Be Sure...
...use RAD-SURE®
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 CE 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

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

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

- 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

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References