



Vascular Solutions Zerusa Limited *
 208 Business Innovation Centre
 NUI Galway, Newcastle Road
 Galway, Ireland
 Tel: +353 91 861611
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www.vasc.com

Directors: J Hennen, L Mulloy, W Rutstein, C Sutton
 Vascular Solutions Zerusa Limited is registered in
 Dublin, Ireland. Reg 493999 * registered office

URGENT - Medical Device Field Safety Notice

27th Feb 2013

Vascular Solutions, Inc
 6464 Sycamore Court North
 Minneapolis, MN 55369 USA

Field Safety Notice

Product Name and Model Number(s):

International / EU Model #	US Model # (VSI only)	Product Name
FH101	8210	Guardian II HV and Guidewire Introducer
FH101-T	8211	Guardian II HV with Guidewire Introducer and Torquer
FH101-25	N/A	Guardian II HV with Guidewire Introducer, Torquer and Sidearm Extension Tube (25cm)
FH101-50	N/A	Guardian II HV with Guidewire Introducer, Torquer and Sidearm Extension Tube (50cm)
FH102	8215	Guardian II NC HV and Guidewire Introducer
FH102-T	8216	Guardian II NC HV with Guidewire Introducer and Torquer
FH102-25	N/A	Guardian II NC HV with Guidewire Introducer, Torquer and Sidearm Extension Tube (25cm)
FH102-50	N/A	Guardian II NC HV with Guidewire Introducer, Torquer and Sidearm Extension Tube (50cm)

Attention: Vascular Solutions, Inc.

Investigation of Vascular Solutions Zerusa, Ltd. (VSZL) complaint number CN 13-009 (Vascular Solutions, Inc. (VSI) Device Experience Report (DER2013-0075) revealed a potential issue with our Guardian™ II and Guardian™ II NC hemostasis valves. Due to the potential harm, VSZL is recalling Guardian II and Guardian II NC hemostasis valves with the lot numbers listed below.

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

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

- Identify the location of all Guardian II and Guardian II NC hemostasis valves in your possession indicated in the table above.
- Immediately remove all Guardian II and Guardian II NC hemostasis valves from your current inventory and place in a secure area.
- Complete the Distributor Inventory Form received with this letter.
- Sign, date and e-mail or fax the completed Distributor Inventory Form to VSZL at the contact information provided on the form.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Sincerely,



Thelma Marley
Quality and Regulatory Manager
Vascular Solutions Zerusa Ltd.
tmrley@vasc.com



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Field Safety Notice Memo:

Attention: Vascular Solutions, Inc.

A Field Safety Notice was issued to Vascular Solutions, Inc on the 27th February 2013.

This memo details additional information relating to specific manufacturing lot numbers and quantities listed within the scope of the HRA 2013-00003.

Lot Number	Quantity	Comment
27293	1250	FSCA 2012-00001.
27686	250	FSCA 2012-00001.
28048	69	Destroyed as Part of CAPA 093
28042	100	Destroyed as Part of CAPA 093
28049	325	Destroyed as Part of CAPA 093
27660	1	Destroyed as Part of CAPA 093
28043	25	Destroyed as Part of CAPA 093
28050	295	Destroyed as Part of CAPA 093
28051	75	Destroyed as Part of CAPA 093
28053	750	Destroyed as Part of CAPA 093
28052	375	Destroyed as Part of CAPA 093
28005	225	Destroyed as Part of CAPA 093
28163	25	Destroyed as Part of CAPA 093
27396	175	Destroyed as Part of CAPA 093
28536	400	Destroyed as Part of CAPA 093
27651	25	Destroyed as Part of CAPA 093
28001	50	Destroyed as Part of CAPA 093
28044	25	Destroyed as Part of CAPA 093
28051	50	Destroyed as Part of CAPA 093
27394	37	Destroyed as Part of CAPA 093
27399	25	Destroyed as Part of CAPA 093
27393	5	Destroyed as Part of CAPA 093
27655	124	Destroyed as Part of CAPA 093
28045	200	Destroyed as Part of CAPA 093
28052	125	Destroyed as Part of CAPA 093
28006	25	Destroyed as Part of CAPA 093
28163	125	Destroyed as Part of CAPA 093
27650	9	Destroyed as Part of CAPA 093

Total Number of Units= 5165 units

The FSN issued to VSI on the 27th of February will be amended accordingly to incorporate the information detailed above relating to the manufacturing lot numbers included in the scope of HRA 2013-00003.

Sincerely,

Thelma Marley
Thelma Marley
Quality and Regulatory Manager
Vascular Solutions Zerus Ltd.
tmalley@vasc.com

27th Feb 2013