



December 2018

## URGENT MEDICAL DEVICE FIELD CORRECTIVE ACTION

**Re: MAVIG® Portegra or Portegra2 Overhead Counterpoise System (OCS) used in conjunction with the Medrad® Stellant™ CT Injection System (Certegra® Workstation), Medrad® Mark 7 Arterion™ Injection System, and Medrad® Mark V ProVis™ Injection System**

### Catalog Numbers:

- OCS CEIL (58-S, 58-P, 85-S, 85-P, 100-S, 100-P, 70Si, 97Si)
- OCS TRACK (58-S, 58-P, 80-S, 80-P)
- OCS WALL (S, P)
- OCS (115A, 115CT, 125CT, 125A, 135A, 135CT, 145, 155A, 165A, 115AS, 115CTS)
- EOC (700, 700S)
- EOW 700
- EOA 700

Dear Customer,

This letter is regarding MAVIG® Portegra and Portegra2 Overhead Counterpoise Systems (OCS) mounted with the following products:



- Medrad® Stellant™ CT Injection System (Stellantor Stellant with Certegra Workstation)
- Medrad® Mark 7 Arterion™ Injection System (Arterion)
- Medrad® Mark V ProVis™ Injection System (ProVis)

We have determined that, if the OCS head mount knob is not properly tightened and the operator directly uses the injector head to move the unit, it may become disengaged, causing the injector head to become loose or fall.

When adhering to the System Operation Manual and ensuring that the OCS head mount knob is properly tightened, disengagement is unlikely, and you may continue using your OCS mounting system.

As an added measure, Bayer will supply you with an OCS/Injector head connection bracket which will provide an additional solution to maintain engagement. This bracket will be supplied in a self-install kit, which will include the following items:

- Bracket Installation Instructions
- Bracket for Stellant & ProVis
- Bracket for Arterion

1 Bayer Drive  
Indianola, PA 15051  
U.S.A.

1-877-229-3767  
[www.radiologysolutions.bayer.com](http://www.radiologysolutions.bayer.com)

Please note that only MAVIG® Portegra and Portegra2 OCS units are impacted. Medrad® OCS units are not impacted by this situation (see picture below).



**NOT IMPACTED**

Note areas circled in green

Does not require Bracket implementation



**IMPACTED**

Requires Bracket implementation



**IMPACTED**

Requires Bracket implementation

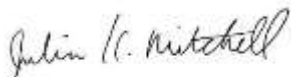
After you receive and install the appropriate bracket from the kit onto your OCS/injector head connection, please confirm that the activity is complete. You may do so by visiting [ocs.bayer.com](https://ocs.bayer.com) (use Customer Number), or by using the enclosed response form.

Please retain a copy of this letter and response form until you have confirmed that the activity is complete.

For questions or assistance please contact Bayer Service Support at 1-877-229-3767 or email [radiologyservice@bayer.com](mailto:radiologyservice@bayer.com) (please reference "OCS FCA" in the subject line).

We appreciate your cooperation and sincerely regret any inconvenience. Safety is Bayer's primary concern and we are committed to providing quality products and service to support your patient care.

Sincerely,



Julia Mitchell  
Director, Issue and Complaint Management - Radiology



### CUSTOMER RESPONSE FORM

Please complete the information below and return the form via Facsimile +1 412-406-0942 or Email [randiproductrecalls@bayer.com](mailto:randiproductrecalls@bayer.com).

**RECALL-ID:** SA-17-RAD-08

**RE: MAVIG® Portegra or Portegra2 Overhead Counterpoise Systems (OCS) used in conjunction with the Medrad® Stellant™ CT Injection System (Certegra® Workstation), Medrad® Mark 7 Arterion™ Injection System, and Medrad® Mark V ProVis™ Injection System**

Our records indicate your institution may have products (referenced above) that may be impacted by a Field Corrective Action.

Bayer will be providing you with a bracket kit in a separate mailing as described in the accompanying letter. We ask that you:

1. Retain this form and the accompanying letter until the bracket kit is received.
2. Install the appropriate OCS/Injector head connection bracket using instructions provided in the kit. Only one bracket is needed per injector.
3. Please fill out this form and fax [or email] it to Bayer after bracket installation is complete.

Fill out the boxes below indicating that you have completed installation of the appropriate OCS/Injector head connection bracket.

Number of <b>Stellant</b> Injectors configured with MAVIG® OCS (CT Room)	Number of <b>Arterion</b> Injectors configured with MAVIG® OCS (Angio/Cath Room)	Number of <b>ProVis</b> Injectors configured with MAVIG® OCS (Angio/Cath Room)

Check this box if your institution does NOT have an above-referenced Injection System configured with MAVIG® Portegra or Portegra2 Overhead Counterpoise System (OCS).

Customer/ Institution Name:	
Contact Person Name/ Title:	
Phone:	
Email:	
Address:	

Signature

Date (MM-DD-YY)

1 Bayer Drive  
Indianola, PA 15051  
U.S.A.

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