



November xx, 2015

[institution]

[address]

[city, state, zip]

URGENT MEDICAL DEVICE FIELD CORRECTIVE ACTION

Re: Source Administration Sets (SAS) used with the Medrad® Intego PET Infusion System [Catalog Number INT CSS]

Dear Customer,

We have identified that certain Source Administration Sets (SAS) used with the Medrad® Intego PET Infusion System may contain out-of-specification saline tubing and/or solvent occluding the Radio Pharmaceutical (RP) tubing. An index of impacted batches is indicated below.

There have been no patient or user injuries reported as a result of this situation.

Our investigation indicates that the inner diameter of the saline tubing is out of specification and may result in the system failing to position the dose correctly during extraction, potentially leading to a low measurement of the extracted dose or to a higher dose being extracted. The occluded SAS tubing may impair the priming function and prompt an "RP prime failed. Check SAS and vial installation, then reprime." error message.

These situations may lead to inaccurate dose reporting in the patient record.

Please immediately take the following steps.

- Please review your current inventory. Do not use any **Source Administration Sets (SAS)** with the impacted batch numbers that are included in the index below.
- If you have unused affected product, immediately quarantine the product and please call Bayer Customer Service at 1-800-633-7231 to receive a Returned Goods Authorization (RGA) number and return the product immediately to Bayer accordingly.
- Please complete the response form and fax it to Bayer at 1-412-406-0942 or e-mail to randiproductrecalls@bayer.com, whether or not you have impacted product.
- To provide you with new product, please submit a new product order. Please note that due to limited new inventory, there may be a delay in fulfillment.

New batches of SAS are currently being shipped and lead times will be dependent on available supply until inventory returns to normal levels.

We appreciate your cooperation and sincerely regret any inconvenience. We are committed to providing effective products and service to support your patient care. If

Local Address/phone/URL to be inserted as shown below

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

1-800-633-7231
www.radiologysolutions.bayer.com

you have questions, please contact our customer support team at [insert local customer service number; US: 1-800-633-7231].

Sincerely,



Bayer Medical Care - Radiology

Index of Impacted Batches

50856405	50886468
50857510	50886469
50860994	50888285
50866789	50888286
50867921	50888287
50869464	50888288
50869465	50888373
50871131	50890483
50872965	50890484
50878229	50890485
50878230	50892357
50878231	50892358
50878232	50892359
50881328	50892360
50881393	60000321
50881394	60000322
50881395	60000323
50881506	60000692
50881511	60000789
50881512	60000790
50882753	60000833
50886316	60000834
50886467	60000835