



27 mars 2014

**Destinataires :** Chirurgiens, responsables matério-vigilance, pharmaciens, personnel de bloc opératoire

**Objet :** **NOTIFICATION URGENTE DE RAPPEL D'UN DISPOSITIF MÉDICAL**

**Référence Zimmer :** 1822565-02-07-2014-001-C

**Produits concernés :** Implants en polyéthylène pour systèmes Gender Solutions® Natural-Knee® Flex, Natural-Knee®, Natural-Knee® II, MOST Options™ et Apollo™

Zimmer entreprend un processus de rappel volontaire d'un petit sous-ensemble de produits concernés à la suite d'une réclamation unique pour décoloration. Notre traçabilité nous indique que vous êtes utilisateur des produits concernés, qui ont été distribués entre le 31 octobre 2006 et le 31 janvier 2014.

Zimmer a reçu une réclamation unique pour décoloration d'un tibia congruent en polyéthylène *Natural-Knee® II*. Une enquête interne a permis de montrer que la décoloration était due à une oxydation résultant d'une exposition prolongée à la lumière artificielle après usinage par un fournisseur tiers et stockage préalable à la finition et au conditionnement stérile dans une installation de production de Zimmer. La majorité des implants en polyéthylène Zimmer sont usinés et moulés par nos soins, puis conditionnés dans un emballage stérile après finition. Ce défaut a été observé sur moins de 2 % seulement des produits concernés.

Grâce aux analyses menées, nous avons pu établir que les implants en polyéthylène exposés à la lumière artificielle pendant plus d'un an présentaient des indices d'oxydation accrus (bien que nettement inférieurs aux indices scientifiquement reconnus comme ayant un impact clinique), ainsi qu'une résistance à la rupture réduite. En conséquence, Zimmer rappelle volontairement tous les lots d'implants articulaires en polyéthylène qui ont été potentiellement exposés à la lumière artificielle avant stérilisation et finition pendant une période supérieure à un an.

Il est important de noter qu'aucune blessure liée à la décoloration ou à l'élévation de l'indice d'oxydation du produit concerné n'a été rapportée chez aucun patient.

Le processus de stockage a été modifié afin d'éviter que ce type d'incident ne se reproduise.

Les lots de fabrication concernés qui ont été produits avant cette modification sont répertoriés dans l'Annexe 1.

### Risques

- La détection d'une décoloration en peropératoire peut retarder l'intervention chirurgicale en raison de la nécessité de se procurer, puis de préparer un autre implant. Cependant, elle ne devrait entraîner aucune blessure ou maladie.
- Un implant en polyéthylène présentant un indice d'oxydation élevé pourrait se dégrader prématurément par rapport à un implant en polyéthylène ayant un indice d'oxydation normal. Cela est dû au risque d'augmentation de l'usure et du délaminage du polyéthylène, qui peut entraîner une ostéolyse et un descellement de l'implant. Il est probable que ce descellement donnerait lieu à une reprise chirurgicale.

### Vos responsabilités

1. Lisez attentivement la notification jointe et vérifiez bien que le personnel concerné en connaît le contenu.
2. Si vous identifiez un produit provenant de la liste figurant en Annexe 1, mettez-le immédiatement en quarantaine et informez Mme Nathalie Zimmer, responsable QA/RA Zimmer France, par retour de l'annexe II.



3. Retournez à Zimmer France les implants concernés ou prenez contact avec notre service clients afin de procéder au retour.
4. Dans le cas des patients déjà porteurs de ce produit, il est recommandé de poursuivre votre procédure de suivi postopératoire habituelle.
5. **Veillez contacter votre correspondant chez Zimmer si vous avez encore des questions ou des doutes après examen de cette notification.**

### **Informations de matériovigilance**

La Food and Drug Administration (FDA) des États-Unis ainsi que l'autorité compétente française, l'ANSM, sont informées de cette notification volontaire.

Conformément au MEDDEV 2.12-1 Rév. 8, il est indispensable de signaler toute réaction indésirable observée lors de l'utilisation des produits et/ou tout problème de qualité à l'autorité compétente française et/ou directement à Zimmer.

Veillez informer Zimmer de tout événement indésirable associé à ce dispositif ou à tout autre produit Zimmer. Pour rapporter des événements indésirables, contactez votre représentant Zimmer local ou directement le service qualité & affaires réglementaires de Zimmer France via l'adresse mail : [per.fr@zimmer.com](mailto:per.fr@zimmer.com).

