Class I Medical Device Recall: Spacelabs Medical, Inc., Spacelabs Anesthesia Workstations and Service Kits

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: Jan. 15, 2013

Product: Spacelabs BleaseSirius Anesthesia Workstation, BleaseFocus Anesthesia Workstation, and CAS I/II Absorber contained in Service Kits Part Number 12200902, 050-0659-00, and 050-0901-00, and any workstation installed with the CAS I/II Absorber.

These products were manufactured and distributed from Oct. 31, 2012 to Jan. 15, 2013.

Serial Numbers:
ABSO-004448, ABSO-004458, ABSO-004459, ABSO-004460, ABSO-004461, ABSO-004462, ABSO-004463, ABSO-004465, ABSO-004466, ABSO-004467, ABSO-004468, ABSO-004469, ABSO-004470, ABSO-004471, ABSO-004472, ABSO-004473, ABSO-004474, ABSO-004475, ABSO-004476, ABSO-004477, ABSO-004478, ABSO-004479, ABSO-004480, ABSO-004481, ABSO-004482, ABSO-004483, ABSO-004487, ABSO-004488, ABSO-004489, ABSO-004490, ABSO-004491, ABSO-004492, ABSO-004493, ABSO-004494, ABSO-004495, ABSO-004497, ABSO-004499, ABSO-004500, ABSO-004503, ABSO-004504, ABSO-004505, ABSO-004506, ABSO-004507, ABSO-004508, ABSO-004510, ABSO-004511, ABSO-004512, ABSO-004513, ABSO-004526, ABSO-004528, ABSO-004529, ABSO-004530, ABSO-004531, ABSO-004532, ABSO-004533, ABSO-004534, ABSO-004535, ABSO-004536, ABSO-004537, ABSO-004538, ABSO-004539, ABSO-004540, ABSO-004541, ABSO-004542, ABSO-004543, ABSO-004544, ABSO-004545, ABSO-004564, ABSO-004566, ABSO-004567, ABSO-004568, ABSO-004569, ABSO-005883, ABSO-005884, ABSO-005885, ABSO-005886, ABSO-005887, ABSO-005945, ABSO-005947, ABSO-005948, ABSO-005949, ABSO-005950, ABSO-100023, ABSO-100024, ABSO-100038, ABSO-100039, ABSO-100040, ABSO-100041, ABSO-100042, ABSO-100043, ABSO-100070, ABSO-100071, ABSO-100072, ABSO-100073, ABSO-100074, ABSO-100075, ABSO-100076, ABSO-100077, ABSO-100078, ABSO-100079, ABSO-100080, ABSO-100081, ABSO-100082, ABSO-100083, ABSO-100084, ABSO-100085, ABSO-100086, and ABSO-100087.

Use: These products are used in the hospital environment and in locations not requiring mobility of the products. They provide respiratory support to deliver oxygen, air, and nitrous oxide in a controlled manner to various patient-breathing circuits with or without the use of a mechanical ventilator, and may be used to

deliver anesthetic vapor.

Recalling Firm:
Spacelabs Healthcare, Inc.
5150 220th Ave SE
Issaquah, Washington 98029-6834

Manufacturer:
Del Mar Reynolds Medical, Ltd.
1-2 Harforde Ct., Foxholes, Business Park
Hertford, United Kingdom

Reason for Recall: There is a defect in CAS I/II Absorbers in the Spacelabs Anesthesia Workstations and Service Kits that may cause a condition leading to an increase in the carbon dioxide concentration within the inhaled gas being delivered to the patient. This product may cause serious adverse health consequences, including death.

Public Contact: Customers with questions about the recall may contact the firm at 1-800-522-7025, Select 2 for Technical Support.

FDA District: Seattle District Office

FDA Comments:
Spacelabs sent an URGENT-MEDICAL DEVICE CORRECTION letter dated Jan. 16, 2013 to all affected customers. The letter identified the affected product, problem and actions to be taken.

Until a Spacelabs representative replaces the affected product, the letter instructed customers to:

1. **Immediately cease use** of BleaseSirius and BleaseFocus Anesthesia Workstations **shipped after Oct. 31, 2012.**
2. **Immediately cease use** of Service Kits Part Number 12200902, 050-0659-00 and 050-0901-00 and any workstation containing a CAS I/II Absorber from a Service Kit.
3. **Advise your staff of this situation.** Customers may call Spacelabs Medical at 1-800-522-7025 and select 2 for Technical support.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

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http://www.mdtmag.com/news/2013/03/class-i-medical-device-recall-spacelabs-medical-inc-spacelabs-anesthesia-workstations-and-service-kits?qt-video_of_the_day=0

Links:
[1] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm