

REPUBLIC OF LEBANON

MINISTRY OF PUBLIC HEALTH

The Director General



الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٣٨/٢٥  
رقم الصادر: ١٣١١/٢٥٢٢  
بيروت، في: ٢١ تموز/أولاد ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

LIFESTENT Solo Vascular Stent Systems

الجهاز المعنى بالمتابعة:

- LIFESTENT Solo Vascular Stent Systems
- Trade Mark: Bard Peripheral Vascular (BPV)
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

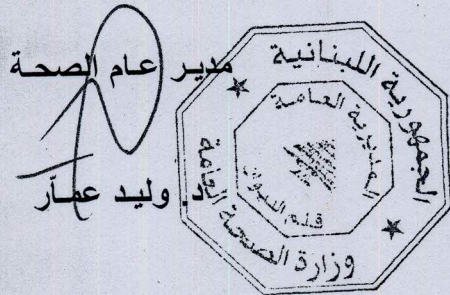
والذي يشير الى وجود خلل في عمل الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



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Medical & Radiation Emitting Device Recalls



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Class 1 Recall  
LifeStent Solo Vascular Stent

See Related Information 21

**Date Classified** October 10, 2013

**Recall Number** Z-0007-2014

**Product** Bard LifeStent Solo Vascular Stent, Item Numbers: EX062001CL, EX072001CL, EX062003CL, EX072003CL. The LifeStent Solo Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 240 mm in length in the native superficial femoral artery (SFA) and in the proximal popliteal artery with reference vessel diameters ranging from 4.0 6.5 mm.

**Code Information** Product Code:EX062001CL Lot Numbers: ANVG3284, ANVH2474, ANVJ1379, ANVJ2590, ANVK3364, ANVL2910, ANVG3862, ANVH2475, ANVJ2089, ANVK3149, ANVK3707, ANVH0592, ANVH3715, ANVK3150, ANVL2902. Product Code: EX062003CL Lot Numbers: ANVG3285 ANVH1962 ANVJ1385 ANVK3655 ANVL2915 ANWA1414 ANVG3286 ANVH2125 ANVJ1799 ANVL0001 ANWA0307 ANWA1415 ANVG3287 ANVH2126 ANVJ1800 ANVL0002 ANWA0308 ANWA1416 ANVG3882 ANVH2127 ANVJ1801 ANVL0169 ANWA0458 ANWA1419 ANVG3883 ANVH2185 ANVJ1802 ANVL0170 ANWA0459 ANWA3834 ANVG3884 ANVH2186 ANVJ1890 ANVL0364 ANWA0493 ANWA3855 ANVG3885 ANVH2187 ANVJ1891 ANVL0526 ANWA0494 ANWB0137 ANVH0325 ANVH2392 ANVJ1892 ANVL0527 ANWA0495 ANWB0139 ANVH0326 ANVH2393 ANVJ1893 ANVL0528 ANWA0698 ANWB1630 ANVH0327 ANVH3089 ANVJ2090 ANVL0811 ANWA0699 ANWB1631 ANVH0328 ANVH3278 ANVJ2091 ANVL0812 ANWA0701 ANWB1632 ANVH0329 ANVH3279 ANVJ2337 ANVL0813 ANWA0820 ANWD3081 ANVH0593 ANVH3434 ANVJ2591 ANVL0814 ANWA0821 ANWE1362 ANVH0594 ANVH3435 ANVK0075 ANVL1027 ANWA0857 ANWE1365 ANVH0596 ANVH3451 ANVK0076 ANVL1028 ANWA0858 ANWE1366 ANVH0597 ANVH3452 ANVK0077 ANVL1029 ANWA0859 ANWE1368 ANVH0598 ANVH3453 ANVK0078 ANVL1219 ANWA0964 ANWE2371 ANVH0997 ANVH3454 ANVK0474 ANVL1220 ANWA0965 ANWE2864 ANVH0998 ANVH3716 ANVK0552 ANVL1221 ANWA0966 ANWE3415 ANVH0999 ANVH3717 ANVK0755 ANVL1391 ANWA0967 ANWE3416 ANVH1000 ANVH3718 ANVK0756 ANVL1392 ANWA1125 ANWE3550 ANVH1001 ANVI0132 ANVK0871 ANVL1393 ANWA1373 ANWE3551 ANVH1002 ANVI0134 ANVK0872 ANVL1394 ANWA1384 ANWE3552 ANVH1182 ANVI0135 ANVK1133 ANVL1604 ANWA1385 ANWE3685 ANVH1183 ANVI0136 ANVK1134 ANVL1605 ANWA1388 ANWE3686 ANVH1184 ANVI0311 ANVK1253 ANVL1608 ANWA1390 ANWE3982 ANVH1185 ANVI0808 ANVK1461 ANVL1609 ANWA1391 ANWE4134 ANVH1186 ANVI0967 ANVK1462 ANVL1762 ANWA1395 ANWE4135 ANVH1187 ANVI1251 ANVK1463 ANVL1763 ANWA1396 ANWE4136 ANVH1188 ANVI1252 ANVK1669 ANVL1764 ANWA1397 ANWF0178 ANVH1189 ANVI2510 ANVK1670 ANVL1765 ANWA1398 ANWF0179 ANVH1190 ANVI2511 ANVK1671 ANVL2346 ANWA1399 ANWF0180 ANVH1191 ANVI2513 ANVK1982 ANVL2347 ANWA1400 ANWF0370 ANVH1324 ANVI2514 ANVK1983 ANVL2687 ANWA1401 ANWF0803 ANVH1325 ANVI2883 ANVK2219 ANVL2688 ANWA1402 ANWF0806 ANVH1326 ANVI2884 ANVK2220 ANVL2689 ANWA1403 ANWF0808 ANVH1327 ANVI2885 ANVK2435 ANVL2690 ANWA1404 ANWF0970 ANVH1328 ANVI3354 ANVK2436 ANVL2785 ANWA1405 ANWF0971 ANVH1822 ANVI3356 ANVK2437 ANVL2786 ANWA1406 ANWF0972 ANVH1823 ANVI3357 ANVK2745 ANVL2897 ANWA1407 ANWF0973 ANVH1940 ANVI3359 ANVK2746 ANVL2898 ANWA1408 ANWF0974 ANVH1941 ANVJ0568 ANVK3004 ANVL2899 ANWA1409 ANWF0975 ANVH1958 ANVJ0569 ANVK3005 ANVL2904 ANWA1410 ANWF0977 ANVH1959 ANVJ0769 ANVK3006 ANVL2908 ANWA1411 ANWF0979 ANVH1960 ANVJ1383 ANVK3653 ANVL2912 ANWA1412 ANVH1961 ANVJ1384 ANVK3654 ANVL2914 ANWA1413. Product Code: EX072001CL Lot Numbers: ANVG3288 ANVI0969 ANVJ1134 ANVK3361 ANVL2913 ANVG3886 ANVI2302 ANVJ1135 ANVK3362 ANWA2569 ANVH0599 ANVJ0940 ANVJ2092 ANVL2903 ANWA2647. Product Code: EX072003CL Lot Numbers: ANVG3289 ANVH2680 ANVJ0768 ANVK2434 ANVL2349 ANWA0707 ANVG3290 ANVH2833 ANVJ1133 ANVK2727 ANVL2350 ANWA0860 ANVG3887 ANVH2834 ANVJ2093 ANVK2728 ANVL2787 ANWA0861 ANVG3888 ANVH2835 ANVJ2338 ANVK3656 ANVL2788 ANWA0968 ANVG3889 ANVH3090 ANVJ2339 ANVK3657 ANVL2900 ANWA0969 ANVH0596 ANVH3091 ANVJ2593 ANVL0003 ANVL2905 ANWA1126 ANVH0597 ANVH3092 ANVJ2595 ANVL0004 ANVL2909 ANWA1386 ANVH0598 ANVH3280 ANVJ2596 ANVL0075 ANVL2911 ANWA1387 ANVH0600 ANVH3281 ANVK0473 ANVL0076 ANVL2916 ANWA2895 ANVH0601 ANVH3449 ANVK0757 ANVL0077 ANVL2917 ANWB0138 ANVH0602 ANVH3450 ANVK0758 ANVL0171 ANWA0055 ANWB0140 ANVH0997 ANVI0673 ANVK0873 ANVL0172 ANWA0056 ANWD3089 ANVH0998 ANVI0809 ANVK0874 ANVL0371 ANWA0057 ANWD3089 ANVH0999 ANVI0968 ANVK1135 ANVL0373 ANWA0058 ANWE2372 ANVH1000 ANVI1080 ANVK1136 ANVL0810 ANWA0059 ANWE2373 ANVH1001 ANVI1081 ANVK1464 ANVL1024 ANWA0309 ANWE2865 ANVH1002 ANVI1082 ANVK1465 ANVL1026 ANWA0310 ANWE3417 ANVH1182 ANVI1083 ANVK1667 ANVL1222 ANWA0455 ANWE3983 ANVH1462 ANVI1084 ANVK1668 ANVL1223 ANWA0456 ANWF0181 ANVH1463 ANVI1085 ANVK1978 ANVL1395 ANWA0457 ANWF0184 ANVH1464 ANVI2299 ANVK1979 ANVL1603 ANWA0496 ANWF0371 ANVH1465 ANVI2300 ANVK1980 ANVL2035 ANWA0497 ANWF0716 ANVH1466 ANVI2301 ANVK1981 ANVL2036 ANWA0498 ANWF0717 ANVH1620 ANVI2515 ANVK2222 ANVL2037 ANWA0705 ANWF0983 ANVH1621 ANVJ0567 ANVK2433 ANVL2348 ANWA0706 ANWF0985

