Date: 21-05-2023
Reference Number: SG-2305-405-H

قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

رسالة سلامة

Safety Communication

To: Healthcare Provider	إلى: مقدمي الرعاية الصحية

Title	Potential of revision risk related to NexGen Stemmed Option Tibial Component with either LPS Flex or LPS Flex GSF Femoral Components	العنوان
Medical Device Description	NexGen Stemmed Option Tibial Component/ Knee Replacement Implants	اسم ووصف الجهاز/المستلزم الطبي
Manufacturer	Zimmer Biomet	اسم المصنع

Medical Devices Marketing Authorization (MDMA)	GHTF-2019-0978	إذن التسويق
Potential /Associated risks:	Long range health consequences (injuries or illness) that may result from use of or exposure to the product issue: - **Most Probable:** Patient may experience minor or moderate pain or ache, minor or moderate range of motion limitation, swelling or edema, minor or moderate tissue damage, and decreased joint function. - **Highest Severity:** Loss of fixation or non-integration and product failure occurs, such as tibial loosening, leading to surgical intervention. Revision TKR may result in major perioperative complications. Limb length discrepancy and moderate pain or ache, tissue damage and range of motion limitation may occur.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	- Remove the affected product from your facility. - For patients implanted with the NexGen Stemmed Option Tibial Component maintain an appropriate index of suspicion for patients with any new pain, inability to bear weight, swelling or instability of the knee. - For more information Link	التوصيات
For Reporting	SFDA 19999 مركز الاتصال الموحد · NCMDR · تيقظ Saudi Vigilance	للإبلاغ: