

RÉPUBLIQUE LIBANAISE

MINISTÈRE DE LA SANTÉ PUBLIQUE

Le Directeur Général



الجمهورية اللبنانية

وزارة الصحة العامة

الدير العام

رقم المحفوظات: ٧٧/٢٠
رقم الصادر: ١٢/١١٨٧/٩٨
بيروت، في: ١٢ تشرين الثاني ٢٠١٢

جانب نقيد، المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغرس Orthopedic external fixation system, fracture,

جهاز المعنى بالمتابعة:

- Orthopedic external fixation system, fracture, wire Bol's Hoffmann LRF
- Trade Mark: Stryker Osteosynthesis
- 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 تفيد بوجود خلل في الصنف المذكور أعلاه،

نرجو منكم تعميم هذه النشرة على جميع المستشفيات.

مرفق ربطا:

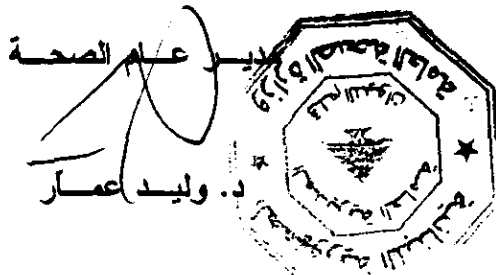
- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع

- المستشفيات الحكومية

- المحفوظات





رقم المحفوظات: ٣٧٩/٢٠١٢
رقم الصادر: ١٩/١/١٨٧٩٨
بيروت، في: ١٣ تشرين الثاني ٢٠١٢

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي مفروس Orthopedic external fixation system, fracture,

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نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن
الشركة المصنعة.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة.
- يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات





رقم المحفوظات: ٣٧٩١٢
رقم الصادر: ١٢/١/١٨٧٩٨
بيروت، في: ١٣ : تشرين الثاني ٢٠١٢

جانب نقيب الاطباء في الشمال/طرابلس

الموضوع: إشعار بمتابعة جهاز طبي مغروس Orthopedic external fixation system, fracture,

الجهاز المعنى بالمتابعة:

- Orthopedic external fixation system, fracture, wire Bolts Hoffmann LRF
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بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في الصنف المذكور أعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة.

يلف:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات





رقم المحفوظات: ١١٢٨

رقم الصادر: ١٤/١٨٨٧٩٨

بيروت، في:

١٣ تمزيقاً ٢٠١٢

جانب شركة Ets. F. A. Kettaneh

الموضوع: إشعار بمتابعة جهاز طبي مغروس Orthopedic external fixation system, fracture,

الجهاز المعنى بالمتابعة:

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بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي بوجود خلل في الصنف المذكور أعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

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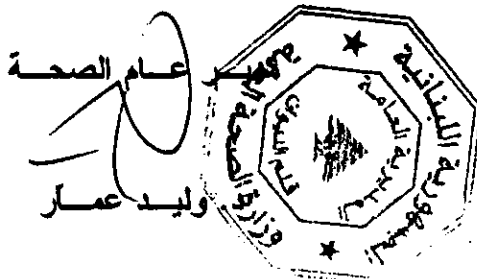
- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع

- المستشفيات الحكومية

- المحفوظات



URGENT Field Safety Notice: RA2012-154

FSCA Identifier: Product Field Action RA 2012-154
Type of Action: Field Safety Corrective Action
Description: Hoffmann LRF Wire Bolts
Catalogue Nos: Refer to the attached list on page 4
Lot Nos: Refer to the attached list on page 4

Dear Customer,

Stryker® Osteosynthesis has initiated a Product Field Action for the devices identified above. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

Issue

Two complaints have been filed where Hoffmann LRF Wires have broken during load bearing application by patients. The reported Hoffmann LRF Wire failures may have been caused by fatigue fracture in combination with the Hoffmann LRF Wire Bolts.

Potential Hazards

Breakage of Wires will possibly cause

- immediate loss of fixation
- painful loss of fragment or segment reduction, resulting in unintended revision surgery.

Mitigating Factors

1. Hoffmann LRF Wire Bolts should not be used for upcoming procedures.
2. All patients having a Hoffmann LRF frame with Wire Bolts should be immediately advised by their surgeon to avoid weight-bearing situations.
3. If Hoffmann LRF frame experienced a loss of fixation an alternative external fixation system should be considered.

Type of Action

Recall of subject devices

Immediate actions

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions:

Our records indicate that you have received at least one of the subject devices listed above. We therefore request that you:

1. Please inform users of this Medical Device Field Removal and pass this notice to all those individuals who need to be aware within your organization.

RA2012-154 HOFFMANN LRF WIRE BOLTS

Date

URGENT FIELD SAFETY NOTICE: RA2012-154

FSCA Identifier: Product Field Action RA 2012-154
Type of Action: Field Safety Corrective Action
Description: Hoffmann LRF Wire Bolts
Catalogue Nos: Refer to the attached list on page 4
Lot Nos: Refer to the attached list on page 4

Dear Customer,

Please find attached details of a Product Field Action that has been initiated by Stryker Osteosynthesis concerning the above referenced devices.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. It may be that you no longer have any physical inventory on site.

This action has been taken to ensure that users are aware of important Information concerning the devices listed above. You are required only to read the attached Field Safety Notice and then sign and return the customer response form confirming that you have completed the actions requested by the manufacturer.

Completing the Customer Response Form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is 21st Dec 2012 and your timely response will enable us to ensure that we meet this target and ensure that non conforming devices are removed from the market as quickly as possible.

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: Daniel Rana
Position: Regulatory Affairs Specialist
E-mail: daniel.rana@stryker.com
Tel: 01635 262 402
Fax: 01635 262 464

RA2012-154 HOFFMANN LRF WIRE BOLTS

In line with the recommendations of the MEDDEV Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA (Field Safety Corrective Action) 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 faithfully,

Daniel Rana
Quality Assurance and Regulatory Affairs

2. Complete and sign the enclosed PFA Acknowledgment Form and return to Daniel Rana by fax (01635 262 464) or by email (daniel.rana@stryker.com). A Stryker representative will then be in contact to arrange for product return.
3. Keep a copy of the completed and executed Business Reply Form for your records.
4. Report all adverse events or product quality problems to Stryker.

We sincerely regret any inconvenience that this action may cause you and on behalf of Stryker would like to thank you for your help and support in completing this action in a timely manner.

Should you have any queries on this matter please do not hesitate to contact the undersigned.

Yours faithfully

Daniel Rana
Quality Assurance and Regulatory Affairs

Appendix:
PFA Acknowledgment Form

RA2012-154 Affected Product and Lot Codes

Pos	Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
1	4933-1-001	Wire Bolt – Short Hoffmann LRF For Wire Ø1.5 to 2.0mm	Z02804, Z08348, Z08350, Z12549, Z16753
2	4933-1-002	Wire Bolt – Medium Hoffmann LRF For Wire Ø1.5 to 2.0mm	Z08351, Z12554, Z16246, Z16752
3	4933-1-003	Wire Bolt – Long Hoffmann LRF For Wire Ø1.5 to 2.0mm	Z08349, Z09344, Z12551, Z16996

RA2012-154 HOFFMANN LRF WIRE BOLTS