



رقم المحفوظات: ٣٨/٢٥
رقم الصادر: ١٣/١٢٠١٥٦
بيروت، في: ١٢ حزيران ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Retractor, surgical instruments, Collins Radioparent
Sternal Blades Nylon.

الجهاز المعنى بالمتابعة:

- Retractor, surgical instruments, Collins Radioparent Sternal Blades Nylon.
- Trade Mark: Symmetry Surgical
- Local Representative:

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 عمل الصنف المذكور

أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

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

مدير عام الصحة

د. وليد عمار





symmetry surgical™

formerly Codman Instruments and SSI

URGENT MEDICAL DEVICE RECALL

9-April-2013

Victoria Rogers
Symmetry Surgical
3034 Owen Drive
Antioch, TN 37013

Dear Customer:

This letter is to inform you of a product recall involving:

Codman & Shurtleff, Inc. labeled product:

50-8081 Collins Radiopaque Sternal Blades Nylon

Lot Numbers:

244576, 244582, 244584, 268916, 268920, 276513, 276514, 296136, 296139, 296141, 296153, 296153, 296155, 296156
296157, 296160

See enclosed example product label

This recall has been initiated due to the possibility that the Collins retractor blade may break during use. Breakage of this product may cause the patient's sternum to close abruptly, which may displace vital equipment as well as obstruct the surgeon's field of vision putting the patient at risk of serious injury or death. If an event occurs, this will prolong surgery and potentially put the patient at further risk of infection which could lead to serious injury or death.

We began shipping this product on October 12, 2012. Immediately examine your inventory and quarantine all product(s) subject to this recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Please examine your inventory immediately to determine if you have any of the product's lot number(s) listed above on hand. If so, please discontinue use of the product immediately and promptly call (800) 251-3000 for a return material authorization (RMA) number and to identify if you would like credit or an alternative product. Please fill out the Recall Response Form (which is enclosed) and fax the completed form to the fax number identified on the form or via parcel post.

Please package the recall product(s) and mark the outside of the box with the RMA number that was provided to you and return the recall product(s) parcel post. Please use our FedEx Ground account number 327096192 and ship the recall product(s) to the following address:

Symmetry Surgical Germany
Maybachstrasse 10
Tuttlingen, Baden-Wuerttemberg, 78532, Germany

This recall should be carried out to the end user level. Your assistance is appreciated and necessary to prevent patient and surgical staff harm.

Please complete and return the enclosed response form as soon as possible. If you have any questions, call Victoria Rogers at (615) 964-5515 M-F 8:00am – 5:00pm CST.

This recall is being made with the knowledge of the Food and Drug Administration, so it is important for you to track all of your actions regarding this recall as they may be audited by the FDA.

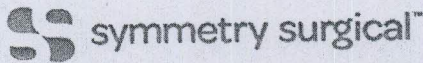
DATE: _____

Victoria Rogers
Senior Director of Quality Assurance and Regulatory Affairs
Symmetry Surgical, Inc.

3034 Owen Drive, Antioch, TN 37013

Office 800.251.3000
Fax 615.964.5567

symmetrysurgical.com



formerly Codman Instruments and SSI

Enclosed Example of Labeling:

(Note: the product has Codman & Shurtleff, Inc. labeling; Symmetry Medical purchased the Codman & Shurtleff, Inc. product line in December of 2011)

BOX/ CARTON LABEL

REF 50-8081 LQT 276514 2017-10
 CODMAN QTY 10
 Collins Radioparent Sternal Blades Nylon

STERILE EO CE 0089

Lames pour sternum radioparentes en Nylon
 Collins strukturenurchlaasige Sternumklappen Nylon
 Collins (cont)gentransparante sternumblader nylon
 Lame sternali radiotransparenti in nylon Collins
 Hojas esternales radiotransparentes de Nylon de Collins
 Laminas esternales radiotransparentes em nylon Collins
 Collines fermegegensprekende sternumbladen nylon
 Collins (cont)gentransparente sternumbladen nylon
 Röntgenparents færdigvaskede sterner Collins (int)stærkt
 Ассортимент стерильных изделий Collins в упаковке
 Collins (cont)gentransparente sternumbladen nylon

Codman & Shurtleff, Inc.
 375 Paramount Drive
 Raynham, MA 02767-0050, USA

MADE IN China

4202506081144
 4202506081144
 4202506081144

Rev. H

PACKAGE LABEL

Codman REF 50-8081

Collins Radioparent Sternal Blades Nylon
 Collins strukturenurchlaasige Sternumklappen Nylon
 Collins (cont)gentransparante sternumbladen nylon
 Lames pour sternum radioparentes en Nylon
 Hojas esternales radiotransparentes de Nylon de Collins
 Laminas esternales radiotransparentes em nylon Collins
 Collines fermegegensprekende sternumbladen nylon
 Collins (cont)gentransparente sternumbladen nylon

STERILE EO

QTY 10

LQT 276514 2017-10

Codman CE 0089

Codman & Shurtleff, Inc.
 375 Paramount Drive
 Raynham, MA 02767-0050, USA