

From: s.22
To: adhocs@aoanjrr.org.au
Subject: Ad Hoc Data Request form - Equinoxe Total Shoulder Replacement
Date: Friday, 24 March 2023 4:32:15 PM
Attachments: [Government Department Regulator Ad Hoc Data Request Form.docx](#)

Dear AOANJRR

Please find attached an Ad Hoc Data Request form for your review.

Many Thanks

s.22

Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

s.22

Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au

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REQUEST ID:

REGULATOR /GOVERNMENT
Ad Hoc Data Request Form

1. This form should be used by Regulators or Government Departments to obtain data based on analysis of the entire AOANJRR data or a subset of that data for regulatory, monitoring and quality assurance purposes.
2. The independence of the reporting of data remains critical to the credibility of AOANJRR.
3. The AOANJRR is a Declared Federal Quality Assurance Activity and is required by law to work within certain requirements of the declaration. It must protect the confidentiality of patients, hospitals and surgeons and maintain high level data security procedures.
4. All ad hoc reports will be prepared using 'up to date data' from the most recent monthly cleaning processes, unless requested otherwise.
5. The AOANJRR Director is responsible for approving the release of ad hoc reports.

To complete this form in word

- Place the cursor in the required field
- Tab to move to the next field
- Click on check box to mark
- Once complete email the form to adhocs@aoanjrr.org.au
- You should expect a response within 2 working days providing you with a reference number to track your request

The AOANJRR will endeavour to provide the report by the nominated date; however, this is dependent on the available resources at the time of the request and the complexity of the analysis required.

CONTACT DETAILS

Date of Request	24/3/2023	Date Information Required by	24/4/2023
Principal Requestor	s.22		
Position	Departmental Office		
Department	Devices Post Market Monitoring Section		
Organisation	Therapeutic Goods Administration		
Address	Level 16/160 Ann Street Brisbane QLD 4000		
Telephone	s.22	Mobile	Click or tap here to enter text.
Email <i>The AOANJRR require an institution/Organisation email</i>	s.22		
Contact Person	s.22		

The Registry will endeavour to provide the report by the nominated date. However, this is dependent on the available resources at the time of the request and the complexity of the analysis required.

Identify personnel who will have access to data report:

Name(s)
Selected members of staff at TGA
Sponsor of the related implant
Click or tap here to enter text.
Click or tap here to enter text.

DATA ANALYSIS

Objective of Requested Analysis and Data Usage

Please provide the reason for requesting this analysis and the intended use of the data

The TGA is investigating the Exactech Equinox total shoulder replacement following a signal received from an international regulator. The TGA is interested in obtaining a detailed ad-hoc revision analysis of the anatomic and reverse configurations of this device used in primary total shoulder replacement.

If regional report required, please specify	<input checked="" type="checkbox"/> National <input type="checkbox"/> State
Name of Prostheses of Interest	Exactech Equinox total shoulder replacement - anatomic shoulder - reverse shoulder
Reporting Period	<input type="checkbox"/> Specific Date from <input type="text"/> Click or tap here to enter text. Date to <input type="text"/> Click or tap here to enter text. or <input checked="" type="checkbox"/> All up-to-date data
Analysis required <i>Please specify</i>	Provide an analysis of reasons for revision and revision procedures for the Equinox anatomic shoulder compared to all other anatomic shoulder replacements Provide an analysis of the reasons for revision and revision procedures for the Equinox reverse shoulder compared to all other reverse shoulder replacements

ADDITIONAL DATA REQUIRED?

Please specify

If there appears to be a higher number/proportion of revisions of a particular Equinox component for a particular reason, please provide an analysis that compares the rate of revision for that component as compared to the overall class (e.g. if there are a high proportion of revisions of the glenoid component due to loosening in reverse configuration, provide a comparison of glenoid revisions due to loosening in the Equinox compared to glenoid revisions for loosening for other reverse shoulder replacements)

To facilitate a timely turnaround of requests please ensure that all relevant sections of this form are completed in full. Incomplete requests will be returned to the requestor for completion and resubmission prior to review by the AOANJRR Registry Working Group.

Please email this form to AOANJRR Ad Hocs adhocs@aoanjrr.org.au

From: [adhocs](#)
To: [s.22](#)
Cc: [adhocs](#)
Subject: RE: Ad Hoc Data Request form - Equinoxe Total Shoulder Replacement
Date: Friday, 24 March 2023 4:42:02 PM

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Dear [s.22](#),

Your ad hoc request has been allocated a reference number. Please use this number for all correspondence including tracking and monitoring purposes.

AOAAHR-3690

Please Note: It generally takes 4-6 weeks for a request to be completed (unfortunately due to unforeseen circumstances it may take longer than 6 weeks).

From: [s.22](#) <[s.22@health.gov.au](#)>
Sent: Friday, 24 March 2023 4:02 PM
To: [adhocs](#) <[adhocs@aoanjrr.org.au](#)>
Subject: [SEC=OFFICIAL] Ad Hoc Data Request form - Equinoxe Total Shoulder Replacement

[External email: Use caution with links and attachments]

Dear AOANJRR

Please find attached an Ad Hoc Data Request form for your review.

Many Thanks

[s.22](#)

Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

[s.22](#)

Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: [adhocs](#)
To: [s.22](#)
Cc: [adhocs](#)
Subject: Ad Hoc Report: 3690 TGA Exactech Equinox TS
Date: Friday, 21 April 2023 4:14:47 PM
Attachments: [3690_APR23Results_\(TGA\).docx](#)
[3690_APR23Results_\(TGA\)_TotalStemmedCementedAllPolyGlenoids.docx](#)
[3690_Ad_Hoc_Letter.pdf](#)

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Dear [REDACTED],

Please find attached the Ad Hoc Report for Request ID 3690:

- 3690_APR23Results_(TGA).docx
- 3690_APR23Results_(TGA)_TotalStemmedCementedAllPolyGlenoids.docx

Please get in touch if you have any questions.

Thank you.

Kind Regards,

[REDACTED]

AOANJRR

Australian Orthopaedic Association National Joint Replacement Registry



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Document 3
Australian
Orthopaedic
Association
National
Joint
Replacement
Registry

21 April 2023

s.22

Therapeutic Goods Administration - Devices Post Market Monitoring Section
Level 16/160
Ann Street
Brisbane QLD 4000

Via email: s.22@health.gov.au

Dear s.22,

**Re: AOANJRR Data Request
Request ID: 3690**

Further to your data request received 24 March 2023, please find attached the report.

These data are for procedures undertaken between 16 April 2004 - 29 March 2023 and between 1 September 1999 - 29 March 2023 and notified to the AOANJRR. The AOANJRR has taken every care to ensure the data supplied are accurate.

The data released to you may only be used for the purpose(s) outlined in the original request. The data cannot be used for publication unless it was indicated on the request and has been approved by the AOANJRR.

It is also AOA approved policy that AOANJRR staff assist in preparing and writing the manuscript(s). Please make sure the necessary arrangements have been made before commencing preparation of a manuscript.

If you have any questions about the data or any other AOANJRR related issue, please feel free to contact me.

Yours sincerely,

s.22

Professor Paul Smith
AOANJRR Clinical Director



Australian
Orthopaedic
Association
National
Joint
Replacement
Registry

AD HOC REPORT

REQUEST ID	PRINCIPAL REQUESTER	POSITION	ORGANISATION	CONTACT
3690	s.22	Departmental Office	Therapeutic Goods Administration	s.22

DATE REQUEST RECEIVED:	24/Mar/23
DATE APPROVED FOR RELEASE:	21/Apr/23

DETAILS OF ANALYSIS PROVIDED

Specific Data Period:	Procedures from 16 April 2004 - 29 March 2023
Comments:	

Approved:	s.22	DATE 21/Apr/23
	Professor Paul Smith AM AOANJRR Clinical Director	

Disclaimer:	<i>The AOANJRR has taken every care to ensure that the data supplied are accurate but does not warrant that the data are error free and does not accept any liability for errors or omissions in the data provided.</i>
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Request 3690 - TGA

Equinoxe/Equinoxe Total Stemmed Shoulder Investigation

Note: This analysis compares the Equinoxe/Equinoxe humeral stem/glenoid combination with all other total stemmed shoulder prostheses.

Note: Procedures using prostheses with no recorded use in 2021 are excluded from the comparator.

