

**Zimmer, Inc.**

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Dear Doctor:

You may have encountered recent advertisements by plaintiff attorneys soliciting potential clients for legal action involving an alleged recall of products in the *Zimmer® NexGen®* family. Many of these advertisements presumably have been inspired by media coverage describing the negative experience of a single surgeon using the *NexGen CR-Flex Porous Femoral Component*.

It is important to note that the FDA has never ordered a recall on any of the *NexGen* family of products, generally, or the *NexGen CR-Flex* system, in particular. Contrary to the claims made in the advertisements, the *NexGen* family of products remains the world's most trusted, most widely used, most studied, and most clinically proven knee system.

The negative experience that was reported last year is isolated to the *NexGen CR-Flex Porous* femur, which is used in less than 4% of all cases. We have not received reports of this experience from any other surgeon or site. In fact, the Australian Registry shows substantially similar, and best-in-class, performance for all *NexGen* knee systems. The attached recent clinical and national joint replacement registry data details the outstanding performance of the *NexGen* family.

We recognize that these media stories and plaintiff attorney solicitations are disruptive to your practice, and can be disturbing to patients who have undergone, or are considering undergoing joint replacement surgery. In turn, you are likely faced with having to address patient concerns, amidst your already busy schedule. Please accept our apologies and know we are committed to providing any support you require. The attached *Patient Information Letter* is intended for use by you and your staff. It includes essential facts about the safety and efficacy of total joint replacement surgery, and the outstanding clinical history and consistent performance of the *Zimmer NexGen* family of products.

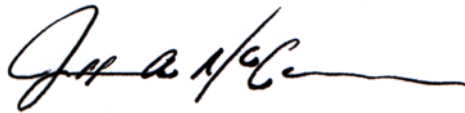
We recognize there is nothing more important than the conversation between a surgeon and your patient. We hope the attached information will facilitate your discussion with patients who have been negatively influenced by these solicitations. As always, our Consumer Call Center is available for your patients (1-877-946-2761 or [CRM@zimmer.com](mailto:CRM@zimmer.com)) to answer any product or issue related questions they might have.

Please also know that we are taking every legal action possible to combat the misleading and false claims made by the plaintiff attorneys, including sending cease and desist letters, and pursuing litigation where warranted.

Thank you for your ongoing support and confidence in Zimmer and our *NexGen* brand. Your confidence in the number one selling knee system in the world is well placed. Together, we have the best clinical results in the world.

We are eager to help you address any concerns that your patients may have regarding the performance of these products. We hope our actions to this end are effective, but please do not hesitate to contact me or your local sales personnel, if there is anything more we can do to support you or your practice.

Regards,

A handwritten signature in black ink, appearing to read "Jeffery A. McCaulley". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Jeffery A. McCaulley  
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Attachments:

- Joint Registry Data
- Bibliography *Zimmer® NexGen®*
- Patient Information Letter



## **National Joint Replacement Registry Data**

Provided by the *Zimmer® NexGen®* Knee Replacement System

At Zimmer, we have been working for decades to earn your trust. Our goal is to provide you with implant and surgical instrument design that streamlines your surgical technique, optimizes intraoperative flexibility, and provides excellent clinical results for your patients.

Zimmer's ongoing surgeon surveys have indicated that you place an important value on long term clinical results. The *NexGen* knee system has excellent outcomes in three of the most highly regarded national joint registries, and remains the number one preferred knee system in the world.

A summary of the most recent published registry results is attached for your reference. Overall, we conclude that when looking at large sample sizes of knee replacement products that have been tracked in patients over many years, the consistent and top performing results of the *Zimmer NexGen* Knee System, as reported in the three major registries, should reinforce your confidence in using *NexGen* in your patients.

If you have questions, or want more data about the proven clinical history of the *Zimmer® NexGen®* Knee System, please call 1-888-743-6563, or email [CRM@zimmer.com](mailto:CRM@zimmer.com).

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**Australian Orthopaedic Association National Joint Replacement Registry 2010. Annual report.  
Adelaide: AOA; 2010; Table KT30, pg 123**

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Zimmer's NexGen® CR-Flex cementless total knee arthroplasty (TKA) components recorded the lowest revision rate (reported as revisions per 100 observed component years) of all major cementless TKA systems utilized in the market (0.56 revisions per 100 observed component years). A revision rate of 0.43 per 100 observed component years was recorded for the NexGen CR Knee, and a revision rate of 0.56 per 100 observed component years was recorded for the NexGen CR-Flex.

