RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨١/ ٥
رقم الصادر : ٣/١/٢٠١٧
بيروت، في : ١٢ حزيران ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Nasal Dilator (Brusis method)

الجهاز المعني بالمتابعة:

- Nasal Dilator (Brusis method)
- Trade Mark: Heinz Kurz GmbH
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة التي تشير الى وجود خلل في عمل الصنف المذكور أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
قلم الديوان
وزارة الصحة العامة

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

[Letterhead of Heinz Kurz GmbH]

[Customer Address]

Voluntary temporary suspension of the sale and implanting of our nasal dilator (using the Brusis method), REF-No. 6002 022

Effective immediately and until further notice the affected dilators may no longer be distributed or implanted.

Dear Sir/Madam,

You purchased the following product from our range of nasal dilators

REF no. 6002 022
Model: nasal dilator (using the Brusis method),

designed for invasive implanting in patients to expand the nasal vestibule by means of the dilating the valvula with the aim of improving breathing. As you are aware, we have the highest standards when it comes to safety and quality. As a result, we take any indications of potential risks very seriously.

We were recently informed by two implanting physicians of cases in which the aforementioned nasal dilator had broken. The broken nasal dilators were surgically removed. In one case the patient suffered from an inflammation of the nose with a severe local infection at around the same time.

It has yet to be established why the dilators broke. In particular, it is still unclear whether the damage resulted from excessive strain or incorrect handling of the implant or this may also occur if the implants were used as intended. We are working diligently to resolve the matter as soon as possible.

As the reasons for the breakage are still unclear, it cannot be ruled out that the affected nasal dilators you are currently stocking pose a safety risk.

Effective immediately, the affected nasal dilators you are currently stocking may not be further distributed or implanted until our assessment is complete.

This voluntary, precautionary measure is aimed at protecting patients' health and physical safety avoiding further incidents. We will immediately inform you of our findings and the next steps once our assessment is complete.

Should you not implant the products yourself but resell or distribute these in any other way, we kindly ask you to pass on the attached information sheet to your customers, and to take all necessary steps to temporarily halt the implanting of further nasal dilators of this kind. Alternatively, you can also provide us with the addresses of your customers whom we would then contact directly.

We would like to thank you for your support and apologise for any inconvenience caused.

Kind regards

[Signed]

Voluntary temporary suspension of the sale and implanting of our nasal dilator (using the Brusis method), REF-No. 6002 022

Effective immediately and until further notice the affected dilators may no longer be distributed or implanted.

You may have purchased the following product from our range of nasal dilators: nasal dilator (using the Brusis method), REF no. 6002 022, designed for invasive implanting in patients to expand the nasal vestibule by means of the dilating the valvula with the aim of improving breathing. As you are aware, we have the highest standards when it comes to safety and quality. As a result, we take any indications of potential risks very seriously.

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