

## Implant Summary Report for:

ConforMIS

## iTotal G2 XE and iTotal G2 (Bicondylar tray)

Comprising PRIMARY knees implanted up to: 07 December 2017  
NJR Database extract: 05 February 2018

Produced on: 10 February 2018  
Licenced for use until: 10 February 2019

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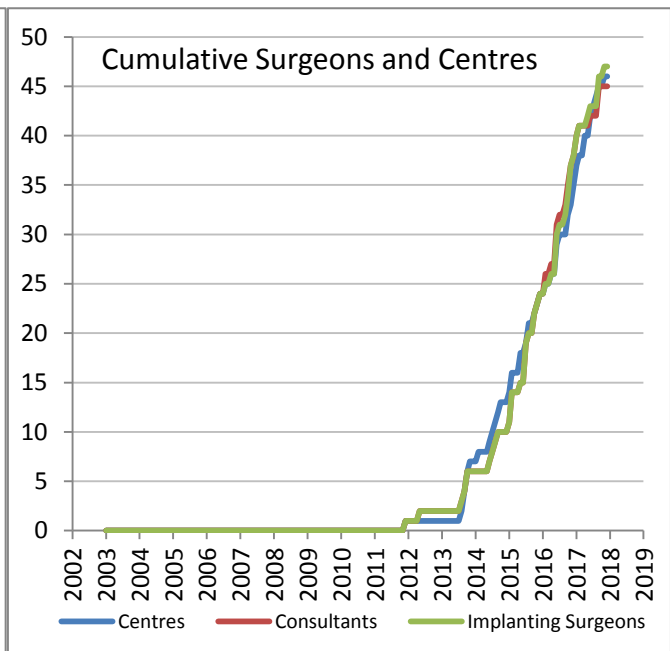
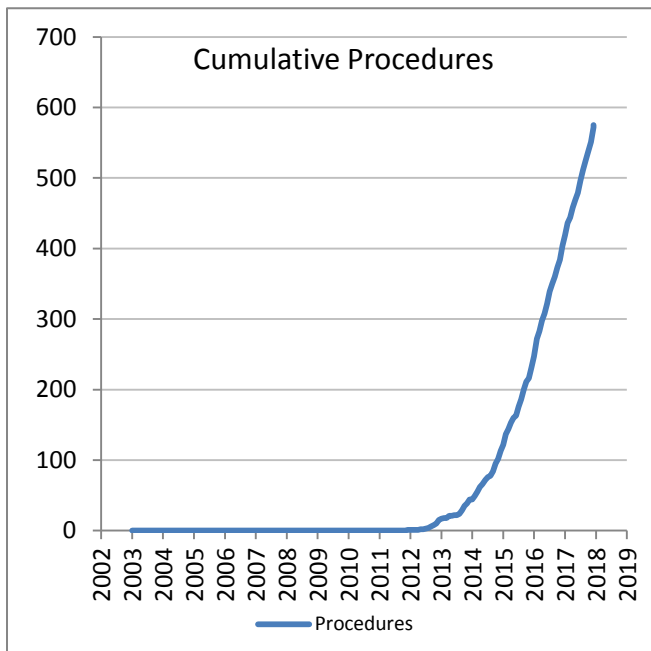
This report has been produced by Northgate Public Services (UK) Ltd. It summarises usage and outcomes associated with the iTotal G2 XE and iTotal G2 (Bicondylar tray), based on data collected by the NJR up to the specified date for the components listed in Appendix A.

**NJR Recorded Usage**

**Implant Usage**

Date of first recorded usage in the NJR: **09 November 2011**  
 Date of last recorded usage in this dataset: **07 December 2017**  
 Maximum implantation time: 5.6 years  
 Mean implantation time: 1.9 years

Totals Recorded in NJR	Cumulative Total
Procedures	576
Patients	504
Centres	46
Consultants	45
Implanting Surgeons	47



Current Outcome	Pre-2006	Year of implantation													Total	%
		2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017			
Death	0	0	0	0	0	0	0	1	1	0	1	1	0	4	0.7%	
Revised	0	0	0	0	0	0	1	0	0	2	0	0	0	3	0.5%	
Unrevised	0	0	0	0	0	0	0	15	26	76	124	171	157	569	98.8%	
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>16</b>	<b>27</b>	<b>78</b>	<b>125</b>	<b>172</b>	<b>157</b>	<b>576</b>	<b>100%</b>	

