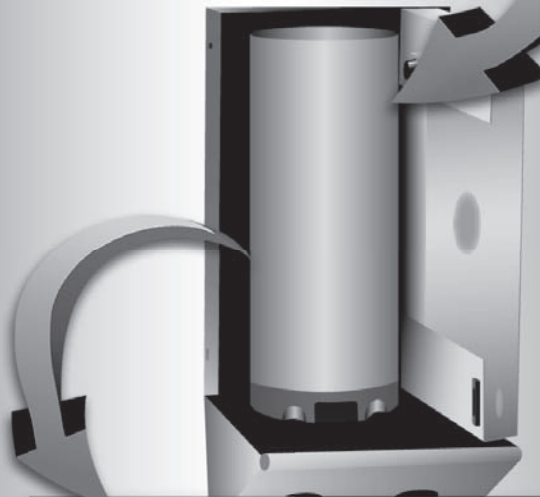


# Be Sure... ...use RAD-SURE®

**ISP RAD-SURE®** OPERATOR: \_\_\_\_\_ DATE: \_\_\_\_/\_\_\_\_/\_\_\_\_

25 Gy INDICATOR **NOT** IRRADIATED

Lot No: XXXXXXXXXX Exp: XX/XX



**ISP RAD-SURE®** OPERATOR: \_\_\_\_\_ DATE: \_\_\_\_/\_\_\_\_/\_\_\_\_

25 Gy INDICATOR **IRRADIATED**

Lot No: XXXXXXXXXX Exp: XX/XX



# RAD-SURE® Blood Irradiation Indicators

Transfusion-associated graft-versus-host disease (TA-GVHD), a rare complication of blood transfusion, is usually fatal. Patients in certain clinical categories, including bone marrow transplants, solid tumors and acquired T cell defects, are at greater risk of developing TA-GVHD. TA-GVHD can be prevented by the irradiation of cellular blood products prior to transfusion.

International Specialty Products (ISP) developed RAD-SURE® blood irradiation indicators to provide positive, visual verification of irradiation. When attached to blood products, RAD-SURE® Type XR 15 Gy, Type XR 25 Gy, Type 15 Gy and Type 25 Gy indicators show whether the blood products have been irradiated or not. 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® indicators only indicate that irradiation has occurred. They should not be used as dosimeters to measure the dose delivered by the irradiator.

RAD-SURE® Type 15 Gy and Type 25 Gy indicators should only be used with irradiators having cesium-137 or cobalt-60 radiation sources, or other sources producing radiation of equal or greater energy. RAD-SURE® Type XR 15 Gy and Type XR 25 Gy indicators should only be used with x-ray irradiators that utilize x-rays generated from 160kVp sources that are filtered through 0.38 mm of copper, or 150kVp sources that are filtered through 1 mm of aluminum.

## RAD-SURE® Indicators are FDA registered medical devices and C € Marked

Registration/Listing Numbers:

- FDA . . . . . BK910018 . . . . . Type 15 Gy Indicators
- FDA . . . . . BK910018/1 . . . . . Type XR 15 Gy Indicators
- FDA . . . . . BK920035 . . . . . Type 25 Gy Indicators
- FDA . . . . . A976736 . . . . . Type XR 25 Gy Indicators

C € Marked

## Examples of RAD-SURE® Type XR 25 Gy and Type 25 Gy Indicators before and after irradiation


ISP RAD-SURE®

OPERATOR: \_\_\_\_\_ DATE: \_\_\_\_/\_\_\_\_/\_\_\_\_

XR 25 Gy INDICATOR

NOT IRRADIATED

Lot No: XXXXXXXXXX Exp: XX/XX



BEFORE IRRADIATION


ISP RAD-SURE®

OPERATOR: \_\_\_\_\_ DATE: \_\_\_\_/\_\_\_\_/\_\_\_\_

XR 25 Gy INDICATOR

IRRADIATED

Lot No: XXXXXXXXXX Exp: XX/XX



AFTER IRRADIATION


ISP RAD-SURE®

OPERATOR: \_\_\_\_\_ DATE: \_\_\_\_/\_\_\_\_/\_\_\_\_

25 Gy INDICATOR

NOT IRRADIATED

Lot No: XXXXXXXXXX Exp: XX/XX



BEFORE IRRADIATION


ISP RAD-SURE®

OPERATOR: \_\_\_\_\_ DATE: \_\_\_\_/\_\_\_\_/\_\_\_\_

25 Gy INDICATOR

IRRADIATED

Lot No: XXXXXXXXXX Exp: XX/XX



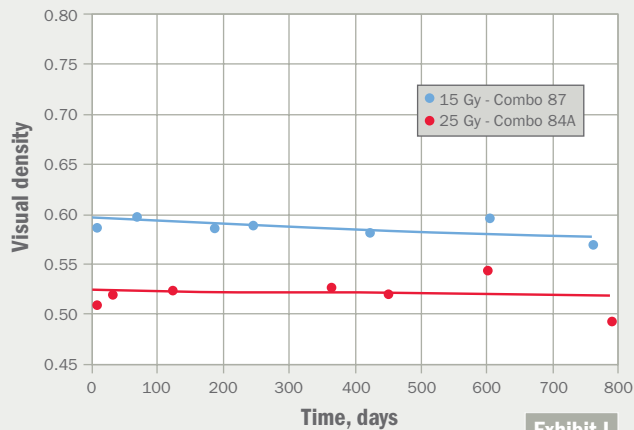
AFTER IRRADIATION

In addition to the above, French, Japanese and Polish versions of RAD-SURE® are manufactured and marketed by ISP.

