



September 1, 2015

To Whom It May Concern:

Thank you for your inquiry regarding the Medrad® Mark 7 Arterion® Injection System Field Safety Corrective Action (FSCA). We have identified that certain Medrad® Mark 7 Arterion® Injection Systems, which utilize Software Version SW 005.006_SH, have a potential situation involving the purge enforcement procedure. The revision to software version 005.006 has resulted in the removal of purge enforcement from traditional New-Case, Power Up and Syringe Change use cases while the injector head is in the upright position.

Only the following countries received the release of software version 005.006 and are therefore impacted by the FSCA:

- United States
- Canada
- France
- Germany
- Netherlands
- Sweden
- United Kingdom

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No action is required of you. All potentially impacted customers have been notified and, if required, the competent authorities within each impacted region have been alerted.

Sincerely,



Julia Mitchell
Director, Commercial Quality
Bayer Medical Care – Radiology