



March 1, 2023

Re: Rad-Sure™ blood irradiation indicators product consolidation

Dear Valued Customer,

In anticipation of the United States Administrator for Nuclear Security goal requiring the replacement of cesium irradiators by December 31, 2027, Ashland has decided to consolidate the RAD-SURE™ blood irradiation indicator types

Ashland Rad-Sure™ X-Ray and Gamma blood irradiation indicators utilize a common technology. By sharing this common platform, they have comparable performance when exposed to gamma or x-ray radiation. When the X-Ray blood irradiation indicator is exposed to x-ray or gamma radiation at the correct dose, it will develop successfully. Likewise, when a Gamma blood irradiation indicator is exposed to gamma or x-ray radiation at the correct dose, it will develop successfully. Before a blood product and its attached indicator are irradiated, the indicator reads "NOT IRRADIATED". After the blood product and its attached indicator are irradiated, the word "NOT" is obscured, and the indicator reads "IRRADIATED".

Ashland will offer a single blood irradiation indicator product that can be used with either energy source (X-Ray or Gamma). The transition is estimated to start on June 1, 2023. During the transition period, the first shipments may contain the new and current Rad-Sure™ indicators until inventory depletion of the current indicators.

Once consolidated, Ashland's Diagnostic Films will offer only four Rad-Sure™ products:

- Rad-Sure™ 15 GY blood irradiation indicator (976631)
- Rad-Sure™ 25 GY blood irradiation indicator (976792)
- Rad-Sure™ 25GY Polish blood irradiation indicator (977352)
- Rad-Sure™ 25 GY NBF blood irradiation indicator (977365)

These products will replace the current Rad-Sure™ product offerings. Additional details are available in Addendum A. The certificate of analysis (COA) for Rad-Sure™ consolidated products will include specification testing for both X-Ray and gamma sources, as shown in Addendum B.

We appreciate your business and continued support. If you have questions, please contact your account manager.

Yours sincerely,

A handwritten signature in black ink that reads "Jonathan Cap". The signature is written in a cursive, flowing style.

Jonathan Cap
Product & Market Manager | Diagnostic Films

MOBILE: +1-302-559-8648
DIRECT: +1-302-995-3037

jonathan.cap@ashland.com

Addendum A

Summary Description of Changes to the Rad-Sure[™] blood irradiation indicators

Change description: Consolidation of the current eight (8) separate Rad-Sure[™] X-Ray and Gamma blood irradiation indicators into four (4) products as described in table 1 below.

Products impacted: Rad-Sure[™] X-Ray and Gamma blood irradiation indicators. Table 1 describes the current products that will be consolidated.

Summary of the changes

Artwork: The consolidated indicator versions will use the gamma version of the current indicators.

Ashland Product Codes: New product codes will be issued for the four (4) new consolidated Rad-Sure[™] indicators.

Lot Designation: A new alpha-numeric designation will be used when generating lot numbers in order to differentiate the new consolidated indicators from the previous gamma indicators (Table 3).

Packaging: Although not specific to the consolidation effort, the Rad-Sure[™] boxes will be updated to include the "Rx Only" symbol. Per FDA requirements, the Rad-Sure[™] blood irradiation indicators are considered prescription devices in the U.S. This change does not impact the device. Ashland Rad-Sure[™] blood irradiation indicators are to be sold only to licensed healthcare practitioners or expert practitioners for use in the course of their professional practice. This is aligned with the current Ashland's offering; this device is not offered for over-the-counter use.

Instructions For Use: The Rad-Sure[™] blood irradiation indicators Instructions for Use (IFUs) have been updated to account for the consolidation of the gamma and x-ray types as well as for the "Rx Only" designation, the "Do not use if package is damaged", and "Manufacturer" symbols.

Labeling: The requirements for the box labels will not change however, the text will change accordingly to match new product codes (REF), new Unique Device Identifier (UDI) bar codes, and the new alpha-numeric lot designation.

