## MiniMax Total Conventional Hip Investigation

Note: This analysis compares the MiniMax femoral stem prosthesis with all other total conventional hip 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-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 MiniMax total conventional hip prosthesis 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)
MiniMax	21	410	1144	1.84 (1.14, 2.81)
Other Total Conventional Hip	15838	453045	2719993	0.58 (0.57, 0.59)
TOTAL	15859	453455	2721137	0.58 (0.57, 0.59)

# Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement

The yearly cumulative percent revision of the MiniMax total conventional hip prosthesis 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
MiniMax	4.2 (2.6, 6.6)	5.0 (3.2, 7.6)	5.4 (3.5, 8.2)	5.4 (3.5, 8.2)			
Other Total Conventional Hip	1.7 (1.7, 1.8)	2.2 (2.1, 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
MiniMax							
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
MiniMax							
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)

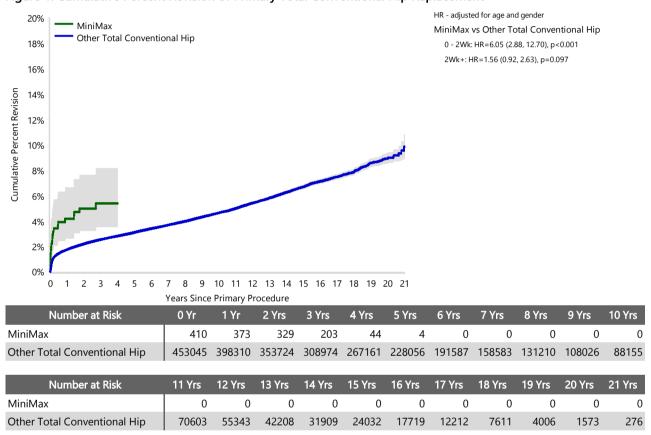
#### FIGURE 1

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

The yearly cumulative percent revision of the MiniMax total conventional hip prosthesis 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



## 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

	MiniMax		Other Total Cor	nventional Hip
Primary Diagnosis	Number	Percent	Number	Percent
Osteoarthritis	21	100.0	13091	82.7
Fractured Neck Of Femur			1164	7.3
Osteonecrosis			718	4.5
Developmental Dysplasia			247	1.6
Rheumatoid Arthritis			173	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
TOTAL	21	100.0	15838	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 Conventional Hip Replacement - Reason for Revision (Follow-up Limited to 5.6 Years)

	MiniMax Other Total Convention			al Hip		
Revision Diagnosis	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Prosthesis Dislocation/Instability	1	0.2	4.8	3262	0.7	25.9
Infection	3	0.7	14.3	3194	0.7	25.4
Fracture	10	2.4	47.6	2551	0.6	20.3
Loosening	2	0.5	9.5	2224	0.5	17.7
Leg Length Discrepancy	2	0.5	9.5	252	0.1	2.0
Pain				242	0.1	1.9
Malposition				196	0.0	1.6
Incorrect Sizing	1	0.2	4.8	90	0.0	0.7
Implant Breakage Acetabular Insert				82	0.0	0.7
Implant Breakage Stem				67	0.0	0.5
Lysis				51	0.0	0.4
Implant Breakage Acetabular				45	0.0	0.4
Metal Related Pathology				32	0.0	0.3
Tumour				32	0.0	0.3
Wear Head				23	0.0	0.2
Heterotopic Bone				21	0.0	0.2
Wear Acetabular Insert				19	0.0	0.2
Implant Breakage Head				14	0.0	0.1
Progression Of Disease				2	0.0	0.0
Wear Acetabulum				2	0.0	0.0
Osteonecrosis				1	0.0	0.0
Synovitis				1	0.0	0.0
Other	2	0.5	9.5	183	0.0	1.5
N Revision	21	5.1	100.0	12586	2.8	100.0
N Primary	410			453045		

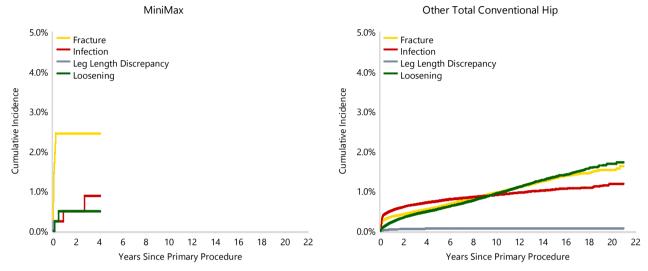
Note: This table is restricted to revisions within 5.6 years for all groups to allow a time-matched comparison of revisions. Note: Prostheses no longer used in 2021 are excluded from the comparator. Procedures using metal/metal prostheses with head size larger than 32mm are excluded from the comparator.