Table KT30: Revision Rates of Primary Total Knee Replacement with Cementless Fixation

Femoral Component	Tibial Component	N Revised	N Total	Obs. Years	Revisions/100 Obs. Yrs (95% CI)
Active Knee	Active Knee	112	3181	12461	0.90 (0.74, 1.08)
Advance	Advance	19	346	1676	1.13 (0.68, 1.77)
Advantim	Advantim	9	751	3402	0.26 (0.12, 0.50)
Columbus	Columbus	13	335	607	2.14 (1.14, 3.66)
Duracon	Duracon	104	3441	15931	0.65 (0.53, 0.79)
Genesis II	Genesis II	17	325	691	2.46 (1.43, 3.94)
Genesis II	Mobile Bearing Knee	16	475	3083	0.52 (0.30, 0.84)
LCS	LCS	116	2314	10211	0.74 (0.61, 0.89)
LCS	MBT	399	14110	46115	0.87 (0.78, 0.95)
Maxim	Maxim	21	603	3758	0.56 (0.35, 0.85)
Natural Knee II	Natural Knee	49	906	5218	0.94 (0.69, 1.24)
Natural Knee II	Natural Knee II	55	1590	7051	0.78 (0.59, 1.02)
Nexgen CR	Nexgen	84	3514	19571	0.43 (0.34, 0.53)
Nexgen CR Flex	Nexgen	65	4950	11615	0.56 (0.43, 0.71)
Nexgen LPS	Nexgen	12	483	887	1.35 (0.70, 2.36)
PFC Sigma	AMK	22	1358	5086	0.43 (0.27, 0.65)
PFC Sigma	MBT	78	1767	5471	1.43 (1.13, 1.78)
Profix	Profix	44	1274	4884	0.90 (0.65, 1.21)
RBK	RBK	87	2969	9879	0.88 (0.71, 1.09)
Rocc	Rocc	10	357	829	1.21 (0.58, 2.22)
Rotaglide Plus	Rotaglide Plus	15	364	1968	0.76 (0.43, 1.26)
Score	Score	6	358	319	1.88 (0.69, 4.09)
Scorpio	Scorpio/Series 7000	151	3651	16005	0.94 (0.80, 1.11)
Scorpio NRG	Scorpio/Series 7000	10	960	1145	0.87 (0.42, 1.61)
Triathlon	Triathlon	31	2958	3905	0.79 (0.54, 1.13)
Vanguard	Maxim	6	357	822	0.73 (0.27, 1.59)
Other (46)		196	1614	5483	3.57 (3.09, 4.11)
<b>TOTAL</b>		<b>1747</b>	<b>55311</b>	<b>203582</b>	<b>0.86 (0.82, 0.90)</b>

Note: Only prostheses with over 300 procedures have been listed.

National Joint Registry for England and Wales, 7<sup>th</sup> Annual Report, Table 3.11, pg. 117

© National Joint Registry 2010

Zimmer® NexGen® is the second most used brand, and is among the top five least revised knee products.

**Table 3.11** Revision rates at three and five years according to the most frequently used brands for knee replacement procedures, undertaken between 1<sup>st</sup> April 2003 and 31<sup>st</sup> December 2009, which were linked to a HES/PPED website.