Nous vous remercions d'avance pour votre collaboration.  
Meilleures salutations.

POUR LE FABRICANT :

Doña M. Reust  
Zimmer Warsaw

Pour ZIMMER FRANCE:

Nathalie ZIMMER  
Responsable qualité & affaires réglementaires



**ANNEXE 1**

<b>Article</b>	<b>Lot</b>	<b>Description générale</b>
502001016	60612572	MOST Options™ System (MOST) Tibia Insert
502001016	60687272	MOST Options™ System (MOST) Tibia Insert
502001016	60707884	MOST Options™ System (MOST) Tibia Insert
502001016	60812397	MOST Options™ System (MOST) Tibia Insert
502001016	60846427	MOST Options™ System (MOST) Tibia Insert
502001016	61047430	MOST Options™ System (MOST) Tibia Insert
502004006	60984403	MOST Options™ System (MOST) Tibia Insert
502004009	61188395	MOST Options™ System (MOST) Tibia Insert
502004016	61011775	MOST Options™ System (MOST) Tibia Insert
502010006	61930083	MOST Options™ System (MOST) Proximal Tibia Insert
00541800000	61460914	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61482392	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61485677	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61502813	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61507021	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61510762	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61516637	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61516638	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61516639	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61518651	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61518652	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61525153	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61528254	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61528255	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61528256	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61528257	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61530238	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61530239	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61570708	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61570709	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61570711	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61570712	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61570715	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61577049	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61577051	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61577053	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61581732	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61581733	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61581734	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61581737	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61581738	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61581742	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61592968	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component
00541800000	61592969	Gender Solutions® Natural-Knee® Flex System Metal Backed Patella Component







Article	Lot	Description générale
00591101128	61729684	Natural-Knee® II System All Poly Patella
00591101128	61840888	Natural-Knee® II System All Poly Patella
00591101137	61661494	Natural-Knee® II System All Poly Patella
611001009	60619111	Natural-Knee® II System Unicompartmental Tibia Inserter
611001009	60713065	Natural-Knee® II System Unicompartmental Tibia Inserter
611001009	60786858	Natural-Knee® II System Unicompartmental Tibia Inserter
611001009	60812384	Natural-Knee® II System Unicompartmental Tibia Inserter
611001009	60928258	Natural-Knee® II System Unicompartmental Tibia Inserter
611001011	61129248	Natural-Knee® II System Unicompartmental Tibia Inserter
611001011	61140472	Natural-Knee® II System Unicompartmental Tibia Inserter
611001011	61140475	Natural-Knee® II System Unicompartmental Tibia Inserter
611001011	61162218	Natural-Knee® II System Unicompartmental Tibia Inserter
611001013	61135505	Natural-Knee® II System Unicompartmental Tibia Inserter
611001013	61140487	Natural-Knee® II System Unicompartmental Tibia Inserter
611002009	61808358	Natural-Knee® II System Unicompartmental Tibia Inserter
611002009	61842970	Natural-Knee® II System Unicompartmental Tibia Inserter
611002009	61913067	Natural-Knee® II System Unicompartmental Tibia Inserter
611002009	62049519	Natural-Knee® II System Unicompartmental Tibia Inserter
611002009	62153667	Natural-Knee® II System Unicompartmental Tibia Inserter
611002011	60928262	Natural-Knee® II System Unicompartmental Tibia Inserter
611002011	60928263	Natural-Knee® II System Unicompartmental Tibia Inserter
611002011	60928264	Natural-Knee® II System Unicompartmental Tibia Inserter
611002011	60928265	Natural-Knee® II System Unicompartmental Tibia Inserter
611002011	61129245	Natural-Knee® II System Unicompartmental Tibia Inserter
611002013	61110613	Natural-Knee® II System Unicompartmental Tibia Inserter
611002013	61129246	Natural-Knee® II System Unicompartmental Tibia Inserter
611002013	61129247	Natural-Knee® II System Unicompartmental Tibia Inserter
611002013	61207467	Natural-Knee® II System Unicompartmental Tibia Inserter
611003009	60713069	Natural-Knee® II System Unicompartmental Tibia Inserter
611003009	60781677	Natural-Knee® II System Unicompartmental Tibia Inserter
611003009	60836175	Natural-Knee® II System Unicompartmental Tibia Inserter
611003009	60842071	Natural-Knee® II System Unicompartmental Tibia Inserter
611003009	60867881	Natural-Knee® II System Unicompartmental Tibia Inserter
611003009	60884719	Natural-Knee® II System Unicompartmental Tibia Inserter
611003009	60902204	Natural-Knee® II System Unicompartmental Tibia Inserter
611003009	60902206	Natural-Knee® II System Unicompartmental Tibia Inserter
611003011	61110614	Natural-Knee® II System Unicompartmental Tibia Inserter
611003011	61129243	Natural-Knee® II System Unicompartmental Tibia Inserter
611003011	61129244	Natural-Knee® II System Unicompartmental Tibia Inserter
611003011	61190236	Natural-Knee® II System Unicompartmental Tibia Inserter
611003013	61135503	Natural-Knee® II System Unicompartmental Tibia Inserter
611003013	61135504	Natural-Knee® II System Unicompartmental Tibia Inserter
611003013	61140464	Natural-Knee® II System Unicompartmental Tibia Inserter
611003013	61150595	Natural-Knee® II System Unicompartmental Tibia Inserter
613001007	61385990	Natural-Knee® II System Unicompartmental Tibia Inserter