## Patient / Procedure Details

## Patient Details

	iTotal G2 XE and iTotal G2 (Bicondylar tray)	All TKR in NJR
<b>Total Procedures</b>	576	958,398
<b>Total Patients</b>	504	786,185
<b>Demographics</b>		
Mean age	<b>66.6</b>	<b>70.1</b>
< 50	5.0%	1.8%
50 – 59	16.7%	11.2%
60 – 69	38.2%	32.4%
70 – 79	32.5%	38.5%
≥ 80	7.6%	16.0%
Median BMI	<b>29</b>	<b>30</b>
% BMI information available	78.6%	60.2%
Underweight ( BMI < 18.5)	0.2%	0.3%
Normal (18.5 ≤ BMI < 25)	14.6%	10.2%
Overweight (25 ≤ BMI < 30)	38.4%	34.2%
Obese I (30 ≤ BMI < 35)	30.2%	32.3%
Obese II (35 ≤ BMI < 40)	10.4%	16.2%
Obese III (BMI ≥ 40)	6.2%	6.9%
% Male	51.6%	42.6%
<b>ASA Grades</b>		
P1 - Fit and healthy	21.4%	11.0%
P2 - Mild disease not incapacitating	68.1%	72.4%
P3 - Incapacitating systemic disease	10.6%	16.2%
P4 / P5	0.0%	0.3%
<b>Indications</b>		
Osteoarthritis	98.61%	97.32%
Rheumatoid Arthritis	0.52%	1.63%
Other Inflammatory Arthropathy	0.52%	0.65%
Previous Trauma	0.35%	0.56%
Avascular Necrosis	0.17%	0.33%
Other	0.52%	0.36%

Total of indications may exceed total number of implants, since more than one indication can be listed per case.

**Patient / Procedure Details**

**Intraoperative Adverse Events**

Adverse Event	Number <sup>†</sup>	Event Rate *		p value
		iTotal G2 XE and iTotal G2 (Bicondylar tray)	All other TKR in NJR	
None	575	99.83%	99.41%	0.275
Fracture	0	0.00%	0.16%	1
Patella Tendon Avulsion	1	0.17%	0.04%	0.226
Ligament Injury	0	0.00%	0.07%	1
Other	0	0.00%	0.34%	0.275

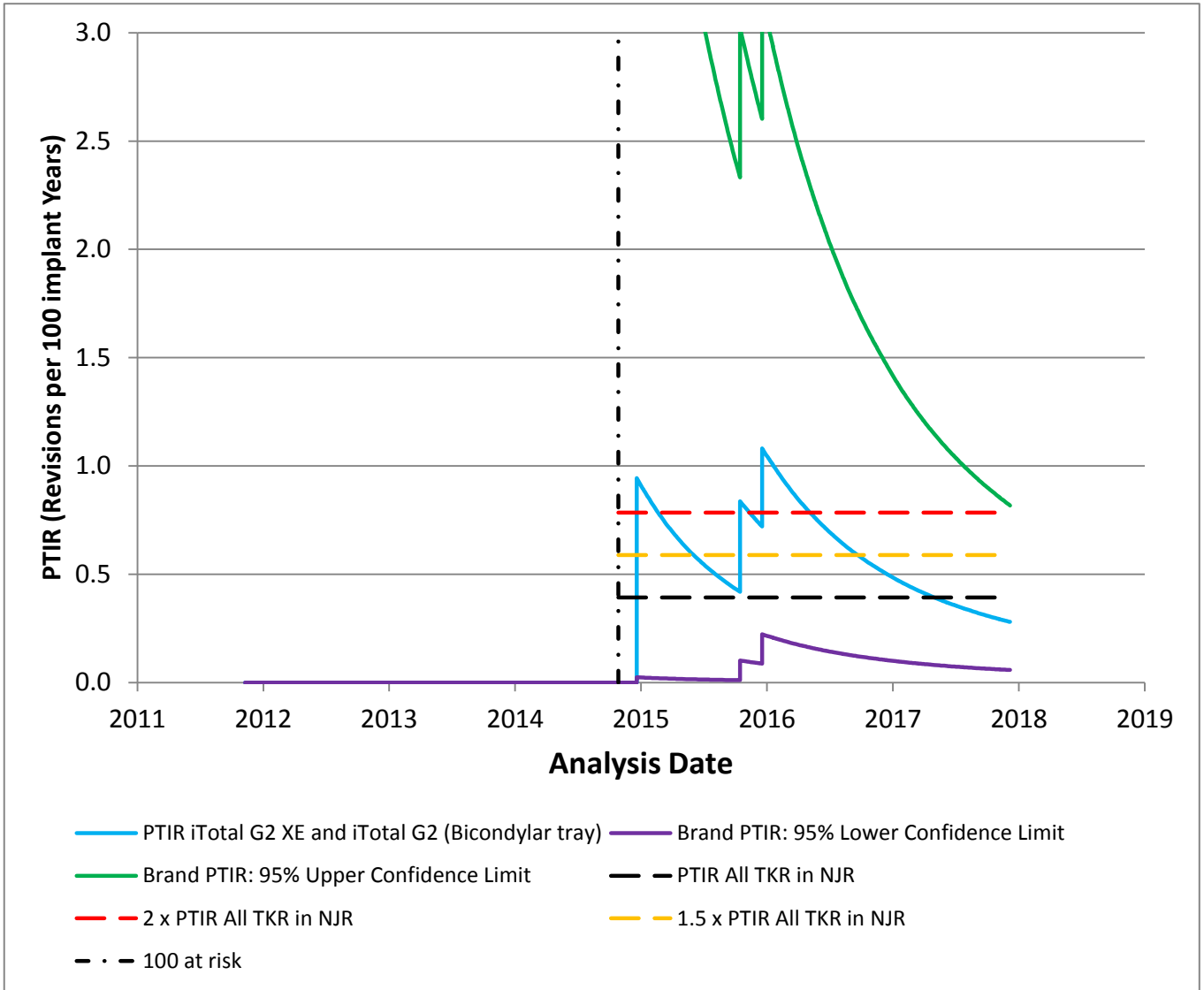
† multiple events may be listed for one procedure