Brand	Number of patients	Revision rate at three years <sup>23</sup> (95%CI)	Revision rate at five years <sup>23</sup> (95% CI)
<b>Total knee</b>			
PFC Sigma	77,195	1.8% (1.7% to 1.9%)	2.4% (2.2% to 2.5%)
Nexgen	29,730	1.9% (1.5% to 2.1%)	2.6% (2.3% to 2.9%)
AGC	26,013	2.1% (1.9% to 2.3%)	3.0% (2.7% to 3.3%)
Scorpio	15,200	2.3% (2.1% to 2.6%)	3.3% (2.9% to 3.8%)
Genesis 2	10,886	2.1% (1.7% to 2.5%)	2.4% (2.0% to 2.9%)
Kinemax	7,702	2.7% (2.4% to 3.2%)	4.1% (3.6% to 4.7%)
LCS complete	7,375	2.2% (1.9% to 2.8%)	3.5% (2.8% to 4.2%)
Endoplus	7,041	2.1% (1.7% to 2.6%)	3.2% (2.5% to 4.2%)
Triathlon	5,354	1.0% (0.6% to 1.6%)	Insufficient follow up
Profix	3,359	2.5% (1.9% to 3.2%)	2.9% (2.2% to 3.7%)
Advanced	2,943	2.1% (1.5% to 2.8%)	2.9% (2.1% to 4.0%)
MRK	2,411	1.3% (0.8% to 2.2%)	1.6% (0.9% to 2.9%)
Vanguard	2,319	2.2% (1.4% to 3.7%)	Insufficient follow up
Insall – Burstein 2	2,227	2.5% (1.9% to 3.3%)	4.1% (3.2% to 5.3%)
LCS	1,687	2.5% (1.9% to 3.4%)	3.5% (2.7% to 4.5%)
Rotaglide +	1,497	3.4% (2.5% to 4.5%)	4.8% (3.7% to 6.3%)
Columbus	1,435	2.5% (1.6% to 4.0%)	2.5% (1.6% to 4.0%)
Maxim	1,395	2.7% (1.9% to 3.9%)	3.7% (2.5% to 5.4%)
NK2	1,330	1.7% (1.1% to 2.8%)	2.6% (1.6% to 4.2%)
<b>All</b>	<b>207,099</b>	<b>2.0% (2.0% to 2.1%)</b>	<b>2.8% (2.7% to 3.0%)</b>
<b>Patello-femoral</b>			
Avon	1,355	5.8% (4.4% to 7.7%)	10.2% (7.9% to 13.2%)
<b>Unicondylar</b>			
Oxford Partial Knee	11,936	6.3% (5.7% to 6.8%)	9.1% (8.3% to 10.0%)
MG Uni	1,746	4.8% (3.7% to 6.3%)	6.3% (4.6% to 8.4%)

## The Swedish Knee Arthroplasty Register, Annual Report 2010, pg. 30

© 2010 The Swedish Knee Arthroplasty Register

When compared to competitive knees with a sample size greater than 300, the Zimmer® NexGen® Knee System demonstrated the lowest relative rate of revision. It is highlighted in the registry as having a “Significant difference with lower risk ratio.”

The risk of revision (RR) with 95% confidence intervals. AGC is the reference in TKA and Link in UKA. The Cox regression adjusts for differences in gender, age and year of operation.

OA / TKA	n	p-value	RR	95% CI	RA / TKA	n	p-value	RR	95% CI
AGC	14,392		ref.		AGC	717		ref.	
F/S MIII	6,472	0.07	0.84	0.70-1.01	F/S MIII	338	0.37	0.69	0.31-1.55
PFC-Sigma	21,238	0.01	0.84	0.73-0.97	PFC-Sigma	822	0.29	0.71	0.38-1.32
Scan	667	0.11	1.35	0.93-1.95	Scan	147	0.17	1.72	0.79-3.74
Kinemax	1,371	<0.01	1.77	1.39-2.26	Kinemax	84	0.09	2.17	0.88-5.37
Duracon	7,518	0.86	0.98	0.83-1.17	Duracon	314	0.21	1.53	0.79-2.98
Profix	926	0.79	0.94	0.59-1.49	Profix	91	0.83	1.14	0.34-3.82
NexGen	14,440	<0.01	0.53	0.44-0.64	NexGen	361	0.03	0.2	0.05-0.87
LCS	269	0.08	0.42	0.16-1.12	LCS	22	0.98	<0.01	
Natural II	473	0.83	0.94	0.53-1.67	Natural II	17	0.43	2.25	0.30-16.96
PFC mob. bearing	509	0.72	1.11	0.63-1.93	PFC mob. bearing	17	0.36	2.59	0.34-19.74
Triathlon	1,198	0.16	0.6	0.30-1.22	Triathlon	17	0.99	<0.01	
Vanguard	924	0.06	1.63	0.98-2.71	Vanguard	49	0.22	2.58	0.56-11.84
Other	779	0.07	1.41	0.97-2.03	Other	131	0.86	0.9	0.27-2.98
Gender (male is ref.)		0.97	1	0.90-1.11	Gender (male is ref.)		0.33	1.31	0.76-2.25
Age (per year)		<0.01	0.96	0.96-0.97	Age (per year)		0.86	1	0.98-1.02
Year of op. (per year)		0.59	1.01	0.98-1.03	Year of op. (per year)		0.55	1.03	0.93-1.15

Implants lacking sufficient numbers for analysis

Significant difference with higher risk ratio.  
Significant difference with lower risk ratio.

