Date: 21 January 2022

Reference Number F22-001

Field Safety Notice

A single manufacturing lot, which has one of two labels on the carton, is the subject of this field safety corrective action (FSCA):

Incorrect Product Code, Description, Lot Number and Expiration Date

Product Code	Product Description	Lot Number	Expiration Date
SH3D05	GalaFLEX™ Scaffold 7.5 cm x 21.0 cm Large Oval	190405	2021-08-22

Correct Product Code, Description, Lot Number and Expiration Date

Product Code	Product Description	Lot Number	Expiration Date
CE0608	GalaFLEX™ Scaffold 15.0cm x 20.0 cm	210456	2023-09-30

Dear Distributor: _____

Galatea Surgical, Inc., a wholly owned subsidiary of Tepha, Inc. is conducting a FSCA (recall) on a single manufacturing lot of GalaFLEX® Scaffold 15.0 cm x 20.0 cm, that is labeled with either of the following information:

	Correct Label	**Incorrect Label**
Product Description	GalaFLEX™ Scaffold 15.0cm x 20.0 cm	GalaFLEX™ Scaffold 7.5 cm x 21.0 cm Large Oval
Product Code	CE0608	SH3D05
Lot number	210456	190405
Expiration Date	2023-09-30	2021-08-22

This recall only applies to GalaFLEX® product with the lot numbers specified above. Additional lots of GalaFLEX® or other Galatea Surgical or Tepha scaffolds are not affected by this recall.

Tepha Inc. initiated this FSCA for a single manufacturing lot based on the observation that there is a labeling error on the product. The use of the product is not likely to cause adverse health issues given that the lot of product has met all safety and performance specifications. In addition, the labeling indicates that the product is expired and therefore should not have been used.

As background for what prompted this FSCA, it was discovered that the outer envelope was labeled with incorrect information on a subset of the lot. For the incorrectly labeled units (Figure 2), the envelope identifies the product as GalaFLEX Scaffold, but with a product description, product code, and lot number for GalaFLEX 3D scaffold. See pictures below:

Figure 1. Correct REF Code, Lot Number and Expiration Date

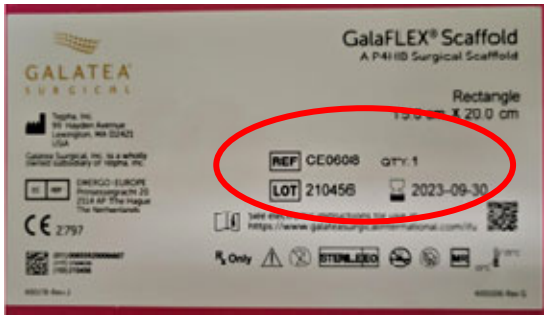
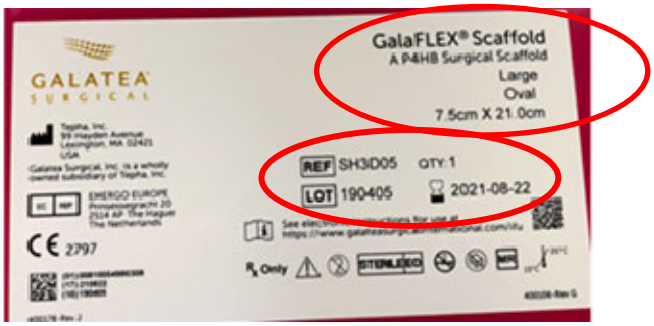


Figure 2. Incorrect REF Code, Lot Number and Expiration Date



A total of 586 devices were released in this lot; 81 devices were shipped to our distributors, while the remaining inventory is on site at Tepha's manufacturing facility.

Our records indicate that you have received _____ unit(s) from this lot that is subject to the FSCA. **We are requesting that you return product from this manufacturing lot regardless of its labeling.**

Please complete the following:

1. Immediately review your inventory for the lot numbers listed above.
2. If you do not have any of the affected product in your inventory, complete the enclosed Recall Acknowledgement Form, indicate that you have zero (0) inventory.
3. If you have shipped any of these devices to your customer(s), notify them immediately to determine if there is any of the affected product in their inventory. Complete the enclosed Recall Acknowledgement Form and indicate the number of devices in the customer's inventory. If there are devices in the customer's inventory, have the customer return the affected product to your facility.
4. If you have inventory from the affected product, complete the enclosed Recall Acknowledgement Form, indicate the number of devices of the lot number that you have in inventory.
5. Fax the completed form to +1 (781) 357-1701 or email it to johnson@tepha.com. A representative will contact you to arrange for the product return and replacement.

We sincerely regret any inconvenience this matter may have caused and we remain committed to providing you with the highest quality products and services. Please do not hesitate to contact me at +1 781-357-1772 or via email at johnson@tepha.com if you have any questions regarding this notification.

The appropriate Competent Authorities have been made aware of the FSCA.

Thank you in advance for your cooperation and support.

Sincerely,

Elizabeth Johnson
Director Quality Assurance, Tepha, Inc.

Attachment: Recall Acknowledgement Form

IMMEDIATE ATTENTION REQUESTED

Recall Acknowledgement Form for:

Correct Product Code, Lot Number and Expiration Date

Product Code	Product Description	Lot Number	Expiration Date
CE0608	GalaFLEX™ Scaffold 15.0cm x 20.0 cm	210456	2023-09-30

Incorrect Product Code and Lot Number

Product Code	Product Description	Lot Number	Expiration Date
SH3D05	GalaFLEX™ Scaffold 7.5 cm x 21.0 cm Large Oval	190405	2021-08-22

Check the appropriate box and complete the tables below. Please fax +1 (781) 357-1701 or email the form to johnson@tepha.com

☐ All devices have been shipped from the affected manufacturing lot and we do not have any remaining inventory. Indicate zero (0) quantity in the table below.

☐ We have shipped _____ devices to customers and have notified our customer to return unused inventory from the affected product to us.

☐ We have product from this manufacturing lot at our facility and have discontinued use. We have quarantined the product. Please indicate quantity of each labeled product and date below.

Please complete the following:

Distribution Facility:	QTY of Devices in Inventory: Lot 210456: _____ Lot 190405: _____
Address:	Completed By (print name):

_____ _____

Signature Date

After we receive this form, a representative will contact you to arrange for product return and replacement (if applicable).