Materials: There will be no change to the materials used in the construction of the indicators.

Performance: There is no change to the performance of Rad-Sure[™] blood irradiation indicators.

Manufacturing: There are no changes to the manufacturing process.

Specification: There is no change to the performance of the Rad-Sure[™] blood irradiation indicator products. Certificate of Analysis has been updated to include the performance testing for both x-ray and gamma radiation sources. Please see an updated sample of a certificate of analysis in Addendum B for reference.

Regulatory: There is no impact to the current 510(k) premarket submission.

Table 1
Current Rad-Sure[™] Indicator Images

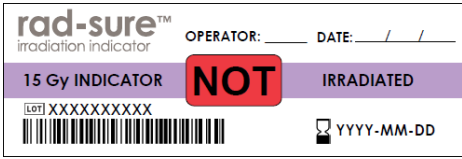
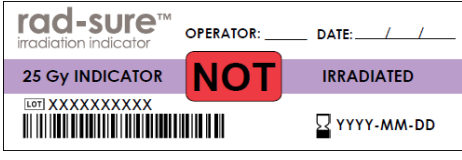
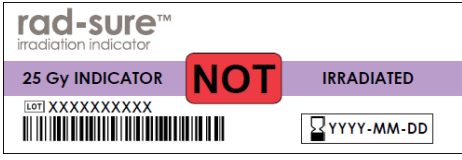
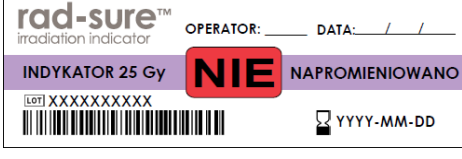
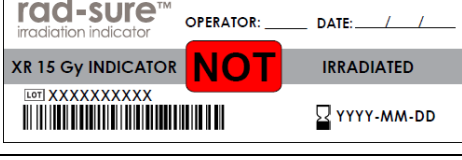
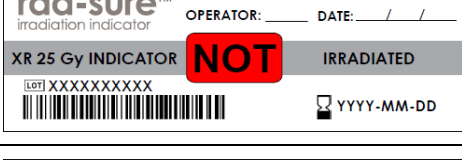


Ashland Product Code	Product Name	Product Image
831377	Rad-Sure [™] 15 Gy (gamma only) TO BE CONSOLIDATED	
831379	Rad-Sure [™] 25 Gy (gamma only) TO BE CONSOLIDATED	
831380	Rad-Sure [™] 25 Gy NBF (gamma only) TO BE CONSOLIDATED	
831382	Rad-Sure [™] 25 Gy Polish (gamma only) TO BE CONSOLIDATED	
831396	Rad-Sure [™] XR15 Gy (x-ray only) TO BE CONSOLIDATED	
831398	Rad-Sure [™] XR25 Gy (x-ray only) TO BE CONSOLIDATED	
867307	Rad-Sure [™] XR25 Gy NBF (x-ray only) TO BE CONSOLIDATED	
960149	Rad-Sure [™] XR25 Gy Polish (x-ray only) TO BE CONSOLIDATED	

Table 2
 New Rad-Sure™ Indicator Images

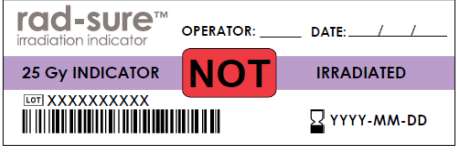
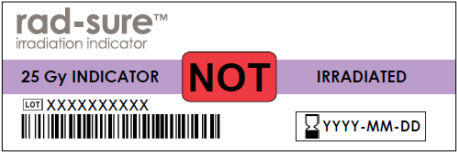
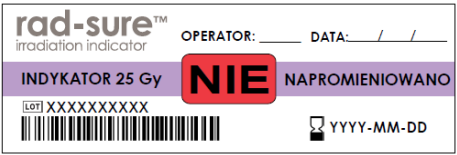
Ashland Product Code	Product Name	Product Image
976631	Rad-Sure™ 15 Gy Indicator (gamma & x-ray)	
976792	Rad-Sure™ 25 Gy Indicator (gamma & x-ray)	
977365	Rad-Sure™ 25 Gy NBF Indicator (gamma & x-ray)	
977352	Rad-Sure™ 25 Gy Polish Indicator (gamma & x-ray)	