TABLE 1

Revision Rate of Primary Total Stemmed Shoulder Replacement

The revision rate of the Equinoxe/Equinoxe total stemmed shoulder combination is compared to all other total stemmed shoulder prostheses.

Table 1: Revision Rates of Primary Total Stemmed Shoulder Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Equinoxe/Equinoxe	56	689	2733	2.05 (1.55, 2.66)
Other Total Stemmed Shoulder	1420	15362	115432	1.23 (1.17, 1.30)
TOTAL	1476	16051	118165	1.25 (1.19, 1.31)

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

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

The yearly cumulative percent revision of the Equinoxe/Equinoxe total stemmed shoulder combination is compared to all other total stemmed shoulder prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Equinoxe/Equinoxe	3.1 (2.0, 4.7)	5.0 (3.5, 7.0)	6.0 (4.4, 8.3)	7.6 (5.6, 10.2)	9.8 (7.3, 13.1)
Other Total Stemmed Shoulder	2.8 (2.6, 3.1)	4.6 (4.3, 5.0)	5.7 (5.3, 6.1)	6.4 (6.0, 6.8)	7.2 (6.8, 7.7)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Equinoxe/Equinoxe	11.4 (8.5, 15.2)	12.9 (9.5, 17.3)	13.8 (10.2, 18.7)		
Other Total Stemmed Shoulder	7.9 (7.4, 8.3)	8.5 (8.1, 9.0)	9.3 (8.8, 9.8)	10.1 (9.6, 10.7)	10.9 (10.3, 11.5)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinoxe/Equinoxe					
Other Total Stemmed Shoulder	11.5 (10.9, 12.2)	12.3 (11.6, 13.0)	13.1 (12.4, 13.9)	13.5 (12.7, 14.3)	13.7 (12.8, 14.6)

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

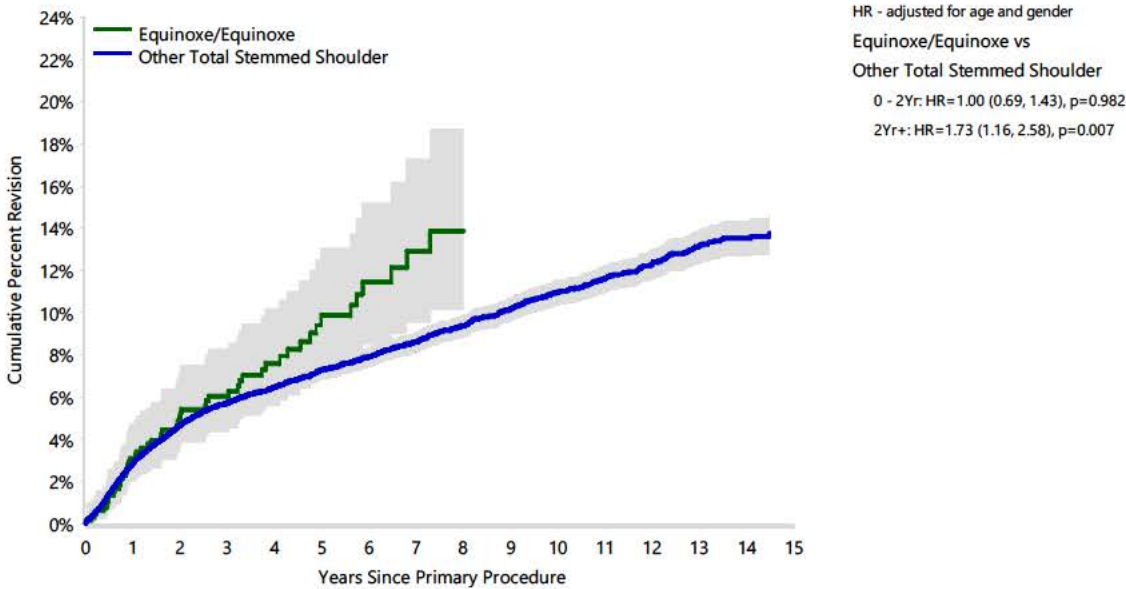
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

The yearly cumulative percent revision of the Equinox/Equinox total stemmed shoulder combination is compared to all other total stemmed shoulder 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 Stemmed Shoulder Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Equinox/Equinox	689	599	493	411	302	216	152	102
Other Total Stemmed Shoulder	15362	14445	13575	12765	11870	10854	9693	8401

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinox/Equinox	70	36	10	3	0	0	0	0
Other Total Stemmed Shoulder	7055	5732	4534	3455	2460	1582	897	359

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

TABLE 3

Primary Diagnosis for Revised Primary Total Stemmed Shoulder 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 stemmed shoulder prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Stemmed Shoulder Replacement

Primary Diagnosis	Equinoxe/Equinoxe		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Osteoarthritis	53	94.6	1316	92.7
Osteonecrosis			33	2.3
Rheumatoid Arthritis	1	1.8	20	1.4
Fracture	2	3.6	16	1.1
Rotator Cuff Arthropathy			12	0.8
Instability			11	0.8
Other Inflammatory Arthritis			11	0.8
Other			1	0.1
TOTAL	56	100.0	1420	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 Stemmed Shoulder Replacement - Reason for Revision (Follow-up Limited to 11.5 Years)

Revision Diagnosis	Equinox/Equinox			Other Total Stemmed Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Rotator Cuff Insufficiency	11	1.6	19.6	356	2.3	25.8
Instability/Dislocation	10	1.5	17.9	309	2.0	22.4
Loosening	16	2.3	28.6	258	1.7	18.7
Infection	5	0.7	8.9	99	0.6	7.2
Implant Breakage Glenoid Insert				93	0.6	6.7
Dissociation				57	0.4	4.1
Fracture	2	0.3	3.6	36	0.2	2.6
Implant Breakage Glenoid	3	0.4	5.4	31	0.2	2.2
Pain	1	0.1	1.8	30	0.2	2.2
Arthrofibrosis	2	0.3	3.6	19	0.1	1.4
Metal Related Pathology				19	0.1	1.4
Incorrect Sizing	3	0.4	5.4	16	0.1	1.2
Lysis	2	0.3	3.6	15	0.1	1.1
Wear Glenoid Insert				13	0.1	0.9
Malposition	1	0.1	1.8	11	0.1	0.8
Glenoid Erosion				3	0.0	0.2
Progression Of Disease				3	0.0	0.2
Implant Breakage Head				1	0.0	0.1
Implant Breakage Humeral				1	0.0	0.1
Wear Glenoid				1	0.0	0.1
Other				10	0.1	0.7
N Revision	56	8.1	100.0	1381	9.0	100.0
N Primary	689			15362		

Note: This table is restricted to revisions within 11.5 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 Stemmed Shoulder 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 Equinoxe/Equinoxe total stemmed shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total stemmed shoulder prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Stemmed Shoulder Replacement

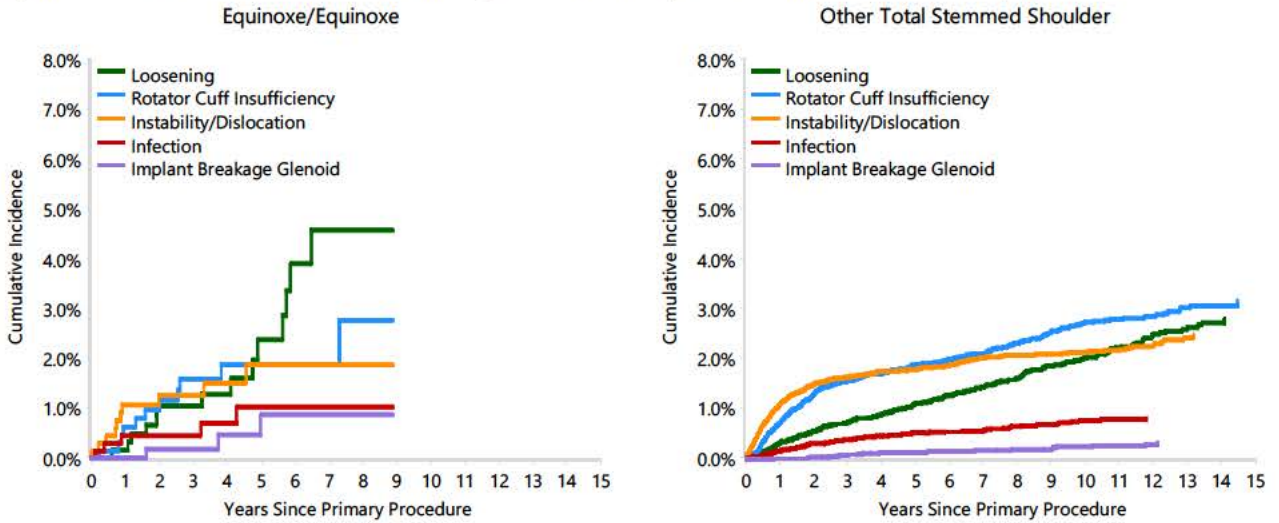


TABLE 5

Type of Revision Performed for Primary Total Stemmed Shoulder Replacement

This analysis identifies the components used in the revision of the Equinox/Equinox total stemmed shoulder combination and compares it to the components used in the revision of all other total stemmed shoulder 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 stemmed shoulder prostheses i.e. is there a difference in the type of revision undertaken for the Equinox/Equinox total stemmed shoulder combination compared to all other total stemmed shoulder prostheses.

