PINNACLE			Other Total Conventional Hip		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	4	1.6	28.6	3699	0.8	23.5
Infection	1	0.4	7.1	3538	0.8	22.5
Fracture	7	2.8	50.0	3405	0.8	21.7
Loosening	1	0.4	7.1	3180	0.7	20.2
Pain				285	0.1	1.8
Leg Length Discrepancy				260	0.1	1.7
Malposition				225	0.0	1.4
Lysis				170	0.0	1.1
Implant Breakage Stem				148	0.0	0.9
Implant Breakage Acetabular Insert	1	0.4	7.1	113	0.0	0.7
Incorrect Sizing				95	0.0	0.6
Wear Acetabular Insert				86	0.0	0.5
Implant Breakage Acetabular				66	0.0	0.4
Metal Related Pathology				64	0.0	0.4
Wear Head				44	0.0	0.3
Tumour				37	0.0	0.2
Implant Breakage Head				30	0.0	0.2
Heterotopic Bone				23	0.0	0.1
Wear Acetabulum				9	0.0	0.1
Progression Of Disease				2	0.0	0.0
Osteonecrosis				1	0.0	0.0
Synovitis				1	0.0	0.0
Other				228	0.1	1.5
<b>N Revision</b>	<b>14</b>	<b>5.7</b>	<b>100.0</b>	<b>15709</b>	<b>3.5</b>	<b>100.0</b>
<b>N Primary</b>	<b>246</b>			<b>453209</b>		

Note: This table is restricted to revisions within 16.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**FIGURE 2**

**Cumulative Incidence Revision Diagnosis of Primary Total Conventional Hip 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 Secur-Fit Plus/PINNACLE total conventional hip combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total conventional hip prostheses.

**Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Conventional Hip Replacement**

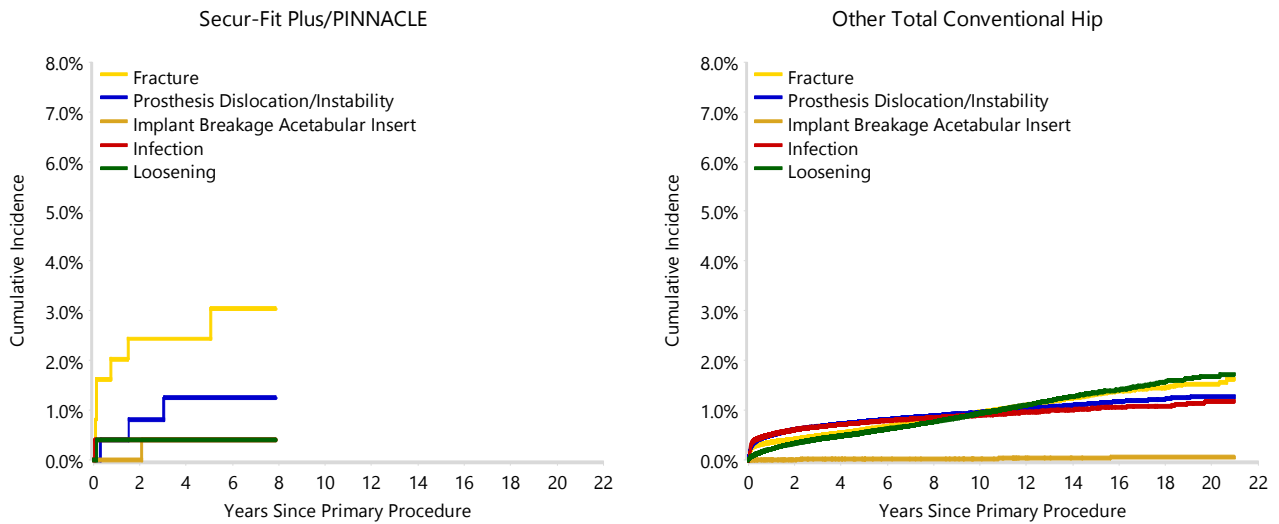


TABLE 5

### Type of Revision Performed for Primary Total Conventional Hip Replacement

This analysis identifies the components used in the revision of the Secur-Fit Plus/PINNACLE total conventional hip combination and compares it to the components used in the revision of all other total conventional hip 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 conventional hip prostheses i.e. is there a difference in the type of revision undertaken for the Secur-Fit Plus/PINNACLE total conventional hip combination compared to all other total conventional hip prostheses.

