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الجمهورية اللبت نانية وزارة الصحة العسامسة المسديثرالعثام

رقم المحفوظات: O > / V إلى رُقَتُم اللصَّادر: ٧٤ ١٨٧ ﴿ ١٠/ ر__ بيسروت، في : الله تريانان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

المويسوع: إشعار بمتابعة جهاز طبي Veri'y Bo vie - Dick Test Card.

الجهاز المعنى بالمتابعة:

- Verify Bov ie - Pick Test Card Trade Mark: Steris Corporation

Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

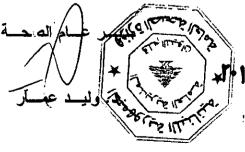
الذي يفيد بوجود خلل أثناء استعمال الصنف المذكور أعلاه والذي يؤدي الى خلسل في عملية مراقبة أجهزة التعقيم، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية.

مرفق ربطا:

التقرير الصادر عن وكالة ال FDA.

دائرة البرامج والمشاريع المستشفيات الحكومية

المحقو ظات







U.C. Food & Orug Adminis ration

Econcement Report - Week of September 26, 20 € 21

242Home³ Enforcement Reports⁴

Back to Previous Page

Product Detail

Product Description	Verify® Bowie-Dick Test Card, Model #S3098, Steris Biological Operations, 9325 Pinecone Drive, Mentor, OH 44060 The Verify Bowie-Dick Test Card consists of a card printed on one side with bars of chemical indicator ink. On the opposite side of the card, space is provided for critical cycle information to be recorded. The card is laminated inside a thin clear plastic enclosure. The enclosure has two holes in it to allow air removal and steam penetration. The preassembled test is used to evaluate the effectiveness of air removal from the sterifizer chamber during prevacuum pulse steam sterifizer cycle. Following a prevacuum cycle, the chemical bars of the Bowie-Dick Test card uniformly darken indicating that residual air has been sufficiently removed to allow complete steam penetration into the test card. If air is trapped in the card during the exposure phase of the cycle, the color change of the bars will be incomplete or uneven. Thus the card can provide an immediate indication of inadequate removal of air during a cycle. The Bowie-Dick Type test is performed in an empty chamber each day the sterifizer is to be used, usually before the first sterifization cycle.
Recall Number	Z-2417-2012
Classification	Class !!
Code Info	Model #S3098, Serial #"s: H20013, H20014, and H2f-U16.
Product Distributed Qty	629 cards
Reason For Recall	STERIS has learned that the Verify Bowle Dick Tent Card are not performing to product specifications. Specifically, test cards have resulted in false fail results when sterilizer performance is within acceptable ranges.

Event Detail

Event Id	63129	
Product Type	Devices	
Status	Ongoing	
Recalling Firm	Steris Corporation	
City	Mentor	
State	ОН	
Country	us	
Voluntary / Mandated	Voluntary: Firm Initiated	
Recali Initiation Date	2012-07-03	
Initial Firm Notification of Consignee or Public	Letter	
Distribution Pattern	Worldwide DistributionUSA (nationwide) Including the states of AL, CA, CO, CT, FL, GA, IA, IN, IL, KS, KY, LA, MA, MD, MI, MN, MO, MS, NC, NE, NJ, NM, NY, OH, OK,OR, PA, RI, SC, TX, UT, VA, WA, WI, WV and WY. and the country of Canada.	

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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