Table 5: Primary Total Stemmed Shoulder Replacement - Type of Revision (Follow-up Limited to 11.5 Years)

Type of Revision	Equinox/Equinox		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Humeral Component	4	7.1	699	50.6
Humeral/Glenoid	36	64.3	389	28.2
Glenoid Component	3	5.4	68	4.9
Cement Spacer	3	5.4	59	4.3
Removal of Prostheses			22	1.6
Reinsertion of Components			1	0.1
N Major	46	82.1	1238	89.6
Head Only	10	17.9	96	7.0
Head/Insert			32	2.3
Minor Components			7	0.5
Reoperation			5	0.4
Cement Only			2	0.1
Insert Only			1	0.1
N Minor	10	17.9	143	10.4
TOTAL	56	100.0	1381	100.0

Note: This table is restricted to revisions within 11.5 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 Equinox/Equinox Primary Total Stemmed Shoulder 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 Equinox/Equinox Primary Total Stemmed Shoulder Replacement by Fixation

Fixation	N Revised	N Total
Cemented	3	28
Cementless	6	52
Hybrid (Glenoid Cemented)	47	609
TOTAL	56	689

TABLE 7

Revision Rates of Primary Total Stemmed Shoulder Replacement by State

This enables a state by state variation to be identified for the Equinoxe/Equinoxe total stemmed shoulder combination and provides the comparative data for each of the states for all other total stemmed shoulder 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 7: Revised Number of Primary Total Stemmed Shoulder Replacement by State

Component	State	N Revised	N Total
Equinoxe/Equinoxe	NSW	17	162
	VIC	14	210
	QLD	4	82
	WA	20	212
	SA	1	8
	TAS	0	14
	ACT/NT	0	1
Other Total Stemmed Shoulder	NSW	412	4593
	VIC	297	3737
	QLD	237	2994
	WA	230	1762
	SA	141	1487
	TAS	44	331
	ACT/NT	59	458
TOTAL		1476	16051

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

TABLE 8

Number of Revisions of Equinox/Equinox Primary Total Stemmed Shoulder Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Equinox/Equinox total stemmed shoulder 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 8: Number of Revisions of Equinox/Equinox Primary Total Stemmed Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2011	4	6
2012	3	10
2013	3	26
2014	3	32
2015	10	46
2016	3	42
2017	4	71
2018	9	79
2019	9	105
2020	4	92
2021	3	91
2022	1	85
2023	0	4
TOTAL	56	689

TABLE 9

Revision Rates of Equinnox/Equinnox Primary Total Stemmed Shoulder 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 Equinnox/Equinnox 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
Humeral Stem					
Equinnox	3000107-3000117	PRESSFIT PRIMARY HUMERAL STEM	NO	METAL	
Equinnox	3003006-3003014	EQUINOX PRESERVE HUMERAL STEM PRESS FIT PLASMA COATED	NO	METAL	
Equinnox	3042107-3042407	PLATFORM FRACTURE HUMERAL STEM	YES	METAL	FRACTURE
Equinnox	3060108-3060212	LONG HUMERAL STEM	YES	METAL	
Glenoid					
Equinnox	3140102-3140114	ALL POLY CEMENTED KEELED GLENOID	YES	NON CROSS-LINKED POLYETHYLENE	
Equinnox	3140202-3140214	ALL POLY CEMENTED PEGGED GLENOID	YES	NON CROSS-LINKED POLYETHYLENE	
Equinnox	3140222-3140634	POSTERIOR AUGMENT CEMENTED PEGGED GLENOID	YES	NON CROSS-LINKED POLYETHYLENE	
Equinnox	3141302-3141315	CEMENTED CAGE GLENOID	YES	NON CROSS-LINKED POLYETHYLENE	
Equinnox	3141322-3141335	CEMENTED CAGE GLENOID POLY POSTERIOR AUGMENT	YES	NON CROSS-LINKED POLYETHYLENE	

Table 9: Revised Number of Equinnox/Equinnox Primary Total Stemmed Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
3000107-3000117	3140102-3140114	1	7
	3140202-3140214	21	229
	3140222-3140634	3	41
	3141302-3141315	18	225
	3141322-3141335	9	149
3003006-3003014	3140202-3140214	0	1
	3141302-3141315	2	15
	3141322-3141335	0	20
3042107-3042407	3140202-3140214	1	1
3060108-3060212	3141302-3141315	1	1
TOTAL		56	689

Table 10: Revised Number of Primary Total Stemmed Shoulder Replacement by Model (All Diagnoses, Revision for Loosening)

Model	N Revised	N Total
Equinoxe/Equinoxe	16	689
Other Total Stemmed Shoulder	272	15362
TOTAL	288	16051

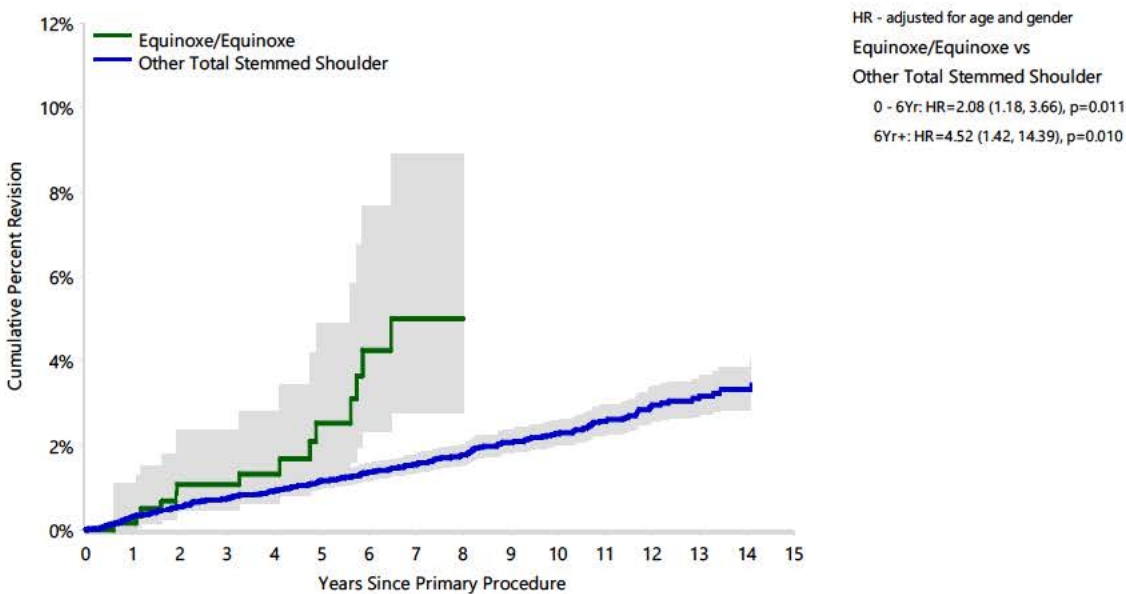
Table 11: Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement by Model (All Diagnoses, Revision for Loosening)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Equinoxe/Equinoxe	0.2 (0.0, 1.1)	1.1 (0.5, 2.4)	1.1 (0.5, 2.4)	1.3 (0.6, 2.8)	2.5 (1.3, 4.9)
Other Total Stemmed Shoulder	0.3 (0.2, 0.4)	0.6 (0.4, 0.7)	0.7 (0.6, 0.9)	0.9 (0.8, 1.1)	1.2 (1.0, 1.4)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Equinoxe/Equinoxe	4.3 (2.3, 7.7)	5.0 (2.8, 8.9)	5.0 (2.8, 8.9)		
Other Total Stemmed Shoulder	1.4 (1.2, 1.6)	1.5 (1.3, 1.8)	1.8 (1.5, 2.0)	2.1 (1.8, 2.4)	2.3 (2.0, 2.6)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinoxe/Equinoxe					
Other Total Stemmed Shoulder	2.6 (2.3, 2.9)	3.0 (2.6, 3.4)	3.2 (2.7, 3.7)	3.3 (2.8, 3.9)	3.4 (2.9, 4.0)