\* As percentage of procedures for which adverse event data was recorded

	Significantly better, p < 0.001
	Significantly better, p < 0.05
	Significantly worse p < 0.05
	Significantly worse p < 0.001

**Revision and Survivorship**

**Patient - Time Incidence Rate**



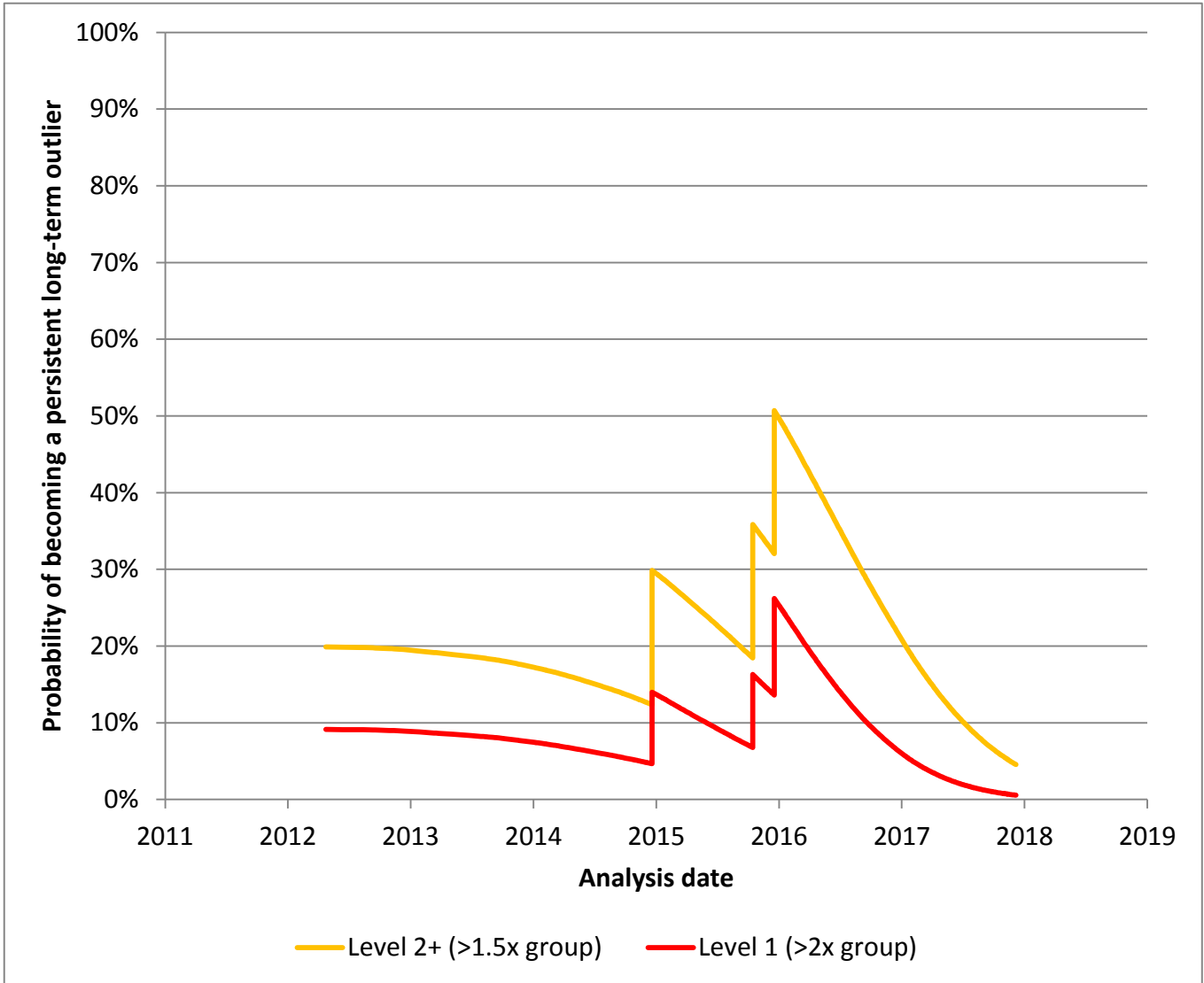
	PTIR (95% Confidence Interval)
iTotal G2 XE and iTotal G2 (Bicondylar tray)	0.280 (0.058 - 0.817)
All TKR in NJR	0.392
Status	Not an outlier

