



Detail Report for

Lima Deutschland GmbH - ZUK (K1.2 Tibial Tray Including Monobloc)

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EPRD Detail Report for

ZUK (K1.2 Tibial Tray Including Monobloc)

Introduction

The following pages contain a summary of the data the EPRD (German Arthroplasty Registry) has collected for primary and revision procedures with specific components. This report consists of three parts. In **part I** of this document, **Article Overview**, the specific articles considered in this report are listed. The number of primary procedures and revision procedures in follow-up is given separately for each article.

In **part II** of this document, **Primary Procedures and Cumulative Revision Rates**, primary procedures using at least one of the aforementioned articles listed in Article Overview A and - if additionally given - one of the articles listed in each Article Overview B, C an D, respectively, are compared to all other primary procedures of the same category. The EPRD separates between the following disjunct categories of primary procedures:

- Elective THA with uncemented stem ● Elective THA with cemented stem
- TKA, Standard ● TKA, constrained (= hinged or varus valgus stabilised PS systems)
- THA for Femoral Neck fracture (regardless of stem fixation)
- Hemiarthroplasty
- Unicondylar Knee Arthroplasty (UKA)
- Patellofemoral arthroplasty (PFA)

Please note that procedures which can not be assigned to one of these categories - normally due to incomplete product classification - will be listed in the makeshift category "??". If implant components are used in different categories of procedures (like e.g. a modular head which is combined with a cemented stem or with a cementless stem), the results in the data overview are presented separately.

The abbreviations in the data overview have the following meanings:

Abbreviation	Meaning
Category	Type of procedure, e.g. unicompartmental knee arthroplasty for primary procedures or aseptic hip revisions for revision procedures.
Procedures with ...	Procedures using at least one of the articles listed in the article overview or procedures from the comparison group
n	Absolute number of procedures of this category / this subgroup in follow-up
%	Percentage of procedures in this subgroup
Age	The median age is presented. In addition, in brackets behind it the interquartile range (IQR) is given.
BMI	The median <i>Body Mass Index</i> is presented. In addition, in brackets behind it the interquartile range (IQR) is given. As BMI information is not available for all procedures, the percentage of valid BMI values (%V) is also listed.
%Male	Percentage of male patients
#Centres	Number of centres in which the procedures were conducted
%OA	Percentage of diagnosis Osteoarthritis in the group. For determination, each patient for whom the ICD code of the main diagnosis starts with M16 or M17 is counted.
#Deaths	Number of patients in this group who suffered death of any cause during follow-up period
#Rev	Number of revised procedures.
Follow-up in years	The median follow-up time in years and its interquartile range

The **cumulative revision rate** is calculated using Kaplan-Meier-estimates. In the EPRD, every procedure in which at least one component has been removed or was exchanged (not necessarily one of those listed in the **Article Overview**) is counted as a revision. There is only one exception: Secondary patellar resurfacing is not counted as a revision even if the insert was also exchanged during the procedure. For the calculation of the revision rate, any revision procedure is considered as an endpoint for the whole implant system. In brackets behind the actual revision rate the corresponding 95% confidence limits are shown. In further brackets below the confidence limits the number of procedures at risk for the specific time point is given.

If any revision occurred in primary procedures with the aforementioned articles, the **reasons for revisions** and **components exchanged during revision** are listed separately. The **reasons for revisions** are shown as absolute numbers and - in brackets beneath - as relative numbers. As in many cases the EPRD only gets the information about a revision from clearance data of insurance companies, the reason of revision often remains unknown. The **components exchanged during revision** are shown as absolute numbers. For each of the main components of the primary procedure (i.e. stem, head, cup, liner for hip arthroplasty and femoral component, tibial component, insert and patellar component for knee arthroplasty) the following numbers are presented:

Abbreviation	Meaning
EX	Number of revision procedures in which a new component of a particular type has been newly implanted, possibly exchanging a formerly implanted one.
UT	Number of revision procedures in which the specific component remained untouched
?	Number of revision procedures for which there are either no information on implanted components at all or for which unknown articles have been documented. In both cases it is not possible to determine (all) the components of the primary procedure which remained or have been exchanged.

Part III of this document, **Revision Procedures and Cumulative Re-Revision Rates**, compares revision procedures using the aforementioned articles to other revision procedures. Part III has the same structure as its counterpart in part II and the cumulative re-revision rate is computed analogously to the cumulative revision rate in part II using Kaplan-Meier-estimates. For this evaluation, the EPRD only differentiates between hip and knee revisions as well as aseptic and septic revisions. A revision is regarded as a septic revision if either an infection was recorded as reason for revision in the registry itself or the ICD code T84.5 was documented in the billing data for the hospital stay of the revision. The EPRD does not differentiate between 1st, 2nd, 3rd revision (and so on), since in most cases information about prior surgeries is not available.

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Part I: Article Overview A

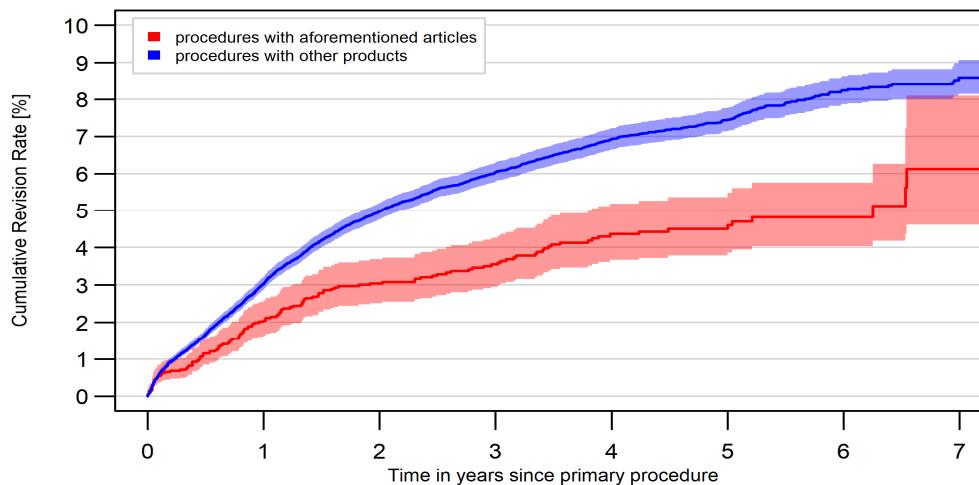
Article Number	Article Shorttext	Trademark	Component Type	No. of procedures	
				primary	revision
00-5842-001-01	UNI FL.FIX TIB PRC MLT/LRT SZ1	ZUK	K1.2 Tibial Tray Including Monobloc	60	0
00-5842-001-02	UNI FL.FIX TIB PRC MRT/LLT SZ1	ZUK	K1.2 Tibial Tray Including Monobloc	36	0
00-5842-002-01	UNI FL.FIX TIB PRC MLT/LRT SZ2	ZUK	K1.2 Tibial Tray Including Monobloc	294	1
00-5842-002-02	UNI FL.FIX TIB PRC MRT/LLT SZ2	ZUK	K1.2 Tibial Tray Including Monobloc	219	0
00-5842-003-01	UNI FL.FIX TIB PRC MLT/LRT SZ3	ZUK	K1.2 Tibial Tray Including Monobloc	567	2
00-5842-003-02	UNI FL.FIX TIB PRC MRT/LLT SZ3	ZUK	K1.2 Tibial Tray Including Monobloc	546	2
00-5842-004-01	UNI FL.FIX TIB PRC MLT/LRT SZ4	ZUK	K1.2 Tibial Tray Including Monobloc	589	2
00-5842-004-02	UNI FL.FIX TIB PRC MRT/LLT SZ4	ZUK	K1.2 Tibial Tray Including Monobloc	514	4
00-5842-005-01	UNI FL.FIX TIB PRC MLT/LRT SZ5	ZUK	K1.2 Tibial Tray Including Monobloc	388	5
00-5842-005-02	UNI FL.FIX TIB PRC MRT/LLT SZ5	ZUK	K1.2 Tibial Tray Including Monobloc	318	1
00-5842-006-01	UNI FL.FIX TIB PRC MLT/LRT SZ6	ZUK	K1.2 Tibial Tray Including Monobloc	173	2
00-5842-006-02	UNI FL.FIX TIB PRC MRT/LLT SZ6	ZUK	K1.2 Tibial Tray Including Monobloc	143	3