Figure 3: Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement by Model (All Diagnoses, Revision for Loosening)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Equinoxe/Equinoxe	689	599	493	411	302	216	152	102
Other Total Stemmed Shoulder	15362	14445	13575	12765	11870	10854	9693	8401

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinoxe/Equinoxe	70	36	10	3	0	0	0	0
Other Total Stemmed Shoulder	7055	5732	4534	3455	2460	1582	897	359

Equinox/Equinox Total Reverse Shoulder Investigation

Note: This analysis compares the Equinox/Equinox humeral stem/glenoid combination with all other total reverse shoulder prostheses.

Note: Procedures using prostheses with no recorded use in 2021 are excluded from the comparator.

TABLE 12

Revision Rate of Primary Total Reverse Shoulder Replacement

The revision rate of the Equinox/Equinox total reverse shoulder combination is compared to all other total reverse shoulder prostheses.

Table 12: Revision Rates of Primary Total Reverse Shoulder Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Equinox/Equinox	153	4695	12954	1.18 (1.00, 1.38)
Other Total Reverse Shoulder	1709	44838	200552	0.85 (0.81, 0.89)
TOTAL	1862	49533	213506	0.87 (0.83, 0.91)

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

TABLE 13

Yearly Cumulative Percent Revision of Primary Total Reverse Shoulder Replacement

The yearly cumulative percent revision of the Equinox/Equinox total reverse shoulder combination is compared to all other total reverse shoulder prostheses.

Table 13: Yearly Cumulative Percent Revision of Primary Total Reverse Shoulder Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Equinox/Equinox	2.2 (1.8, 2.6)	3.2 (2.7, 3.8)	3.4 (2.9, 4.0)	4.0 (3.3, 4.7)	4.2 (3.5, 5.0)
Other Total Reverse Shoulder	2.4 (2.2, 2.5)	3.0 (2.9, 3.2)	3.5 (3.3, 3.7)	3.8 (3.6, 4.0)	4.1 (3.9, 4.3)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Equinox/Equinox	4.9 (3.9, 6.0)	5.3 (4.1, 6.7)	6.2 (4.3, 8.7)		
Other Total Reverse Shoulder	4.4 (4.1, 4.6)	4.6 (4.3, 4.8)	5.0 (4.7, 5.3)	5.2 (4.9, 5.5)	5.5 (5.2, 5.9)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinox/Equinox					
Other Total Reverse Shoulder	5.8 (5.4, 6.2)	6.1 (5.7, 6.6)	6.5 (5.9, 7.1)	6.9 (6.1, 7.7)	6.9 (6.1, 7.7)

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

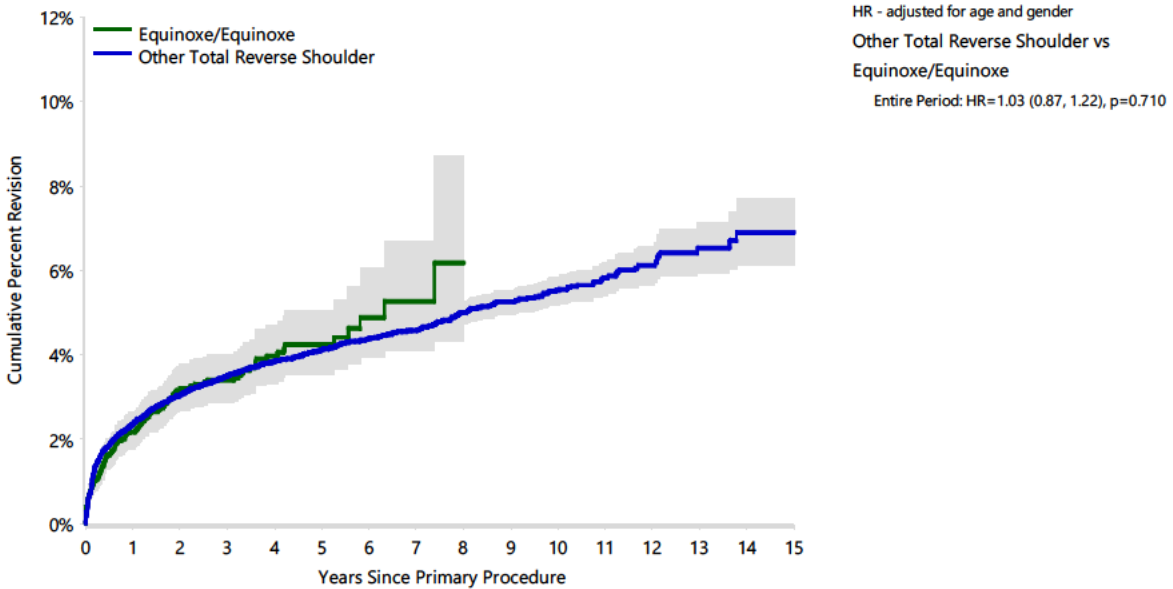
FIGURE 4

Yearly Cumulative Percent Revision of Primary Total Reverse Shoulder Replacement

The yearly cumulative percent revision of the Equinoxe/Equinoxe total reverse shoulder combination is compared to all other total reverse shoulder 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 4: Cumulative Percent Revision of Primary Total Reverse Shoulder Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Equinoxe/Equinoxe	4695	3706	2763	1857	1153	660	317	147
Other Total Reverse Shoulder	44838	38642	32529	26840	21545	16791	12679	9404

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinoxe/Equinoxe	50	15	4	2	0	0	0	0
Other Total Reverse Shoulder	6856	4873	3337	2181	1356	799	400	150

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

TABLE 14

Primary Diagnosis for Revised Primary Total Reverse Shoulder 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 reverse shoulder prostheses.

Table 14: Primary Diagnosis for Revised Primary Total Reverse Shoulder Replacement

Primary Diagnosis	Equinoxe/Equinoxe		Other Total Reverse Shoulder	
	Number	Percent	Number	Percent
Osteoarthritis	68	44.4	653	38.2
Rotator Cuff Arthropathy	51	33.3	618	36.2
Fracture	23	15.0	300	17.6
Rheumatoid Arthritis	5	3.3	45	2.6
Instability	3	2.0	37	2.2
Tumour	2	1.3	25	1.5
Osteonecrosis			21	1.2
Other Inflammatory Arthritis	1	0.7	9	0.5
Other			1	0.1
TOTAL	153	100.0	1709	100.0

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

TABLE 15

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 15: Primary Total Reverse Shoulder Replacement - Reason for Revision (Follow-up Limited to 11.1 Years)

Revision Diagnosis	Equinox/Equinoxe			Other Total Reverse Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Instability/Dislocation	44	0.9	28.8	561	1.3	33.1
Infection	51	1.1	33.3	406	0.9	23.9
Loosening	24	0.5	15.7	278	0.6	16.4
Fracture	16	0.3	10.5	190	0.4	11.2
Dissociation	5	0.1	3.3	61	0.1	3.6
Pain	1	0.0	0.7	36	0.1	2.1
Lysis	1	0.0	0.7	23	0.1	1.4
Arthrofibrosis				21	0.0	1.2
Malposition	2	0.0	1.3	19	0.0	1.1
Implant Breakage Glenoid				14	0.0	0.8
Incorrect Sizing	1	0.0	0.7	11	0.0	0.6
Metal Related Pathology	1	0.0	0.7	10	0.0	0.6
Wear Humeral Cup				6	0.0	0.4
Heterotopic Bone	1	0.0	0.7	5	0.0	0.3
Rotator Cuff Insufficiency	1	0.0	0.7	5	0.0	0.3
Tumour				4	0.0	0.2
Implant Breakage Glenoid Insert				3	0.0	0.2
Implant Breakage Humeral				3	0.0	0.2
Wear Glenoid Insert				2	0.0	0.1
Glenoid Erosion				1	0.0	0.1
Synovitis				1	0.0	0.1
Other	5	0.1	3.3	37	0.1	2.2
N Revision	153	3.3	100.0	1697	3.8	100.0
N Primary	4695			44838		

Note: This table is restricted to revisions within 11.1 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 5

Cumulative Incidence Revision Diagnosis of Primary Total Reverse Shoulder 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 Equinoxe/Equinoxe total reverse shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total reverse shoulder prostheses.

Figure 5: Cumulative Incidence Revision Diagnosis for Primary Total Reverse Shoulder Replacement

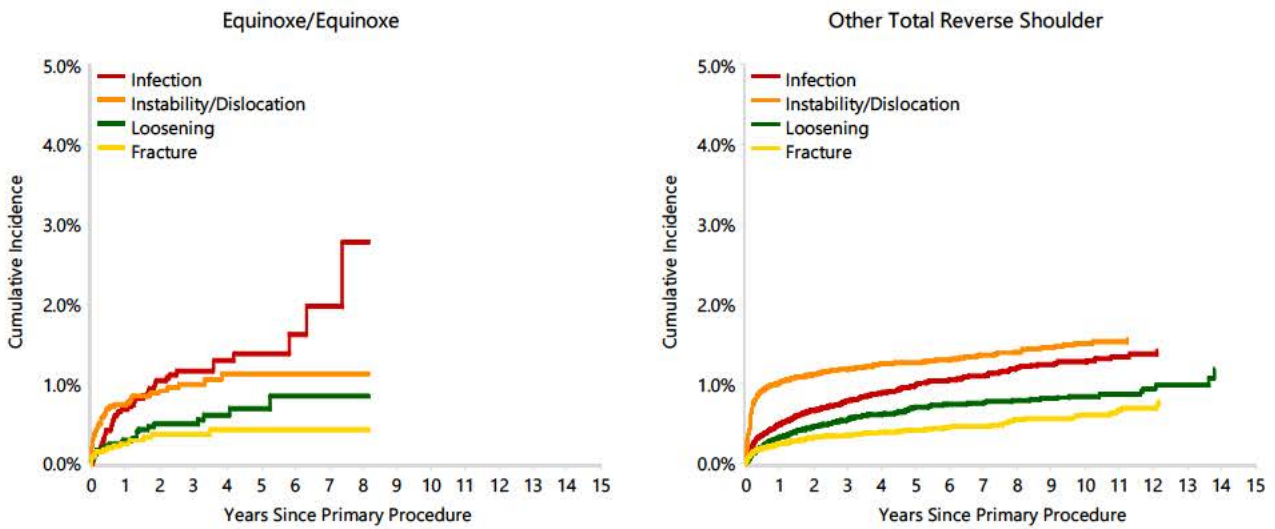


TABLE 16

Type of Revision Performed for Primary Total Reverse Shoulder Replacement

This analysis identifies the components used in the revision of the Equinox/Equinox total reverse shoulder combination and compares it to the components used in the revision of all other total reverse shoulder 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 reverse shoulder prostheses i.e. is there a difference in the type of revision undertaken for the Equinox/Equinox total reverse shoulder combination compared to all other total reverse shoulder prostheses.

Table 16: Primary Total Reverse Shoulder Replacement - Type of Revision (Follow-up Limited to 11.1 Years)

Type of Revision	Equinox/Equinox		Other Total Reverse Shoulder	
	Number	Percent	Number	Percent
Humeral Component	60	39.2	396	23.3
Cement Spacer	19	12.4	141	8.3
Humeral/Glenoid	11	7.2	138	8.1
Glenoid Component	2	1.3	132	7.8
Removal of Prostheses	2	1.3	32	1.9
Reinsertion of Components	1	0.7	2	0.1
N Major	95	62.1	841	49.6
Cup/Head	23	15.0	342	20.2
Cup Only	23	15.0	295	17.4
Head Only	8	5.2	183	10.8
Minor Components	2	1.3	12	0.7
Reoperation	1	0.7	12	0.7
Cement Only	1	0.7	10	0.6
Head/Insert			2	0.1
N Minor	58	37.9	856	50.4
TOTAL	153	100.0	1697	100.0

Note: This table is restricted to revisions within 11.1 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 17

Revision Rates of Equinox/Equinox Primary Total Reverse Shoulder 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 17: Revised Number of Equinox/Equinox Primary Total Reverse Shoulder Replacement by Fixation

Fixation	N Revised	N Total
Cemented	0	21
Cementless	125	4092
Hybrid (Glenoid Cemented)	1	15
Hybrid (Glenoid Cementless)	27	567
TOTAL	153	4695

TABLE 18

Revision Rates of Primary Total Reverse Shoulder Replacement by State

This enables a state by state variation to be identified for the Equinoxe/Equinoxe total reverse shoulder combination and provides the comparative data for each of the states for all other total reverse shoulder 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 18: Revised Number of Primary Total Reverse Shoulder Replacement by State

Component	State	N Revised	N Total
Equinoxe/Equinoxe	NSW	49	1290
	VIC	36	844
	QLD	35	1226
	WA	28	1159
	SA	3	112
	TAS	2	63
	ACT/NT	0	1
Other Total Reverse Shoulder	NSW	511	14807
	VIC	341	8452
	QLD	386	9667
	WA	228	5431
	SA	168	4222
	TAS	23	978
	ACT/NT	52	1281
TOTAL		1862	49533

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

TABLE 19

Number of Revisions of Equinox/Equinox Primary Total Reverse Shoulder Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Equinox/Equinox total reverse shoulder 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 19: Number of Revisions of Equinox/Equinox Primary Total Reverse Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2011	0	1
2012	1	9
2013	2	14
2014	3	32
2015	3	103
2016	7	168
2017	18	332
2018	22	495
2019	21	675
2020	32	855
2021	19	950
2022	25	1009
2023	0	52
TOTAL	153	4695

TABLE 20

Revision Rates of Equinoxe/Equinoxe Primary Total Reverse Shoulder 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 Equinoxe/Equinoxe 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
Humeral Stem					
Equinoxe	3000107-3000117	PRESSFIT PRIMARY HUMERAL STEM	NO	METAL	
Equinoxe	3003006-3003014	EQUINOXE PRESERVE HUMERAL STEM PRESS FIT PLASMA COATED	NO	METAL	
Equinoxe	3042107-3042407	PLATFORM FRACTURE HUMERAL STEM	YES	METAL	FRACTURE
Equinoxe	3060108-3060212	LONG HUMERAL STEM	YES	METAL	
Equinoxe	3080106-3080308	HUMERAL RECONSTRUCTION PROSTHESIS DISTAL STEM CEMENTED	YES		
Glenoid					
Equinoxe	3201501-3201508	REVERSE GLENOID PLATE	NO	METAL	
Equinoxe	3203501-3203508	SMALL REVERSE GLENOID BASEPLATE	NO		

Table 20: Revised Number of Equinoxe/Equinoxe Primary Total Reverse Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
3000107-3000117	3201501-3201508	134	4067
	3203501-3203508	2	140
3003006-3003014	3201501-3201508	2	82
	3203501-3203508	0	6
3042107-3042407	3201501-3201508	12	340
	3203501-3203508	0	20
3060108-3060212	3201501-3201508	1	10
	3203501-3203508	0	1
3080106-3080308	3201501-3201508	2	27
	3203501-3203508	0	2
TOTAL		153	4695

Table 21: Revised Number of Primary Total Reverse Shoulder Replacement by Model (All Diagnoses, Revision for Infection)

Model	N Revised	N Total
Equinoxe/Equinoxe	51	4695
Other Total Reverse Shoulder	408	44838
TOTAL	459	49533

