

Sterile Packaging: Labeling and Use Guidelines

The Valleylab Clinical Hotline has received calls requesting clarification of the international symbols for “**Expiration Date**” and “**Manufacture Date**” and guidelines regarding the use of Valleylab products that may have been exposed to temperature and humidity extremes.

- The **Expiration Date** on Valleylab products indicates that the packaged product has been tested for a specific shelf life. This means that Valleylab guarantees both the product materials and sterility of the product inside an **intact package**, under normal storage conditions, until the end of the month of the expiration date indicated on the package labeling.
- Beginning in the year 2000, expiration date labeling has been used exclusively on all Valleylab sterile products. Valleylab expiration dates vary from 2 to 5 years, depending on the product.



Date of Manufacture (January 2000) Date of Expiration (June 2010)



- The **Manufacture Date** on any product label indicates the date the product was packaged.
- Valleylab recommends following American National Standard AAMI (Association for the Advancement of Medical Instrumentation) guidelines for shelf life of sterile products.

- AAMI standard 4.2.3.4 “*packaging and shelf life*”, states that sterile products should be manufactured and packaged to meet:
 - a specified shelf life as labeled by the original manufacturer (expiration date) or
 - a minimum of 5 years shelf life after the date of manufacture (if no expiration date is specified).

Because Valleylab labeling has not included manufacture dates since 2000, any Valleylab product with a manufacture date should be considered for replacement under the above AAMI standard.

Although the product and packaging may fall within the AAMI guidelines, other factors need to be considered. The 2005 AORN Recommended Practices for Selection and Use of Packaging Systems, states the following factors and events should be considered:

- type and configuration of packaging materials used
- number of times a package is handled before use
- number of personnel who may have handled the package
- storage on open or closed shelves
- condition of the storage area (cleanliness, temperature, humidity)
- use of dust covers and method of sealing²

As a manufacturer, Valleylab maintains control of the configuration of packaging materials, the method of sealing, and to some extent the product storage, while hospitals and



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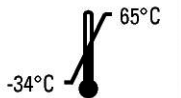


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staff have control of the other factors listed in the AORN guideline. Perioperative nurses have a responsibility to use guidelines and good nursing judgment when evaluating products and packaging. If there is any question as to the sterility of an item, do not place the product on the sterile field.

Valleylab customers have called the Clinical Hotline requesting guidelines on the use of products packaged by Valleylab that have been exposed to temperature and humidity extremes. Disasters, such as hurricanes, may cause a loss of electrical power resulting in significant fluctuations of temperature and humidity in operating rooms and sterile product storage areas.

Valleylab does not test for all circumstances that may occur in the hospital setting. However, in order to provide safe transportation of products, Valleylab does test temperature and humidity variations that may occur during transport and storage of product. Valleylab sterile product and packaging is exposed to extreme temperatures from -22° C to 65° C at a relative humidity up to 75%. The temperature and humidity are increased and decreased at various timed cycles. Valleylab "Storage and Transport Parameters" may be used as a guideline if **both** the temperature and humidity exposures are known. Validation of this testing is printed on all Valleylab shipping cartons:

Storage and Transport Parameters	
	Relative Humidity: 0% - 75% noncondensing

(-34° C = -29° F 65° C = 149° F)

"Noncondensing" means no moisture in or on the packaging. An abrupt drop in room temperature, which may occur when air conditioning is turned on after a power failure, could cause condensation. If condensation is present outside or within the package, the product should be considered contaminated.

Although close inspection of the product is vital, the appearance of the product and packaging may not give an accurate indication of the product's sterility once there is exposure to moisture. As an example, the temperature exposure may have stayed within the testing parameters, but the humidity exposure might be unknown. The packaging in question could appear to be intact, but the heat seal coating that attaches the Tyvek® lid stock to the plastic tray is water-based and exposure to humidity above 75% may affect the seal. If the product has been exposed to any conditions outside the above parameters, or if the exposure is unknown, the product should be considered contaminated.

The 2005 AORN Recommended Practice for Sterilization in Perioperative Practice Settings, states: *The shelf life of a packaged sterile item is event related.* Additional events that may compromise the sterility of a package include:

- multiple handling that leads to seal breakage or loss of package integrity,
- moisture penetration, and
- airborne contaminants.³

A recent ECRI publication recommends:

- Discard any single-use devices that have been exposed to floodwaters or have evidence of exposure of uncertain history, even if the packaging and seals appear to be intact.
- Discard any equipment, supplies, or accessories with temperature or humidity storage limitations that may have been exceeded.⁴

To summarize, product sterility is event related. Valleylab guarantees the sterility of a product in an intact package under the AAMI Standards and AORN event related guidelines; however, product materials may degrade with time depending on handling and storage conditions. Valleylab recommends facilities follow manufacture guidelines, AORN guidelines, AAMI standards for shelf life, and good nursing judgment. Inspect all packages and products. Do not use any item if the package integrity or the product materials may be in question.

1) Association for the Advancement of Medical Instrumentation, American National Standard ANSI/AAMI HF18 – Electrosurgical devices, Standard 4.2.3.4 "Packaging and shelf life," 1993

2) Recommended Practices for Selection and Use of Packaging Systems; Recommended Practice VIII; AORN Standards, Recommended Practices, and Guidelines; (Denver: AORN, Inc, 2005) 418

3) Recommended Practices for Sterilization in Perioperative Practice Settings: Recommended Practice VII; AORN Standards, Recommended Practices, and Guidelines; (Denver: AORN, Inc, 2005) 464

4) ECRI, "Recovering Medical Devices after Water Damage", Health Devices Alerts Special Reports, Accession Number: S0093, October, 7 2005