Article	Lot	Description générale
613001009	61269858	Natural-Knee® II System Unicompartmental Tibia Inserter
620001100	60674275	Natural-Knee® II System Metal Backed Patella Component
620001100	61566657	Natural-Knee® II System Metal Backed Patella Component
620001100	61587666	Natural-Knee® II System Metal Backed Patella Component
620001100	61650258	Natural-Knee® II System Metal Backed Patella Component
620001100	61681080	Natural-Knee® II System Metal Backed Patella Component
620001100	62151759	Natural-Knee® II System Metal Backed Patella Component
620001100	62261472	Natural-Knee® II System Metal Backed Patella Component
620001100	62274638	Natural-Knee® II System Metal Backed Patella Component
620001100	62274645	Natural-Knee® II System Metal Backed Patella Component
620001100	62283811	Natural-Knee® II System Metal Backed Patella Component
620001100	62298755	Natural-Knee® II System Metal Backed Patella Component
620001100	62322959	Natural-Knee® II System Metal Backed Patella Component
620001101	61487827	Natural-Knee® II System Metal Backed Patella Component
620001101	61587665	Natural-Knee® II System Metal Backed Patella Component
620001101	61621642	Natural-Knee® II System Metal Backed Patella Component
620001101	61650259	Natural-Knee® II System Metal Backed Patella Component
620001101	61676693	Natural-Knee® II System Metal Backed Patella Component
620001101	61702703	Natural-Knee® II System Metal Backed Patella Component
620001101	61740149	Natural-Knee® II System Metal Backed Patella Component
620001101	61781730	Natural-Knee® II System Metal Backed Patella Component
620001102	60531353	Natural-Knee® II System Metal Backed Patella Component
620001102	61505267	Natural-Knee® II System Metal Backed Patella Component
620001102	61615680	Natural-Knee® II System Metal Backed Patella Component
620001102	61707733	Natural-Knee® II System Metal Backed Patella Component
620001102	61754019	Natural-Knee® II System Metal Backed Patella Component
620001102	61865180	Natural-Knee® II System Metal Backed Patella Component
620001102	61940711	Natural-Knee® II System Metal Backed Patella Component
620001102	61995984	Natural-Knee® II System Metal Backed Patella Component
620001102	62195133	Natural-Knee® II System Metal Backed Patella Component
620001102	62225725	Natural-Knee® II System Metal Backed Patella Component
620001102	62322961	Natural-Knee® II System Metal Backed Patella Component
620005819	61091304	Natural-Knee® Congruent Tibial Insert with Screw
620005909	62049531	Natural-Knee® Congruent Tibial Insert with Screw
620006916	61066561	Natural-Knee® Congruent Tibial Insert with Screw
621800809	61016365	Natural-Knee® II System All Poly Ultra Congruent Tibia
621801809	61722681	Natural-Knee® II System All Poly Ultra Congruent Tibia
621801809	62188790	Natural-Knee® II System All Poly Ultra Congruent Tibia
621801819	60923828	Natural-Knee® II System All Poly Ultra Congruent Tibia
621801819	61129203	Natural-Knee® II System All Poly Ultra Congruent Tibia
621801913	61330819	Natural-Knee® II System All Poly Ultra Congruent Tibia
621801913	61834837	Natural-Knee® II System All Poly Ultra Congruent Tibia
621801916	61009484	Natural-Knee® II System All Poly Ultra Congruent Tibia
621801916	61487209	Natural-Knee® II System All Poly Ultra Congruent Tibia
621810816	61717377	Natural-Knee® II System All Poly Ultra Congruent Tibia