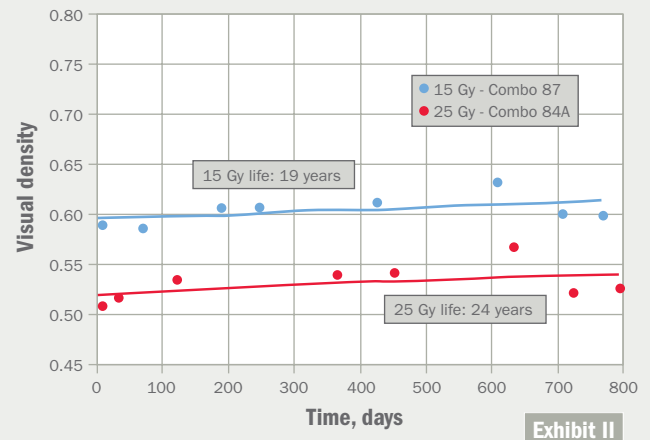
## RAD-SURE® Blood Irradiation Indicators - Stability

While RAD-SURE® indicators should not be used after their stated expiration date and should be handled according to the Use Instructions, we have built a large margin of safety into the performance of the product. The stability of every batch of radiation-sensitive film is monitored at least until the shelf-life of the indicators expire. The results predict that indicators should remain stable long after their 18-month shelf life expires.

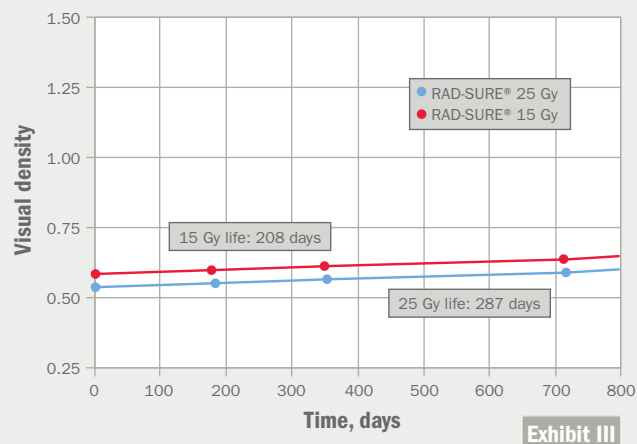
**Stability of RAD-SURE® Indicators Under Refrigeration (0 °C - 6 °C)**



**Stability of RAD-SURE® Indicators at Room Temperature (22 °C)**



**Stability of RAD-SURE® Indicators Under Continuous Exposure to Room Light Before Irradiation (1000 lux cool white fluorescent light)**



Exhibits I & II: Measurements of the stability of the radiation-sensitive film in RAD-SURE® indicators stored at, or below, room temperature predict that the film should remain transparent for many years.

Exhibit III: While the Use Instructions state that prolonged exposure of RAD-SURE® indicators to light should be avoided, test data shows that the radiation-sensitive film should remain transparent even after six months of continuous exposure to room light.



## Features of RAD-SURE®

- Simple to use
- Easy to interpret
- Attaches easily to units of blood
- Contains radiation-sensitive film

## Benefits of RAD-SURE®

- Reduces operator errors
- Provides positive, visual verification of irradiation
- Enhances quality assurance of blood irradiation
- Meets cGMP requirements

## Ordering Information

Version	Product Code	Packaging
RAD-SURE® 15 Gy	61409612877	200/Box
RAD-SURE® 25 Gy	61409662877	200/Box
RAD-SURE® XR 15 Gy	61409652877	200/Box
RAD-SURE® XR 25 Gy	62409652877	200/Box

## References

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### INTERNATIONAL SPECIALTY PRODUCTS – ADVANCED MATERIALS GROUP

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# rad-sure™

## gamma blood irradiation indicators

### indicators for positive visual verification of irradiation

#### description

Rad-Sure™ blood irradiation indicators provide positive, visual verification of irradiation at the minimum specified dose. Manufactured from Gafchromic™ film, the world's highest resolution dosimeter, Rad-Sure™ has been the standard for blood irradiation indicators for over 25 years. 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." Rad-Sure™ gamma irradiation indicators should be used with irradiators that have cesium-137 or cobalt-60 radiation sources or other sources producing radiation of equal or greater energy.

