

Health Hazard Analysis

HHA Detailed Report - PR # 700086

(Root Parent) GQA Tracking Number: QALC-2025-0042

PR ID: 700086

PR State: Assessment Complete

Parent ID: 700084

Since: 22-Apr-2025 2:36 pm

Date Created: 17-Apr-2025 5:36 pm

Division/Project: Surgical/Health Hazard Analysis (HHA)

HHA Information

HHA Info.

Originator: Maritza Mendez

Date Opened: 17-Apr-2025 5:36 pm

(Root Parent) Description of Issue : During the Korea Affiliate relabeling process, holes were discovered in the Tyvek of the Constellation Paks.

HHA Description : Damaged Constellation Paks were found during an internal Alcon Korea relabeling process. Assessment of samples has confirmed the possibility of holes/tears in the Tyvek lids for some of the units within specific lots of Constellation Vit Paks. Initial investigation has determined that the holes/tears are likely the result of product interference within the Tyvek sealing machine. To date, there have been no reported complaints for this issue from customers for the product in scope.

Initiating Site: HTX - Houston

Platform: Consumables - VIT

Product Type : Constellation

Product : 8065751617 - ASSY,SHIP,PRM 25+ 7.5 CPM V

To Be Completed By Alcon

Is a HHA Required? : Yes

Is a HHA Required? Rationale : Yes, defects of Tyvek Lidding were identified in certain Constellation Procedure Paks at Alcon's manufacturing facility, which can potentially have impact to patient health.

External PMRA Used? : No

External PMRA Used? - Report# : N/A

Medical Safety Representative : Jean Fayet

Criteria for Health Hazard Assessment

Deficiency Obvious to Consumer: Limited (Barely distinguishable to the consumer)

Extent Justification/Comments : Constellation Procedure Paks are expected to undergo visual inspection by the surgical staff prior to use, ensuring sterile integrity by checking for any defects, such as damage (i.e. tears/holes) to packaging of components, such as the Tyvek lid. If a defect is readily visible (i.e., larger than a pinpoint puncture), it is expected to be identified by surgical staff during handling and preoperative procedures. However, smaller pinpoint type defects may be less obvious and could potentially go unnoticed.

Likelihood of AE : Remote (Small or slight chance that an AE would occur due to the escalated event)

Likelihood : There is a slight chance that an adverse event could result from the escalated situation. Visually detectable tears or holes in the Tyvek lid will allow surgical staff to identify the defect(s) and replace the Pak with an unaffected Pak, thus precluding potential patient harm to occur. However, if a tear or hole in the Tyvek lid is left unnoticed during preoperative handling and inspection, an adverse event secondary to compromised sterility could potentially occur.

Product AEs : No

Report Generated By: Stacy Payne

Generated On: 22-Apr-2025 02:40 PM (GMT-05:00)

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Complaint Report# :

Severity - Adv Health Outcome : Necessitates medical or surgical intervention to preclude or reverse permanent damage to a body structure or permanent impairment of a body function

HHA Severity : The use of a Constellation Procedure Pak with compromised sterility resulting from a tear or hole in the Tyvek lid poses a risk of microbial contamination and subsequent ocular infection which may necessitate additional medical and/or surgical intervention.

HHA Summary : Constellation Procedure Paks are expected to undergo visual inspection by the surgical staff prior to use, thus ensuring sterile integrity by checking for any defects to the component packaging, such as damage (i.e. tears/holes) to the Tyvek lid.

Visually detectable tears or holes in the Tyvek lid will allow surgical staff to identify the defect(s) and replace the Pak with an unaffected Pak, thus precluding potential patient harm to occur. However, if a tear or hole in the Tyvek lid is left unnoticed during preoperative handling and inspection, an adverse event secondary to compromised sterility could potentially occur. If the surgical staff do not identify a defect in the Tyvek lid, and proceed to use the Pak, microbial contamination and subsequent ocular infection requiring additional medical and/or surgical intervention as treatment is possible.

Attachments :

-End of Report-