**Table 5: Primary Total Conventional Hip Replacement - Type of Revision (Follow-up Limited to 16.4 Years)**

Type of Revision	Secur-Fit Plus/PINNACLE		Other Total Conventional Hip	
	Number	Percent	Number	Percent
Femoral Component	6	42.9	5112	32.5
Acetabular Component	2	14.3	3015	19.2
THR (Femoral/Acetabular)	2	14.3	1782	11.3
Cement Spacer			592	3.8
Removal of Prostheses			96	0.6
Reinsertion of Components			25	0.2
Total Femoral			6	0.0
Bipolar Head and Femoral			4	0.0
Saddle			1	0.0
<b>N Major</b>	<b>10</b>	<b>71.4</b>	<b>10633</b>	<b>67.7</b>
Head/Insert	3	21.4	3852	24.5
Head Only			777	4.9
Minor Components	1	7.1	271	1.7
Insert Only			172	1.1
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
<b>N Minor</b>	<b>4</b>	<b>28.6</b>	<b>5076</b>	<b>32.3</b>
<b>TOTAL</b>	<b>14</b>	<b>100.0</b>	<b>15709</b>	<b>100.0</b>

Note: This table is restricted to revisions within 16.4 years for all groups to allow a time-matched comparison of revisions.

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**TABLE 6****Revision Rates of Secur-Fit Plus/PINNACLE Primary Total Conventional Hip 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 Secur-Fit Plus/PINNACLE Primary Total Conventional Hip Replacement by Fixation**

Fixation	N Revised	N Total
Cementless	14	246
<b>TOTAL</b>	<b>14</b>	<b>246</b>

**TABLE 7****Revision Rates of Secur-Fit Plus/PINNACLE Primary Total Conventional Hip 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 Secur-Fit Plus/PINNACLE Primary Total Conventional Hip Replacement by Bearing Surface**

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	11	199
Ceramic/XLPE	3	38
Metal/XLPE	0	9
<b>TOTAL</b>	<b>14</b>	<b>246</b>



**TABLE 8****Revision Rates of Secur-Fit Plus/PINNACLE Primary Total Conventional Hip Replacement by Approach**

This analysis is provided as some prostheses are used with a variety of surgical approaches. All surgical approaches used with this combination are listed.

**Table 8: Revised Number of Secur-Fit Plus/PINNACLE Primary Total Conventional Hip Replacement by Approach**

Approach	N Revised	N Total
Posterior	6	158
<b>TOTAL</b>	<b>6</b>	<b>158</b>

Note: Excludes 88 procedures with no approach recorded

TABLE 9

**Revision Rates of Primary Total Conventional Hip Replacement by State**

This enables a state by state variation to be identified for the Secur-Fit Plus/PINNACLE total conventional hip combination and provides the comparative data for each of the states for all other total conventional hip 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 9: Revised Number of Primary Total Conventional Hip Replacement by State**

Component	State	N Revised	N Total
Secur-Fit Plus/PINNACLE	NSW	14	241
	VIC	0	3
	WA	0	2
Other Total Conventional Hip	NSW	4284	132728
	VIC	3982	116995
	QLD	3146	80122
	WA	2184	53950
	SA	1415	41929
	TAS	372	15098
	ACT/NT	462	12387
<b>TOTAL</b>		<b>15859</b>	<b>453455</b>

Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

**TABLE 10****Number of Revisions of Secur-Fit Plus/PINNACLE Primary Total Conventional Hip Replacement by Year of Implant**

This analysis details the number of prostheses reported each year to the Registry for the Secur-Fit Plus/PINNACLE total conventional hip 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 10: Number of Revisions of Secur-Fit Plus/PINNACLE Primary Total Conventional Hip Replacement by Year of Implant**

Year of Implant	Number Revised	Total Number
2004	0	1
2005	0	3
2013	4	42
2014	4	42
2015	3	53
2016	1	25
2017	0	33
2018	1	31
2019	1	16
<b>TOTAL</b>	<b>14</b>	<b>246</b>

TABLE 11

### Revision Rates of Secur-Fit Plus/PINNACLE Primary Total Conventional Hip 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 Secur-Fit Plus/PINNACLE 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	Material	Coating	Fixation
<b>Femoral Stem</b>						
Secur-Fit Plus	60540509A-60541420S	NECK ANGLE HIP STEM	NO	METAL	HA COATED	
<b>Acetabular</b>						
PINNACLE	121712048-121712066	SECTOR ACETABULAR CUP W/DUOFIX HA	NO	METAL	HA COATED	
PINNACLE	121730048-121730072	MULTIHOLE ACETABULAR SHELL W/GRIPTION	NO	METAL		HIGHLY POROUS

**Table 11: Revised Number of Secur-Fit Plus/PINNACLE Primary Total Conventional Hip Replacement by Catalogue Number Range**

Femoral Stem Range	Acetabular Range	N Revised	N Total
60540509A-60541420S	121712048-121712066	14	245
	121730048-121730072	0	1
<b>TOTAL</b>		<b>14</b>	<b>246</b>