March 16, 2012

To: **Surgeons using the *NexGen*® Cruciate Retaining (CR) Micro Articular Surface Components**

Subject: **URGENT CORRECTIVE ACTION NOTICE**

Affected Products: See attached list (Tables 1 & 2)

ZIMMER *NEXGEN* CRUCIATE RETAINING (CR) MICRO ARTICULAR SURFACE COMPONENTS

Dear Surgeon:

The purpose of this notification is to inform you of an implant component compatibility issue with the *NexGen* Cruciate Retaining (CR) Complete Knee System, how to prevent the issue, and what to do with patients who may have been implanted with an incompatible component combination.

Zimmer has received complaints where a *NexGen* CR **micro** articular surface was used with a **standard** CR femur, even though the compatibility chart indicates that these combinations are NOT approved. CR **micro** articular surfaces are used in approximately 2.2% of all *NexGen* CR procedures. It is believed that a CR micro articular surface and standard femoral component combination may have been used in some of those procedures. It is important to note, however, that there have been no reported failures due to this situation.

You are receiving this letter as a user of the NexGen CR System to ensure you refer to the compatibility chart and labeling and to make certain you are aware of the correct use combinations of CR **micro** articular surfaces with **standard** CR femoral components. The part numbers of the CR micro articular surfaces are listed on the last pages of this document (Tables 1 and 2). It is important to conform to the *NexGen* compatibility chart and package labeling for all combinations of available femoral components, tibial components and polyethylene articular surfaces for the *NexGen* CR implant system. The compatibility chart and labeling correctly reflects the approved combinations of available femoral components, tibial components, and polyethylene articular surfaces for the *NexGen* CR implant system. Please refer to the attached *NexGen CR* Compatibility Chart (Figure 1) for detailed information. The following is a summary of certain key information contained in that chart:

- Solid purple CR articular surfaces should not be used with standard CR femurs.
- Solid purple CR articular surfaces should only be used with A-B **Micro** Femurs that are compatible with 1-2 Tibias.
- Striped yellow CR articular surfaces should not be used with standard CR femurs.
- Striped yellow CR articular surfaces should only be used with A-B **Micro** Femurs that are compatible with 3-4 Tibias.
- Outside US micro femurs may be available in sizes C-E- thus micro articular surfaces may be used with **micro** surfaces A through E

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zimmer Confidence in your hands®

NexGen Knee
Cruciate Retaining CR/CRA and CR-Flex Fixed

NexGen® Complete Knee Solution

		Femoral Size							
		A** MICRO	B MICRO	C	D	E	F	G	H**
Tibial Size	1-2	AB/1-2 SOLID PURPLE		CDEFGH/1-2 STRIPED PURPLE					
	3-4	AB/3-4 STRIPED YELLOW		CDEFGH/3-4 SOLID YELLOW					
	5-6	AB/5-6† STRIPED GREEN		CDEFGH/5-6 SOLID GREEN					
	7-10			CDEFGH/7-10 SOLID BLUE					
Patella Size		Use micro size patellas with A-B micro size femoral components*				26mm (inset only) 29mm	32mm 35mm		
		Use standard size patellas with C-H standard femoral components				26mm (inset only) 29mm	32mm 35mm	38mm 41mm	

* Do not use standard size patellas with A-B micro size femoral components.
** CR only
† Japan only

Figure 1: *NexGen* CR Compatibility Chart

The approved combinations are driven by differences in the condylar bearing spaces. The standard CR femur and articular surfaces have a condylar bearing space of 44 mm, while the CR micro femur and articular surfaces have a condylar bearing space of 36 mm.

Risks

An incompatible combination of articular surface and standard femoral component may lead to higher contact stresses at the medial and lateral edges of the articular surface. Therefore, Zimmer has determined that using standard and micro components in an incompatible combination could potentially lead to the following risks:

- The immediate risk could be that the knee cannot be properly balanced, thereby potentially leading to long term pain and instability.
- The long term risk of using a micro articular surface with a standard size femoral component could be increased wear of the polyethylene which may lead to pain, osteolysis, tibial loosening, instability, and revision surgery.

Edge Loading Analysis

Loading at the edge of the tibial polyethylene surface condition is much more prevalent in size combinations where the femoral component overhangs the articular surface. As the tibial plate and articular surface size increases, the amount of femoral component overhang decreases and loading at the edge of the tibial polyethylene surface is much less likely to occur. For example, the size E

standard CR femoral component overhangs the purple (Tibial 1, 2) micro articular surfaces by 7 mm (0.276") on each side of the polyethylene. The femoral component overhangs the striped yellow (Tibial 3, 4) articular surfaces by 3 mm (.116") per side. The size C standard CR femoral component only overhangs the purple micro articular surfaces by 3 mm (.118") per side and does not overhang the striped yellow articular surfaces. Thus, edge loading with a size C femoral and striped yellow articular surface is unlikely to occur. (See Appendix 1).