Cumulative Revision Rates		Cumulative Revision Rate in % after ...						
Category	Procedures with ...	1 year	2 years	3 years	4 years	5 years	6 years	7 years
OVERALL	aforementioned articles	2.1 [1.7, 2.6] (3,086)	3.1 [2.6, 3.7] (2,528)	3.6 [3.0, 4.3] (2,133)	4.4 [3.7, 5.2] (1,603)	4.5 [3.8, 5.4] (968)	4.9 [4.1, 5.8] (444)	6.2 [4.7, 8.1] (119)
UKA	aforementioned articles	2.1 [1.6, 2.6] (3,080)	3.0 [2.5, 3.7] (2,522)	3.6 [3.0, 4.3] (2,128)	4.4 [3.7, 5.2] (1,598)	4.5 [3.8, 5.4] (965)	4.8 [4.0, 5.8] (443)	6.1 [4.6, 8.1] (119)
UKA	other products	3.0 [2.9, 3.2] (34,807)	5.0 [4.8, 5.2] (27,755)	6.0 [5.8, 6.3] (20,268)	6.9 [6.6, 7.2] (13,704)	7.5 [7.1, 7.8] (8,064)	8.2 [7.9, 8.6] (3,706)	8.6 [8.1, 9.1] (1,419)
PFA	aforementioned articles	20.0 [3.1, 79.6] (4)	20.0 [3.1, 79.6] (4)	20.0 [3.1, 79.6] (3)	20.0 [3.1, 79.6] (3)	20.0 [3.1, 79.6] (1)		
PFA	other products	4.9 [3.5, 6.8] (598)	7.9 [6.0, 10.3] (465)	10.1 [7.9, 12.8] (336)	12.9 [10.2, 16.2] (231)	15.9 [12.5, 20.1] (140)	16.8 [13.1, 21.5] (60)	16.8 [13.1, 21.5] (23)
???	aforementioned articles	33.3 [5.5, 94.6] (2)	33.3 [5.5, 94.6] (2)	33.3 [5.5, 94.6] (2)	33.3 [5.5, 94.6] (2)	33.3 [5.5, 94.6] (2)	33.3 [5.5, 94.6] (1)	

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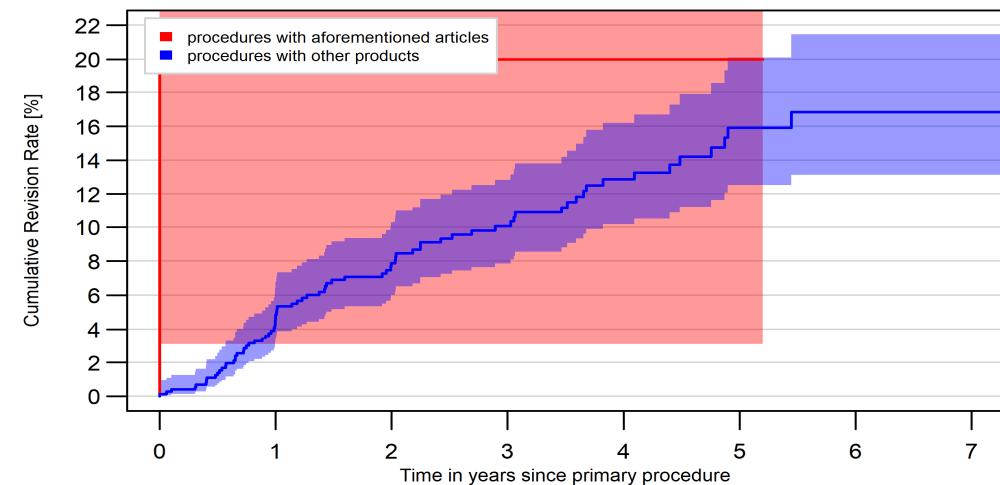
Part II: Primary Procedures and Cumulative Revision Rates

Cumulative Revision Rate for UKA



Number at Risk	3,836	3,080	2,522	2,128	1,598	965	443	119
	41,973	34,807	27,755	20,268	13,704	8,064	3,706	1,419

Cumulative Revision Rate for PFA



Number at Risk	5	4	4	3	3	1	0	0
	746	598	465	336	231	140	60	23

**EPRD Detail Report for
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Part II: Primary Procedures and Cumulative Revision Rates