Outlier level 1: Used in  $\geq 100$  primary operations and PTIR 95% lower confidence  $> 2 \times$  group PTIR

Outlier level 2: Used in  $\geq 100$  primary operations and PTIR 95% lower confidence  $> 1.5 \times$  group PTIR OR  
Used in  $< 100$  primary operations and PTIR 95% lower confidence  $> 2 \times$  group PTIR

**Revision and Survivorship**

**Probability of becoming a long term outlier**



Outlier Level	Estimated probability of becoming a persistent outlier
Level 2+ (>1.5x group PTIR)	4.5%
Level 1 (>2x group PTIR)	0.6%

The probability of iTotal G2 XE and iTotal G2 (Bicondylar tray) becoming a persistent long-term outlier is estimated from all the NJR evidence to date, and will change as more evidence is accumulated. The probability will approach 0% or 100% in the long term with a large number of implants. The product is likely to be identified by the product outlier process if the probability calculated here exceeds 95%.

**Revision and Survivorship**

**Reasons for Revision**

Reasons for revision of primary procedures in which the implant was used.

Reason for Revision	Revised †	Expected Revisions *	p value
Infection	1	1.75	1
Progressive Arthritis Remaining	0	0.28	1
Aseptic Loosening Femur	1	0.34	0.288
Aseptic Loosening Tibia	1	0.77	0.537
Aseptic Loosening Patella	1	0.19	0.172
Pain	0	0.96	1
Stiffness	0	0.60	1
Malalignment	0	0.50	1
Instability	2	0.92	0.234
Dislocation / Subluxation	0	0.19	1
Periprosthetic Fracture	0	0.14	1
Wear of Polyethylene Component	1	0.10	0.095
Lysis - Tibia	1	0.16	0.146
Lysis - Femur	1	0.10	0.093
Component Dissociation	0	0.05	1
Implant Fracture	0	0.02	1
Other / Not recorded	0	0.46	1
<b>Total Revised</b>	<b>3</b>	<b>5.80</b>	<b>0.399</b>

† multiple reasons may be listed for one revision procedure

\* Adjusted for agegroup, gender and indications

Significantly better, p < 0.001

Significantly better, p < 0.05

Significantly worse p < 0.05

Significantly worse p < 0.001



Components Revised	Number of procedures	iTotal G2 XE and iTotal G2 (Bicondylar tray)	All other TKR in NJR
Femoral and/or Tibial Revision	3	100.0%	71.4%
Isolated bearing exchange	0	0.0%	11.9%
Patella revision / resurfacing only	0	0.0%	15.6%
No component revision recorded	0	0.0%	1.2%

