

URGENT – NOTIFICATION DE SÉCURITÉ

Objet :	Possible détachement du couvercle du collimateur en cas de montage incorrect
Appellation commerciale du produit concerné :	accélérateur linéaire Varian Clinac®
Identifiant FSCA :	CP-03256
Date de notification :	2011-03-17
Type d'action :	Notification et correction
Détails sur les dispositifs concernés :	Tous les Clinac dotés du couvercle de collimateur n° de référence 1106900-xx, y compris les Clinac équipés de collimateurs multilames (MLC) Millennium et HD-120. Voir l'annexe B.

Description du problème :

Le présent courrier a pour but de vous informer du fait qu'un couvercle de collimateur incorrectement installé peut se détacher et tomber de la machine et heurter le patient ou le personnel se trouvant à proximité. Varian a reçu plusieurs réclamations concernant un défaut du couvercle du collimateur, de par lequel le couvercle tombe de l'accélérateur linéaire. Dans tous les cas, il semble que le couvercle du collimateur n'ait pas été correctement monté et que le mouvement de l'accélérateur linéaire ait provoqué le détachement et la chute du couvercle de la machine.

Détails :

Une étude ultérieure effectuée par Varian a établi que la mise en place du mécanisme d'enclenchement du couvercle est difficile et, de ce fait, la probabilité d'un détachement accidentel du couvercle est plus élevée. Aucun patient n'a été blessé par ce couvercle, mais certains ont été heurtés et effrayés.

Varian a donc modifié le mécanisme d'enclenchement en ajoutant des vis de fixation pour améliorer la mise en place du couvercle. Un bulletin technique de service contenant les instructions de montage du mécanisme d'enclenchement modifié a été publié à l'attention du personnel de service qui doit impérativement le lire.

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Procédure corrective recommandée :

Varian recommande d'effectuer les actions suivantes :

- Maintenance par le personnel qualifié
Varian recommande fermement que la maintenance des accélérateurs linéaires Varian, notamment le retrait et le remontage du couvercle du collimateur, soit effectuée par un personnel qualifié, autorisé par l'exploitant de l'appareil et ayant reçu la formation appropriée en matière de maintenance.
- Montage correct du couvercle du collimateur
Si le couvercle du collimateur est retiré, suivre la procédure documentée dans l'annexe A pour le remontage correct du couvercle et s'assurer que le couvercle est solidement mis en place avant de remettre en fonction l'accélérateur linéaire. En particulier, il est recommandé de s'assurer que toutes les fixations sont en place et de vérifier que le couvercle est bien fixé en tirant dessus et en essayant de le faire tourner manuellement après l'avoir monté.
- Surveillance des mouvements de la machine
Il est recommandé de toujours surveiller le patient et la machine pendant les mouvements de celle-ci.

Mesures correctives prises par Varian :

- Les clients sont informés au moyen de la présente notification urgente de sécurité.
- Varian a modifié le mécanisme d'enclenchement du couvercle du collimateur pour le rendre plus fiable. Si cette modification n'a pas encore été apportée sur votre Clinac, le service de maintenance Varian vous contactera afin de prendre les dispositions nécessaires pour monter le nouveau mécanisme d'enclenchement du couvercle du collimateur.

Veillez informer du contenu de ce courrier les personnels concernés de votre service de radiothérapie.

Nous vous prions de bien vouloir nous excuser pour toute gêne éventuelle occasionnée par ce problème et vous remercions d'avance pour votre coopération. Pour toute clarification complémentaire, n'hésitez pas à contacter le support technique de Varian dont vous dépendez localement.

Le signataire confirme par la présente que cet avis a été communiqué aux agences réglementaires compétentes.

Michael Pignataro, directeur des rapports et corrections

2011-03-17
Date

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**Pour contacter le Centre d'assistance technique Varian pour l'oncologie
(Oncology Helpdesk) :**

Téléphone : États-Unis et Canada – 1 888 VARIAN5 (888 827 4265)
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Europe : support-emea@varian.com
Asie du Sud-Est : seasia.apps.helpdesk@varian.com
Chine/Asie : china.apps.helpdesk@varian.com
Japon : japan.apps.helpdesk@varian.com
Amérique latine : soporte.al@varian.com

Internet : Oncology Systems - www.myvarian.com
Varian Medical Systems - www.varian.com

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ANNEXE A – RETRAIT ET REMPLACEMENT DU COUVERCLE DU COLLIMATEUR

1. RETRAIT DU COUVERCLE DU COLLIMATEUR

- 1.1. Pivoter le bras et le positionner tête vers le bas.
- 1.2. Éteindre le Clinac à l'aide du bouton d'arrêt d'urgence.
- 1.3. Retirer la vis d'enclenchement (n° de référence 12-313908-10) du couvercle du collimateur à l'aide d'une clé hexagonale 9/64" (3,57 mm). Voir la figure 1. Si cette vis manque, en commander une nouvelle auprès du service logistique.

