URGENTE: RICHIAMO DI DISPOSITIVO

NEXGEN ® COMPLETE KNEE SOLUTION ZIMMER MINIMALLY INVASIVE SOLUTIONS PROCEDURES TRABECULAR METAL ™ TECHNOLOGY TIBIAL TRAY FIXED BEARING, TAGLIA 8

8 dicembre 2009

DESTINATARI	Forza vendite di Zimmer, Inc. & Distributori	
PRODOTTO	**Nome del prodotto**	**Codice e numero di lotto**
	NEXGEN® COMPLETE KNEE SOLUTION ZIMMER MINAMILLY INVASIVE SOLUTIONS PROCEDURES TRABECULAR METAL ™ TECHNOLOGY TIBIAL TRAY FIXED BEARING	**Codice prodotto: 00-5954-057-02** **Numero di lotto: CFR di seguito**
MOTIVAZIONI DEL IL RICHIAMO	Zimmer , Inc, sta iniziando un richiamo volontario del prodotto *NexGen ® Complete Knee Solution Zimmer Minamilly Invasive Solutions Procedures Trabecular Metal ™ Technology Tibial Tray Fixed Bearing* (Codice 00-5954-057-02, lotti: CFR di seguito). Si sta intraprendendo questa azione a causa di un'indagine condotta da Zimmer Inc. Circa la robustezza del legame tra trabecular metal e sottostrato di titanio. *Figure 1: Sample Photograph Tibial Tray*	
IMPLICAZIONI CLINICHE (Rischio per la salute)	Come evidenziato dalle indagini condotte da Zimmer Inc, lo strato di trabecular metal potrebbe staccarsi dal sottostrato di titanio in alcuni punti del dispositivo affetto. Un paziente con un dispositivo affetto potrebbe provare dolore ed un certo grado di instabilità. I pazienti dovrebbero essere monitorati attraverso visite periodiche in ufficio per determinare qualsiasi necessità di intervento.	

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AZIONE	**Istruzioni per i distributori ed il personale vendita** **1. Localizzare ogni dispositivo inutilizzato e metterlo immediatamente in quarantena.** **2. Fare il conteggio fisico di tutti i prodotti coinvolti nel proprio paese e registrare tale dato sul modulo "Inventory Return Certification Form" incluso in questa lettera.** **3. Se il prodotto è stato impiantato, fornire il nome del chirurgo, l'ospedale e se possibile i dati del paziente.** **4. Inviare tramite FAX una copia del modulo "Inventory Return Certification form" ad uso interno a:** **Zimmer, Inc. al numero +1 (574) 371-8603** **5. Restituire i prodotti richiamati unitamente al modulo "Inventory Return Certification Form" presso:** **Zimmer Distribution Center** **Attn: Product Service** **1777 West Center Street** **Warsaw, IN 46580**
ALTRE INFORMAZIONI	Notifica di questo recall è inviata a tutti i clienti diretti coinvolti di Zimmer inc; Per assistenza alla spedizione, domande o assistenza nella notifica ai vostri clienti per quanto riguarda il richiamo contattare direttamene Zimmer,Inc al numero +1-800-613-6131. Zimmer Inc, si impegna a fornire ai suoi clienti il più alto livello di servizio e qualità del prodotto. Apprezziamo la vostra cooperazione e ci rammarichiamo per qualsiasi inconveniente questa azione possa causare al suo ospedale e al suo staff.
SEGNALAZIONE MEDWATCH	Qualsiasi reazione avversa sperimentata con l'uso di questi prodotti, e/o problemi relativi alla qualità può inoltre essere segnalato all' FDA's MedWatch Program telefonando al 1-800-FDA-1088, inviando un FAX al 1-800-FDA-0178, inviando una lettera MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, oppure sul sito MedWatch www.fda.gov/medwatch. In ottemperanza al Code of Federal Regulation 21 Parte 803, I fabbricanti sono inoltre tenuti a segnalare qualsiasi danno grave qualora il dispositivo medico vi abbia contribuito o potrebbe aver contribuito all'evento. Vi preghiamo di tenere Zimmer informata di qualsiasi evento avverso associato a questo dispositivo o a qualsiasi altro prodotto Zimmer.

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Item #	*Description*	*Lot #*
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	00111134
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60747593
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60747594
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60752676
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60752677
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60760248
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60768076
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60821507
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60824004
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60830411
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60830412
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60845351
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60850604
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60852670
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60852671
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60860895

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00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60866613
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60872311
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60879050
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60892605
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60900745
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60907449
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60917234
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60922494
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60938889
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60938890
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60947027
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60947028
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60963035
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60963036
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60963037
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60963039

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00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	60983254
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61015851
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61028168
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61033723
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61033724
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61068387
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61068388
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61068389
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61074754
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61074755
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61084771
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61096604
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61116246
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61116247
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61137056
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61143427

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00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61149041
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61157940
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61173295
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61193516
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61193520
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61198179
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61204038
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61215644
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61225562
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61235612
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61240323
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61248321
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61259184
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61263170
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61272449
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61280371

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00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61285508
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61298201
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61306497
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61315873
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61319581
00-5954-057-02	NexGen ® Complete Knee Solution Zimmer Minimally Invasive Solutions Procedures Trabecular Metal ™ Tibial Tray Fixed Bearing	61329266