Article	Lot	Description générale
621810816	62112290	Natural-Knee® II System All Poly Ultra Congruent Tibia
621810909	61348036	Natural-Knee® II System All Poly Ultra Congruent Tibia
621810909	62060282	Natural-Knee® II System All Poly Ultra Congruent Tibia
621820809	61990695	Natural-Knee® II System All Poly Ultra Congruent Tibia
621820811	60923830	Natural-Knee® II System All Poly Ultra Congruent Tibia
621820811	62207659	Natural-Knee® II System All Poly Ultra Congruent Tibia
621820911	60757906	Natural-Knee® II System All Poly Ultra Congruent Tibia
621820911	61074407	Natural-Knee® II System All Poly Ultra Congruent Tibia
621820911	62088695	Natural-Knee® II System All Poly Ultra Congruent Tibia
621830811	60765958	Natural-Knee® II System All Poly Ultra Congruent Tibia
621830811	61323227	Natural-Knee® II System All Poly Ultra Congruent Tibia
621830811	62105429	Natural-Knee® II System All Poly Ultra Congruent Tibia
621830909	61240169	Natural-Knee® II System All Poly Ultra Congruent Tibia
621850916	62188788	Natural-Knee® II System All Poly Ultra Congruent Tibia
625001609	61074797	Natural-Knee® II Ultra Congruent Tibial Insert
625001609	61085748	Natural-Knee® II Ultra Congruent Tibial Insert
625001609	61188694	Natural-Knee® II Ultra Congruent Tibial Insert
625001613	60548568	Natural-Knee® II Ultra Congruent Tibial Insert
625001613	61121435	Natural-Knee® II Ultra Congruent Tibial Insert
625001613	61419333	Natural-Knee® II Ultra Congruent Tibial Insert
625001613	61567373	Natural-Knee® II Ultra Congruent Tibial Insert
625001613	62195341	Natural-Knee® II Ultra Congruent Tibial Insert
625001619	61085742	Natural-Knee® II Ultra Congruent Tibial Insert
625001619	61567371	Natural-Knee® II Ultra Congruent Tibial Insert
625001709	60886831	Natural-Knee® II Ultra Congruent Tibial Insert
625001709	60976516	Natural-Knee® II Ultra Congruent Tibial Insert
625001709	61091795	Natural-Knee® II Ultra Congruent Tibial Insert
625001711	62127482	Natural-Knee® II Ultra Congruent Tibial Insert
625001713	60872580	Natural-Knee® II Ultra Congruent Tibial Insert
625001713	60979731	Natural-Knee® II Ultra Congruent Tibial Insert
625001713	61699518	Natural-Knee® II Ultra Congruent Tibial Insert
625001719	61219748	Natural-Knee® II Ultra Congruent Tibial Insert
625002613	61827810	Natural-Knee® II Ultra Congruent Tibial Insert
625002616	61085656	Natural-Knee® II Ultra Congruent Tibial Insert
625002616	61162828	Natural-Knee® II Ultra Congruent Tibial Insert
625002616	61253229	Natural-Knee® II Ultra Congruent Tibial Insert
625002719	61232452	Natural-Knee® II Ultra Congruent Tibial Insert
625002719	61312433	Natural-Knee® II Ultra Congruent Tibial Insert
625002722	61102130	Natural-Knee® II Ultra Congruent Tibial Insert
630809510	61003976	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630809510	61107491	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630811410	60956303	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630811410	61847308	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630811510	60902038	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630811510	61847307	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert





Article	Lot	Description générale
630813410	60902039	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630813410	61782747	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630813410	61847309	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630813510	60902036	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630813510	61811364	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630816210	60946833	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630816210	61811365	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630816210	62188786	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630816410	61085003	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630816410	61808182	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630816410	61834828	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630816510	60875580	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630816510	61814416	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630816510	61857141	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819010	61875213	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819010	62157103	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819110	61814417	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819110	61824703	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819210	60902037	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819310	61599381	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819310	61814418	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819410	61814419	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819410	61825403	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
630819510	60902040	Natural-Knee® II Rotating Platform Ultra Congruent Tibial Insert
635000009	62026046	Natural-Knee® II System All Poly Congruent Tibia
635001009	60996796	Natural-Knee® II System All Poly Congruent Tibia
635001009	61184673	Natural-Knee® II System All Poly Congruent Tibia
635001011	61052406	Natural-Knee® II System All Poly Congruent Tibia
635001011	61782748	Natural-Knee® II System All Poly Congruent Tibia
635001111	61129156	Natural-Knee® II System All Poly Congruent Tibia
635001111	61566726	Natural-Knee® II System All Poly Congruent Tibia
635001116	61175171	Natural-Knee® II System All Poly Congruent Tibia
635002009	60757894	Natural-Knee® II System All Poly Congruent Tibia
635002009	61016364	Natural-Knee® II System All Poly Congruent Tibia
635002009	61520050	Natural-Knee® II System All Poly Congruent Tibia
635002011	61160880	Natural-Knee® II System All Poly Congruent Tibia
635002011	61516858	Natural-Knee® II System All Poly Congruent Tibia
635002011	61686052	Natural-Knee® II System All Poly Congruent Tibia
635002011	61940750	Natural-Knee® II System All Poly Congruent Tibia
635002109	60940084	Natural-Knee® II System All Poly Congruent Tibia
635002111	60591562	Natural-Knee® II System All Poly Congruent Tibia
635002111	60902055	Natural-Knee® II System All Poly Congruent Tibia
635002111	61175172	Natural-Knee® II System All Poly Congruent Tibia
635002111	62112285	Natural-Knee® II System All Poly Congruent Tibia
635002113	61107559	Natural-Knee® II System All Poly Congruent Tibia



Article	Lot	Description générale
635002113	61520049	Natural-Knee® II System All Poly Congruent Tibia
635003009	60902053	Natural-Knee® II System All Poly Congruent Tibia
635003009	60902054	Natural-Knee® II System All Poly Congruent Tibia
635003009	61160882	Natural-Knee® II System All Poly Congruent Tibia
635003011	60902051	Natural-Knee® II System All Poly Congruent Tibia
635003011	61062788	Natural-Knee® II System All Poly Congruent Tibia
635003011	61184646	Natural-Knee® II System All Poly Congruent Tibia
635003013	61058081	Natural-Knee® II System All Poly Congruent Tibia
635003013	61184676	Natural-Knee® II System All Poly Congruent Tibia
635003013	61782750	Natural-Knee® II System All Poly Congruent Tibia
635003016	61129149	Natural-Knee® II System All Poly Congruent Tibia
635003016	61242110	Natural-Knee® II System All Poly Congruent Tibia
635003109	60902052	Natural-Knee® II System All Poly Congruent Tibia
635003109	60908325	Natural-Knee® II System All Poly Congruent Tibia
635003109	61184657	Natural-Knee® II System All Poly Congruent Tibia
635003109	61717374	Natural-Knee® II System All Poly Congruent Tibia
635003109	61950477	Natural-Knee® II System All Poly Congruent Tibia
635003113	61878438	Natural-Knee® II System All Poly Congruent Tibia
635003116	61129158	Natural-Knee® II System All Poly Congruent Tibia
635003116	61184675	Natural-Knee® II System All Poly Congruent Tibia
635004009	61899915	Natural-Knee® II System All Poly Congruent Tibia
635004009	62191926	Natural-Knee® II System All Poly Congruent Tibia
635004009	61175095	Natural-Knee® II System All Poly Congruent Tibia
635004009	60781217	Natural-Knee® II System All Poly Congruent Tibia
635004011	61717375	Natural-Knee® II System All Poly Congruent Tibia
635004016	61111635	Natural-Knee® II System All Poly Congruent Tibia
635004016	61184649	Natural-Knee® II System All Poly Congruent Tibia
635004111	61160890	Natural-Knee® II System All Poly Congruent Tibia
635004111	61973957	Natural-Knee® II System All Poly Congruent Tibia
635004113	61184651	Natural-Knee® II System All Poly Congruent Tibia
635004113	61949828	Natural-Knee® II System All Poly Congruent Tibia
635004119	61147593	Natural-Knee® II System All Poly Congruent Tibia
635005013	61184652	Natural-Knee® II System All Poly Congruent Tibia
635005013	61950474	Natural-Knee® II System All Poly Congruent Tibia
635005019	61119496	Natural-Knee® II System All Poly Congruent Tibia
635005019	61135549	Natural-Knee® II System All Poly Congruent Tibia
635005111	61085021	Natural-Knee® II System All Poly Congruent Tibia
635005111	61150539	Natural-Knee® II System All Poly Congruent Tibia
635005111	61592577	Natural-Knee® II System All Poly Congruent Tibia
635005116	61129162	Natural-Knee® II System All Poly Congruent Tibia
635005116	61184677	Natural-Knee® II System All Poly Congruent Tibia
635006109	61129153	Natural-Knee® II System All Poly Congruent Tibia
635006109	61184659	Natural-Knee® II System All Poly Congruent Tibia
670501916	62097955	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670501916	62188801	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert



Article	Lot	Description générale
670501919	60490437	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670501919	60908398	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670501919	61013451	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670501919	61091888	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670501919	61118370	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670501919	61213573	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670501919	61223653	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670501919	61251657	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	60631734	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	60728035	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	60737467	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	60737468	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	60826364	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	60846402	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	60902182	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	61007106	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	61074465	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	61074466	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	61091881	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	61286937	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	61865302	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	61868154	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	62157118	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	62297652	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670502811	62298396	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670503819	61052443	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670503819	61169351	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670503911	61650986	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670503916	61004133	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670503916	61004134	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670503916	61013460	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670503916	61058092	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670503916	61147605	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
670503916	61814420	Natural-Knee® II Posterior Stabilized (P.S) Tibial Insert
672009100	60598386	Natural-Knee® II Constrained Knee System Tibia Insert
672009100	60742310	Natural-Knee® II Constrained Knee System Tibia Insert
672009100	61990701	Natural-Knee® II Constrained Knee System Tibia Insert
672009101	60681716	Natural-Knee® II Constrained Knee System Tibia Insert
672009103	61434138	Natural-Knee® II Constrained Knee System Tibia Insert
672009103	61782765	Natural-Knee® II Constrained Knee System Tibia Insert
672009103	62017005	Natural-Knee® II Constrained Knee System Tibia Insert
672009103	62162057	Natural-Knee® II Constrained Knee System Tibia Insert
672009200	60856124	Natural-Knee® II Constrained Knee System Tibia Insert
672009200	61639391	Natural-Knee® II Constrained Knee System Tibia Insert
672009200	62055481	Natural-Knee® II Constrained Knee System Tibia Insert



Article	Lot	Description générale
672009203	60923898	Natural-Knee® II Constrained Knee System Tibia Insert
672009203	61016489	Natural-Knee® II Constrained Knee System Tibia Insert
672009203	61367019	Natural-Knee® II Constrained Knee System Tibia Insert
672009203	62088735	Natural-Knee® II Constrained Knee System Tibia Insert
672011101	61016472	Natural-Knee® II Constrained Knee System Tibia Insert
672011103	60693032	Natural-Knee® II Constrained Knee System Tibia Insert
672011103	60946870	Natural-Knee® II Constrained Knee System Tibia Insert
672011103	61147607	Natural-Knee® II Constrained Knee System Tibia Insert
672011200	61475713	Natural-Knee® II Constrained Knee System Tibia Insert
672011200	61827804	Natural-Knee® II Constrained Knee System Tibia Insert
672011200	62049509	Natural-Knee® II Constrained Knee System Tibia Insert
672011201	60624824	Natural-Knee® II Constrained Knee System Tibia Insert
672011201	60737477	Natural-Knee® II Constrained Knee System Tibia Insert
672011203	61016493	Natural-Knee® II Constrained Knee System Tibia Insert
672011203	61571527	Natural-Knee® II Constrained Knee System Tibia Insert
672011203	61923057	Natural-Knee® II Constrained Knee System Tibia Insert
672011203	62127481	Natural-Knee® II Constrained Knee System Tibia Insert
672013100	61016491	Natural-Knee® II Constrained Knee System Tibia Insert
672013100	61650989	Natural-Knee® II Constrained Knee System Tibia Insert
672013100	61729751	Natural-Knee® II Constrained Knee System Tibia Insert
672013100	61788440	Natural-Knee® II Constrained Knee System Tibia Insert
672013101	61118389	Natural-Knee® II Constrained Knee System Tibia Insert
672013103	60693033	Natural-Knee® II Constrained Knee System Tibia Insert
672013103	60908439	Natural-Knee® II Constrained Knee System Tibia Insert
672013200	60786856	Natural-Knee® II Constrained Knee System Tibia Insert
672013200	61016492	Natural-Knee® II Constrained Knee System Tibia Insert
672013200	62097958	Natural-Knee® II Constrained Knee System Tibia Insert
672013203	62148866	Natural-Knee® II Constrained Knee System Tibia Insert
672016101	61788436	Natural-Knee® II Constrained Knee System Tibia Insert
672016103	60990345	Natural-Knee® II Constrained Knee System Tibia Insert
672016103	61426861	Natural-Knee® II Constrained Knee System Tibia Insert
672016103	61487222	Natural-Knee® II Constrained Knee System Tibia Insert
672016200	60737475	Natural-Knee® II Constrained Knee System Tibia Insert
672016200	61286952	Natural-Knee® II Constrained Knee System Tibia Insert
672016200	61717387	Natural-Knee® II Constrained Knee System Tibia Insert
672016200	62088737	Natural-Knee® II Constrained Knee System Tibia Insert
672016203	60707870	Natural-Knee® II Constrained Knee System Tibia Insert
672016203	60946858	Natural-Knee® II Constrained Knee System Tibia Insert
672016203	61788437	Natural-Knee® II Constrained Knee System Tibia Insert
672019100	60693028	Natural-Knee® II Constrained Knee System Tibia Insert
672019100	60990351	Natural-Knee® II Constrained Knee System Tibia Insert
672019100	61592609	Natural-Knee® II Constrained Knee System Tibia Insert
672019101	60710377	Natural-Knee® II Constrained Knee System Tibia Insert
672019101	60923987	Natural-Knee® II Constrained Knee System Tibia Insert
672019101	61650991	Natural-Knee® II Constrained Knee System Tibia Insert