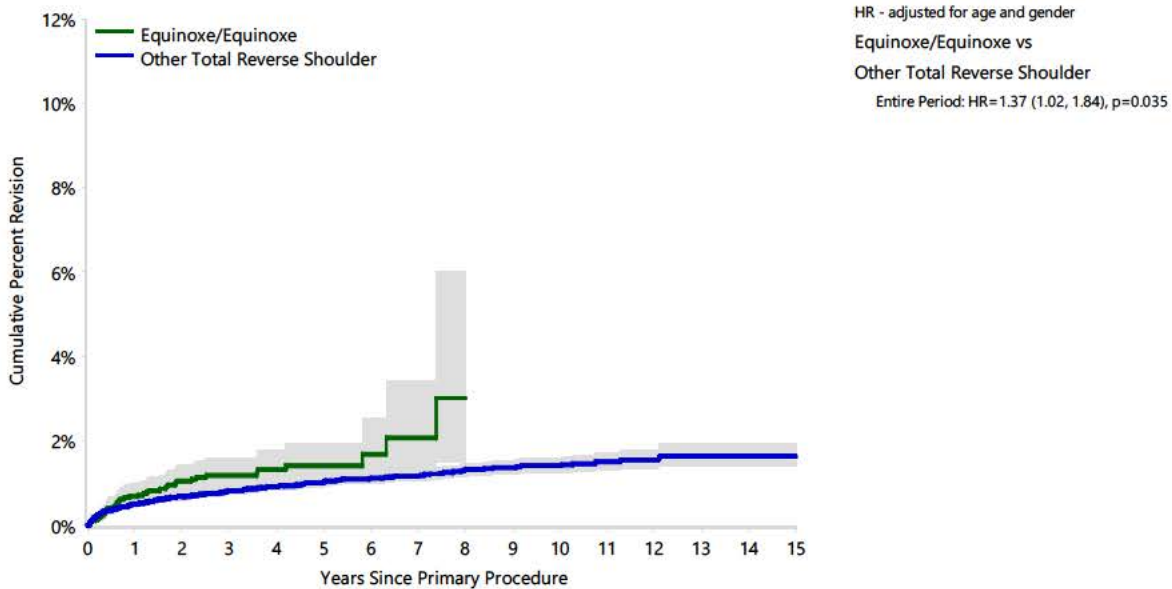
Table 22: Yearly Cumulative Percent Revision of Primary Total Reverse Shoulder Replacement by Model (All Diagnoses, Revision for Infection)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Equinoxe/Equinoxe	0.7 (0.5, 1.0)	1.1 (0.8, 1.4)	1.2 (0.9, 1.6)	1.3 (1.0, 1.8)	1.4 (1.0, 1.9)
Other Total Reverse Shoulder	0.5 (0.4, 0.6)	0.7 (0.6, 0.8)	0.8 (0.7, 0.9)	0.9 (0.8, 1.0)	1.0 (0.9, 1.1)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Equinoxe/Equinoxe	1.7 (1.1, 2.5)	2.1 (1.3, 3.4)	3.0 (1.5, 6.0)		
Other Total Reverse Shoulder	1.1 (1.0, 1.2)	1.2 (1.0, 1.3)	1.3 (1.2, 1.5)	1.4 (1.2, 1.5)	1.4 (1.2, 1.6)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinoxe/Equinoxe					
Other Total Reverse Shoulder	1.5 (1.3, 1.7)	1.6 (1.3, 1.8)	1.6 (1.4, 1.9)	1.6 (1.4, 1.9)	1.6 (1.4, 1.9)

Figure 6: Cumulative Percent Revision of Primary Total Reverse Shoulder Replacement by Model (All Diagnoses, Revision for Infection)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Equinoxe/Equinoxe	4695	3706	2763	1857	1153	660	317	147
Other Total Reverse Shoulder	44838	38642	32529	26840	21545	16791	12679	9404

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinoxe/Equinoxe	50	15	4	2	0	0	0	0
Other Total Reverse Shoulder	6856	4873	3337	2181	1356	799	400	150



Australian
Orthopaedic
Association
National
Joint
Replacement
Registry

AD HOC REPORT

REQUEST ID	PRINCIPAL REQUESTER	POSITION	ORGANISATION	CONTACT
3690	s.22	Departmental Office	Therapeutic Goods Administration	s.22

DATE REQUEST RECEIVED:	24/Mar/23
DATE APPROVED FOR RELEASE:	21/Apr/23

DETAILS OF ANALYSIS PROVIDED

Specific Data Period:	Procedures from 1 September 1999 - 29 March 2023
Comments:	

Approved:	s.22	DATE 21/Apr/23
	Professor Paul Smith AM AOANJRR Clinical Director	

Disclaimer:	<i>The AOANJRR has taken every care to ensure that the data supplied are accurate but does not warrant that the data are error free and does not accept any liability for errors or omissions in the data provided.</i>
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Request 3690 - TGA

Equinoxe/Equinoxe Total Stemmed Shoulder Investigation

Note: This analysis compares the Equinoxe/Equinoxe humeral stem/glenoid combination with all other total stemmed shoulder prostheses.

Note: Procedures using prostheses with no recorded use in 2021 are excluded from the comparator.

Only cemented all polyethylene glenoids are included in the comparator.

TABLE 1

Revision Rate of Primary Total Stemmed Shoulder Replacement

The revision rate of the Equinoxe/Equinoxe total stemmed shoulder combination is compared to all other total stemmed shoulder prostheses.

Table 1: Revision Rates of Primary Total Stemmed Shoulder Replacement

Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Equinoxe/Equinoxe	56	689	2733	2.05 (1.55, 2.66)
Other Total Stemmed Shoulder	585	11287	85391	0.69 (0.63, 0.74)
TOTAL	641	11976	88124	0.73 (0.67, 0.79)

Note: Prostheses no longer used in 2021 are excluded from the comparator.
Only cemented all-polyethylene glenoids are included in the comparator.

TABLE 2

Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

The yearly cumulative percent revision of the Equinoxe/Equinoxe total stemmed shoulder combination is compared to all other total stemmed shoulder prostheses.

Table 2: Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Equinoxe/Equinoxe	3.1 (2.0, 4.7)	5.0 (3.5, 7.0)	6.0 (4.4, 8.3)	7.6 (5.6, 10.2)	9.8 (7.3, 13.1)
Other Total Stemmed Shoulder	1.6 (1.3, 1.8)	2.5 (2.2, 2.8)	3.0 (2.7, 3.4)	3.4 (3.1, 3.8)	3.9 (3.5, 4.3)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Equinoxe/Equinoxe	11.4 (8.5, 15.2)	12.9 (9.5, 17.3)	13.8 (10.2, 18.7)		
Other Total Stemmed Shoulder	4.2 (3.8, 4.6)	4.6 (4.2, 5.1)	5.1 (4.6, 5.6)	5.7 (5.3, 6.3)	6.3 (5.8, 6.9)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinoxe/Equinoxe					
Other Total Stemmed Shoulder	6.8 (6.3, 7.5)	7.5 (6.9, 8.2)	8.0 (7.2, 8.7)	8.1 (7.4, 9.0)	8.3 (7.5, 9.2)

Note: Prostheses no longer used in 2021 are excluded from the comparator.
Only cemented all-polyethylene glenoids are included in the comparator.

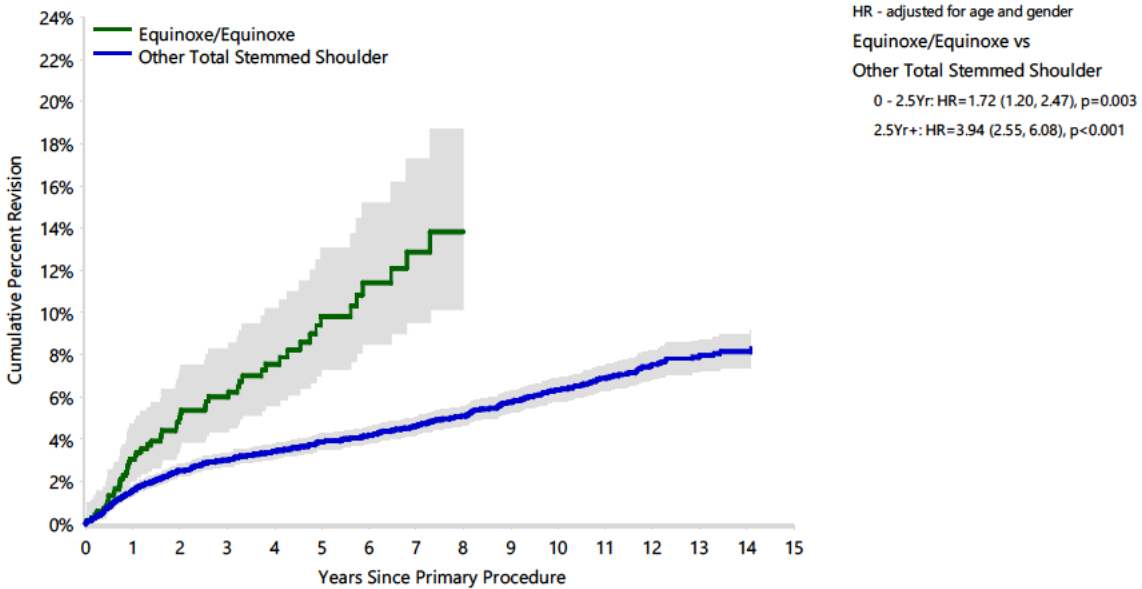
FIGURE 1

Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement

The yearly cumulative percent revision of the Equinox/Equinox total stemmed shoulder combination is compared to all other total stemmed shoulder 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 Stemmed Shoulder Replacement