#### benefits


- not subjective — the product has been properly irradiated when the film turns black and "NOT" is completely obscured
- color-blind friendly — no need to match colors, just read the indicator to know the blood product has been irradiated
- made with accurate and reliable film used in radiation oncology centers around the world
- uses a powerful adhesive to help the indicator stick and stay on blood bags
- easy to use: just peel, stick, irradiate, and read
- U.S. FDA listed medical device
- ISBT 128 bar-coded lot numbers
- minimum dose of 15 Gy or 25 Gy available





#### product list

product	product code
rad-sure™ 15 Gy blood irradiation indicators	831377
rad-sure™ 25 Gy blood irradiation indicators	831379

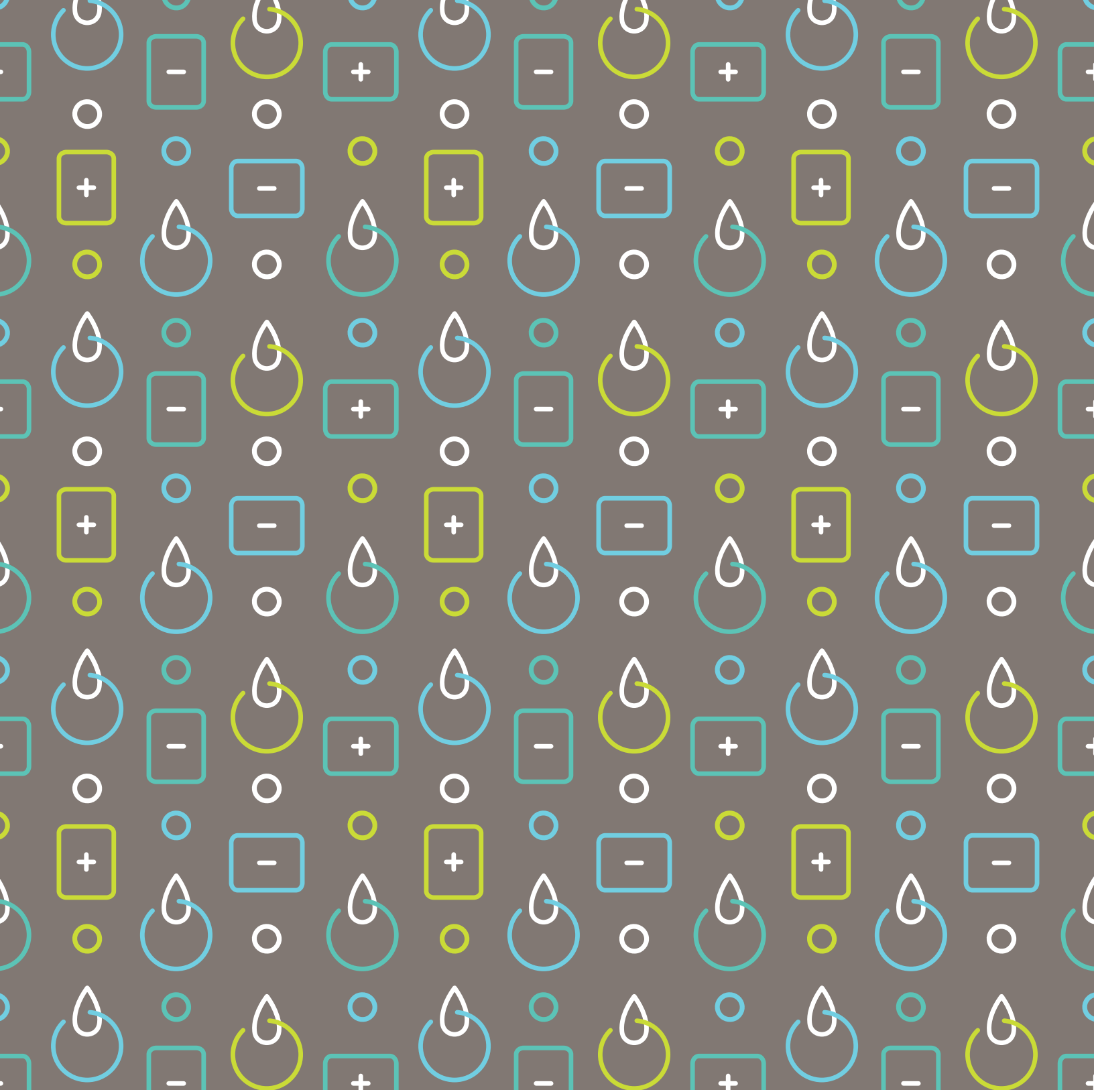
#### examples

<b>RAD-SURE™</b>	OPERATOR: _____	DATE: ____/____/____
<b>25 Gy INDICATOR</b>	<b>NOT</b>	<b>IRRADIATED</b>
Lot No: xxxxxxxxxx		Exp. xxxxx
		

<b>RAD-SURE™</b>	OPERATOR: _____	DATE: ____/____/____
<b>25 Gy INDICATOR</b>		<b>IRRADIATED</b>
Lot No: xxxxxxxxxx		Exp. xxxxx
		

Rad-Sure™ gamma irradiation indicators before and after irradiation.



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