



رقم المحفوظات: ٢٥ / ٨١
رقم الصادر: ٨١ / ١٤٤٤ / ٣
بيروت، في: ٢٦ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Vascular cannula and catheters, catheter introducer, Guardian II and Guardian II NC Hemostatis valves

الجهاز المعني بالمتابعة:

- Vascular cannula and catheters, catheter introducer, Guardian II and Guardian II NC Hemostatis valves
- Trade Mark: Vascular Solutions Zerusa Limited (VSZL)
- 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 حدوث مضاعفات جراء استعمال الصنف المذكور اعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

الجمهورية اللبنانية
المديرية العامة
قلم البعوت
وزارة الصحة العامة
د. وليد عمار
مدير عام الصحة



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



Please immediately check your SuperCross microcatheter inventory and follow the steps outlined below:

- Identify the location of all SuperCross microcatheters in your possession indicated in the table above.
- Immediately remove all SuperCross microcatheters from your current inventory and place in a secure area.
- Complete the VSI Account Inventory Form received with this letter.
- Sign, date and e-mail or fax the completed VSI Account Inventory Form to the Customer Service Department using the e-mail, fax number and contact information provided on the form.
- VSI Customer Service will contact you within 1-2 business days after receiving the completed VSI Account Inventory Form, at the phone number or e-mail address provided, with a return material authorization (RMA) number. All devices will be replaced upon receiving your returned devices.

IMPORTANT: Please use the enclosed "SAMPLE" Field Safety Notice and Customer Inventory Form as a template to notify your customers, who have or may have received the affected product. Please update the items highlighted in green, have both documents translated at your earliest convenience and distributed to your customers. In addition to the completed Distributor Inventory Form, a copy of the translated Field Safety Notice and Customer Inventory Form sent to your customers must be returned to Vascular Solutions by e-mail to customerservice@vasc.com or fax at 011-877-656-4251.

We apologize for the inconvenience this may cause. If you have specific questions or concerns regarding this matter, please contact your local Sales Representative.

Sincerely,

Carrie Powers
Vice President of Marketing
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Minneapolis, Minnesota 55369
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