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Equinox/Equinox	689	599	493	411	302	216	152	102
Other Total Stemmed Shoulder	11287	10708	10107	9500	8804	8006	7105	6141

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinox/Equinox	70	36	10	3	0	0	0	0
Other Total Stemmed Shoulder	5150	4216	3356	2583	1846	1196	686	269

Note: Prostheses no longer used in 2021 are excluded from the comparator.
 Only cemented all-polyethylene glenoids are included in the comparator.

TABLE 3

Primary Diagnosis for Revised Primary Total Stemmed Shoulder 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 stemmed shoulder prostheses.

Table 3: Primary Diagnosis for Revised Primary Total Stemmed Shoulder Replacement

Primary Diagnosis	Equinoxe/Equinoxe		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Osteoarthritis	53	94.6	542	92.6
Osteonecrosis			14	2.4
Rheumatoid Arthritis	1	1.8	12	2.1
Instability			6	1.0
Other Inflammatory Arthritis			5	0.9
Fracture	2	3.6	4	0.7
Rotator Cuff Arthropathy			2	0.3
TOTAL	56	100.0	585	100.0

Note: Prostheses no longer used in 2021 are excluded from the comparator.
Only cemented all-polyethylene glenoids are included in 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 Stemmed Shoulder Replacement - Reason for Revision (Follow-up Limited to 11.5 Years)

Revision Diagnosis	Equinox/Equinoxe			Other Total Stemmed Shoulder		
	Number	% Primaries Revised	% Revisions	Number	% Primaries Revised	% Revisions
Loosening	16	2.3	28.6	199	1.8	35.1
Rotator Cuff Insufficiency	11	1.6	19.6	107	0.9	18.9
Instability/Dislocation	10	1.5	17.9	106	0.9	18.7
Infection	5	0.7	8.9	60	0.5	10.6
Pain	1	0.1	1.8	23	0.2	4.1
Fracture	2	0.3	3.6	18	0.2	3.2
Arthrofibrosis	2	0.3	3.6	11	0.1	1.9
Lysis	2	0.3	3.6	10	0.1	1.8
Malposition	1	0.1	1.8	8	0.1	1.4
Incorrect Sizing	3	0.4	5.4	7	0.1	1.2
Dissociation				4	0.0	0.7
Implant Breakage Glenoid	3	0.4	5.4	2	0.0	0.4
Glenoid Erosion				2	0.0	0.4
Implant Breakage Glenoid Insert				2	0.0	0.4
Implant Breakage Humeral				1	0.0	0.2
Other				7	0.1	1.2
N Revision	56	8.1	100.0	567	5.0	100.0
N Primary	689			11287		

Note: This table is restricted to revisions within 11.5 years for all groups to allow a time-matched comparison of revisions.

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

Only cemented all-polyethylene glenoids are included in the comparator.

FIGURE 2

Cumulative Incidence Revision Diagnosis of Primary Total Stemmed Shoulder 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 Equinoxe/Equinoxe total stemmed shoulder combination. A comparative graph is provided of the cumulative incidence for the same reasons for revisions for all other total stemmed shoulder prostheses.

Figure 2: Cumulative Incidence Revision Diagnosis for Primary Total Stemmed Shoulder Replacement

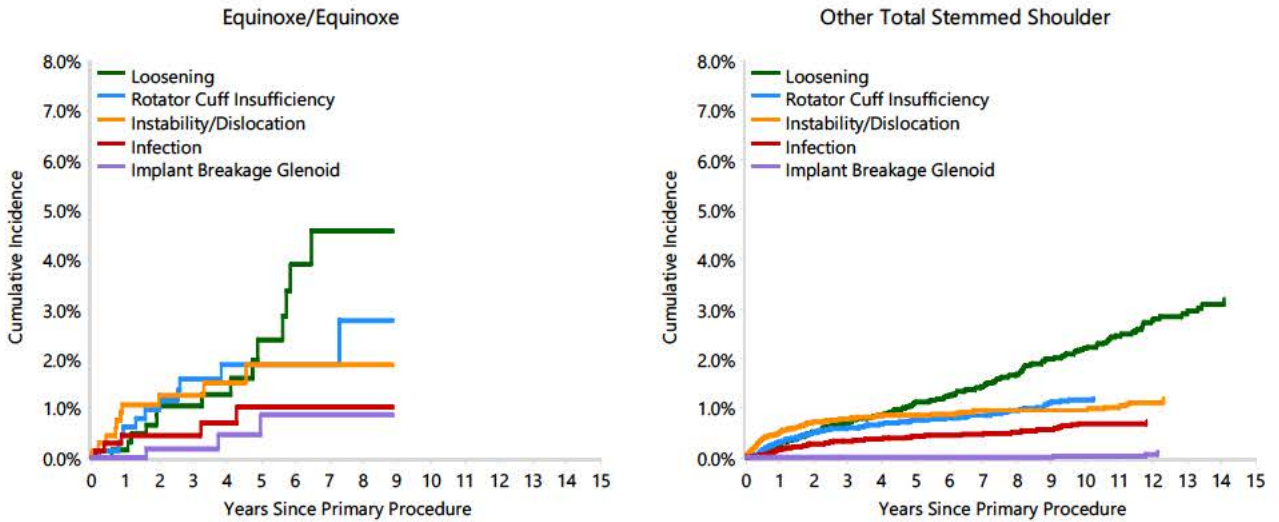


TABLE 5

Type of Revision Performed for Primary Total Stemmed Shoulder Replacement

This analysis identifies the components used in the revision of the Equinox/Equinox total stemmed shoulder combination and compares it to the components used in the revision of all other total stemmed shoulder 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 stemmed shoulder prostheses i.e. is there a difference in the type of revision undertaken for the Equinox/Equinox total stemmed shoulder combination compared to all other total stemmed shoulder prostheses.

Table 5: Primary Total Stemmed Shoulder Replacement - Type of Revision (Follow-up Limited to 11.5 Years)

Type of Revision	Equinox/Equinox		Other Total Stemmed Shoulder	
	Number	Percent	Number	Percent
Humeral/Glenoid	36	64.3	339	59.8
Glenoid Component	3	5.4	48	8.5
Humeral Component	4	7.1	47	8.3
Cement Spacer	3	5.4	40	7.1
Removal of Prostheses			15	2.6
Reinsertion of Components			1	0.2
N Major	46	82.1	490	86.4
Head Only	10	17.9	69	12.2
Reoperation			4	0.7
Minor Components			3	0.5
Cement Only			1	0.2
N Minor	10	17.9	77	13.6
TOTAL	56	100.0	567	100.0

Note: This table is restricted to revisions within 11.5 years for all groups to allow a time-matched comparison of revisions.

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

Only cemented all-polyethylene glenoids are included in the comparator.

