

**To All MAVIG Customers**

Munich, January 07<sup>th</sup> 2019

**MAVIG's Clarification to the Safety Notice from Bayer –  
Medical Device Field Corrective Action**

Dear Customer,

On December 20, 2018, Bayer issued a safety notice regarding the OCS, EOC, EOW, and EOA ceiling-mounted systems in the form of a client letter.

The letter mentions a possible loosening or disengagement of the injector head, and explains that it pertains only to MAVIG Portegra and Portegra2 OCS systems in conjunction with MEDRAD injectors.

**We assure all MAVIG customers:**

This safety notice **was based on an insufficient description in the Bayer Installation Instructions**, which is described below.

**In no way, does this affect the product quality or safety of the Portegra2 system. All MAVIG Portegra2 products are completely reliable and safe.**

**Explanation:**

Bayer's safety notice applies exclusively to a special mount ("J-Bow") for Medrad injectors. The Medrad Stellant, Medrad Mark 7 Arterion, and Medrad Mark V ProVis systems are equipped with a mounting pin, which is connected to the mount. Only this mounting pin developed by Medrad is affected by the Bayer safety notice.

Both the constructive implementation of the above mentioned Assembly, as well as their description in operating instructions are outside of MAVIG's control.

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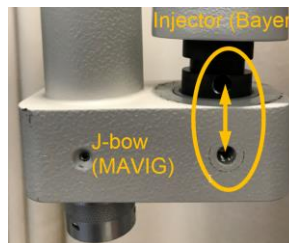
**Geschäftsführer:**  
Christian Stoian  
Alexia Stoian-Lepère

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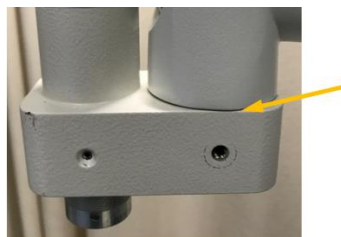
Description of the effected part, as well as the effected screw hole:



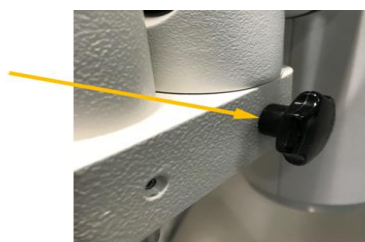
For safe installation, it is necessarily to pay attention to the alignment between the threaded screw hole in the "J-bow" (Injector holder from MAVIG) and the drill hole in the mounting pin of the injector from Bayer:



Only then can the injector be mounted flush to the "J-bow":



And subsequently secured through the properly tightened mounting knob:



The incident described in the Bayer safety notice was beyond the control of MAVIG, and has now been successfully remedied by a more concise installation construction by Bayer.

For questions, please feel free to contact us.

Sincerely,

**MAVIG GmbH**

  
 Alexia Lepère  
 Managing Director  
 Quality & Regulatory Affairs

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