## Literature References for the Zimmer® NexGen® Knee Replacement System

1. Barrington JW, Sah A, Malchau H, Burke DW. Contemporary cruciate-retaining total knee arthroplasty with a pegged tibial baseplate. Results at a minimum of ten years. *J Bone Joint Surg Am* 2009 April;91(4):874-8.  
**Abstract:** CONCLUSIONS: This study demonstrated excellent, durable clinical and radiographic results at a minimum of ten years after replacement with this cemented, modular, fixed-bearing, cruciate-retaining total knee prosthesis with a four-peg tibial baseplate. We believe that this design is an acceptable option for total knee arthroplasty.
2. Bertin KC. Cruciate-retaining total knee arthroplasty at 5 to 7 years follow-up. *Clin Orthop Relat Res* 2005 July;(436):177-83.  
**Abstract:** Cruciate-retaining total knee implants may improve postoperative function in total knee arthroplasty, but whether patients experience good restoration of kinematics, undue wear, or increased revision rates is debatable. I evaluated clinical results, radiographs, and survival rates of the NexGen posterior cruciate-retaining implant at 5-7 years follow-up in 251 knees (198 patients) in a prospective, consecutive total knee replacement series done from 1996-1997. A consistent improvement in knee scores and range of motion was observed from preoperative evaluation through 5 years follow-up. Alignment remained constant and knee stability did not deteriorate. Knee Society scores were good or excellent for 90% of patients. The average range of motion was 123 degrees, and 73% of patients achieved a mean range of motion of 116 degrees -130 degrees. Mean physical quality of life measures improved from preoperative evaluation to the last follow-up. There were no complete or progressive radiolucencies. Four screw radiolucencies had progressive increases in diameter. Survival of the implant at 7 years was more than 98%. The NexGen posterior cruciate-retaining implant provided satisfactory kinematic and clinical results with no substantive polyethylene wear.
3. Bozic KJ, Kinder J, Meneghini RM, Zurakowski D, Rosenberg AG, Galante JO. Implant survivorship and complication rates after total knee arthroplasty with a third-generation cemented system: 5 to 8 years followup. *Clin Orthop Relat Res* 2005 January;(430):117-24.  
**Abstract:** We evaluated implant survivorship, reoperation rates, and complication rates of a group of patients who had total knee arthroplasty with a third-generation cemented prosthetic device using cruciate-retaining and posterior-stabilized designs at 5 to 8 years followup. Three hundred thirty-four consecutive primary total knee arthroplasties (186 cruciate retaining and 148 posterior stabilized) were done in 287 patients at our institution during a 2-year period. Kaplan Meier survivorship using revision for any reason and revision for aseptic loosening as endpoints were 95.9% and 99.5% respectively at 8 years. Nine patients (four with cruciate-retaining total knee arthroplasties, five with posterior-stabilized total knee arthroplasties; 3.1%) had reoperations for any reason. No patients had reoperation for problems related to the patellofemoral joint. Thirty-two patients (11.1%) had intraoperative or postoperative complications. There were no differences in any of the outcomes analyzed between patients who had cruciate-retaining or posterior-stabilized total knee replacements. Our results show that with appropriate patient selection and meticulous attention to surgical technique, excellent clinical and radiographic results can be achieved with a third-generation total knee arthroplasty system at intermediate followup.
4. Anthony S. Unger, MD, and John P. Duggan, MD. Midterm Results of a Porous Tantalum Monoblock Tibia Component: Clinical and Radiographic Results of 108 Knees Original Research Article. *The Journal of Arthroplasty*, 29 October 2010.  
**Abstract:** The use of Trabecular Metal (TM), a biomaterial manufactured from elemental tantalum metal, has recently increased in orthopedics. One hundred eight consecutive TM monoblock tibias were implanted in 95 patients and followed for a minimum of 2 years. The average follow-up was 4.5 years. The average age was 65 years. The Knee Society score of 36 improved to 89. One hundred five of the knees were rated good/excellent, and 3 knees were rated poor. Two patellar revisions were

performed for loose components and one for patellar misalignment. One patella fracture required open reduction and internal fixation. One femur was revised. There were no tibia revisions. There were no progressive radiographic lucencies. Midterm clinical and radiographic results of 108 consecutive TM tibia components have a high rate of success.