**Recalling Firm/Manufacturer** Bard Peripheral Vascular Inc  
1625 W 3rd St Ste 109  
Tempe, Arizona 85281-2438

<b>Manufacturer Reason for Recall</b>	Bard Peripheral Vascular is recalling specific lots of Bard Lifestent Solo Vascular Stent because they have determined a higher incidence rate of partial stent deployment associated with their use.
<b>Action</b>	The firm, Bard Peripheral Vascular, sent a "Urgent: Medical Device Recall Notification" letter dated September 30, 2013 via FedEx to all the customers who received the specific lots on recall. The letter informs the customers of the problems identified and the actions to be taken. Customers are instructed to fill out the Recall and Effectiveness Check Form and fax to: BPV at 1-800-994-6772, even if you no longer have possession of the recalled product; call Bard Peripheral Vascular's Recall Coordinator at (800) 321-4254 Option #2 Ext 2727 (M-F 7am to 4pm MST) or email silvia.carrillo@crbard.com. The Recall Coordinator will issue you either a Return Authorization (RCL) Number or Consignment Recall Number (CRC) to facilitate the expedient return of the product; and to return the product to Bard Peripheral Vascular, Inc., 1415 W. 3rd Street, Tempe, AZ 85281. BPV will provide replacement product for your returned product. If you have any questions, call 1-800-321-4254 Option #2 Ext. 2727.
<b>Quantity in Commerce</b>	4112 units
<b>Distribution</b>	US Nationwide Distribution.

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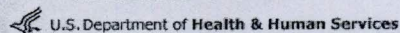
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