جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار متابعة جهاز طبي
Vascular cannula and catheters; catheter arterial. Supercross microcatheters

الجهاز المعني بالمتابعة:
- Vascular cannula and catheters; catheter arterial. Supercross microcatheters
- Trade Mark: Vascular Solutions Inc
- Local Representative:

بناءً على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA
والتصويت الصادرة عن الشركة المصنعة، والتي تشير إلى احتمال وجود تلوث في الجهاز مما قد يؤثر
على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ريبطاً:
- التوصية الصادرة عن الشركة المصنعة

بلاغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

P. de la Meslié - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: directorgeneral@moph.gov.lb
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):

<table>
<thead>
<tr>
<th>Lot Number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>551750</td>
</tr>
<tr>
<td>552370</td>
</tr>
<tr>
<td>552761</td>
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<tr>
<td>552840</td>
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<td>552954</td>
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<td>553267</td>
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<td>553647</td>
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<td>553931</td>
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<td>554269</td>
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<td>554270</td>
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<td>554413</td>
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<tr>
<td>555958</td>
</tr>
<tr>
<td>557192</td>
</tr>
<tr>
<td>557824</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Quantity of SuperCross microcatheters Shipped (Total Number of Units)</th>
<th>Affected SuperCross microcatheter Lot Numbers Shipped to Account</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Confidential

FR-Q51018-12 Rev. C
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  
Vascular Solutions, Inc.  
6464 Sycamore Court  
Minneapolis, Minnesota 55369  
(763) 656-4300 (Tel.)  
(763) 656-4250 (Fax)  
www.vasc.com