



December 10, 2015

O'Connor's Singapore Pte Ltd
801 Lor 7 Toa Payoh, Singapore 319319

URGENT MEDICAL DEVICE FIELD CORRECTIVE ACTION

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

Dear Distributor,

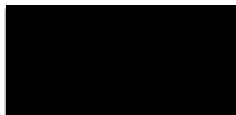
We have identified that certain Source Administration Sets (SAS) used with the Medrad® Intego PET Infusion System may contain out-of-specification saline tubing and/or solvent occluding the Radio Pharmaceutical (RP) tubing.

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

We have developed the attached letter and response form for you to adapt and distribute to your customers. We have included an index of impacted batches below for your reference.

We appreciate your cooperation and assistance in this matter and regret any inconvenience. If you have questions, please contact our customer support team at +65 6752 5318.

Sincerely,



Kelvin Wong
Head of Radiology
South Asia Region

Bayer HealthCare
Medical Care

Bayer (South East Asia) Pte Ltd
63, Chulia Street; OCBC Centre
East, 14th Floor
Singapore 049514

Tel: +65 6752 5318
Fax: +65 6752 5807
www.radiology.bayer.com

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

December 14, 2015

Singapore General Hospital
Nuclear Medicine Department
Outram Rd, Singapore 169608

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 O'Connor's Customer Service at +65 6473 7944 to receive a Returned Goods Authorization (RGA) number and return the product immediately to O'Connor's accordingly.
- Please complete the response form and fax it to O'Connor's at +65 6472 4508 or e-mail to wendy.wong@oconnors.wbl.com.sg, 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 fulfilment.

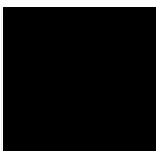
O'CONNOR'S

A Wearnes Company

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 you have questions, please contact O'Connor's at +65 6473 7944.

Sincerely,



Stanley Yee
General Manager

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

Customer Response Form

Tracking #

December 14, 2015

Return via Facsimile: +65 6473 7944 or E-mail wendy.wong@oconnors.wbl.com.sg

FCA-ID: SA-15-RAD-12 & SA-15-RAD-14

RE: Customer Response Form for Source Administration Sets (SAS) used with Medrad® Intego PET Infusion System [Catalog Number INT CSS]

Our records indicate your institution may have SAS used with the Medrad® Intego PET Infusion System that may be impacted by a field corrective action. We ask that you:

Please fill out this form and fax (+65 6472 4508) or email (wendy.wong@oconnors.wbl.com.sg) it back to O'Connor's as soon as possible. Thank you for your cooperation and we sincerely regret any inconvenience.

☐

Check this box if your institution does NOT have product from the affected batches of SAS listed below.

☐

Check this box if your institution has product from the affected batches of SAS listed below. If so, do not use any SAS with the impacted batch numbers – immediately quarantine the product and return the product immediately to Bayer accordingly.

Please also indicate the quantity of SAS from each batch being returned in this table:

Batch #	# SAS Returned	Batch #	# SAS Returned
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	-

O'CONNOR'S

A Wearnes Company

50881328	-	50892360	-
50881393	-	60000321	-
50881394	-	60000322	-
50881395	-	60000323	-
50881506	-	60000692	-
50881511	-	60000789	-
50881512	-	60000790	-
50882753	-	60000833	-
50886316	-	60000834	-
50886467	-	60000835	-

Customer/Organization Name:

Contact Person Name/Title:

Phone:

Email:

Address:

RGA #:

Please call O'Connor's Customer Service at 6473 7944 to receive a Returned Goods Authorization (RGA) number.

Signature

Date