

## **Gambro Dasco S.p.A. Issues Worldwide Safety Alert for the Prisma<sup>®</sup> System**

**Lakewood, Colo.--Gambro Dasco S.p.A, a production unit within Gambro Renal Products, announced today that it is issuing a worldwide Safety Alert for the Prisma<sup>®</sup> continuous renal replacement system (all catalog numbers).**

Gambro Dasco has become aware of several serious injuries and deaths relating to the use of its Prisma System. As a result, caregivers must pay particular attention to the "Incorrect Weight Change Detected" alarm. This alarm should never be overridden without first identifying and removing the cause of the alarm. The injuries and deaths are the result of excessive ultrafiltration (fluid being removed from the patient's body). This problem can occur when the user does not address the cause of the "Incorrect Weight Change Detected" alarm. The device remains appropriate for use when these directions are followed.

"Gambro's top priority is the health and safety of the patients we serve," emphasizes Nick Mendez, President Gambro Renal Products Americas. "We take very seriously any situation that may be linked to our products in any way. We are cooperating fully with the FDA to issue a Safety Alert to our customers, and we are committed to thoroughly investigating and promptly responding to this issue."

As a follow-up to this Safety Alert, Gambro will initiate an Advisory Notice and Field Corrective Action in the immediate future. This Action will include updated Prisma System Operator's Manuals with an additional warning; a label for customers to place on machines; and enhanced training specifically addressing the "Incorrect Weight Change Detected" alarm. It is imperative that users follow the manufacturer's Instructions For Use, Operator's Manual, and the User Interface of the Prisma System.

Customers in the U.S. with questions or concerns about the Prisma System or this Safety Alert, should contact Gambro Renal Products, Inc., Intensive Care Therapy Specialists at 1-800-525-2623. For customers outside the U.S., contact your local country manager or sales representative.

### **For further information, please contact:**

Anne Bonelli, GRP Communications U.S., 303-231-4671

Maria Langberg, Vice President, GRP Communications, +46-70-513 65 73

Pia Irell, Acting Vice President GRP Communications, +46-70-513 65 91

*Gambro Renal Products develops and supplies hemodialysis, peritoneal dialysis and acute renal and liver dialysis products, therapies and services. With production facilities in 11 countries, sales subsidiaries in over 40 countries and sales in more than 100 countries, Gambro Renal Products is a global leader. The business area has over 7000 employees and more than SEK10 billion in revenues. Gambro Renal Products is a business area belonging to the Gambro Group*

**Gambro Renal Products**  
10810 W. Collins Avenue  
Lakewood, CO 80215  
USA  
Tel 303 232 6800  
Fax 303 231 4032  
[www.usa-gambro.com](http://www.usa-gambro.com)