Reasons for Revision Category	Procedures with ...	Infection	Recurrent dislocation	Peripr. Fracture	Malposition / Malalignment	Aseptic loosening	Wear	Other	Unknown
OVERALL	aforementioned articles	21 (14.9%)	7 (5.0%)	6 (4.3%)	2 (1.4%)	24 (17.0%)	1 (0.7%)	38 (27.0%)	42 (29.8%)
UKA	aforementioned articles	21 (15.1%)	7 (5.0%)	6 (4.3%)	2 (1.4%)	24 (17.3%)	1 (0.7%)	38 (27.3%)	40 (28.8%)
UKA	other products	187 (7.8%)	93 (3.9%)	81 (3.4%)	43 (1.8%)	579 (24.2%)	35 (1.5%)	692 (28.9%)	683 (28.5%)
PFA	aforementioned articles	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
PFA	other products	6 (7.9%)	1 (1.3%)	0 (0.0%)	1 (1.3%)	4 (5.3%)	2 (2.6%)	38 (50.0%)	24 (31.6%)
???	aforementioned articles	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)

Components exchanged during Revision Category	Procedures with ...	#Rev	Tibial Tray			Tibial Insert			Femoral Comp.			Patellar Comp.		
			EX	UT	?	EX	UT	?	EX	UT	?	EX	UT	?
OVERALL	aforementioned articles	141	65	23	53	86	2	53	65	23	53	7	73	61
UKA	aforementioned articles	139	65	23	51	86	2	51	65	23	51	7	73	59
UKA	other products	2,393	1,292	348	753	1,639	8	746	1,239	399	755	149	1,396	848
PFA	aforementioned articles	1	0	0	1	0	0	1	0	0	1	0	0	1
PFA	other products	76	44	4	28	44	4	28	46	3	27	14	33	29
???	aforementioned articles	1	0	0	1	0	0	1	0	0	1	0	0	1

**EPRD Detail Report for
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Part II: Primary Procedures and Cumulative Revision Rates

Specific Implant Combinations		Trademarks for ...					Number of Implantations
Category	Tibial Tray	Tibial Insert	Femoral Knee	Patellar Component			
1 UKA	ZUK	ZUK	ZUK				3,836
2 PFA	ZUK	ZUK	<from another company>	<from another company>			4
3 ???	ZUK	ZUK	ZUK				3
4 PFA	ZUK	ZUK	<from another company>				1
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Cumulative Revision Rates for specific Implant Combinations in % after ...														
Age	%Male	#Centres	#Rev	1 year	2 years	3 years	4 years	5 years	6 years	7 years				
1	64	44.9	100	139	2.1 [1.6, 2.6]	(3,080)	3.0 [2.5, 3.7]	(2,522)	3.6 [3.0, 4.3]	(2,128)	4.4 [3.7, 5.2]	(1,598)	4.5 [3.8, 5.4]	(965)
2	62	75.0	2	1	25.0 [3.9, 87.2]	(3)	25.0 [3.9, 87.2]	(3)	25.0 [3.9, 87.2]	(3)	25.0 [3.9, 87.2]	(3)	25.0 [3.9, 87.2]	(1)
3	63	33.3	2	1	33.3 [5.5, 94.6]	(2)	33.3 [5.5, 94.6]	(2)	33.3 [5.5, 94.6]	(2)	33.3 [5.5, 94.6]	(2)	33.3 [5.5, 94.6]	(2)
4	54	100.0	1	0	0	(1)	0	(1)					33.3 [5.5, 94.6]	(1)
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**EPRD Detail Report for
ZUK (K1.2 Tibial Tray Including Monobloc)**
Part II: Primary Procedures and Cumulative Revision Rates