Summary Report for:

iTotal G2 XE and iTotal G2 (Bicondylar tray)

**Revision and Survivorship**

**Revision Details**

NJR Index No	Procedure ID	Primary Date	Revision Date	Years implanted	Age at Primary	Revision Reasons
1812172	1597990	09/11/2011	18/12/2015	4.11	48	aseptic loosening femur; aseptic loosening patella; aseptic loosening tibia; Instability; LysisFemur; LysisTibia; WearOfPolyethyleneComponent
1892906	1677844	19/03/2014	15/10/2015	1.57	65	Instability
2042935	1825319	11/11/2014	20/12/2014	0.11	74	infection

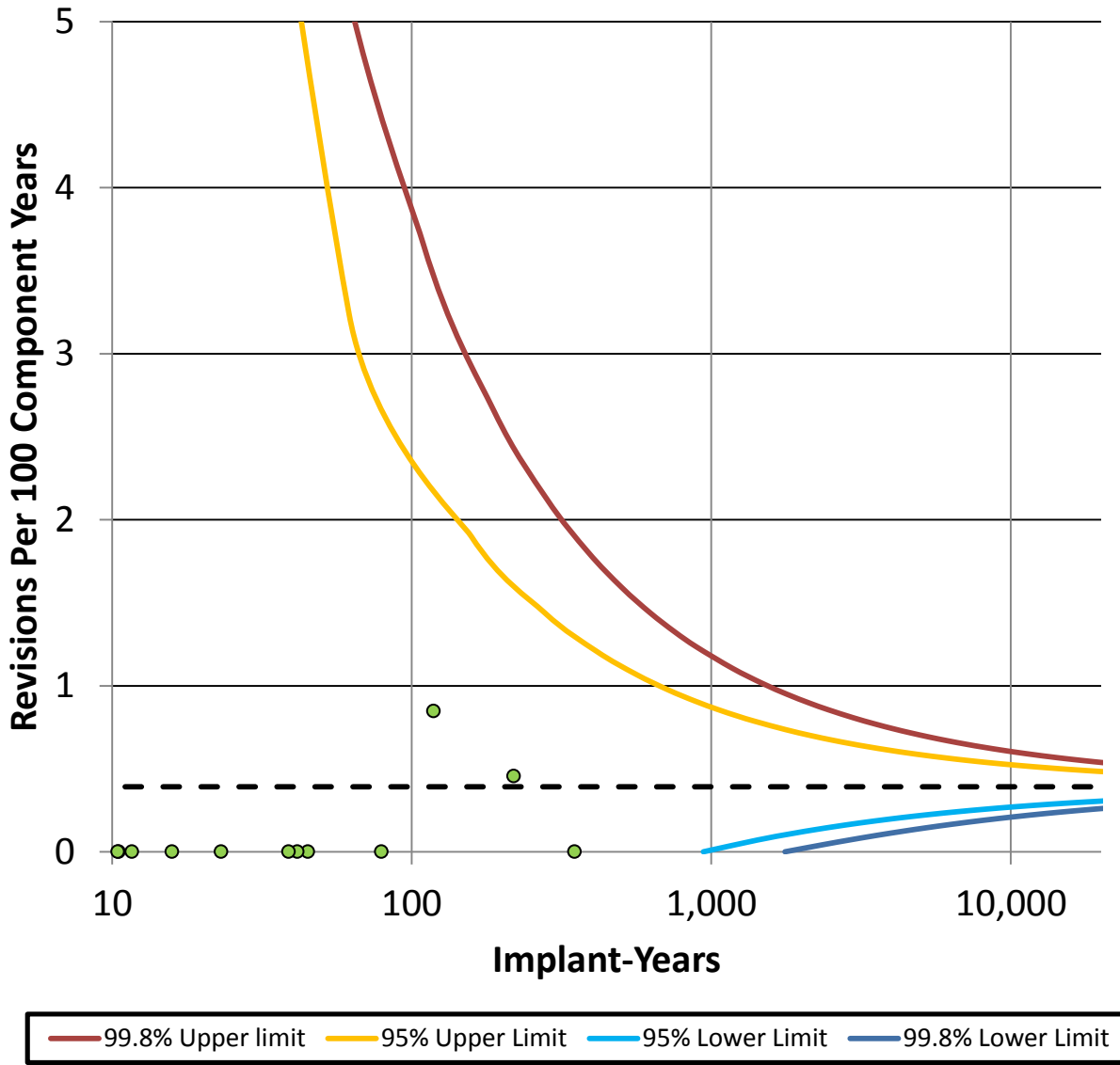
Table contains Most recent 20 revisions



**Revision and Survivorship**

**Patient - Time Incidence Rate**

Lead Surgeons implanting iTotal G2 XE and iTotal G2 (Bicondylar tray)

