



January 26, 2017



URGENT MEDICAL DEVICE FIELD CORRECTIVE ACTION

Re: Medrad® Spectris® Solaris EP MR Injection System
Catalog number: 3012011



Dear Radiology MRI Manager,

We have determined that the battery/cable power assemblies in Spectris Solaris EP MR Injection Systems (SSEP) distributed from September – November 2016 do not meet our specifications. This could result in intermittent power failure of the device which could result in a degraded image or a delay of the imaging procedure requiring a repeat of the contrast-enhanced MR scan should it occur during a procedure.

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

If your organization has more than one SSEP, you can identify the system subject to this action by locating the serial number referenced above on the device as shown below:

1-800-633-7237
www.radiologysolutions.bayer.com

The SSEP serial number is located on the back of the Scan Room Unit (SRU) head.



The distributor through which you purchased your SSEP unit will be contacting you to replace the battery/cable power assembly by June 30, 2017.

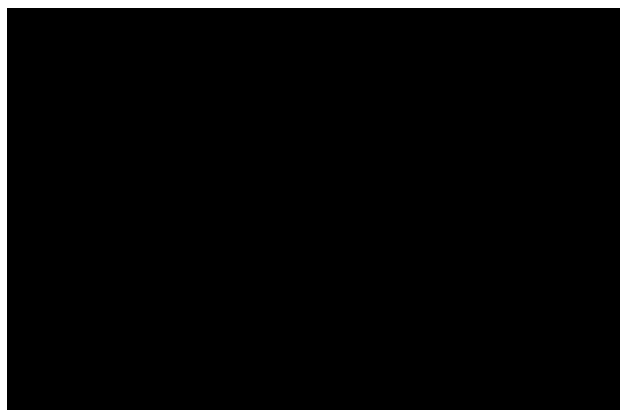
If the impacted SSEP unit has a power failure prior to the replacement of the battery/cable assembly, or you would like to have this situation addressed sooner, please call O'Connor's Singapore Pte Ltd at 64702000 to schedule the replacement repair sooner.

Patient safety is Bayer's primary concern. We appreciate your cooperation and sincerely regret any inconvenience.

Sincerely,

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Julia Mitchell
Director, Commercial Quality – Radiology

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Product Information

Catalog #	SAP Part Number	SAP Description
3012011	60726769	ASSY, TOP LEVEL, SPECTRIS SOLARIS EP,MC

Impacted Serial Numbers

201945, 201946, 201950, 201951, 201952, 201955, 201958, 201960, 201961, 201963, 201965, 201970, 201972, 201973, 201985, 201989, 201998, 201999, 202002, 202003, 202005, 202006, 202007, 202008, 202009, 202010, 202011, 202012, 202013, 202014, 202015, 202016, 202017, 202018, 202019, 202020, 202021, 202022, 202023, 202025, 202029, 202049, 202050, 202051, 202052, 202053, 202054

Units Affected

A total of 112 SSEP injectors are suspect to this issue. On November 4, 2016, a material hold (DN-245254) was initiated for 65 units still within Bayer control. There are 47 impacted fielded units in the US, Canada, Peru and APAC regions.

Country	# of impacted SSEP Injectors
United States	30
Korea	5
Peru	4
Thailand	2
Canada	1
Singapore	1
Myanmar	1
Vietnam	1
Philippines	1
Hong Kong	1
Grand Total	47