Be Sure ... Use RAD-SURE™

blood irradiation indicators

RAD-SURE™
OPERATOR: _____ DATE: ___/___/

25 Gy INDICATOR
NOT IRRADIATED
Lot No: xxxxxxxxxx
Exp. xxxxx

RAD-SURE™
OPERATOR: _____ DATE: ___/___/

25 Gy INDICATOR
IRRADIATED
Lot No: xxxxxxxxxx
Exp. xxxxx
Indicators for positive visual identification of irradiation

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.

Ashland 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 blood irradiation 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 blood irradiation 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 blood irradiation 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 blood irradiation 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 blood irradiation indicators are FDA registered medical devices and ŒŒ marked

**Registration/Listing Numbers:**
- FDA....................... BK910018 ......................... Type 15 Gy blood irradiation indicators
- FDA....................... BK910018/1 ..................... Type XR 15 Gy blood irradiation indicators
- FDA....................... BK920035 ......................... Type 25 Gy blood irradiation indicators
- FDA....................... A976736 ........................ Type XR 25 Gy blood irradiation indicators

Examples of RAD-SURE Type XR 25 Gy and Type 25 Gy blood irradiation indicators before and after irradiation

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*In addition to the above, French, Japanese and Polish versions of RAD-SURE are available*
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 expires. The results predict that indicators should remain stable long after their 18-month shelf life expires.

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™ indicators

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

Benefits of RAD-SURE indicators

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

### RAD-SURE blood irradiation indicators ordering information

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<th>Version</th>
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### References