REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ص٥ / ٣٨
رقم االصادر: ١٢/١/٢٥٧٤٩
بيروت، في: ٣٠ تموز ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Osteosynthesis, bone plates. Oasys midline occiput plate.

الجهاز المعني بالمتابعة:

- Osteosynthesis, bone plates. Oasys midline occiput plate.
- Trade Mark: Stryker Spine SA
- Local Representative:Ets.F.A. Kettaneh

بناء على التقارير الصادرة عن الوكالة البريطانية
Medicine and Health Care Products Regulatory Agency (UK) MHRA
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في تصنيع الصنف الوارد أعلاه، 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

Date

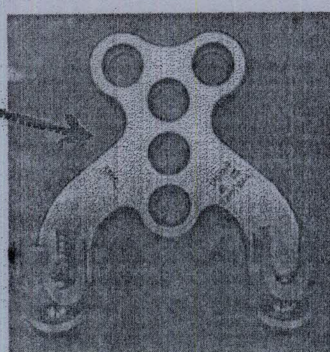
URGENT FIELD SAFETY NOTICE: RA2013-033

Dear Customer

Product Description: OASYS MIDLINE PLATES
Reference No.: 4855104(4)-(8) & 4857104(4)-(8)

A Product Field Action has been initiated by Stryker Spine concerning the above referenced products.

Customer reports for revision surgeries due to pin breakage have exceeded pre market identified thresholds. The pin connects the tulip head to the Midline Plate.



An internal investigation has been initiated to determine the root cause for discrepancy and to ensure that appropriate corrective actions are put into effect. Pending the results of this investigation a removal action is taken as a precautionary measure in order to preserve patient safety.

This notice serves as the communication means to inform you of this removal action.

Our records indicate that you have received at least one of the associated implants for this device

Please complete the Customer Response Form as this will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. It may be that you no longer have any physical inventory on site, if that is the case, please continue to complete this form as it will allow us to keep our records up to date and negate the need for us to send further reminder notifications.

We request that you respond to this notice within five calendar days from the date of receipt. The target date for completion of the notification process is XX XX 2013 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: E-mail:

In line with the recommendations of the Meddev Vigilance Guidance Document, Reference 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours....

URGENT FIELD SAFETY NOTICE: RA2013-033

Product Description: OASYS MIDLINE PLATES
Reference No.: 4855104(4)-(8) & 4857104(4)-(8)

Issue:
Customer reports for revision surgeries due to pin breakage have exceeded pre market identified thresholds. The pin connects the tulip head to the Midline Plate.

Potential hazards
If the plate fractures post-op, a revision surgery would be required.

Patient follow up and monitoring
Further information will be provided on this subject when the internal investigation has been completed. At this time we can confirm that there is no requirement for surgeons to contact patients with implanted devices.

Actions required:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations. (Please provide contact details so that Stryker can inform the recipients appropriately).
5. Complete the attached customer response form.
6. (Please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice)
7. Please inform Stryker of any adverse events and comply with any local regulations for reporting to your National Competent Authority.
8. Complete the attached customer response form and return any affected devices to your local Stryker Representative.
9. Please respond to this notice within five days from date of receipt.

Once again, on behalf of Stryker we thank you sincerely for your help and support in completing this action within date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Should you have queries in the meantime please do not hesitate to contact (insert local franchise name) or the undersigned.

Yours ……