

rad-sure™

15 Gy, 25 Gy, and 25 Gy NBF blood irradiation indicator

use instructions

rev. 0 January 2023

figure 1a
Rad-Sure™ irradiation indicator
before irradiation

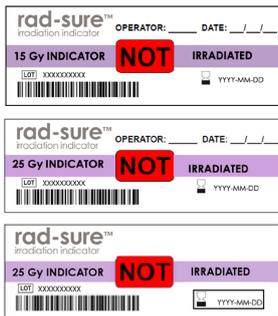
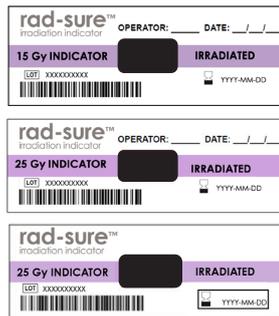


figure 1b
Rad-Sure™ irradiation indicator
after irradiation



When attached to blood products, Rad-Sure™ 15 Gy, 25 Gy and 25 Gy NBF blood irradiation indicators show whether the blood products have been irradiated. 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" in the indicator window is obscured and the indicator reads "IRRADIATED". Rad-Sure™ blood irradiation indicators can be used with irradiators which utilize x-ray and gamma sources. For x-ray irradiation, Rad-Sure™ blood irradiation indicators should be used with irradiators that utilize x-rays generated from 160kVp sources that are filtered through 0.38 mm of copper, or 150kVp sources filtered through 1 mm of aluminum. For gamma irradiation, Rad-Sure™ blood irradiation indicators should be used with irradiators having cesium-137 or cobalt-60 radiation sources, or other sources of equal or greater energy.

Note: Rad-Sure™ blood irradiation indicators only indicate that irradiation has occurred. They do not measure the dose from an irradiator. They must be used only with irradiators that are working properly and are properly calibrated. However, because of

variation in lighting conditions, product batches, and user eyesight, Rad-Sure™ blood irradiation indicators may appear fully opaque even after exposure to less than the minimum dose for the product. Therefore, Rad-Sure™ blood irradiation indicators should never be used to calibrate an irradiator.

1. Do not expose to >50°C (122°F). Avoid prolonged exposure to elevated temperatures.
2. Remove the required number of indicators from the box. Look for the word "NOT" in the window of each indicator. Do not use an indicator unless the word "NOT" is clearly visible (see figure 1a).
3. Observe the product expiration date on the indicator. If the product is beyond the expiration date, do not use the indicator.
4. Enter the date and operator's initials in the spaces provided on the indicator. This step does not apply if using the NBF version of the Rad-Sure™ blood irradiation indicators.
5. Peel the indicator from its backing by bending the sheet. Avoid touching the adhesive layer with rubber gloves. Apply the indicator firmly to an appropriate, clean, dry place on the unit of blood prior to irradiation.
6. Irradiate the unit of blood with the attached indicator in an irradiator at or above the stated minimum dose.
7. After irradiation, check the indicator to verify that the window is black and obscures the word "NOT". The indicator should now read "IRRADIATED" (see figure 1b). If the word "NOT" remains visible, notify your supervisor immediately.
8. Return any remaining indicators to the box and close the lid to avoid prolonged exposure of the indicators to direct sunlight or ultraviolet light.

9. Do not use the indicators in microwave ovens.
10. Store indicators at or below 25°C (77°F).
Store away from all radiation sources, including gamma rays, x-rays, electron devices, and microwaves.
11. Rad-Sure™ blood irradiation indicators can be disposed of with non-hazardous waste when they are not attached to a container containing hazardous waste.
12. Rad-Sure™ blood irradiation indicators have a shelf life of 36 months from the date of manufacture.

Disclaimer

The information contained herein is believed to be reliable, but is not to be taken as a representation, warranty, or guarantee and customers are urged to perform their own tests. No recommendation or permission is implied to violate any patents or other proprietary rights and Ashland Specialty Ingredients G.P. assumes no liability for any such violation.

Rad-Sure™ is a registered trademark of the Ashland U.S. Patent Nos. 7445880

Manufactured for:
Ashland Specialty Ingredients G.P.
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USA

For reorders within the U.S., email:
DFOrdersNA@Ashland.com.

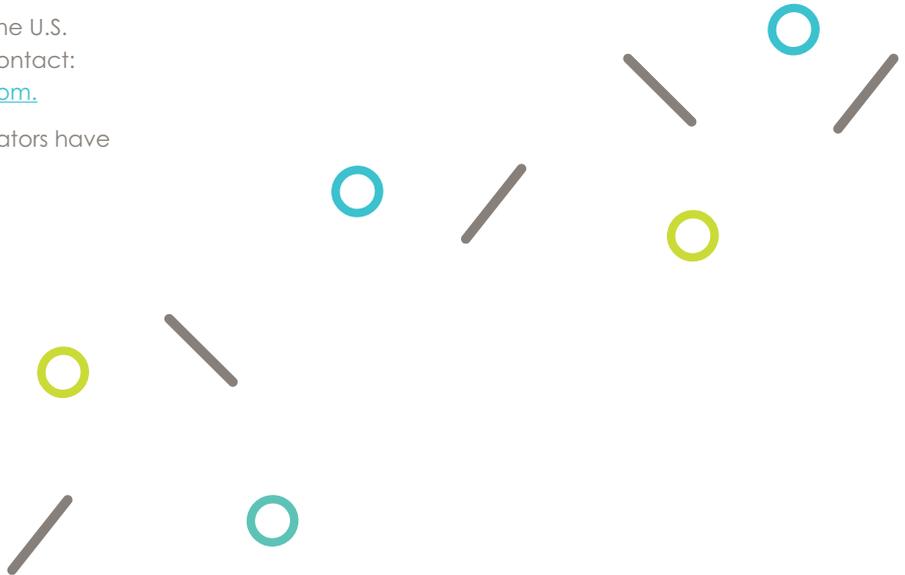
For service or information within the U.S.
or for orders outside of the U.S., contact:
DiagnosticFilmOrders@Ashland.com.

Rad-Sure™ blood irradiation indicators have obtained U.S. FDA 510(k).

product list

product	product code
Rad-Sure™ 15 Gy blood irradiation indicators	976631
Rad-Sure™ 25 Gy blood irradiation indicators	976792
Rad-Sure™ 25 Gy NBF blood irradiation indicators	977365

symbol	symbol title
	batch code
	product code
	use-by date
	manufacturer
	do not re-use
	do not use if package is damaged
Rx only	This is a prescription device in the U.S. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.



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