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URGENT: FIELD SAFETY NOTICE

Biohyalur™ and Biohyalur™ HV
– Voluntary Product Recall (Removal) –

Date: [20/02/2026]

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: Biohyalur 1 ml PFS, Batch Number: 2304068
Product Name: Biohyalur HV 1 ml PFS, Batch Number: 2304063

Please distribute this information to all staff within your facility who store, handle, or use BIOHYALUR™ and BIOHYALUR™ HV 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:

- Biohyalur™ viscoelastic preparation, Batch Number: 2304068
- Biohyalur™ HV viscoelastic preparation, Batch Number: 2304063

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 Biohyalur™ and Biohyalur™ HV. The occurrence of this defect is rare, with an estimated rate of 0.20% of distributed product means 99.8% 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.

BIOTECH VISION CARE PVT. LTD.

Manufacturing Unit 1:
Plot No. 555-556-557,
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Manufacturing Unit 2:
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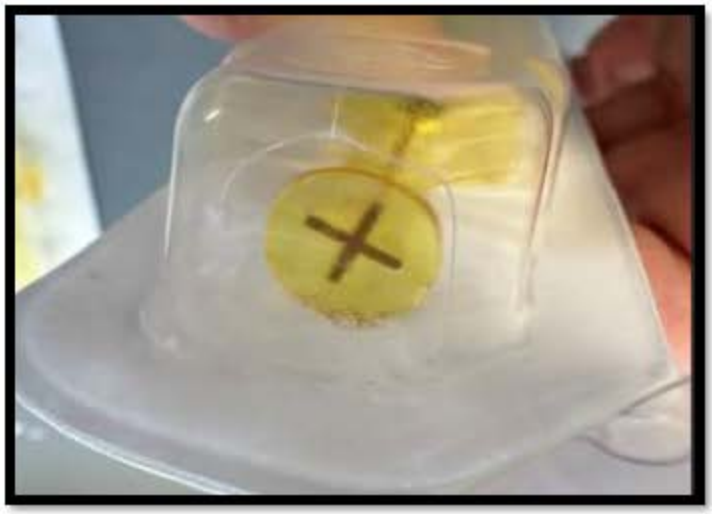

Figure 1 Damaged Blister Product

Figure 2 Good Blister Product

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. Additionally, verification procedures conducted by our representatives may further identify and remove affected units from further use.

However, the reported issue is easily detectable with the unaided eye. Furthermore, the sterility of the primary solution and the product remains intact even if the blister is damaged. Therefore, the likelihood of patient-related serious health consequences is considered very low to negligible.

Biotech has identified the root cause of the packaging issue that led to this recall and has implemented appropriate corrective and preventive actions to address the matter, same is mentioned in attached investigation and corrective preventive action letter (Attachment I).

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ACTION REQUIRED

1. Inventory Review: Determine whether you have inventory from the above listed lots.
   If yes,
   - Quarantine & Return all inventory from impacted lots by dated 13th March 2026.
   - Biotech representative will visit your facility and collect the units from your inventory with record.
   - Ensure any affected product forwarded to other facilities is also returned.

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.

For Bio-Tech Vision Care Pvt. Ltd,

BIOTECH VISION CARE PVT. LTD.

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Attachment – I: Investigation and Corrective Preventive Action Letter

Complaint Details:

TrackWise PR No.	:	20633
Product	:	Bio Hyalur HV 1mL PFS and Bio Hyalur 1mL PFS
Complaint Code	:	BIO/S/B4
Dosage / Device Form	:	Pre-Filled Syringe
Country	:	Germany
Market	:	Europe
Brief description of Complaint	:	Blister Damage Observed in Product Bio Hyalur HV 1mL PFS and Bio Hyalur 1mL PFS

➢ **Background:** Complaint has been received for blister damage by customer "BIOTECH IBERIA" for product mentioned underneath:

Sr. No.	Product Name	Batch No.	Country	Mfg. Date	Exp. Date
1.	Bio Hyalur HV 1mL PFS	2304063	Germany	2023/04	2026/03
2.	Bio Hyalur 1mL PFS	2304068	Germany	2023/04	2026/03

- The complaint batches of the product Bio Hyalur HV 1mL PFS and Bio Hyalur 1mL PFS was manufactured and packed as per the validated process.
- Biotech Germany, has sold 355 units of batch 2304063 and 125 units of batch 2304068 to the customer "Kaffka."
- The invoice copy and packing list from both the manufacturing site and the warehouse have been thoroughly reviewed for investigation purposes.

➢ **Investigation:**

Detailed Investigation as below,

Detailed Assessment of Product Blistering Process:

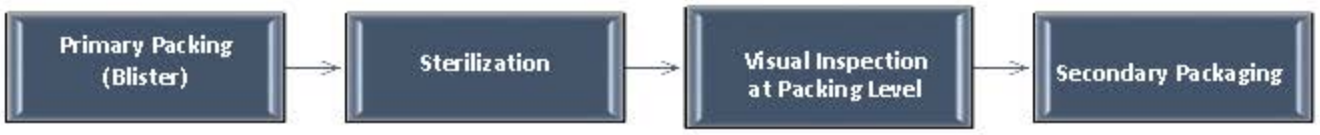

Figure – 1

❖ **Control Sample Review:**

- The 20 control samples from the same complaint batches have been thoroughly inspected, and no signs of blister damage were detected.
- Furthermore, the control samples from the preceding and succeeding batch were also reviewed, and no abnormalities were found during the inspection.

