



URGENT: Medical Device Recall

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February 26, 2013

ViCare Medical A/S
 Birkerød Kongevej 150B
 Birkerød, DENMARK 3460

Medical Device Recall – Guardian™ II and Guardian™ II NC Hemostasis Valves, Model Numbers: FH101, FH101-T, FH101-25, FH101-50, FH102, FH102-T, FH102-25, FH102-50

Dear Ladies and Gentlemen,

We have become aware of a potential issue with our Guardian II and Guardian II NC Hemostasis Valves. There is a low risk that air may be introduced into the device, which may lead to an air embolism. Due to the potential harm, VSI is recalling Guardian II hemostasis valves with the lot numbers listed below.

27215	27653	28052	29133	29843	30617
27216	27654	28053	29134	29844	30698
27217	27655	28054	29135	30035	30699
27294	27656	28163	29137	30068	30737
27295	27657	28245	29138	30126	30904
27334	27658	28246	29141	30211	30928
27390	27659	28247	29453	30212	30929
27391	27660	28427	29454	30213	30930
27392	27779	28428	29455	30215	30931
27393	28001	28429	29456	30216	30932
27394	28002	28430	29457	30218	30933
27395	28003	28431	29458	30238	30934
27396	28004	28536	29459	30419	30935
27397	28005	28538	29538	30420	30936
27398	28006	28539	29649	30421	30937
27399	28007	28745	29680	30578	30938
27400	28041	28815	29686	30579	30939
27401	28042	28816	29709	30580	31020
27402	28043	28817	29833	30581	31102
27403	28044	28818	29834	30582	31128
27646	28045	28819	29835	30607	31241
27647	28046	28820	29836	30608	31242
27648	28047	29016	29837	30609	31243
27649	28048	29129	29838	30611	
27650	28049	29130	29839	30613	
27651	31340	31418	29840	30614	
31339	28050	29131	29841	30615	
27652	28051	29132	29842	30616	

Our records indicate that the Guardian II hemostasis valves listed below shipped to your location are affected by this action.

Lot Number	Model Number	Quantity (Total Number of Units)
28001	FH101	25
29686	FH101	25

Please immediately check your Guardian II hemostasis valve inventory and follow the steps outlined below:

- Identify the location of all Guardian II hemostasis valves in your possession indicated in the table above.
- Immediately remove all Guardian II hemostasis valves 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 authorization (RA) number. All devices will be replaced upon receiving your returned devices.

IMPORTANT: Please use the enclosed "SAMPLE" Medical Device Recall 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 Medical Device Recall letter 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