

16 septembre 2015

À : gestionnaires des risques et chirurgiens

Objet : **NOTIFICATION DE SECURITÉ URGENTE SUR LE TERRAIN**

Produits concernés : 00-2228-024-00 Guide clou à pointe biseautée de 2,4 mm de diamètre ;
00-2255-025-00 Guide clou lisse huméral de 2,4 mm, longueur 70 cm ;
00-2255-026-00 Guide clou à pointe biseautée huméral de 2,4 mm de diamètre, longueur 70 cm ;
47-2237-033-00 Guide clou lisse de 2,4 mm de diamètre, longueur 100 cm ;
47-2237-037-00 Guide clou lisse de 3,0 mm de diamètre, longueur 100 cm ;
47-2237-038-00 Guide clou à pointe biseautée de 3,0 mm de diamètre, longueur 100 cm ;
47-2255-008-00 Guide clou à pointe ronde de 2,4 mm de diamètre, longueur 70 cm ;
47-2255-008-01 Guide clou à pointe ronde de 3,0 mm de diamètre, longueur 100 cm ;

Tous les lots non périmés et distribués dont l'étiquette indique une période de validité de 10 ans.

(Voir annexe 1 pour la liste complète des combinaisons de lots de pièces.)

Zimmer Biomet entreprend un rappel volontaire de fils-guides dont l'étiquette indique une période de validité de 10 ans. En effet, il a été mis en évidence, au travers de l'examen des tests de durée de vie d'emballage, que l'étiquetage produit de ces fils-guides stériles (étiquette du carton externe et étiquette de dossier patient) indique une période de validité de 10 ans, alors que les tests d'emballage indiquent une période de validité de 5 ans pour ces mêmes fils-guides. Zimmer Biomet rappelle tous les lots de fils-guides non périmés et non utilisés étiquetés avec une période de validité de 10 ans. Les lots affectés ont été distribués entre août 2005 et décembre 2011. Du fait du renouvellement rapide de ce produit dans l'inventaire et de la fréquence avec laquelle il s'est retrouvé en réassort, nous ne nous attendons pas à ce qu'il reste en circulation une quantité significative d'unités concernées par cette notification. Aucun dommage ni blessure n'a été signalé pour cet événement.



Exemple d'image de guide clou en manchon stérile

Risques		
Conséquences immédiates pour la santé (blessures ou maladie) pouvant résulter de l'utilisation du dispositif ou de l'exposition au problème.	Les plus probables	Pire scénario
	Le plus probable est que les fils-guides restent stériles dans l'emballage avant ouverture du produit pour l'opération, ce qui annule l'impact du problème.	L'une des conséquences potentielles pour la santé à court terme est l'infection postopératoire aiguë du fait d'un guide clou de stérilité insuffisante.
Conséquences à long terme pour la santé (blessures ou maladie) pouvant résulter de l'utilisation du dispositif ou de l'exposition au problème.	Les plus probables	Pire scénario
	Le plus probable est que les fils-guides restent stériles dans l'emballage avant ouverture du produit pour l'opération, ce qui annule l'impact du problème.	Les phénomènes à long terme peuvent inclure l'ostéomyélite, les abcès des tissus mous et la septicémie.

Vos responsabilités

1. Lisez attentivement la notification et assurez-vous que le personnel concerné en connaît le contenu.
2. Mettez en quarantaine les produits concernés (qui sont dans leur emballage d'origine).
3. Informez votre représentant commercial Zimmer Biomet afin de procéder à la reprise des produits rappelés dans votre établissement, le cas échéant.
4. Renvoyez-nous le Certificat de confirmation de réception (Annexe 2) complété à : per.fr@zimmerbiomet.com

Veillez contacter votre représentant Zimmer Biomet pour toute question relative à 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 de ces 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 Biomet. Pour déclarer des événements indésirables, écrivez à Zimmer Biomet à l'adresse per.fr@zimmerbiomet.com, ou contactez votre représentant Zimmer Biomet local.

ANNEXE 1

Référence pièce	Numéro de lot	Référence pièce	Numéro de lot	Référence pièce	Numéro de lot	Référence pièce	Numéro de lot
00-2228-024-00	60348289	47-2237-037-00	60896539	47-2255-008-01	60412453	47-2255-008-01	61009521
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ZIMMER BIOMET

ANNEXE 2

RÉPONSE IMMÉDIATE REQUISE – ACTION À ENTREPRENDRE RAPIDEMENT

Certificat de confirmation de réception :

FSN/FSCA : 1822565-08-19-2015-010-R

Produits concernés : 00-2228-024-00 Guide clou à pointe biseautée de 2,4 mm de diamètre ;
00-2255-025-00 Guide clou lisse huméral de 2,4 mm, longueur 70 cm ;
00-2255-026-00 Guide clou à pointe biseautée huméral de 2,4 mm de diamètre, longueur 70 cm ;
47-2237-033-00 Guide clou lisse de 2,4 mm de diamètre, longueur 100 cm ;
47-2237-037-00 Guide clou lisse de 3,0 mm de diamètre, longueur 100 cm ;
47-2237-038-00 Guide clou à pointe biseautée de 3,0 mm de diamètre, longueur 100 cm ;
47-2255-008-00 Guide clou à pointe ronde de 2,4 mm de diamètre, longueur 70 cm ;
47-2255-008-01 Guide clou à pointe ronde de 3,0 mm de diamètre, longueur 100 cm ;

Tous les lots non périmés et distribués dont l'étiquette indique une période de validité de 10 ans.

(Voir annexe 1 pour la liste complète des combinaisons de lots de pièces.)

En signant ci-dessous, je confirme avoir reçu et compris le contenu de la Notification de sécurité urgente sur le terrain – Correction, et que les mesures requises ont été prises conformément à la notification.

Nom en caractères
d'imprimerie : _____ Signature : _____

Fonction _____ Téléphone : () _____ - _____

Date : ____ / ____ / ____

Nom et adresse de l'hôpital :

Merci de joindre ce formulaire aux pièces retournées.

Remarque : Veuillez remplir ce formulaire et en envoyer une copie par e-mail à : per.fr@zimmerbiomet.com. Veuillez conserver une copie pour vos dossiers.

ZFA 2015-111