❖ **Batch Record Review:**

- A comprehensive review of the batch manufacturing and packing record for both the impacted products i.e. Bio Hyalur HV 1mL PFS and Bio Hyalur 1mL PFS were conducted. The evaluation confirmed that no discrepancies or deviations were identified throughout the entirety of the batch documentation.
- All stages of the manufacturing and packaging process were executed in full compliance with the procedures and instructions specified in the approved batch packing record.
- In-process controls were diligently carried out by both the Production and IPQA teams at the designated checkpoints and time intervals as defined within the batch record.
- The results of these checks consistently met the predetermined acceptance criteria, with no out- of-specification or abnormal findings reported.

❖ **Blistering:**

- Labelling and blistering activity process were executed in full compliance with the procedures and instructions specified in the approved batch packing record.
- Persons involve in blistering activity is qualified and trained to perform activity and during blistering activity no discrepancy observed in blister formation throughout activity.
- In-process controls were diligently carried out by both the Production and IPQA teams at the designated checkpoints and time intervals as defined within the batch record during blistering activity.
- No breakdown or incident observed during blistering activity and no rejection observed during visual inspection activity related to reported complaint.

❖ **Sterilization:**

- Sterilization process carried out as per instructions mentioned in Batch Record. Sterilization print out record has been reviewed and no discrepancy observed.
- No ambiguities and blister damage has been observed after sterilization when units were visually inspected.

❖ **Final Packing:**

- 100 % visual inspection has been carried out during final carton packing activity performed as per process.
- During In-process, checks no discrepancy observed related to reported complaint, during in- process check blisters were thoroughly verified and found satisfactory.
- Hence, there is no probability that any in-house damage blisters are packed and shipped to customer.

❖ **Out Bond for Delivery (OBD) Verification:**

- OBD verification activity carried out as per process mentioned in respective SOP during activity no discrepancy observed.
- Physical verification of shipment ready for dispatch was done by IPQA personnel as per dispatch checklist duly signed by dispatch manager / designee and found as satisfactory.
- Quantity of product and OBD has been verified by QA, throughout OBD verification process, no anomaly observed related to quantity of product.
- When the Batches were dispatched from site there is no damage blisters has been found and shipment was dispatched in appropriate condition.

❖ **Transport Validation:**

- The transport validation of product has been carried out along with product validation during product / blister introduction.
- As per the transport validation performed, it was identified that the transport validation is performed with all required standard requirement and it meets predefined specification limits.

❖ **Review of deviation/ OOS reported during manufacturing and testing of the complaint batch**

- No deviation / laboratory investigation (OOS/OOT) has been reported relevant to the reported product complaint batch.
- The investigation conducted including all potential factors and process steps and found to be in compliance with established procedures and standards. Personnel are qualified and trained, materials are from approved vendors, equipment is maintained and calibrated, all processes followed approved methods, in-process controls and testing results were within specifications.
- Therefore, no issues were identified in any of these areas, ruling out all potential causes at manufacturing site for received market complaint.

- **To addressed this cause of complaint, below detailed studies were planned for following actions,**
  - Detailed evaluations were conducted to assess blister performance under different conditions, including temperature exposure. Stability studies and performance tests were performed to evaluate the robustness of the blister under defined storage and handling conditions.
  - **In-House Studies and Design Assessment:** Multiple in-house studies were carried out to understand potential risk factors. These included evaluation of temperature-induced volume expansion, the impact of sterilization on blister thickness, and possible design improvements in coordination with the approved blister supplier. Additional studies assessed the effect of PP film roll thickness and polymer characteristics on blister quality.
  - From the above although assignable root cause is not identified since all factors were with in required criteria the scope for improvements in machine and process optimization was identified and implemented as described below;
  - **Machine and Process Optimization:** Several machine-level assessments and process optimization activities were implemented to improve blister formation consistency. Support was obtained from the Original Equipment Manufacturer (OEM). The OEM team visited the site and evaluated the blistering machine. Based on their recommendations, additional assessments and process optimizations were suggested. An in-house study was conducted to evaluate blister stability at various temperatures. Based on the study outcomes, optimized process parameters were finalized and implemented for commercial production.
  - In parallel with the above optimization activities as per **CAPA PR#5104** and to meet market requirements, ready-to-use blisters (Outsourced) from an approved external vendor were introduced. These blisters were qualified for use, and in-house studies were conducted to assess their robustness and stability. Based on satisfactory results, the Outsourced blisters were implemented for commercial use. Blister performance and product condition continue to be monitored during in-process stages, and critical quality parameters are routinely evaluated.
  - **For further improvements, a CAPA PR#16280** for the new mould has been taken and implanted. Qualification and evaluation studies are currently in progress. These activities are planned for completion by March 2026, with commercial production using the new blister configuration planned from April 2026.
  - A comprehensive investigation confirmed that all manufacturing processes, materials, equipment, and sterilization parameters were compliant with approved specifications, and no assignable root cause was identified at site.

- As part of continuous improvement action all above actions under CAPA PR#5104, extended blister performance studies, OEM-supported machine assessments, and process parameter optimizations were implemented.
- Further development of a new mold (CAPA PR#16280) is completed and installation qualification is ongoing.
- Following implementation of these measures, blister performance has been optimized. Any potential blister damage is visually detectable prior to use and does not impact product safety.
- A risk assessment confirms that other distributed lots are not affected by this incident. Continuous monitoring remains in place to ensure sustained compliance and product robustness.