Reasons for Revision for specific Implant Combinations											
Category	Number of Implantations	#Rev	Infection	Recurrent dislocation	Fracture	Malposition / Malalignment	Aseptic loosening	Wear	Other	Unknown	
1 UKA ZUK, ZUK, ZUK	3,836	139	21 (15.1%)	7 (5.0%)	6 (4.3%)	2 (1.4%)	24 (17.3%)	1 (0.7%)	38 (27.3%)	40 (28.8%)	
2 PFA ZUK, ZUK, <from another company>, <from another company>	4	1	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	
3 ??? ZUK, ZUK, ZUK	3	1	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	
4 PFA ZUK, ZUK, <from another company>	1	0									
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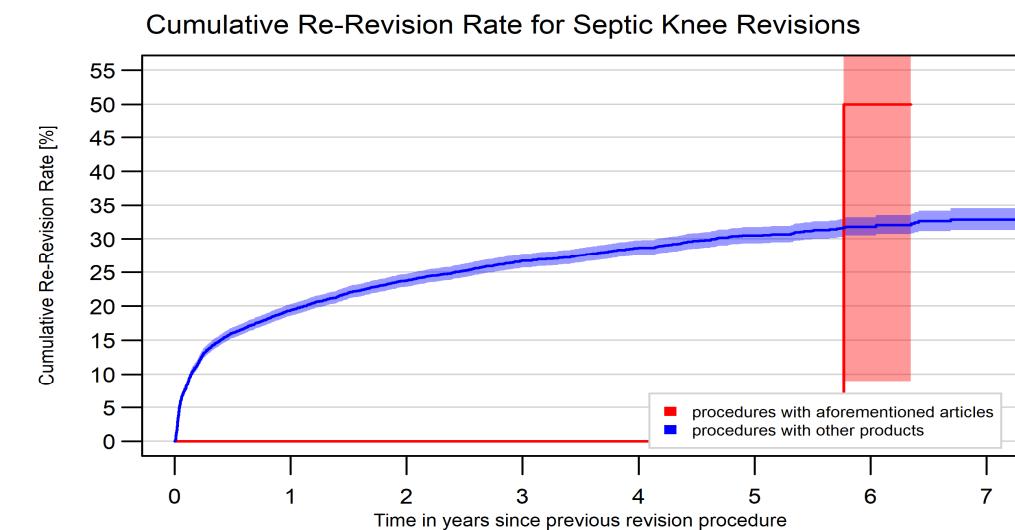
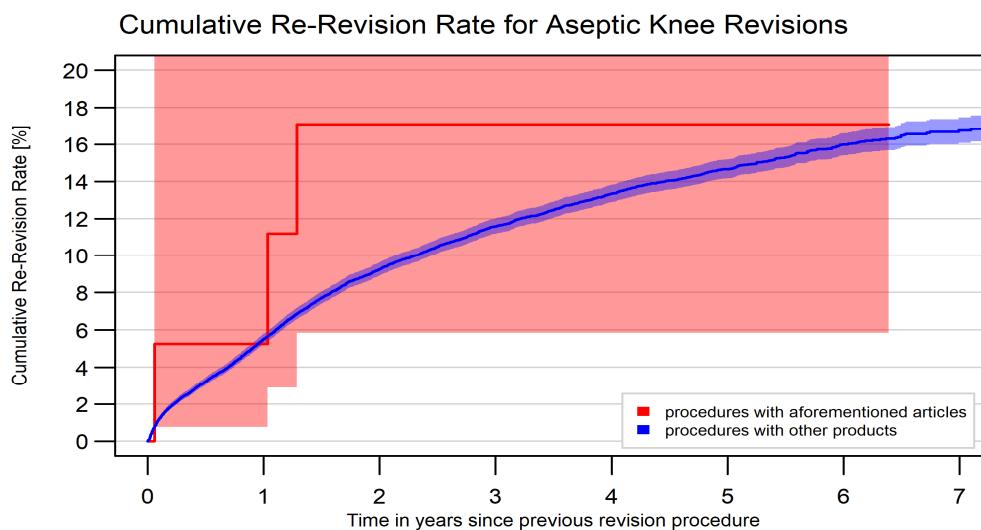
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**EPRD Detail Report for
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Part III: Revision Procedures and Cumulative Re-Revision Rates**

Data Overview Revision Procedures		n	Age			BMI			#Deaths	#Rev	Follow-Up (years)		Procedures from	
Category	Procedures with ...		Median	Range	%Male	Median	Range	%V	#Centres		Median	Range		
OVERALL	aforementioned articles	22	58.5	[54; 66]	50.0	32.5	[26.6; 35.4]	55	7	0	4	3.6	[1.3, 6.1]	11/15-11/21
Aseptic Knee Revisions	aforementioned articles	20	59	[54; 67]	45.0	32.5	[26.6; 35.4]	60	7	0	3	2.9	[1.2, 6.1]	11/15-11/21
Aseptic Knee Revisions	other products	29,628	70	[61; 77]	33.2	30.1	[26.7; 34.5]	67	672	2,368	3,240	2.8	[1.2, 4.6]	11/12-03/22
Septic Knee Revisions	aforementioned articles	2	53.5	[48; 59]	100.0			0	1	0	1	6.1	[5.8, 6.3]	11/15-04/16
Septic Knee Revisions	other products	8,785	72	[63; 78]	47.1	29.9	[26.2; 34.8]	68	599	1,410	2,169	1.9	[0.5, 3.8]	12/12-03/22