Article	Lot	Description générale
672019101	61788439	Natural-Knee® II Constrained Knee System Tibia Insert
672019200	60804168	Natural-Knee® II Constrained Knee System Tibia Insert
672019200	61323247	Natural-Knee® II Constrained Knee System Tibia Insert
672019200	61827805	Natural-Knee® II Constrained Knee System Tibia Insert
672019200	62088736	Natural-Knee® II Constrained Knee System Tibia Insert
672019201	60624822	Natural-Knee® II Constrained Knee System Tibia Insert
672019201	60792148	Natural-Knee® II Constrained Knee System Tibia Insert
672019201	61617346	Natural-Knee® II Constrained Knee System Tibia Insert
672019201	61956605	Natural-Knee® II Constrained Knee System Tibia Insert
672019201	62127480	Natural-Knee® II Constrained Knee System Tibia Insert
672022101	60923892	Natural-Knee® II Constrained Knee System Tibia Insert
672022101	61434133	Natural-Knee® II Constrained Knee System Tibia Insert
672022101	61883555	Natural-Knee® II Constrained Knee System Tibia Insert
672022103	60696647	Natural-Knee® II Constrained Knee System Tibia Insert
672022103	60990350	Natural-Knee® II Constrained Knee System Tibia Insert
672022103	61305375	Natural-Knee® II Constrained Knee System Tibia Insert
672022103	61923053	Natural-Knee® II Constrained Knee System Tibia Insert
672022200	60792151	Natural-Knee® II Constrained Knee System Tibia Insert
672022201	60624818	Natural-Knee® II Constrained Knee System Tibia Insert
672022201	60737474	Natural-Knee® II Constrained Knee System Tibia Insert
672022201	61012531	Natural-Knee® II Constrained Knee System Tibia Insert
672022201	61782763	Natural-Knee® II Constrained Knee System Tibia Insert
672022201	61974009	Natural-Knee® II Constrained Knee System Tibia Insert
672025100	60693029	Natural-Knee® II Constrained Knee System Tibia Insert
672025100	61923055	Natural-Knee® II Constrained Knee System Tibia Insert
672025200	60792141	Natural-Knee® II Constrained Knee System Tibia Insert
672025200	61363285	Natural-Knee® II Constrained Knee System Tibia Insert
672025200	61974007	Natural-Knee® II Constrained Knee System Tibia Insert
672509100	60909403	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672509100	61074719	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672509101	60713056	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672509101	62017009	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672509200	60909404	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672509203	60863521	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672509203	60909417	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672509203	61016552	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672511100	61274799	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672511103	60863519	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672511103	61007978	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672511103	61782768	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672513101	61363318	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672513101	61747147	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672513103	61016554	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672513103	61808357	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672513201	60792157	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert



Article	Lot	Description générale
672513201	61754163	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672516103	60909395	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672516103	61016540	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672516103	61650994	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672519103	60909402	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672519103	61286990	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672522201	60909396	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672522201	61080279	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672525103	60747318	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
672525203	60792159	Natural-Knee® II Posterior Stabilized (P.S.) Condylar Tibial Insert
680001000	61756167	Apollo™ Knee System Patella Component
681100019	61176049	Apollo™ Knee Tibial Baseplate/Knee Congruent Tibial Insert
681100022	61282848	Apollo™ Knee Tibial Baseplate/Knee Congruent Tibial Insert
681101009	61929803	Apollo™ Knee Tibial Baseplate/Knee Congruent Tibial Insert
681101011	61929804	Apollo™ Knee Tibial Baseplate/Knee Congruent Tibial Insert
681101019	61160228	Apollo™ Knee Tibial Baseplate/Knee Congruent Tibial Insert
681102013	61990704	Apollo™ Knee Tibial Baseplate/Knee Congruent Tibial Insert
681102019	61160229	Apollo™ Knee Tibial Baseplate/Knee Congruent Tibial Insert
681103009	61990703	Apollo™ Knee Tibial Baseplate/Knee Congruent Tibial Insert
681103013	61990702	Apollo™ Knee Tibial Baseplate/Knee Congruent Tibial Insert
681600016	61145695	Apollo™ Knee System Posterior Stabilized Tibial Insert
681600019	61207113	Apollo™ Knee System Posterior Stabilized Tibial Insert
681600022	61291144	Apollo™ Knee System Posterior Stabilized Tibial Insert
681601016	61183328	Apollo™ Knee System Posterior Stabilized Tibial Insert
681602016	61277999	Apollo™ Knee System Posterior Stabilized Tibial Insert
681602022	61287024	Apollo™ Knee System Posterior Stabilized Tibial Insert
681603016	61287025	Apollo™ Knee System Posterior Stabilized Tibial Insert
681603019	61175475	Apollo™ Knee System Posterior Stabilized Tibial Insert
681604009	61990705	Apollo™ Knee System Posterior Stabilized Tibial Insert
681604011	61179664	Apollo™ Knee System Posterior Stabilized Tibial Insert
681604013	61207114	Apollo™ Knee System Posterior Stabilized Tibial Insert
681604016	61920302	Apollo™ Knee System Posterior Stabilized Tibial Insert
681604019	61913087	Apollo™ Knee System Posterior Stabilized Tibial Insert
681604022	61291164	Apollo™ Knee System Posterior Stabilized Tibial Insert
681605009	61188482	Apollo™ Knee System Posterior Stabilized Tibial Insert
681605019	61150215	Apollo™ Knee System Posterior Stabilized Tibial Insert
682000016	61278008	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682001011	62157194	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682001016	60659970	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682001016	61929807	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682001022	61278014	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682001030	61175476	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682002011	62157193	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682002013	62083333	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682002016	61972595	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert



<b>Article</b>	<b>Lot</b>	<b>Description générale</b>
682002022	61972596	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682002030	61929808	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682003016	62186237	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682003022	60659966	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682003025	60659968	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682003025	61930084	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682004013	61287029	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682004016	61326987	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert
682005011	61287027	Apollo™ Revision/Constrained Knee System Constrained Tibial Insert



## ANNEXE 2

Confirmation de réception d'une notification de sécurité urgente  
FSA/FSCA : 1822565-02-07-2014-001-C

Ce document certifie que vous avez reçu l'avis de sécurité urgent relatif aux produits suivants :  
**implants en polyéthylène pour systèmes Gender Solutions® Natural-Knee® Flex, Natural-Knee®, Natural-Knee® II, MOST Options™ et Apollo™.**

Je certifie que toutes les informations utiles m'ont été communiquées par Zimmer dans l'intérêt et pour la sécurité des patients.

Je vous retourne les dispositifs suivants :

REFERENCE	LOT	QUANTITE

Nom en majuscules \_\_\_\_\_ Signature \_\_\_\_\_

Fonction \_\_\_\_\_ Téléphone : (    ) \_\_\_\_\_ - \_\_\_\_\_

Date : \_\_\_\_/\_\_\_\_/\_\_\_\_

Merci de joindre ce formulaire aux pièces retournées.