5. Gao F, Henricson A, Nilsson KG. Cemented versus uncemented fixation of the femoral component of the NexGen CR total knee replacement in patients younger than 60 years: a prospective randomised controlled RSA study. *Knee* 2009 June;16(3):200-6.  
**Abstract:** The optimal mode of femoral fixation in total knee arthroplasty (TKA) remains controversial, especially for the young patient. In a prospective randomised study we compared the magnitude and pattern of the fixation of cemented versus uncemented femoral components during 2 years in patients younger than 60 years. Forty-one knees in 41 patients were randomised to receive a NexGen (Zimmer, Warsaw, USA) cruciate-retaining TKA with either a cemented or an uncemented non HA-coated femoral component. The patients were examined by radiostereometric analysis (RSA), as well as clinical and radiological evaluation. The magnitude and pattern of migration as measured by RSA did not differ significantly between the cemented and uncemented fixation during the 2-year follow-up, nor were there any differences between the groups in clinical parameters. These findings suggest that an uncemented and non HA-coated femoral component may behave equally as well as a cemented one in the long-term
6. Kubiak P, Archibeck MJ, White RE, Jr. Cruciate-retaining total knee arthroplasty in patients with at least fifteen degrees of coronal plane deformity. *J Arthroplasty* 2008 April;23(3):366-70.  
**Abstract:** There has been debate regarding the superiority of posterior stabilized (PS) or cruciate-retaining knee designs in total knee arthroplasty (TKA). The proponents of PS TKA argue that a relative contraindication to the use of cruciate-retaining total knee arthroplasty is that of significant coronal plane deformity. The purpose of this study is to compare our minimum 10-year results of posterior cruciate ligament-retaining TKAs in patients with preoperative coronal plane deformity of at least 15 degrees ( $>$  or  $=$ 10 degrees of varus or  $>$  or  $=$ 20 degrees of valgus) to historical results of PS TKA designs in similar patients. We found, at a minimum 10-year follow-up, very good results with a 93% (95% confidence interval, 87%-98%) revision-free survivorship at 10 years and no revisions for instability or loosening
7. Nicoll D, Rowley DI. Internal rotational error of the tibial component is a major cause of pain after total knee replacement. *J Bone Joint Surg Br* 2010 September;92(9):1238-44.  
**Abstract:** This study used CT analysis to determine the rotational alignment of 39 painful and 26 painless fixed-bearing total knee replacements (TKRs) from a cohort of 740 NexGen Legacy posterior-stabilised and cruciate-retaining prostheses implanted between May 1996 and August 2003. The mean rotation of the tibial component was 4.3 degrees of internal rotation (25.4 degrees internal to 13.9 degrees external rotation) in the painful group and 2.2 degrees of external rotation (8.5 degrees internal to 18.2 degrees external rotation) in the painfree group ( $p = 0.024$ ). In the painful group 17 tibial components were internally rotated more than 9 degrees compared with none in the painfree group ( $p < 0.001$ ). Additionally, six femoral components in the painful group were internally rotated more than 6 degrees compared with none in the painfree group ( $p = 0.017$ ). External rotational errors were not found to be associated with pain. Overall, 22 (56.4%) of the painful TKRs had internal rotational errors involving the femoral, the tibial or both components. It is estimated that at least 4.6% of all our TKRs have been implanted with significant internal rotational errors
8. Sharma A, Komistek RD, Scuderi GR, Cates HE, Jr. High-flexion TKA designs: what are their in vivo contact mechanics? *Clin Orthop Relat Res* 2007 November;464:117-26.:117-26.  
**Abstract:** To accommodate for high flexion, new total knee arthroplasties (TKAs) have been designed. Unlike older designs which have been found to exhibit decreasing contact area with increasing flexion, we hypothesized the new designs would be associated with improved contact mechanics. We compared in vivo contact mechanics for 10 subjects having a fixed-bearing high-flexion posterior-stabilized (LPS-Flex) TKA and 10 subjects having a fixed-bearing high-flexion posterior cruciate-retaining (CR-Flex) TKA. All subjects performed deep knee bends to maximum

flexion while under fluoroscopic surveillance. In vivo kinematics obtained using a three-dimensional to two-dimensional registration technique, were input into a three-dimensional inverse dynamic mathematical model to determine the contact forces. The contact areas and contact stresses were determined using a deformable contact model. The contact forces, contact areas, and contact stresses in both these implants increased with increasing flexion. The medial contact area in the LPS-Flex was higher than the CR-Flex for most of the flexion cycle. The lateral contact area was higher in the CR-Flex than the LPS-Flex in early and midflexion ranges. Although the lateral contact stresses were similar in both implants, the CR-Flex experienced higher medial contact stress than the LPS-Flex throughout flexion. However, both these implants were able to maintain sufficient contact area so the contact stress values were well below the yield strength of crosslinked polyethylene

