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المدير العام

رقم المحفوظات: ٢٧٨٥
رقم الصادر: ٢٨٤
بيروت، في: ٣ - كانون الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي Tourniquet System,

الجهاز المعني بالمتابعة:

- Tourniquets, A.T.S. 3000 Automatic Tourniquet Systems
- Trade Mark: Zimmer Inc
- Local Representative: Intermedic S. A. L.

بناء على التقرير الصادر عن وكالة الـ fda،

الذي يفيد بوجود خلل في عمل الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على الاطباء المعنيين في جميع المستشفيات.

مرفق ربطاً:

- التوصية الصادرة عن وكالة الـ fda.

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المدير العام
د. وليد عمار

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U.S. Food & Drug Administration

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Class 2 Recall
ATS 3000 Automatic Tourniquet System

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Date Posted	November 15, 2012
Recall Number	Z-0296-2013
Product	ATS 3000 Automatic Tourniquet System w/HOSES AND LOP SENSOR Intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities.
Code Information	Catalog 60-3000-101-00, Serial # 3005IACJ, 3006JAEP, 3007CADR, 3007EACT, 3007EAKT, 3007GAGR, 3007HABK, 3007KAAR, 3007KAET, 3008CADE, 3008HAHC, 3008LACK, 3009AACN, 3009HABA, 3009LAEF, 3010CABH, 3010DAHG, 3010GAAC, 3010GAAJ, 3011LABL, 3011LABN, 3011LABQ, 3011LACC, 3011LACE, 3011LACF, 3011LACG, 3011LACH, 3011LACJ, 301 1LACK, 3011LACL, 3011LACM, 3011LACN, 3011LACP, 3011LACQ, 3011LACR, 3011LACS, 3011LACT, 3011LACU, 3011LACW, 3011LADA, 3011LADE, 3011LADF, 3011LADG, 3011LADH, 3011LADJ, 3011LADK, 3011LADM, 3011LADP, 3011LADQ, 3011LADR, 3011LADS, 3011LADT, 3011LADU, 3011LADW, 3011LAEA, 3011LAEB, 3011LAEC, 3011LAED, 3011LAEE, 3011LAEF, 3011LAEH, 3012AAAG, 3012AAAK, 3012AAAM, 3012AAAN, 3012AAAP, 3012AAAQ, 3012AAAR, 3012AAAS, 3012AAAT, 3012AAAU, 3012AAAW, 3012AABA, 3012AABB, 3012AABC, 3012AABE, 3012AABG, 3012AABH, 3012AABK, 3012AABL, 3012AABM, 3012AABN, 3012AABQ, 3012AABR, 3012AABS, 3012AABU, 3012AACA, 3012AACB, 3012AACC, 3012AACD, 3012AACE, 3012AACH, 3012AACJ, 3012AACM, 3012AACN, 3012AACP, 3012AACQ, 3012AACR, 3012AACS, 3012AACT, 3012AACW, 3012AADA, 3012AADB, 3012AADC, 3012AADD, 3012AADE, 3012AADF, 3012AADG, 3012BAAA, 3012BAAB, 3012BAAC, 3012BAAD, 3012BAAE, 3012BAAF, 3012BAAG, 3012BAAH, 3012BAAJ, 3012BAAK, 3012BAAL, 3012BAAM, 3012BAAN, 3012BAAP, 3012BAAQ, 3012BAAR, 3012BAAS, 3012BAAT, 3012BAAU, 3012BAAW, 3012BABA, 3012BABB, 3012BABC, 3012BABD, 3012BABE, 3012BABF, 3012BABG, 3012BABH, 3012BABJ, 3012BABK, 3012BABL, 3012BABM, 3012BABN, 3012BABP, 3012BABQ, 3012BABR, 3012BABS, 3012BABT, 3012BABU, 3012BABW, 3012BACE, 3012BACG, 3012BACH, 3012BACJ, 3012BACK, 3012BACL, 3012BACM, 3012BACN, 3012BACP, 3012BACQ, 3012BACR, 3012BACS, 3012BACT, 3012BACU, 3012BACW, 3012BADA, 3012BADB, 3012BADC, 3012BADD, 3012BADG, 3012BADH, 3012BADJ, 3012BADK, 3012BADL, 3012BADN, 3012BADP, 3012BADR, 3012BADS, 3012BADU, 3012BADW, 3012BAEA, 3012BAEB, 3012BAEC, 3012BAEH, 3012BAEJ, 3012BAEL, 3012BAEM, 3012BAEN, 3012BAEQ, 3012BAER French Catalog 60-3000 301-02 Serial # 3012 AAAE German Catalog 60-300060-301-03, Serial # 3012AAAF Spanish Catalog 60-3000-301-11, Serial # 3012AAAB, 3012AAAC, 3012AACG, 3012BACA, 3012BACB, 3012BACC, 3012BACD Dutch 60-3000-301-12, Serial # 3012AAAA, 3012AAAD, 3012EACA
Recalling Firm/ Manufacturer	Zimmer, Inc. 345 E Main St Warsaw, Indiana 46580-2746
For Additional Information Contact	Jaime L. Weeks 574-372-4807
Reason for Recall	Zimmer is conducting a voluntary removal of some Zimmer A.T.S. 3000 tourniquets after receiving complaints of both out-of-box failures and failures during surgical procedures on some of the affected units. During failure the unit will alarm, lock into a non-operational mode, and the display screen will go blank. Based on investigation, this problem appears to be due to a counterfeit chip on the
Action	Zimmer sent an Urgent Device Removal Notice letter dated September 5, 2012, to all affected customers. Zimmer Distributors and Sales Leadership were notified via E-mail of the pending recallthe product under recall beginnig September 11, 2012. The notification listed the reason for the recall, risks involved, and requested return of the unit for repair To: Zimmer Surgical, Attn: QAIRA Dept. - Recall, 200 West Ohio Avenue, Dover, Ohio 44622 USA The notice asked to ensure all users be made aware of the recall, remove the affected ATS 3000 tourniquest sytem for repair and return the fax back form/acknowledgement certification to 1-888-429-7380 or email it to zimmer3611@stericycle.com. Questions should be directed to 1-888®943®5167 between 8 a.m. and 5 p.m. EDT. For questions regarding this recall call 574-372-4807.
Quantity in Commerce	204
Distribution	Worldwide Distribution - USA (nationwide) and Internationally to Belgium, Czech Republic, Egypt, France, Germany, Morocco, Netherlands, Romania, Saudi Arabia, Spain, Switzerland, Turkey, and UAE.

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