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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨١٢٥
رقم الصادر: ١٣/١/٢٠١٦
بيروت، في: ١٢ حزيران ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
5mm Versaport Bladeless Optical Trocars with Fixation Cannulae

الجهاز المعني بالمتابعة:

- 5mm Versaport Bladeless Optical Trocars with Fixation Cannulae
- Trade Mark: Covidien LLC
- Local Representative: Dima Health Care/ Mediline

بناء على التوصية الصادرة عن الشركة المصنعة التي تشير الى وجود خلل في استخدام 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

الجمهورية اللبنانية – المديرية العامة – قلم الديوان – وزارة الصحة العامة

عام الصحة
وليد عمار

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

COVIDIEN

URGENT FIELD SAFETY NOTICE

Versaport™ Bladeless Optical 5 mm Trocar with Fixation Cannula

May 14th, 2013
Attention: Risk Management Director and OR Materials Management
Please forward this communication to all surgeons, surgical personnel, and any other potential users of the product.

Dear Valued Customer,

The purpose of this letter is to advise you that Covidien is conducting a Field Safety Corrective Action (FSCA) of various production lots of the Versaport™ Bladeless Optical 5 mm Trocar with Fixation Cannula. The Versaport™ Bladeless Optical 5mm trocars are intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.

Covidien has received reports of seals disengaging from the cannula which may result in a component inadvertently disengaging into the patient's cavity. No related adverse events have been reported at this time.

The seal, made of inert thermoplastic material is biocompatible polymer blend which meets or exceeds the current United States Pharmacopoeia Class VI test requirements. This material does not contain latex rubber, polyvinyl chloride, silicone rubber, or polyurethane. The seal is opaque-white in color, pliable to touch, and is approximately 13mm in diameter by 0.5mm thick, with a 3mm hole centrally located. This seal is located within the trocar body itself and when defective, may detach from the trocar and be pushed by the laparoscopic instrument into the body cavity. If detected the detached seal should be removed. As with all foreign bodies, if undetected and left free in the body, the seal may lead to a complication, the nature of which is undetermined.

This FSCA is limited to the material codes and ranges of lot numbers listed below and does NOT affect any other lots of Covidien devices.

Product Code	Product Description	Lot Numbers / Ranges
ONB5LGF	Versaport™ Bladeless Optical Trocar With Fixation Cannula - 5mm Long	N2H0414X through N3A0294X
ONB5SHF	Versaport™ Bladeless Optical Trocar With Fixation Cannula - 5mm Short	N2H0413X through N3A0391X
ONB5STF	Versaport™ Bladeless Optical Trocar With Fixation Cannula - 5mm	N2H0353X through N3D0033X
ONB5STF2C	Versaport™ Bladeless Optical Trocar With (2) Fixation Cannulae - 5mm	N2J0211X through N3D0118X
ONBFCA5SH	Versaport™ Bladeless Optical Fixation Cannula - 5mm Short	N2J0315X through N3A0389X
ONBFCA5ST	Versaport™ Bladeless Optical Fixation Cannula - 5mm	N2J0150X through N3C0683X

Note: The specific lot numbers listed below are not affected by this FSCA and are acceptable for use:

N2H0045X, N2H0166X, N2H0286X, N2H0357X, N2H0516UX

REQUIRED ACTIONS:

1. Immediately quarantine and discontinue use of the affected devices.

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REQUIRED ACTIONS:

2. Please return affected product as follows:

- CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM COVIDIEN

  Please complete the attached Verification Form in its entirety. Fax the completed Form to the fax number or email address stated on the form. If you do not have any units in your inventory, simply return the Verification Form indicating you have zero (0) units. Upon receiving your form, Customer Service will be contacting you to organize the return of your products. You will receive credit for returned products.

- CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR

  If you purchased product from a distributor please complete the verification form (attached) and contact your Distributor directly. The completed form and all affected units must be returned through the Distributor.

- ALL CUSTOMERS

  We ask that all **customers** reply to Covidien ***WHETHER OR NOT*** you have affected product at your site. Your response is vital to our monitoring of the effectiveness of this FSCA. Please complete the attached Verification Form and return to Covidien via the instructions provided above. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

  This action is being taken with the knowledge of the Saudi Food & Drug Authority If you have any questions or concerns, please do not hesitate to contact your Covidien representative at +96626623153.

  We know you share our interest in the primacy of patient safety and we sincerely apologize for any inconvenience this may cause. Thank you for your business and continued support.

Sincerely,

Bryan Dannettell
Covidien
Surgical Supplies
Vice President, Quality Assurance