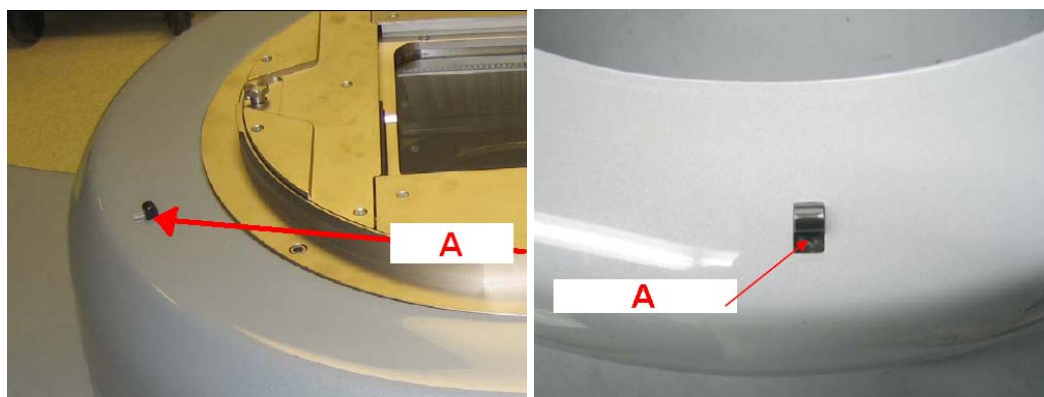


Figure 1 – « A » = Vis d'enclenchement

- 1.4. Pousser la vis d'enclenchement en l'éloignant du centre et tourner le couvercle du collimateur dans le sens inverse des aiguilles d'une montre.
 - 1.5. Retirer soigneusement le couvercle de manière à ne pas accrocher les câbles du MLC.
- ##### 2. REMONTER LE COUVERCLE DU COLLIMATEUR
- 2.1. Monter soigneusement le couvercle de manière à ne pas accrocher les câbles du MLC. Veiller à le tourner à fond vers la droite et le bloquer à sa place.
 - 2.2. Monter la vis d'enclenchement noire à l'aide d'une clé hexagonale 9/64" (3,57 mm). Voir la figure 1. Si cette vis manque, en commander une nouvelle (n° de référence 12-313-908-10) auprès du service logistique.
 - 2.3. **Tirer le couvercle et tenter de le faire tourner manuellement afin d'assurer qu'il est bien fixé.**
 - 2.4. Rallumer le Clinac.
 - 2.5. Pivoter le bras pour le repositionner tête en haut.

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ANNEXE B LISTE DES NUMÉROS DE SÉRIE

H140001	H140049	H140097	H140144	H140235	H140742	H140788	H140856	H180473	H180645	H180718
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H272160	H272211	H272267	H272318	H272371	H272423	H272475	H272831	H272888	H272939	H272992
H272161	H272212	H272268	H272319	H272372	H272424	H272476	H272833	H272889	H272940	H272993
H272162	H272213	H272269	H272320	H272373	H272425	H272477	H272834	H272890	H272941	H272994
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H272164	H272216	H272271	H272322	H272375	H272427	H272479	H272837	H272892	H272943	H272996
H272165	H272217	H272272	H272323	H272376	H272428	H272480	H272838	H272893	H272944	H272997
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H273048	H273102	H273156	H273711	H290276	H290348	H290404	H290541	H291035	H291091	H291147
H273049	H273103	H273157	H290003	H290278	H290349	H290405	H290542	H291036	H291092	H291148
H273050	H273104	H273158	H290012	H290279	H290350	H290406	H290544	H291037	H291093	H291149
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URGENT – NOTIFICATION DE SÉCURITÉ

Possible détachement du couvercle du collimateur en cas de montage incorrect

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