RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

٢٤ نيسان ٢٠١٢

رقم المحفوظات: ٣٨١/٢٥
رقم الصادر: ١٣/١/١٤١١٥
بيروت، في: ٢٤ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Prosthesis Implantation Instruments, Orthopedic, Ceramic Insertion Tool

الجهاز المعنى بالمتابعة:

- Prosthesis Implantation Instruments, Orthopedic, Ceramic Insertion Tool
- Trade Mark: Stryker Orthopaedics
- Local Representative:

بناء على التقرير الصادر عن الشركة المصنعة الذي يشير الى خلل في طريقة تصنيع الجهاز ، 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

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

URGENT FIELD SAFETY NOTICE: RA2012-155

Date

Dear Customer

Description: Ceramic Insertion Tool Assembly

Catalog #: 2216-0005

Lot #: All

Dear Customer

Please find attached details of a Product Action that has been initiated by Stryker Orthopaedics concerning the above referenced subject devices. This action has been taken to ensure that users are aware of important Information concerning the device listed above.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. 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. It may be that you no longer have any physical inventory on site. Completing this 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 25th May 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:

Tel: Fax: E-mail:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 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: RA2012-155

February XX , 2013

FSCA identifier: Product Field Action RA2012-155

Type of Action: Field Safety Corrective Action

Description: Ceramic Insertion Tool Assembly

Catalog #: 2216-0005

Lot #: All

Dear Distributor:

Stryker® Orthopaedics initiated a Field Safety Corrective action for the recall of product referenced above.

An investigation that was made into a customer report alleging issues with the functioning of a Ceramic Insertion Tool, Stryker® has determined that the third party suppliers of a sub-component of the Insertion Tool, the silicone suction cup, are unable to confirm the material purity of the suction cup. Preliminary testing indicates that some suction cups were manufactured from a non-silicone polymer, polyvinyl chloride (PVC), and that these PVC cups contain latex.

Potential Hazards and Risk Mitigation Factors

The investigation into this matter is not yet complete. At this stage, the possibility exists that an individual with latex sensitivity may have an allergic reaction if they are exposed to the product. As more information becomes available, a follow-up communication will be provided.

Immediate actions

We request that you read this notice carefully and complete the following actions:

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. Please inform Stryker of any adverse events.
   Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. Complete the attached customer response form.
   Please complete this form even if you do not have any product to return. This will preclude the need for Stryker to send any unnecessary reminder notices.

7. Return the completed form to your nominated Stryker Representative.
   On receipt of the form a Stryker representative will contact you to arrange for the collection of any remaining inventory.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please contact your local Sales Representative.

Yours .....