

Rad-Sure™ Blood Irradiation Indicator Updates

May 23, 2022


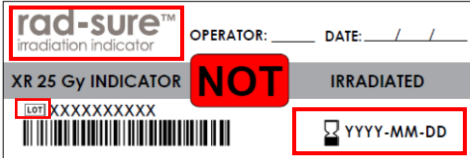
Dear Valued Customer,

This is to notify you that the Ashland Diagnostic Films Group has recently implemented minor changes to our Rad-Sure™ blood irradiation indicator labels and product box labeling. Please see the list of affected products below. These changes were made to meet Ashland corporate branding guidelines and to align with labeling guidelines related to the expiration date format and to use the International Organization for Standardization (ISO) standard ISO 15223: symbols for medical device labels, labeling and information. The meanings of the symbols are defined in the product user instructions.

Affected Rad-Sure™ Blood Irradiation Indicator Products:

| Ashland Part # | Ashland Product Name |
|----------------|-------------------------------------|
| 831377 | RAD-SURE™ 15 GY INDICATOR |
| 831396 | RAD-SURE™ XR 15 GY INDICATOR |
| 831379 | RAD-SURE™ 25 GY INDICATOR |
| 831380 | RAD-SURE™ 25 GY NBF INDICATOR |
| 831382 | RAD-SURE™ 25 GY POLISH INDICATOR |
| 831398 | RAD-SURE™ XR 25 GY INDICATOR |
| 867307 | RAD-SURE™ XR 25 GY NBF INDICATOR |
| 960149 | RAD-SURE™ XR 25 GY POLISH INDICATOR |

The specific changes to the Rad-Sure™ blood irradiation indicator labels and product box labels are identified in the tables below.

| Current Indicator | New Indicator | Changes |
|---|--|---|
| Rad-Sure™ Blood Irradiation Indicator Label | | |
|  |  | <ul style="list-style-type: none"> Rad-Sure™ logo was updated to meet Ashland branding standard. Replaced text for lot number and expiration with the corresponding ISO symbols. Revised the expiration date format to YYYY-MM-DD. |

| Current Labels | New Labels | Changes |
|---|---|--|
| <p>Product Label - Top</p>  |  | <ul style="list-style-type: none"> The expiration date with ISO symbol was added. |
| <p>Product Label – Left Side</p>  |  | <ul style="list-style-type: none"> The text “Do Not Use After Expiration Date” and “Lot Number” were replaced with the corresponding ISO symbols. The expiration date was updated to the YYYY-MM-DD format. The expiration date and lot number originally underneath the ISBT bar code were moved to the left of the ISBT bar code. |
| <p>Product Label – Right Side</p>  |  | <ul style="list-style-type: none"> The Ashland part number and corresponding ISO symbol were added to the left of the ISBT bar code. |

Please be assured that while we have made the above listed changes to the Rad-Sure[™] blood irradiation indicator labels and product box labels, there have been no changes made to the functionality or specifications of the product.

Ashland continually strives to maintain the highest standards in our services and products. Feel free to contact us if there are any concern or questions pertaining to these changes.

Sincerely,



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