



رقم المحفوظات: ٢٠١٣ / ٢٦

رقم الصادر: ١٣/١/١٤٤٤٨

بيروت، في: ٢٦ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Vascular cannula and catheters; catheter arterial.
Supercross microcatheters

الجهاز المعنى بالمتابعة:

- Vascular cannula and catheters; catheter arterial. Supercross microcatheters
- Trade Mark: Vascular Solutions Inc
- 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 احتمال وجود تلوث في الجهاز مما قد يؤثر

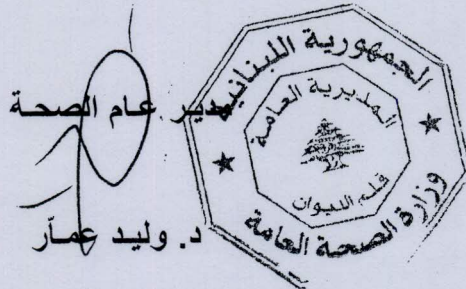
على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



د. وليد عمار

د. وليد عمار



URGENT: Medical Device Recall

January 28, 2013

Distributor's Name
 Address
 City, Country and Postal Code

Medical Device Recall – SuperCross microcatheter, Model Numbers 5300, 5301, 5302, 5304, 5305, 5306, 5307, 5325, 5325, 5329, 5332, 5336, 5340, 5341

Dear Ladies and Gentlemen,

Upon completion and review of recent device quality testing, Vascular Solutions, Inc. has discovered a potential problem with our SuperCross microcatheters manufactured with the following lot number(s):

| | | | | | |
|--------|--------|--------|--------|--------|--------|
| 551750 | 555759 | 559707 | 558222 | 556536 | 558992 |
| 552370 | 555953 | 560433 | 558894 | 556747 | 561208 |
| 552761 | 557251 | 561207 | 559827 | 557124 | 560221 |
| 552840 | 559570 | 554040 | 560215 | 558327 | 560222 |
| 552954 | 559981 | 555007 | 551751 | 558991 | 560223 |
| 553267 | 560253 | 555224 | 552371 | 560115 | 560995 |
| 553647 | 560079 | 555358 | 552841 | 561206 | 560996 |
| 553931 | 554210 | 558542 | 553090 | 554208 | 560080 |
| 554269 | 555991 | 560434 | 553218 | 555490 | 554123 |
| 554270 | 556842 | 561459 | 553434 | 555993 | 556182 |
| 554413 | 557253 | 554122 | 553529 | 556674 | 558905 |
| 555958 | 554209 | 555008 | 554029 | 556843 | 560114 |
| 557192 | 555223 | 555225 | 554268 | 558018 | 559450 |
| 557824 | 555992 | 555994 | 554271 | 558798 | |

A potential for surface contamination on aged catheters was observed during in-house testing. There have been no related field complaints or observations. The catheters are being recalled as a precautionary measure. The contamination source is manufacturing material residue on a supplied component, which has now been eliminated from the supplier's manufacturing process.

Our records indicate that the SuperCross microcatheters listed below were shipped to your location and are affected by this action.

| Quantity of SuperCross microcatheters Shipped (Total Number of Units) | Affected SuperCross microcatheter Lot Numbers Shipped to Account |
|--|--|
| | |
| | |