



California Medical Device Recall Information



Recall Name

Vascular Solutions Zerusa Recalls Guardian II and Guardian II NC Hemostasis Valves Due to a Possible Defect

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|--------------|--|--|---|
| 3/15/13 | Guardian II and Guardian II NC Hemostasis Valves | Vascular Solutions, Inc. Minneapolis, MN | <i>Valves have the potential for air leakage.</i> <i>Air leakage may lead to an air embolism, serious injury or death.</i> |
| Recall Class | Product Identification | Distribution | Affected Dates |
| I | Guardian II and Guardian II NC Hemostasis Valves Model Numbers: <ul style="list-style-type: none"> 8210, 8211, 8215, 8216, 8241, 8242, 8244, 8272, 8274 List of Suspect Lots Recalled | CA , nationwide | Distributed from February 2012 to February 2013 |

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/Safety/Recalls/ucm344019.htm?source=govdelivery>