In general, patients receiving a size 1 or 2 tibial plate are lighter in weight and thus would be expected to place lower loads on the implant, lessening the risk of increased wear or fracture. This may minimize the potential complications due to loading at the edge of the tibial polyethylene surface in this patient group.

Frequently Asked Questions

What should I tell my patients?

- It is at the surgeon's discretion whether a patient should be called back to the clinic for examination and radiographic review to determine if there is any related problem. If the surgeon decides to call back a patient, the patient can be informed of the potential complications and advised of the need for annual physical examination and radiographs.

Do patients already implanted with an incompatible component combination require revision?

- It is at the discretion of the surgeon regarding any patient care. Zimmer recommends that the surgeon continue with their normal post-operative follow-up and monitor the patient, especially if they present with pain more than three months after the surgery took place. Zimmer does not want to unnecessarily alarm patients especially if they have a perfectly functioning implant and are not experiencing pain. Again, it is important to note that there have been no reported long-term failures due to the incompatible combination of standard and micro components.

Is there information available to me or my patients from Zimmer?

- A call support team is ready and equipped to handle your call; the contact number is [national country contact]

Why are you emphasizing the use of the Compatibility Chart?

- Zimmer received reports describing the use of incompatible combinations of its *NexGen* Cruciate Retaining (CR) Micro Articular Surface components. Because of these incidents, we want to answer any questions and prevent any possible future occurrences.

Is the current labeling correct?

- Yes, the compatibility chart and package labeling reflects the approved combinations of available femoral components, tibial components, and poly articular surfaces for the *NexGen* CR implant system.

Your Responsibilities

1. Review the attached Compatibility Chart and familiarize yourself with the appropriate component combinations.
2. Complete the acknowledgement certification and return to [national procedure – to national QA/RA Zimmer department]
3. For assistance, questions or assistance in notifying your accounts about this correction please contact Zimmer, National contact : sales rep / Marketing & product manager + contact number

This voluntary action will be reported to the U.S. Food and Drug Administration & International Competent Authorities. The FDA & Competent Authorities will also receive from Zimmer progress reports on the implementation of this recall. Your urgent cooperation is requested.

Vigilance Reporting: Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 6 to the local health authority in your country.

Product Scope

Table 1

Micro Articular Surfaces - Purple (Femur A,B - Tibia 1,2)			
Part Number	**Description**	**Part Number**	**Description**
00-5952-020-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 10mm Height	00-5972-020-09	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 9mm Height
00-5952-020-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 12mm Height	00-5972-020-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 10mm Height
00-5952-020-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 14mm Height	00-5972-020-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 12mm Height
00-5952-020-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 17mm Height	00-5972-020-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 14mm Height
00-5952-020-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 20mm Height	00-5972-020-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 17mm Height
90-5952-020-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 17mm Height	00-5972-020-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 20mm Height
90-5952-020-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 20mm Height	00-5976-020-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Purple 10mm Height
00-5970-020-09	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 9mm Height	00-5976-020-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Purple 12mm Height
00-5970-020-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 10mm Height	00-5976-020-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Purple 14mm Height
00-5970-020-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 12mm Height	00-5976-020-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Purple 17mm Height
00-5970-020-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 14mm Height	00-5976-020-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Purple 20mm Height
00-5970-020-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 17mm Height	00-5970-020-23	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 23mm Height
00-5970-020-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 20mm Height	00-5972-020-23	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple 23mm Height
90-5970-020-09	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 9mm Height	00-5976-020-23	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Purple 23mm Height
90-5970-020-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 10mm Height		
90-5970-020-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 12mm Height		
90-5970-020-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 14mm Height		
90-5970-020-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 17mm Height		
90-5970-020-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Purple/A-E Micro 20mm Height		