9. Sharma A, Leszko F, Komistek RD, Scuderi GR, Cates HE, Jr., Liu F. In vivo patellofemoral forces in high flexion total knee arthroplasty. *J Biomech* 2008;41(3):642-8.  
**Abstract:** This study compares the in vivo patellofemoral contact forces generated in high flexion fixed bearing posterior cruciate retaining Nexgen CR-Flex (PCR) and high flexion posterior stabilized Nexgen LPS-Flex (LPS) TKAs with that of normal knees from full knee extension to maximum weight bearing flexion. Ten patients with the PCR total knee arthroplasty (TKA), ten with the LPS TKA and seven patients having normal knees were fluoroscoped while performing a deep knee bend activity. In vivo femorotibial kinematics, obtained from 3D-to-2D registration technique, and patellar kinematics obtained by direct measurements from the fluoroscopic images were entered into a 3D inverse dynamics mathematical model to determine the in vivo contact forces at the knee. The variation in the patellofemoral and quadriceps forces with flexion were found to be similar across the three groups-increasing from full extension to 90 degrees of flexion, reaching a maximum between 90 degrees and 120 degrees of flexion and then decreasing until maximum flexion. At maximum knee flexion, these forces were found to be significantly lower in the normal knees than in the TKAs. The patellar ligament to quadriceps force ratio decreased with the increase in knee flexion while the patellofemoral to quadriceps force ratio increased. A strong correlation was found to exist between the patellofemoral forces, the femorotibial contact forces and the forces in the extensor mechanism. The PCR TKA in this study exhibited greater resemblance to the normal patients with respect to the patellofemoral forces than the LPS TKA though significant differences in the two implant types were not observed
  
10. Suggs JF, Kwon YM, Durbhakula SM, Hanson GR, Li G. In vivo flexion and kinematics of the knee after TKA: comparison of a conventional and a high flexion cruciate-retaining TKA design. *Knee Surg Sports Traumatol Arthrosc* 2009 February;17(2):150-6.  
**Abstract:** This study investigated the in vivo 6DOF knee kinematics and tibiofemoral contact location after total knee arthroplasty using a conventional and a high flexion cruciate retaining component (15 NexGen CR, 11 NexGen CR-Flex). Each patient performed a single-leg lunge while being imaged by a dual fluoroscopic imaging system. Data were analyzed at hyperextension, 0 degrees to 90 degrees in 15 degrees intervals, and at maximum flexion. The average maximum weight-bearing flexion for all the CR patients was 110.1 degrees +/- 13.4 degrees , and for all the CR-Flex patients was 108.2 degrees +/- 13.2 degrees . No difference was seen in the maximum flexion achieved by the patients, and the kinematics demonstrated by the groups was similar. However, at high flexion, the tibiofemoral articulating surfaces were more conforming in the CR-Flex design than the CR design, suggesting that the use of the high flexion component improved the tibiofemoral contact environment at high flexion in patients who could achieve high flexion
  
11. Tanzer M, Smith K, Burnett S. Posterior-stabilized versus cruciate-retaining total knee arthroplasty: balancing the gap. *J Arthroplasty* 2002 October;17(7):813-9.  
**Abstract:** A prospective, randomized, double-blind trial was carried out to compare cruciate-retaining (CR) and posterior-stabilized (PS) total knee arthroplasties (TKAs). A total of 40 knees were randomized to receive either a NexGen CR (Zimmer, Warsaw, IN) or a Legacy PS (Zimmer, Warsaw, IN) TKA. All knees were implanted with identical surgical technique, making sure to balance precisely

the flexion-extension gaps before implantation of the components. At 2-year follow-up, there was no difference between the CR and the PS TKAs with respect to their Knee Society clinical, functional, and radiographic scores. These findings suggest that with careful attention to surgical technique and balancing the knee, orthopaedic surgeons should expect similar results whether they use a CR or PS TKA.