TABLE 6

Revision Rates of Equinox/Equinox Primary Total Stemmed Shoulder 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 Equinox/Equinox Primary Total Stemmed Shoulder Replacement by Fixation

Fixation	N Revised	N Total
Cemented	3	28
Cementless	6	52
Hybrid (Glenoid Cemented)	47	609
TOTAL	56	689

TABLE 7

Revision Rates of Primary Total Stemmed Shoulder Replacement by State

This enables a state by state variation to be identified for the Equinox/Equinox total stemmed shoulder combination and provides the comparative data for each of the states for all other total stemmed shoulder 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 7: Revised Number of Primary Total Stemmed Shoulder Replacement by State

Component	State	N Revised	N Total
Equinox/Equinox	NSW	17	162
	VIC	14	210
	QLD	4	82
	WA	20	212
	SA	1	8
	TAS	0	14
	ACT/NT	0	1
Other Total Stemmed Shoulder	NSW	153	3165
	VIC	149	2997
	QLD	118	2399
	WA	71	1096
	SA	58	1120
	TAS	7	191
	ACT/NT	29	319
TOTAL		641	11976

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

Only cemented all-polyethylene glenoids are included in the comparator.

TABLE 8

Number of Revisions of Equinox/Equinox Primary Total Stemmed Shoulder Replacement by Year of Implant

This analysis details the number of prostheses reported each year to the Registry for the Equinox/Equinox total stemmed shoulder 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 8: Number of Revisions of Equinox/Equinox Primary Total Stemmed Shoulder Replacement by Year of Implant

Year of Implant	Number Revised	Total Number
2011	4	6
2012	3	10
2013	3	26
2014	3	32
2015	10	46
2016	3	42
2017	4	71
2018	9	79
2019	9	105
2020	4	92
2021	3	91
2022	1	85
2023	0	4
TOTAL	56	689

TABLE 9

Revision Rates of Equinnox/Equinnox Primary Total Stemmed Shoulder 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 Equinnox/Equinnox 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
Humeral Stem					
Equinnox	3000107-3000117	PRESSFIT PRIMARY HUMERAL STEM	NO	METAL	
Equinnox	3003006-3003014	EQUINOXE PRESERVE HUMERAL STEM PRESS FIT PLASMA COATED	NO	METAL	
Equinnox	3042107-3042407	PLATFORM FRACTURE HUMERAL STEM	YES	METAL	FRACTURE
Equinnox	3060108-3060212	LONG HUMERAL STEM	YES	METAL	
Glenoid					
Equinnox	3140102-3140114	ALL POLY CEMENTED KEELED GLENOID	YES	NON CROSS-LINKED POLYETHYLENE	
Equinnox	3140202-3140214	ALL POLY CEMENTED PEGGED GLENOID	YES	NON CROSS-LINKED POLYETHYLENE	
Equinnox	3140222-3140634	POSTERIOR AUGMENT CEMENTED PEGGED GLENOID	YES	NON CROSS-LINKED POLYETHYLENE	
Equinnox	3141302-3141315	CEMENTED CAGE GLENOID	YES	NON CROSS-LINKED POLYETHYLENE	
Equinnox	3141322-3141335	CEMENTED CAGE GLENOID POLY POSTERIOR AUGMENT	YES	NON CROSS-LINKED POLYETHYLENE	

Table 9: Revised Number of Equinnox/Equinnox Primary Total Stemmed Shoulder Replacement by Catalogue Number Range

Humeral Stem Range	Glenoid Range	N Revised	N Total
3000107-3000117	3140102-3140114	1	7
	3140202-3140214	21	229
	3140222-3140634	3	41
	3141302-3141315	18	225
	3141322-3141335	9	149
3003006-3003014	3140202-3140214	0	1
	3141302-3141315	2	15
	3141322-3141335	0	20
3042107-3042407	3140202-3140214	1	1
3060108-3060212	3141302-3141315	1	1
TOTAL		56	689

Table 10: Revised Number of Primary Total Stemmed Shoulder Replacement by Model (All Diagnoses, Revision for Loosening)

Model	N Revised	N Total
Equinoxe/Equinoxe	16	689
Other Total Stemmed Shoulder	211	11287
TOTAL	227	11976

Note: Prostheses no longer used in 2021 are excluded from the comparator.
Only cemented all-polyethylene glenoids are included in the comparator.

Table 11: Yearly Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement by Model (All Diagnoses, Revision for Loosening)

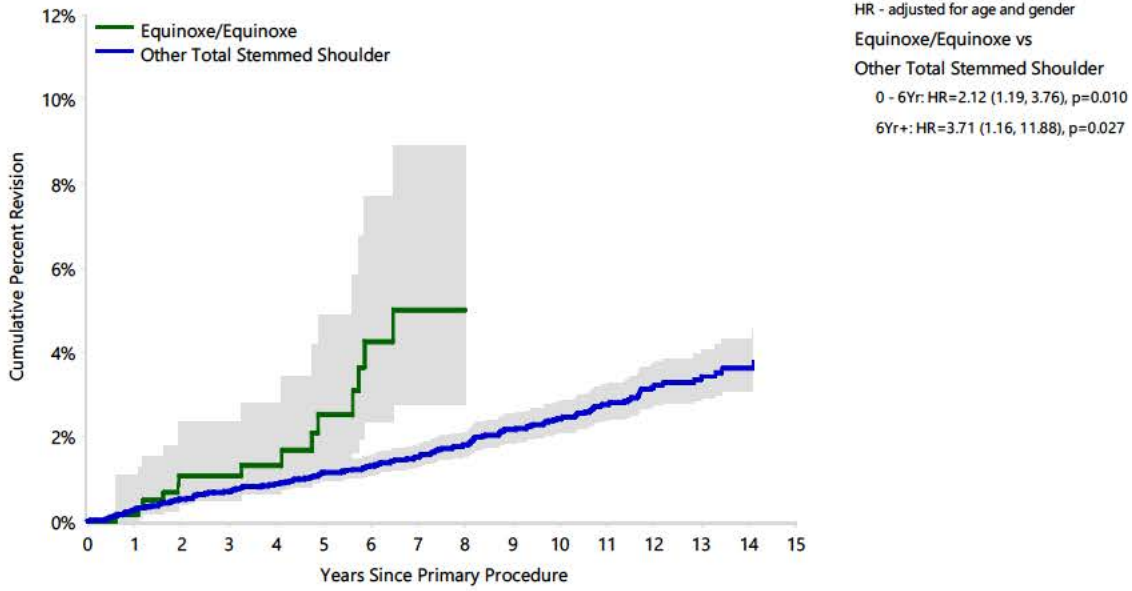
CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs
Equinoxe/Equinoxe	0.2 (0.0, 1.1)	1.1 (0.5, 2.4)	1.1 (0.5, 2.4)	1.3 (0.6, 2.8)	2.5 (1.3, 4.9)
Other Total Stemmed Shoulder	0.3 (0.2, 0.4)	0.5 (0.4, 0.7)	0.7 (0.6, 0.9)	0.9 (0.7, 1.1)	1.2 (1.0, 1.4)

CPR	6 Yrs	7 Yrs	8 Yrs	9 Yrs	10 Yrs
Equinoxe/Equinoxe	4.3 (2.3, 7.7)	5.0 (2.8, 8.9)	5.0 (2.8, 8.9)		
Other Total Stemmed Shoulder	1.3 (1.1, 1.6)	1.5 (1.3, 1.8)	1.8 (1.5, 2.1)	2.2 (1.9, 2.5)	2.4 (2.1, 2.8)

CPR	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinoxe/Equinoxe					
Other Total Stemmed Shoulder	2.8 (2.4, 3.2)	3.2 (2.8, 3.8)	3.4 (2.9, 4.1)	3.6 (3.1, 4.3)	3.8 (3.2, 4.5)

Note: Prostheses no longer used in 2021 are excluded from the comparator.
Only cemented all-polyethylene glenoids are included in the comparator.

Figure 3: Cumulative Percent Revision of Primary Total Stemmed Shoulder Replacement by Model (All Diagnoses, Revision for Loosening)



Number at Risk	0 Yr	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs	7 Yrs
Equinoxe/Equinoxe	689	599	493	411	302	216	152	102
Other Total Stemmed Shoulder	11287	10708	10107	9500	8804	8006	7105	6141

Number at Risk	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs	13 Yrs	14 Yrs	15 Yrs
Equinoxe/Equinoxe	70	36	10	3	0	0	0	0
Other Total Stemmed Shoulder	5150	4216	3356	2583	1846	1196	686	269

Note: Prostheses no longer used in 2021 are excluded from the comparator.
 Only cemented all-polyethylene glenoids are included in the comparator.