File No. PAC/BP/19/Baxter/Voluntary recall of Fibrin sealant kit Tisseel Lyo/2024-BD
Directorate General of Health Services
Office of Drugs Controller General (India)
(Blood Product)
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi 110 002
Dated: 02 SEP 2024

To

All Stake Holders/General Public

Public Notice

Subject: Voluntary Recall (Grade III) Notification for the Product Generic Name: Fibrin Sealant VHS/D powder and solvent for Sealant I.P. Name: Tisseel LYO from the manufacturing facility Takeda Manufacturing Austria AG, Industriestrasse 67, A-1221, Vienna, Austria-reg.

Reference: Firm Letter no. BAX/AS/CDSCO/2024/058 dated 19.06.2024 and E. NO. 41359.

Sir,

With reference to letter cited above on the subject matter wherein the Firm M/s Baxter (India) Pvt. Ltd, 5th Floor, Tower A, Building No. 9, DLF Cyber City, DLF phase III, Gurgaon-122002, Haryana, India has informed about the voluntary recall of imported product Generic Name: Fibrin Sealant VHS/D powder and solvent for Sealant I.P. Name: Tisseel LYO imported from the manufacturing facility Takeda Manufacturing Austria AG, Industriestrasse 67, A-1221, Vienna, Austria.

M/s Baxter Healthcare Corporation has issued a voluntary recall for the 4 mL and 10 mL Tisseel Fibrin Sealant Kits listed below due to extended dissolution time of the sealer protein concentrate, observed during stability studies at storage temperature of 25°C.

All other quality parameters (chemical and physical) comply with product specifications and no instances have been observed during testing where the Sealer Protein concentrate does not completely dissolve. The portion of the product that took longer to dissolve was approximately 1% and consists of fibrinogen, human albumin, and fibronectin, which are all part of the product composition. Firm does not have replacement kits for the 4 mL and 10 mL Tisseel Lyo Fibrin Sealant Kits.

The impacted lots detail is as below:

Product Code	Product Name	Pack size	Affected Batch No.	Quantity Imported	Quantity Available in Warehouse
1504384	Fibrin Sealant VHS/D powder and solvent for Sealant I.P.	4 ml	T5A010AA T5A047AC T5X053AD T5X056AD T5X075AA	3112 2685 3120 3120 3119	500
1505816	Fibrin Sealant VHS/D powder and solvent for Sealant I.P.	10 ml	T5X036AE	62	43

Further, Firm submitted letter dated 11.06.2024 for urgent Drug Recall informing the Problem Description, affected product, hazard Involved, Action to be taken by Customers. (Copy enclosed). This is for the information and necessary action.

Yours faithfully

(RAJEEV SINGH RAGHUVANSHI)
DRUGS CONTROLLER GENERAL (INDIA)

Copy to: CDSCO Website for information.

Baxter

Urgent Drug Recall

Jun 11, 2024

Dear Healthcare Provider or distributor:

Problem Description

Baxter Healthcare is issuing an Urgent Drug Recall for the 4 mL and 10 mL **Tisseel** Fibrin Sealant Kits (commonly referred to as **Tisseel** Lyo fibrin sealant), listed below due to extended dissolution time of the sealer protein concentrate, observed during stability studies at storage temperature of 25°C.

All other quality parameters (chemical and physical) comply with product specifications and no instances have been observed during testing where the Sealer Protein concentrate does not completely dissolve. The portion of the product that took longer to dissolve was approximately 1% and consists of fibrinogen, human albumin, and fibronectin, which are all part of the product composition.

Baxter does not have replacement kits for the 4 mL and 10 mL Tisseel Lyo Tisseel Fibrin Sealant Kits. **Healthcare providers may continue to safely use the products** listed below if the fibrin sealant is prepared in advance to ensure it is fully dissolved and ready to be used when needed. If the Sealer Protein Concentrate has not fully dissolved within 20 min, discard the vial, and prepare a fresh kit.

Affected Product

Distribution of the impacted product began on 06 Aug 2022 in India.

Product Code	Product Description	Lot Number
1504384	**TISSEEL KIT VHSD SA 4ML INDIA**	See attachment A
1505816	**TISSEEL KIT,VHSD,SA,10ML**	

Hazard Involved

If the sealer protein concentrate is insufficiently dissolved, intraoperative delay in therapy could result while a fresh kit is being prepared. **The likelihood that this would lead to harm for the patient is remote** as **Tisseel** is an adjunct to hemostasis and sealing. Furthermore, as shown in laboratory testing, the product is still usable and effective even if the sealer protein is not completely dissolved. **Tisseel** is intended for epilesional use only; it is not to be used intravascularly.

As of 05/22/2024, Baxter has not received any confirmed complaints or adverse events reported associated with this issue on the impacted products.

Actions to be taken by Customers

1. **Healthcare providers may continue to safely use the products listed above if the fibrin sealant is prepared in advance to ensure it is fully dissolved and ready to be used when needed.** If the Sealer Protein Concentrate has not fully dissolved, discard the vial, and prepare a fresh kit.
2. If you have unused **Tisseel** Fibrin Sealant Kits that you would like to return, contact Baxter Healthcare Center for Service to arrange for return and credit.
3. Once Baxter has implemented corrective actions to resolve the issue, a follow-up notification will be sent to customers to provide additional instructions.
4. **If you purchased this product directly from Baxter, complete the enclosed Baxter Customer Reply Form** and return it to Baxter by scanning and e-mailing it to Baxter sales team or **india product complaints@baxter.com**. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices,

Clinician comments on units that were affected: No comments from Clinician yet, however based on the FA letter sent to the impacted customers, if there are any comments we will update your good offices.

Currently, investigation is ongoing to determine the root cause and further information will be provided once available.

Please be assured of our full cooperation for any additional information that may be required.

Thank you.

Yours sincerely,

For Baxter (India) Pvt. Ltd.

Electronically signed by: Deepali Deshmukh
Reason: I approve this document
Date: Jun 20, 2024 09:16 GMT+5.5

Deepali Deshmukh
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Enclosure:

Copy of Healthcare provide/distributer communication letter.