 Table 3
 Summary Table of Current and New Rad-Sure™ Indicators

Current RadSure Indicators:			Future Consolidated Indicators:		
Ashland Product Codes	Ashland Product Description	Lot Suffix	Ashland Product Codes	Ashland Product Description	Lot Suffix
831377	RAD-SURE 15 GY INDICATOR @200E	OU15	976631	RAD-SURE 15GY INDICATOR @200EA	GX15
831396	RAD-SURE XR 15 GY INDICATOR@200EA	XR15			
831379	RAD-SURE 25 GY INDICATOR@200EA	OU25	976792	RAD-SURE 25GY INDICATOR @200EA	GX25
831398	RAD-SURE XR 25 GY INDICATOR@200EA	XR25			
831380	RAD-SURE 25 GY NBF INDICATOR @200EA	NU25	977365	RAD-SURE 25GY NBF INDICATOR @200EA	GN25
867307	RAD-SURE XR25 GY NBF INDICATOR@200EA	NX25			
831382	RAD-SURE 25 GY POLISH INDICATOR @200EA	OP25	977352	RAD-SURE 25GY POLISH INDICATOR @200EA	GP25
960149	RAD-SURE XR 25 GY POLISH INDICATOR @200EA	XP25			

Addendum B

Figure 1: Rad-Sure™ 25GY Blood Irradiation Indicators Certificate of Analysis (Current)



Certificate of Analysis

RAD-SURE 25 GY INDICATOR@200EA Rad-Sure(TM) 25 GY INDICATOR blood irradiation indicators Ashland Material Number: 831379		
Batch: 0367210U25		
Characteristics	Specification	Results
Visual density, before irradiation, du	<= 0.60	0.50
Visual density, after irradiation, du	>= 1.52	1.72
Date of Manufacture		April 14, 2022
Expiry Date		April 14, 2025

Notes:

This COA is printed from a secure computer system ensuring the batch was properly released by the Quality Department and is valid without signature.

Manufactured for:
ASHLAND

Quality Release by:
ASHLAND SPECIALTY INGREDIENTS G.P.
AFFILIATE OF ASHLAND
1005 RTE. 202-206
BRIDGEWATER NJ 08807
USA

Contact:
Jessica Waleryszak
Phone: +1 (401) 535-4472
Email: jessica.waleryszak@ashland.com

Printed: February 16, 2023 13:58:03

Figure 2 : Rad-Sure™ 25GY Blood Irradiation Indicators Certificate of Analysis (New)



Certificate of Analysis

RAD-SURE 25GY INDICATOR @200EA Rad-Sure(TM) 25 GY INDICATOR blood irradiation indicators Ashland Material Number: 976792		
		Batch: RS25GYTEST
Characteristics	Specification	Results
Gamma visual density, before irradiation, du	<= 0.60	0.34
Gamma visual density, after irradiation, du	>= 1.52	1.61
X-Ray visual density, before irradiation, du	<= 0.60	0.34
X-Ray visual density, after irradiation, du	>= 1.52	1.65
Date of Manufacture		February 08, 2023
Expiry Date		February 07, 2026

Notes:

This COA is printed from a secure computer system ensuring the batch was properly released by the Quality Department and is valid without signature.

Manufactured for:
ASHLAND

Quality Release by:
ASHLAND SPECIALTY INGREDIENTS G.P.
AFFILIATE OF ASHLAND
1005 RTE. 202/206
BRIDGEWATER NJ 08807
USA

Contact:
Jessica Waleryszak
Phone: +1 (401) 535-4472
Email: jessica.waleryszak@ashland.com

Printed: February 08, 2023 15:48:20