



June 02, 2021

**URGENT RECALL**

**FiberCel Fiber Viable Bone Matrix  
Donor Lot # NMDS210011  
Product Numbers: VBM9901, VBM9905, VBM9910**

Hospital Name: xxxxxxxxxxxxxx  
Address: xxxxxxxxxxxxxxxxxxxx

Dear Risk Manager,

Aziyo Biologics, Inc., (“Aziyo”) is the manufacturer of record for FiberCel Fiber Viable Bone Matrix (“FiberCel”), and is voluntarily recalling **one Lot** of the FiberCel product, **Donor Lot Number: NMDS210011**. This voluntary recall is being issued out of an abundance of caution following a customer complaint from one hospital that reported post-surgical infection in 7 of the 23 patients that have received FiberCel from this Donor Lot. As of the date of this communication, four of these patients have tested positive for Tuberculosis.

Patient safety is our utmost priority. Accordingly, Aziyo is instructing any customer who received FiberCel product from this single Donor Lot to immediately examine its inventory and quarantine any remaining product. If you further distributed FiberCel product from this Donor Lot elsewhere, please identify your customers and notify them at once of this request to immediately quarantine and return any remaining product. Your communication to your customers may be complemented by including a copy of this Recall letter. Further information on return of this product is attached to this communication.

Our records indicate that your facility received product from this donor lot of FiberCel. Please review your inventory records under the potential inventory category names of: FiberCel; Aziyo Biologics; Spinalgraft Technologies; and/or Medtronic:

- **Shipping Date(s):** xxxxxxxxxxxxxxxxxxxx
- **Product Name:** FiberCel
- **Donor Lot Number:** NMDS210011
- **Allograft ID(s):** xxxxxxxxxxxxxxxxxxxx

Please complete the enclosed response forms with all available information even if you do not have remaining FiberCel product from this Donor Lot, including potential adverse reactions, and return it to Aziyo as soon as possible. Aziyo will provide prepaid shipping containers for the return of any unused FiberCel product from this Donor Lot. Your assistance with this matter is greatly appreciated.

Aziyo Biologics, Inc.  
880 Harbour Way South  
Suite 100  
Richmond, CA 94804  
T: 855 416 0596 | [Aziyo.com](http://Aziyo.com)



Please monitor for any adverse health consequences experienced with the use of this product. If an adverse health consequence is observed, it should be reported to Medtronic and may also be reported to FDA's MedWatch Adverse Event Reporting program:

- Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- Regular Mail: use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Phone: (800) FDA-1088

If you have any questions about this recall please contact Aziyo Biologics at:

Name: Petar Georgiev  
Phone: 510-730-7886  
Email: [recall@aziyo.com](mailto:recall@aziyo.com)

This recall is being made with the knowledge of the Food and Drug Administration and the Centers for Disease Control and Prevention.

Enclosures:

- Recall Return Response Form 1, for report product units in inventory
- Recall Return Response Form 2, for transplanted or destroyed product units

Petar Georgiev

Regulatory Compliance Manager  
Aziyo Biologics, Inc.

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