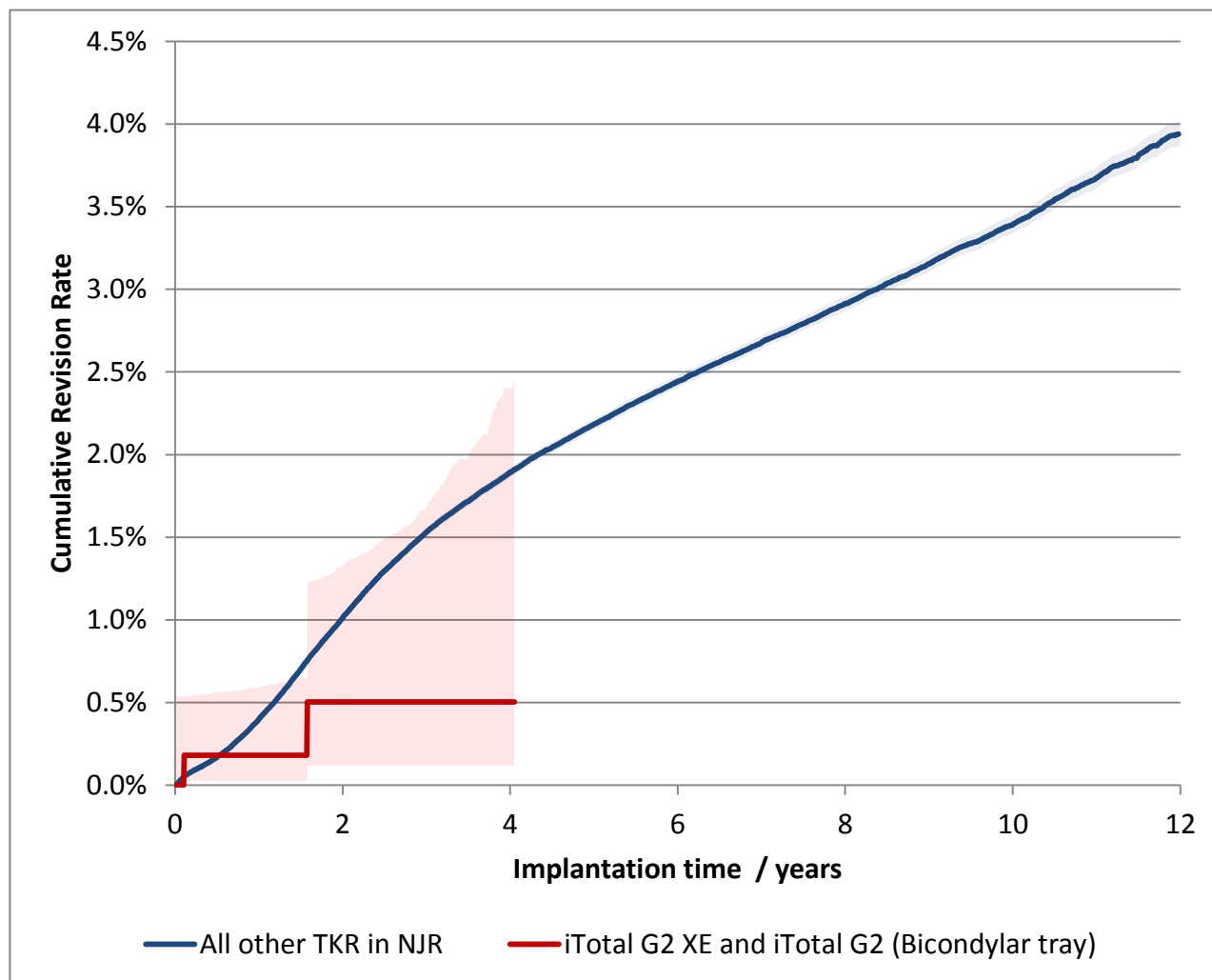


Each circle represents one surgeon. Red circles represent surgeons with a higher than expected revision rate ( $p < 0.001$ ), and blue circles represent surgeons with a lower than expected revision rate ( $p < 0.001$ ). Note that these rates have not been adjusted for case mix, or for variants of implant chosen.

