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URGENT: FIELD SAFETY NOTICE

EYEVISC™

– Voluntary Product Recall (Removal) –

Date: [25/03/2026]

Dear Sir /Madam,

Records indicate that you may have ordered or received product subject to this voluntary recall. Product affected by this recall can be identified by the product name and batch number as mentioned below:

Product Name: Eyevisc 2% 2mL PFS, Batch Number: 2511272

Please distribute this information to all staff within your facility who store, handle, or use EYEVISC™ viscoelastic preparations.

Purpose of this Letter

Biotech is initiating a voluntary medical device recall (removal) of specific units of viscoelastic preparation from identified lots of the below products:

- Eyevisc™ viscoelastic preparation, Batch Number: 2511272

Reason for the Voluntary Removal:

Biotech identified an issue associated with specific packaging blisters that resulted in post-dispatch blister damage in a very small percentage in Eyevisc™.

The occurrence of this defect is rare, with an estimated rate of 0.006% of distributed product means 99.994% of product is not impacted.
All available units of product lots mentioned above in this letter to be returned.

However, the units that does not have a crack in the Blister Packaging is safe to use, in accordance with the approved Instructions for Use (IFU). As not every box will contain a defective unit, if present, the defect will be visible and consistently located in the same area shown in Figure 1.

When present, the defect appears as a crack in the blister sidewall, located at the plunger side, as illustrated in Figure 1 and good blister product illustrated in Figure 2.

Description of Defect:

- Clearly visible cracks or damage on the blister
- Damage not always consistently located only at one position (although currently only observed at plunger side)
- Hairline fractures which may not be readily detectable without careful visual inspection
- To identify of hairline cracks in product blister edges near the plunger side, close monitoring shall be performed by applying slight compression to the blister at plunger side and visually inspecting under adequate lighting conditions.
- Such hair line crack may not be directly visible under normal observation present at Blister corner at plunger side as encircled in Figure 1.

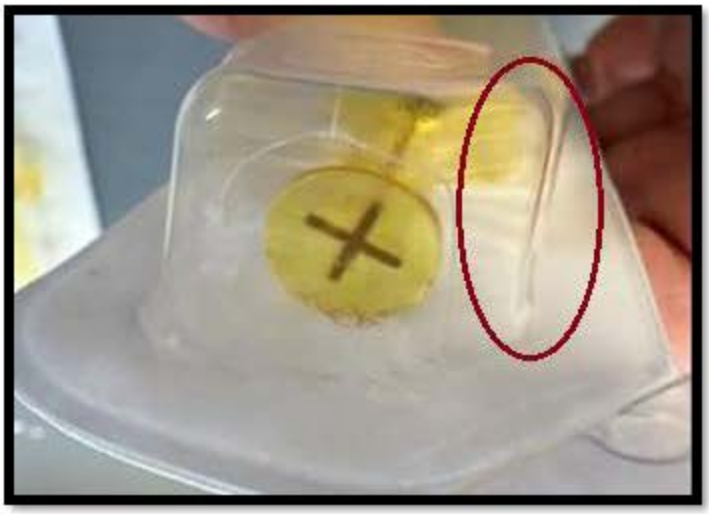

Figure 1: Damaged Blister Product

Figure 2: Good Blister Product

Root Cause:

Although all required Packaging Validation Studies, Transport Validation Studies, Stability Studies, Sterile Barrier System Validation, Seal Strength Testing, Container Closure Integrity Testing (CCIT), Temperature Excursion/Environmental Studies, Thickness and Material Distribution Studies, Sterilization Validation, Visual Inspection Validation, Blister Forming Process Validation, Equipment Qualification (IQ/OQ/PQ – Blister Machine), Re-qualification, and Shipping Simulation Studies (drop, vibration, and compression) have been performed and found satisfactory, there remains a potential possibility of minor blister damage under certain conditions, such as inherent process variability in blister forming and alignment, transport or any other external stresses.

This residual risk has been identified through risk assessment, evaluated, and deemed acceptable, and is effectively mitigated through implemented risk control measures, including clear warnings and precautions in the Instructions for Use (IFU), which state: "Do not use if the package is opened or damaged."

Risk to Health:
Biotech has not received any reports of serious adverse events related to this issue. It is likely that the defect would be detected prior to use.
The reported issue may be detectable upon careful visual inspection; however, in certain cases (e.g., hairline cracks), the defect may not be readily apparent without close examination.

Overall, the likelihood of occurrence is considered low; however, appropriate precautions must be followed to mitigate risk.

This risk is considered a residual risk and may occur in cases of improper handling or failure to detect packaging damage. To mitigate this risk, clear instructions are provided in the Warning and Precautions section of Instructions for Use (IFU) and on the packaging stating: **"Do not use if the package is opened or damaged."**

ACTION REQUIRED

1. Inventory Review: Determine whether you have inventory from the lot no. 2511272.
   If yes,
   - We are advising to temporarily stop use of the lot 2511272 until further guidance is provided.
2. Please inform all relevant personnel of this issue.

At Biotech, patient safety and product quality are our highest priorities. We recognize that this recall may cause inconvenience and sincerely appreciate your cooperation.