HOW SUPPLIED.
ViBone® bone allograft is supplied frozen and packaged in a sterile polycarbonate jar placed in a sterile outer peel pouch. The exterior surface of peel pouch is not sterile. Allograft volume is indicated on the package label.

STERILITY CONTROL
ViBone® allografts have been processed under aseptic conditions to prevent contamination and cross-contamination of the product. Destructive microbiological testing per USP <71> Sterility Tests is performed on samples from each lot and must show “No Growth” after a 14-day incubation in growth promoting media.

PRECAUTIONS
Inspect the integrity of the package upon receipt and before use. Do not use ViBone® under the following conditions:

• The container in which the allograft is stored is damaged or the label has been damaged or defaced.
• The allograft expiration date has passed.
• Recommended storage conditions have not been maintained.

INSTRUCTIONS FOR USE
It is important to utilize aseptic techniques when unpacking the allograft.

1. Examine the labeling and outer peel pouch. Do not use if there is evidence that the integrity of the outer peel pouch has been compromised.
2. Aseptically present the inner jar onto a sterile field.
3. Don sterile surgical gloves; place the unopened jar into a sterile basin and fill with warm (approximately 37°C) sterile saline to just below the jar lid. DO NOT submerge the jar lid.
4. Thaw ViBone® for approximately 5-15 minutes, depending on allograft size.
5. Remove the jar lid and remove the product from the jar.
6. The allograft tissue should be pliable. If the allograft is still frozen, warm by holding the allograft with sterile gloved hands until completely thawed and pliable.
7. ViBone® should be transplanted within two hours of thawing and all unused product must be discarded. Product is intended for single use and should not be refrozen or sterilized.

TRACEABILITY
The FDA requires traceability from the donor to the recipient. The physician is responsible for completing the recipient records to ensure traceability. As a convenience, pre-printed peel-off labels are included with each allograft. Using the labels, record the allograft tissue identification information in the patient medical record. In addition, an Allograft Usage Report is included with the allograft. The physician is to complete the report and affix one of the pre-printed labels to it. Scan and email the completed report to AllograftUsage@Aziyo.com.

ADVERSE REACTION
The physician must promptly report any adverse outcomes potentially attributable to ViBone® to Aziyo at 800-922-3100.

Manufactured By:
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FDA Registration No. 1000100754
CTO Registration Certificate No. 100242
Accredited by the AATB®

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