**Revision and Survivorship**

**Cumulative Revision Rate**

Endpoint: All reasons for revision



Cox Proportional Hazards model for revision risk ratio of iTotal G2 XE and iTotal G2 (Bicondylar tray) / All other TKR in NJR:

Adjustment	Hazard Ratio (95% CI)	p-value
Unadjusted	0.58 (0.19 - 1.81)	0.349
Adjusted for age, gender, year cohort and indications.	0.55 (0.18 - 1.71)	0.305

**Revision and Survivorship**

**Cumulative Revision Rate**

Endpoint: All revisions

Period /years	At Risk	iTotal G2 XE and iTotal G2 (Bicondylar tray)	All TKR in NJR
0	576	-	-
1	407	0.2% (0.0% - 0.6%)	0.4% (0.4% - 0.4%)
2	234	0.5% (0.1% - 1.3%)	1.0% (1.0% - 1.0%)
3	114	0.5% (0.1% - 1.7%)	1.5% (1.5% - 1.6%)
4	42	0.5% (0.1% - 2.4%)	1.9% (1.9% - 1.9%)
5		( - )	2.2% (2.1% - 2.2%)
6		( - )	2.4% (2.4% - 2.5%)
7		( - )	2.7% (2.6% - 2.7%)
8		( - )	2.9% (2.9% - 3.0%)
9		( - )	3.2% (3.1% - 3.2%)
10		( - )	3.4% (3.3% - 3.4%)

Cumulative revision rate with 95% confidence intervals  
 Rate is only reported for times where more than 40 remain at risk

## Disclaimer

### Disclaimer

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## Appendix A1 - Femoral Components

Catalogue Number	Description	Number Implanted
M5725INT0600010 - FI	Left KNEE - Femoral Implant	142
M5725INT0600020 - FI	Right KNEE - Femoral Implant	171
M5725INT060XE10 - FI	LEFT KNEE - Femoral Implant	127
M5725INT060XE20 - FI	RIGHT KNEE - Femoral Implant	136

## Appendix A2 - Tibial Components

Catalogue Number	Description	Number
M5725INT0600010 - TT	Left KNEE - Tibial Tray	143
M5725INT0600020 - TT	Right KNEE - Tibial Tray	169
M5725INT060XE10 - TT	LEFT KNEE - Tibial Tray	127
M5725INT060XE20 - TT	RIGHT KNEE - Tibial Tray	137

## Appendix A3 - Bearing Components

Catalogue Number	Description	Number
M5725INT0600010 - 6MI	Left KNEE - 6mm Medial Insert	27
M5725INT0600010 - 7MI	Left KNEE - 7mm Medial Insert	1
M5725INT0600010 - 8MI	Left KNEE - 8mm Medial Insert	1
M5725INT0600010 - ALI	Left KNEE - A Lateral Insert	4
M5725INT0600010 - BLI	Left KNEE - B Lateral Insert	1
M5725INT0600020 - 6MI	Right KNEE - 6mm Medial Insert	24
M5725INT0600020 - 7MI	Right KNEE - 7mm Medial Insert	2
M5725INT0600020 - ALI	Right KNEE - A Lateral Insert	7
M5725INT060XE10 - 6M	LEFT KNEE - 6mm Medial Insert	5
M5725INT060XE10 - 8M	LEFT KNEE - 8mm Medial Insert	6
M5725INT060XE10 - ALI	LEFT KNEE - A Lateral Insert	2
M5725INT060XE10 - BLI	LEFT KNEE - B Lateral Insert	1
M5725INT060XE10 - CLI	LEFT KNEE - C Lateral Insert	4
M5725INT060XE20 - 6M	RIGHT KNEE - 6mm Medial Insert	5
M5725INT060XE20 - 7M	RIGHT KNEE - 7mm Medial Insert	2
M5725INT060XE20 - 8M	RIGHT KNEE - 8mm Medial Insert	2
M5725INT060XE20 - ALI	RIGHT KNEE - A Lateral Insert	4
M5725INT060XE20 - BLI	RIGHT KNEE - B Lateral Insert	2
M5725INT060XE20 - CLI	RIGHT KNEE - C Lateral Insert	3