

November 7, 2018

**URGENT FIELD SAFETY NOTICE**

Dear Customer:

The purpose of this letter is to advise you that Collagen Matrix, Inc., the manufacturer of ZCORE™ Porcine Xenograft Particulate, is voluntarily recalling a specific lot number of ZCORE™ Porcine Xenograft Particulate 4.0 cc that has been recently supplied to you.

**DETAILED PRODUCT INFORMATION**

<b>Product</b>	ZCORE™ Porcine Xenograft Particulate
<b>Contents</b>	4.0 cc (as labeled)
<b>Particle Size</b>	0.25 – 1.0 mm
<b>Reference Number</b>	ZS400
<b>Lot Number</b>	ZD0027
<b>Expiration Date</b>	2021-04-30
<b>UDI</b>	+D765ZS4000/\$\$3210430ZD0027Q

**REASON FOR THE RECALL**

The reason for the recall is that there is a possibility that the product labeled as 4.0 cc volume may only contain 2.0 cc volume and is therefore mislabeled.

**RISK TO HEALTH - NONE**

There is **no risk to patient health** as a result of the labeling error.

The product met all other product specifications for release and distribution.

No treatment or action beyond normal follow-up needs to be taken for patients who have already been implanted with the product.

**ACTIONS TO BE TAKEN BY THE USER:**

Complete the attached Certificate of Acknowledgement within 15 days of receipt and email the completed form to **QA@osteogenics.com** or return the form to:

Attn: QA Department  
Osteogenics Biomedical, Inc.  
4620 71<sup>st</sup> Street, Building 78-79  
Lubbock, TX 79424

If any of the items noted in the scope of this letter remain in your possession, please return them along with a copy of the form to the address shown above. Replacement product will be provided upon receipt of the return.

## TRANSMISSION OF THIS FIELD SAFETY NOTICE

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

## OTHER INFORMATION

If you have any questions after reviewing this notice, please call Osteogenics Biomedical, Inc. at **806-796-1923** between **8:00 am and 5:00 pm CST, Monday through Friday.**

Sincerely,



Shane Shuttlesworth  
President

**Certificate of Acknowledgement**

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<b>UDI</b>	+D765ZS4000/33210430ZD0027Q

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

Complete this form within 15 days of receipt and email completed form to QA@osteogenics.com or return the form to the address below along with any of the above referenced product to return.

**PRODUCT DISPOSITION (TO BE COMPLETED BY CUSTOMER)**

Product Code	Lot Number	Qty to be returned	Qty used / implanted	Qty not located

Printed Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Title: \_\_\_\_\_ Telephone: ( ) \_\_\_\_ - \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Facility Name: \_\_\_\_\_

Facility Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_

**Note:** This form must be returned to Osteogenics Biomedical, Inc. before this action is closed for your account. It is important that you complete this form and email a copy to [QA@osteogenics.com](mailto:QA@osteogenics.com) or mail to the address below.

Product Recall  
Attn: QA Department  
Osteogenics Biomedical, Inc.  
4620 71st Street, Building 78-79  
Lubbock, TX 79424