

AmerisourceBergen

EYLEA[®]

TransTracker[®] CF

temperature indicators

removal FAQs

Q: Why are the temperature indicators being removed from EYLEA® and EYLEA® HD shipments?

A: The decision to remove the temperature indicators was made after careful consideration and validation of the standard ISTA certified cooler and packing. AmerisourceBergen has determined that its standard packout procedures are sufficient to maintain the quality and integrity of the products, including EYLEA and EYLEA HD, while in transit.

Q: I've experienced the temperature indicator being triggered in the past, sometimes inaccurately, why is this?

A: Besse Medical is aware of false positive triggers with the temperature indicators. Most of the time, the devices were inaccurately triggered due to being too close to ice packs. In those cases, the product was found to be safe and unharmed despite the trigger and resulted in an unnecessary return of the product.

Q: Will my EYLEA PAP shipments be impacted by this change?

A: Yes, your PAP shipments will no longer include the temperature indicator.

Q: Did the additional temperature indicator provide specific temperature information?

A: No, the additional temperature indicator had no actionable data to record temperature.

Q: What should I expect when I receive my EYLEA and EYLEA HD shipments on or after February 12, 2024?

A: As product moves throughout the network, gel packs start frozen and will begin to thaw to maintain proper temperatures. When you receive your product, the gel packs may feel warm or "melted" to the touch, which is expected and normal in the ordinary course in order to maintain proper refrigerated temperatures for the shipment.

Q: How do I accurately test temperature?

A: To properly check the temperature of your product, you may use a calibrated thermometer and temperature probe to obtain an accurate internal reading of your refrigerated product. Please be sure to use a probe that allows the cooler to be closed which should increase the accuracy of the reading. If your product is delivered as expected within the validated excursion time, your product temperature integrity is reliable. (Please reference packout guide.)

Q: How long is product integrity qualified for cold chain shipments to maintain the proper refrigerated temperature?

A: All packages have been qualified to perform a minimum 24 hours in both summer and winter months when tested against industry standards [ISTA 7D (cold) and ISTA 7E (hot)]. (Please reference packout guide.)

Q: What about weekends, how do the Friday orders that arrive Monday work?

A: Friday orders are picked and packed on Saturday where they are then placed back into the refrigerated temperature-controlled environment in the distribution centers until Sunday evening. The carriers pick them up Sunday for delivery Monday morning. (Please reference packout guide.)

Q: What are legitimate reasons to call with a concern for your product integrity?

A: If your package was not delivered within a 24-hour delivery window, please call Besse Medical Customer Service at 800.543.2111.

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