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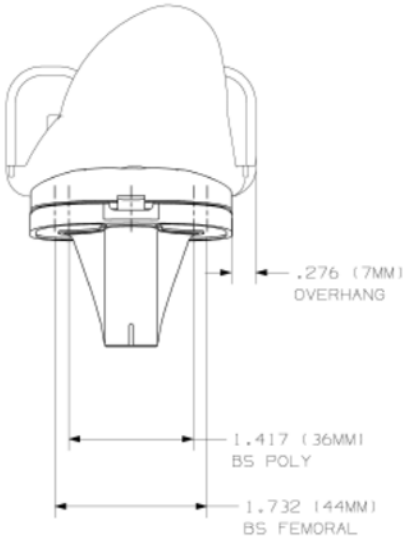
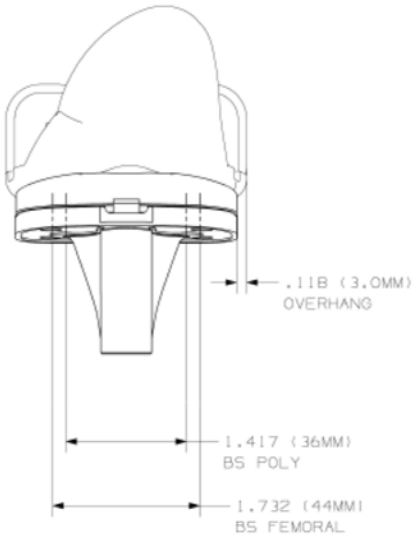
Table 2

Micro Articular Surfaces - Striped Yellow (Femur A,B - Tibia 3,4)			
Part Number	**Description**	**Part Number**	**Description**
00-5952-031-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 10mm Height	00-5972-031-09	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 9mm Height
00-5952-031-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 12mm Height	00-5972-031-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 10mm Height
00-5952-031-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 14mm Height	00-5972-031-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 12mm Height
00-5952-031-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 17mm Height	00-5972-031-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 14mm Height
00-5952-031-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 20mm Height	00-5972-031-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 17mm Height
90-5952-031-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 17mm Height	00-5972-031-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 20mm Height
90-5952-031-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 20mm Height	00-5976-031-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Striped Yellow 10mm Height
00-5970-031-09	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 9mm Height	00-5976-031-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Striped Yellow 12mm Height
00-5970-031-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 10mm Height	00-5976-031-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Striped Yellow 14mm Height
00-5970-031-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 12mm Height	00-5976-031-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Striped Yellow 17mm Height
00-5970-031-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 14mm Height	00-5976-031-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Striped Yellow 20mm Height
00-5970-031-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 17mm Height	00-5970-031-23	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 23mm Height
00-5970-031-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 20mm Height	00-5972-031-23	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow 23mm Height
90-5970-031-09	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 9mm Height	00-5976-031-23	NexGen Cruciate Retaining (CR) Micro Articular Surface – AC Size Striped Yellow 23mm Height
90-5970-031-10	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 10mm Height		
90-5970-031-12	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 12mm Height		
90-5970-031-14	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 14mm Height		
90-5970-031-17	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 17mm Height		
90-5970-031-20	NexGen Cruciate Retaining (CR) Micro Articular Surface – Size Striped Yellow/A-E Micro 20mm Height		

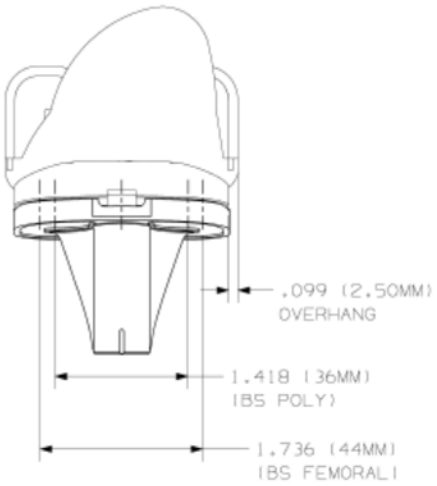
APPENDIX 1



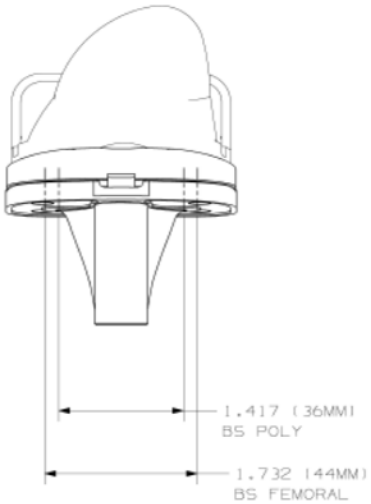
- Size E CR Femur
- Purple Micro Articular Surface



- Size E CR Femur
- Striped Yellow Micro Articular Surface



- Size C CR Femur
- Purple Micro Articular Surface



- Size C CR Femur
- Striped Yellow Micro Articular Surface

Layouts of Various Size Combinations for Standard CR Femoral Components and Micro CR Articular Surfaces

CERTIFICATE OF ACKNOWLEDGEMENT

By signing below, I acknowledge that I have received and understand the content of the letter subject to Zimmer Inc. Urgent Correction Notice for the NexGen® Cruciate Retaining (CR) Micro Articular Surface Compatibility

Printed Name_____ Signature_____

Date: ____/____/____

Hospital Name: _____

Hospital Address: _____

Complete and return to national QA/RA Zimmer department]