

Urgent Field Safety Notice

Commercial name of the affected product:	Biplanar
FSCA-id:	20160529GL
Type of FSCA:	Check of device
FSN-id:	20160531GL-01
Date:	2016-06-22
Details on affected device(s)	
<p>Biplanar</p> <ul style="list-style-type: none"> • Model 500e with SN5181 – SN5282 • Model 600s with SN6101 – SN6111 	
Description of the problem	
<p>Swemac Medical Appliances AB has become aware of an incident where a screw joint between the Image Intensifier and the G-stand was identified as loose. During internal transportation within the hospital the Image Intensifier (in the yellow plane) came off the G-stand. This incident did not injure any personnel.</p> <p>Since user and patient safety are always the highest priority for Swemac Medical Appliances AB we would like to prevent that this incident occurs again.</p>	
Advise on action to be taken by the user	
<p>The screw joint between the Image Intensifiers and the G-stand (yellow and blue plane) needs to be checked.</p> <p>If Preventive Maintenance has been performed by Swemac Medical Appliances AB during the past 12 months the following instructions can be disregarded.</p> <p>If this is not the case, you have to contact your local Biplanar service provider in order to get instructions on how to check the Biplanar system.</p> <p>You will receive the instructions by sending an e-mail request to <Distributor e-mail address> If you don't have access to e-mail please call your local Biplanar service provider.</p> <p>Please provide the serial number of system(s) in all communications.</p> <p>We would also like to re-emphasize the importance that you must assure that the annual Preventive Maintenance of your Biplanar system shall be performed in accordance with the Service Manual. An updated Service Manual will be provided by your local Biplanar service provider.</p>	
Transmission of this Field Safety Notice (if appropriate)	
<p>This notice needs to be passed on to all those within your organization who must be informed, and to any other organization the potentially affected devices have been transferred to.</p>	
Main contact person	Swemac Medical Appliances AB contact person
<Distributor contact person>	Gustav Lins, Q&R Manager
<Distributor company name>	Swemac Medical Appliances AB
<Distributor address>	Måttbandsvägen 12, SE-187 66 Täby, SWEDEN
<Distributor phone>	Telefon: +46 (0) 8 522 455 60
<Distributor e-mail address>	E-post: gustav.lins@swemacimaging.com
Confirmation of receipt	
<p>Please acknowledge the reception of this notice by an e-mail to your local Biplanar service provider with reference to this document.</p>	

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.



Gustav Lins, Q&R Manager