REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧١٥٥
رقم الصادر: ١٢/٧/٨٤١٢
بيروت، في: ٢٩ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Instrument, Clamp, Triathlon Tibial Alignment Ankle Clamp EM

الجهاز المعني بالمتابعة:

- Instrument, Clamp, Triathlon Tibial Alignment Ankle Clamp EM
- Trade Mark: Stryker Orthopaedics
- Local Representative: Ets. F.A Kettaneh

بناء على التوصية الصادرة عن الشركة المصنعة
والتي تشير الى وجود خلل في عمل الصنف المذكور 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

Museum Street - Hussein Mansour Bldg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

stryker
Orthopaedics

July 2013

RA2013-083: URGENT FIELD SAFETY NOTICE

Description: Triathlon Tibial Alignment Ankle Clamp EM (Instrument)

Catalog #: 6541-2-609

Lot #: All

Stryker® Orthopaedics has initiated a Field Safety Corrective Action for the Triathlon Tibial Alignment Ankle Clamp EM, an instrument associated with the Triathlon Knee Instrumentation System.

Issue

Stryker has received customer complaints in which it has been reported that the Triathlon Tibial Alignment Ankle Clamp has cracked or fractured.

Potential Hazards

The Triathlon Tibial Alignment Ankle Clamp EM cracks or fractures intraoperatively. The stability of the instrument is compromised. The following sequence of events may result:

A Triathlon TKA has progressed to the stage where proximal tibial resection is required to proceed with the surgery. The surgeon chooses to use Extramedullary (EM) referencing to ensure proper position and orientation of the proximal Tibial Resection Guide. The Ankle Clamp's Yoke or Flipper fractures prior to being attached to the ankle for EM referencing.

1. A sterile replacement Ankle Clamp is requested, located, and immediately available. The replacement Ankle Clamp is retrieved and the surgeon completes the remainder of surgery according to the established surgical technique.

   As a result, there is the potential for complications associated with extended surgery time of less than 5 minutes, the time required to retrieve the sterile replacement Ankle Clamp.

2. A sterile replacement Ankle Clamp is requested and located but not immediately available. The replacement Ankle Clamp is retrieved. The surgeon completes the remainder of surgery according to the established surgical technique.

   As a result, there is the potential for complications associated with extended surgery time of greater than or less than 30 minutes, the time required to retrieve the sterile replacement Ankle Clamp.

3. A sterile replacement Ankle Clamp is requested and is not available. The surgeon completes the positioning and alignment of the tibial resection guide using alternate intramedullary referencing instrumentation available within the kit. The proximal tibial

resection is completed using the IM referencing method and the surgery proceeds following the established surgical technique.

As a result, there is the potential for complications associated with extended surgery time of less than 30 minutes, the time required to complete proximal tibial resection using alternate intramedullary referencing (IM) method.

4. A sterile replacement Ankle Clamp is requested but is not located or immediately available. The surgeon notices the fractured instrument and makes a decision to use the instrument "as-is" with manual assistance for stabilization of the distal portion of the EM Tibial Resection Assembly. The surgeon completes the remainder of surgery according to the established surgical technique.

   As a result, there is the potential for complications associated with extended surgery time of less than 5 minutes, the time required to use the Ankle Clamp instrument with manual assistance for stabilization.

Patient Follow Up

There is no requirement to perform any additional patient monitoring or follow up. Should this event have occurred intraoperatively, the operating surgeon would have been immediately aware and undertaken appropriate measures to complete the surgery.

Device Usage

In the long term, Stryker will be replacing all of the above referenced devices. In the interim, customers may continue to use subject devices in conjunction with the information provided in the Product Correction Bulletin.

In accordance with the IFU for these devices (QIN 4382, Rev. D and instrument cleaning instructions provided by Stryker Orthopaedics (LSTPI-B, available at www.stryker.com/orthopaedics/cleaning)), please note that:

"**Functional checks should be performed at all times:**

- Mating devices should be checked for proper assembly.
- Instruments with moving parts should be operated to check correct operation..."

Risk Mitigation Factors

- In accordance with Triathlon Surgical Protocol (Literature# LSPK47), the surgeon could equally elect to use Intramedullary (IM) Instrumentation and referencing to ensure proper positioning and alignment. The Instrument for this is catalogue reference 65412600, IM Tibial Assembly Instrument.

- In the event of a fracture of the ankle clamp portion of the tibial alignment assembly at the flipper or at the yolk, the instrument will still function as intended with manual stabilization. See attached Product Correction Bulletin, figures 1 and 2.

Immediate actions

Please complete the following actions for all Triathlon EM Tibial Alignment Ankle Clamp Instruments in your possession.

1. Circulate this Field Safety Notice internally to all interested/affected parties.
2. Maintain awareness of this notice internally until all required actions have been completed within your facility.
3. 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.
4. 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.
5. Complete the attached customer response form.
   This will preclude the need for Stryker to send any unnecessary reminder notices.
6. Return the completed form to your Stryker Distributor. The contact details are given on the customer response form.

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 Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries regarding this Field Safety Notice please do not hesitate to contact your designated Stryker Representative as indicated on the covering letter.

Yours Sincerely,