### 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 MiniMax total conventional hip prosthesis. 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



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

This analysis identifies the components used in the revision of the MiniMax total conventional hip prosthesis 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 MiniMax total conventional hip prosthesis compared to all other total conventional hip prostheses.

Table 5: Primary Total Conventional Hip Replacement - Type of Revision (Follow-up Limited to 5.6 Years)

Table 3. I filliary Total Co	MiniMax		Other Total Conventional Hip	
Type of Revision	Number	Percent	Number	Percent
Femoral Component	11	52.4	3851	30.6
Acetabular Component	1	4.8	2367	18.8
THR (Femoral/Acetabular)	2	9.5	1305	10.4
Cement Spacer	1	4.8	495	3.9
Removal of Prostheses			86	0.7
Reinsertion of Components	1	4.8	23	0.2
Bipolar Head and Femoral			4	0.0
Total Femoral			4	0.0
Saddle			1	0.0
N Major	16	76.2	8136	64.6
Head/Insert	2	9.5	3344	26.6
Head Only	3	14.3	728	5.8
Minor Components			211	1.7
Insert Only			163	1.3
Bipolar Only			2	0.0
Cement Only			1	0.0
Head/Neck			1	0.0
N Minor	5	23.8	4450	35.4
TOTAL	21	100.0	12586	100.0

Note: This table is restricted to revisions within 5.6 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.

### Revision Rates of MiniMax 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 MiniMax Primary Total Conventional Hip Replacement by Fixation

Fixation	N Revised	N Total
Cementless	21	410
TOTAL	21	410

#### **TABLE 7**

### Revision Rates of MiniMax 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 prosthesis are listed.

Table 7: Revised Number of MiniMax Primary Total Conventional Hip Replacement by Bearing Surface

Bearing Surface	N Revised	N Total
Ceramic/Ceramic	11	210
Ceramic/Non XLPE	5	123
Ceramic/XLPE	4	73
Metal/Non XLPE	0	2
Metal/XLPE	1	2
TOTAL	21	410

# Revision Rates of MiniMax 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 prosthesis are listed.

Table 8: Revised Number of MiniMax Primary Total Conventional Hip Replacement by Approach

Approach	N Revised	N Total
Anterior	21	396
Posterior	0	14
TOTAL	21	410

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

This enables a state by state variation to be identified for the MiniMax total conventional hip prosthesis 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
MiniMax	NSW	8	57
	VIC	7	166
	QLD	0	1
	WA	1	4
	SA	3	151
	TAS	2	31
Other Total Conventional Hip	NSW	4290	132912
	VIC	3975	116832
	QLD	3146	80121
	WA	2183	53948
	SA	1412	41778
	TAS	370	15067
	ACT/NT	462	12387
TOTAL		15859	453455

### Number of Revisions of MiniMax Primary Total Conventional Hip Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the MiniMax total conventional hip 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 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 MiniMax Primary Total Conventional Hip Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2016	0	4
2017	3	43
2018	7	170
2019	8	133
2020	2	41
2021	1	19
TOTAL	21	410

# Revision Rates of MiniMax 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 MiniMax 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	Stem Type
Femoral Stem					
MiniMax	0113100L-0113108R	ANATOMICAL FEMORAL STEM TI6AL7NB HA	NO	METAL	MINI STEM

Table 11: Revised Number of MiniMax Primary Total Conventional Hip Replacement by Catalogue Number Range

Femoral Stem Range	N Revised	N Total	
0113100L-0113108R	21	410	
TOTAL	21	410	

# Revision Rates of MiniMax Primary Total Conventional Hip 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 12: Revised Number of MiniMax Primary Total Conventional Hip Replacement by Acetabular Component

Acetabular Component	N Revised	N Total
Agilis	0	1
Mpact	11	181
Trinity	0	1
Versafitcup CC	5	107
Versafitcup DM	5	120
TOTAL	21	410