12. Watanabe T, Tomita T, Fujii M, Hashimoto J, Sugamoto K, Yoshikawa H. Comparison between mobile-bearing and fixed-bearing knees in bilateral total knee replacements. *Int Orthop* 2005 June; 29(3):179-81.

**Abstract:** The purpose of this study was to compare mid-term results of mobile-bearing and fixed-bearing in bilateral total knee arthroplasty (TKA). Twenty-two patients underwent bilateral TKA with a mobile-bearing prosthesis (Rotaglide, Corin, UK) on one side and a fixed-bearing prosthesis (NexGen-CR, Zimmer, USA) on the other. There were 21 female patients, and in 18 patients, the diagnosis was rheumatoid arthritis. The average age was 59.6 (35-78) years. In all procedures, the posterior cruciate ligament was retained and patella re-surfaced. The average follow-up in the mobile-bearing group was 98 (79-107) months and 96 (79-107) months in the fixed-bearing group. At the final follow-up, the knee score was 91.8 points and 91.1 points, respectively, and the function score 65.5 points. The range of motion was similar in the two groups (1.1-106.9 degrees; 0.4-106.9 degrees). Five patients favoured the fixed-bearing prosthesis, but 16 found no difference. In patients with bilateral TKA, there was no difference in the short-term result between mobile-bearing and fixed-bearing prostheses.

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January 2011

## **The *Zimmer® NexGen®* Knee Replacement System is the world's most clinically proven knee system**

Zimmer is a pioneer and leader in providing knee replacement solutions that alleviate pain, restore mobility and improve the quality of life for patients. As the world's leading manufacturer of knee replacement products, we have a responsibility to our patients to not only ensure that our products are safe and effective, but also, to correct inaccurate information about our products that may have reached patients like you.

Recently, you may have seen television and internet advertisements being run by plaintiff law firms about alleged recalls of *Zimmer NexGen* knee products. Many of these ads are misleading, and some are deliberately wrong.

The FDA has never ordered a recall on any of the *Zimmer NexGen* knee replacement products. We believe these attorneys are causing undue concern about our product in hopes of making money, without regard for the truth, or your safety. It is common practice for these law firms to intentionally manipulate information to create fear and uncertainty. Their presentation is aggressive and convincing, even citing reports and surgeon experience, but none of it in a fair, balanced, truthful manner.

If you receive an unexpected call from an attorney about "Zimmer knees," or have questions based on these advertisements, please contact us so we can provide you with the facts.

The truth is the *Zimmer NexGen* Knee Replacement System is the most clinically proven and trusted knee replacement system in the world. It is chosen by more surgeons for their patients, every day, than any other knee replacement system in the world. Whether you already have had a knee replaced, or are considering knee replacement, you should feel confident that joint replacement surgery is one of the most successful surgical interventions available. Having the facts about knee replacement and a conversation with your doctor will go a long way to renewing your life.

### **What to Know About Knee Replacement and the *Zimmer NexGen* Knee System**

- In the U.S. alone, more than 500,000 knee replacement surgeries are conducted every year and patients report improved pain relief, knee function and overall quality of life.

- When considering joint replacement surgery, you and your doctor can select an implant system that is best suited to your gender, physical activity and lifestyle situation. *Zimmer NexGen* has the most comprehensive line of products available to orthopedic surgeons helping them to personalize a solution for you.
- In independent “joint replacement registries,” that compare how knee systems perform in patients over time, *Zimmer NexGen* Knee Replacement products are among the best, and usually *the* best performing of all major knee replacement systems. That’s why they have become one of the most trusted and widely used implant systems around the world.
  - According to the *2010 Australian Orthopaedic Association National Joint Replacement Registry* report, the *NexGen CR* and *NexGen CR-Flex Porous Femoral* components remain among the least revised of all major knee systems in the industry.
  - In the *Swedish Knee Arthroplasty Register*, the *NexGen* Knee System has the lowest relative risk of revision when compared to competitive knee systems.

The Australian and Swedish joint registries are the most comprehensive, and often cited in comparing the performance of knee replacement systems over time.

Zimmer is extremely proud of the performance of the *NexGen* Family of products. It is because of this performance over decades of use that more surgeons trust Zimmer for their patients than any other knee system.

If you have any questions about claims made in misleading legal advertisements, or want to learn more about Zimmer joint replacements call toll-free, 1-888-743-6563, email us, [Consumer@zimmer.com](mailto:Consumer@zimmer.com) or visit [www.Zimmer.com](http://www.Zimmer.com).