		Cumulative Re-Revision Rate in % after ...						
Category	Procedures with ...	1 year	2 years	3 years	4 years	5 years	6 years	7 years
OVERALL	aforementioned articles	4.8 [0.7, 29.3] (18)	15.3 [5.2, 40.5] (15)	15.3 [5.2, 40.5] (12)	15.3 [5.2, 40.5] (11)	15.3 [5.2, 40.5] (9)	25.9 [9.7, 58.6] (7)	
Aseptic Knee Revisions	aforementioned articles	5.3 [0.8, 31.9] (16)	17.1 [5.8, 44.3] (13)	17.1 [5.8, 44.3] (10)	17.1 [5.8, 44.3] (9)	17.1 [5.8, 44.3] (7)	17.1 [5.8, 44.3] (6)	
Aseptic Knee Revisions	other products	5.5 [5.3, 5.8] (23,529)	9.3 [8.9, 9.6] (18,389)	11.6 [11.2, 12.0] (13,656)	13.3 [12.9, 13.8] (9,540)	14.7 [14.2, 15.2] (5,876)	16.0 [15.4, 16.6] (2,912)	16.8 [16.1, 17.5] (1,100)
Septic Knee Revisions	aforementioned articles	0.0 [0.0, 0.0] (2)	0.0 [0.0, 0.0] (2)	0.0 [0.0, 0.0] (2)	0.0 [0.0, 0.0] (2)	0.0 [0.0, 0.0] (2)	50.0 [9.0, 99.4] (1)	
Septic Knee Revisions	other products	19.4 [18.6, 20.3] (5,709)	23.8 [22.8, 24.7] (4,256)	26.7 [25.7, 27.7] (2,996)	28.6 [27.6, 29.8] (1,965)	30.5 [29.3, 31.7] (1,137)	31.8 [30.5, 33.2] (538)	32.9 [31.3, 34.5] (174)

**EPRD Detail Report for
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Part III: Revision Procedures and Cumulative Re-Revision Rates



Number at Risk	20	16	13	10	9	7	6	0
■	29,628	23,529	18,389	13,656	9,540	5,876	2,912	1,100

Number at Risk	2	2	2	2	2	2	1	0
■	8,785	5,709	4,256	2,996	1,965	1,137	538	174

Reasons for Re-Revision		Infection	Recurrent dislocation	Peripr. Fracture	Malposition / Malalignment	Aseptic loosening	Wear	Other	Unknown
Category	Procedures with ...								
OVERALL	aforementioned articles	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)	2 (50.0%)
Aseptic Knee Revisions	aforementioned articles	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	2 (66.7%)
Aseptic Knee Revisions	other products	344 (10.6%)	247 (7.6%)	63 (1.9%)	52 (1.6%)	657 (20.3%)	69 (2.1%)	633 (19.5%)	1,175 (36.3%)
Septic Knee Revisions	aforementioned articles	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Septic Knee Revisions	other products	658 (30.3%)	32 (1.5%)	23 (1.1%)	9 (0.4%)	134 (6.2%)	12 (0.6%)	318 (14.7%)	983 (45.3%)

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Part III: Revision Procedures and Cumulative Re-Revision Rates

Specific Implant Combinations		Trademarks for ...				Number of Implantations
Category	Tibial Tray	Tibial Insert	Femoral Knee	Patellar Component		
1 Aseptic Knee Revisions	ZUK	ZUK				12
2 Aseptic Knee Revisions	ZUK	ZUK	ZUK			8
3 Septic Knee Revisions	ZUK	ZUK	ZUK			2
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Cumulative Re-Revision Rates for specific Implant Combinations in % after ...												
Age	%Male	#Centres	#Rev	1 year	2 years	3 years	4 years	5 years	6 years	7 years		
1	61	33.3	5	3	8.3 [1.2, 46.1]	(9)	28.7 [10.2, 65.6]	(6)	28.7 [10.2, 65.6]	(4)	28.7 [10.2, 65.6]	(3)
2	53.5	62.5	4	0	0	(7)	0	(7)	0	(6)	0	(5)
3	53.5	100.0	1	1	0	(2)	0	(2)	0	(2)	0	(2)
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