

MAQUET

14-15 Burford Way
Baldon Business Park
Sunderland
Tyne & Wear
NE35 0PZ

Tel: 0191 519 6200
Fax: 0191 5196201

Website: www.maquet.co.uk
E-mail: sales@maquet.co.uk

Customer Notification Letter

28.8.09

Subject :Use of Harness Safety System for transport of the CS300 intra-aortic Balloon Pump.

Maquet has become aware of a potential safety issue when using the Harness Safety System for transporting patients on the CS300 intra-aortic balloon pump for which the Harness Safety System was not specifically designed.

The Harness Safety System is not designed for the unique profile of the CS300 intra-aortic balloon pump and can potentially leave the device not properly secured during ambulance transport.

Maquet recommend that customers who have purchased the Harness Safety System do not use them for securing the CS300 intra-aortic balloon pump during transport.

Maquet are actively looking at solutions for those users who specifically purchased the CS300 intra-aortic balloon pump as a transportable device and were provided with the CS100 harness. Maquet advise hospitals to consider using the CS300 Universal Transport System and lightweight docking station specifically designed for use with the CS300 intra-aortic balloon pump and contact their local ambulance service who may be able to offer a solution.

Harnesses that have been specifically sold with the CS300 intra-aortic balloon pump can be returned to Maquet for a full refund.

Maquet apologizes for the inconvenience this customer notification letter may cause and assures users that we will work with your organization to enable a suitable transport system to be developed. Please contact your local sales representative for further assistance.



Regulatory Affairs Officer



Managing Director



UK Registration No. 2195291
V.A.T. Registration No. 468 8508 93
Certificate No. 21809
Producer Registration No. WEE/BA0053TQ