

# Augment<sup>®</sup>

## Regenerative Solutions

BioMimetic Therapeutics, LLC, a wholly owned subsidiary of Stryker Corporation, manufactures Augment<sup>®</sup> Bone Graft and Augment<sup>®</sup> Injectable (Augment<sup>®</sup> Regenerative Solutions). These products received FDA Premarket Approval (PMA) as an alternative to autograft in arthrodesis (fusion) of the ankle and hindfoot. Augment<sup>®</sup> Regenerative Solutions are different from any other biologic options available today for hindfoot and ankle fusions because of the level of supporting clinical evidence, having succeeded in securing approval via the rigorous FDA PMA review process.

### Below are some frequently asked questions.

#### Is Augment<sup>®</sup> human tissue?

**No.** Augment<sup>®</sup> is not human tissue and is not regulated as a tissue product, but rather is classified as a combination drug/device product and has been approved via PMA P100006. Augment<sup>®</sup> is composed of synthetic recombinant human platelet derived growth factor-BB (rhPDGF-BB) at a concentration of 0.3mg of recombinant protein per ml, which is combined with the included calcium phosphate carrier material intra-operatively. This product is free of any human tissues, cells or blood, and therefore avoids conflict with religious or cultural prohibitions against transfusion of whole blood or blood products.

#### How is the product shipped?

The product is shipped from our facilities directly to the intended customer using a specialized shipping container that is validated to maintain a FDA approved shipping range of **34-63°F/1-17°C mean kinetic temperature<sup>1</sup> (MKT) for up to 119 hours from the time of shipment.**

#### How is the product stored?

Once received, the product should be stored in standard refrigerated conditions for drugs, vaccines, and drug/device combination products (**36-46°F/2-8°C**) to preserve protein quality for the labeled shelf life. The most appropriate storage location for the product is likely to be in a pharmacy refrigerator with other drug and drug combination products (e.g. insulin with Injector, pre-mixed antibiotics, etc.)

#### Can an Augment<sup>®</sup> kit be returned?

Yes, if the **shipping container** is unopened and the return is processed and shipped within 48 hours of original receipt. If either of these conditions are not met, the product **cannot** be returned, and the facility will be charged for the product.

<sup>1</sup>Mean kinetic temperature is a way of calculating the overall effect of temperature fluctuations during transit of temperature sensitive pharmaceuticals. Using a validation process with MKT calculations allows for temperature fluctuations above 63°F/17°C. The MKT validation process was reviewed and approved by the FDA, confirming this shipping method preserves product viability.

**A shipper containing an Augment<sup>®</sup> kit is delivered to the pharmacy and stored unopened for a few days. When opened the internal temp tag reads 64<sup>o</sup>F/18<sup>o</sup>C. Is this a problem? The package insert says to store at a temp of 2-8<sup>o</sup>C/36-46<sup>o</sup>F.**

The FDA approved shipping temperature range is **34-63<sup>o</sup>F/1-17<sup>o</sup>C MKT<sup>1</sup>**. If the product remained in the sealed shipper within the shipping window of 119 hours or less, then 64<sup>o</sup>F/18<sup>o</sup>C or warmer is still within the validated range<sup>2</sup>. If it was removed from the shipper after the 119-hour shipping window and the temperature was read at 64<sup>o</sup>F/18<sup>o</sup>C, the product would fall outside the validated range, and should be discarded.

**An account has a refrigerator storing Augment<sup>®</sup> that was open for over 16 hours. When discovered, they noted that the temperature was 65<sup>o</sup>F and the product was warm to the touch. Can the product be used?**

In this scenario, or in a similar scenario in which the refrigerator does not function for a period of time, the safest option is to discard and replace.

## **Augment<sup>®</sup> is removed from refrigerated storage for a surgery...**

**The Augment<sup>®</sup> kit is removed from refrigerated storage, opened on the back table, and mixed. The surgery has unexpected complications delaying the implantation of the product. Is the product ok to use?**

Once mixed the product should be implanted **within 60min or discarded**.

**An Augment<sup>®</sup> kit has been taken out of refrigerated storage (36-46<sup>o</sup>F/2-8<sup>o</sup>C) and brought to room temperature (60-86<sup>o</sup>F/15-30<sup>o</sup>C) prior to a scheduled surgery. The surgery is postponed. Can the kit be returned to refrigerated storage and used at a later date?**

Assuming that the box is undamaged and security seal is unbroken, the product can be placed back into refrigerated storage after being brought to room temperature (60-86<sup>o</sup>F/15-30<sup>o</sup>C). This cycle can occur **twice** and the duration of each exposure to room temperature **should not exceed 10 hours**. If the product is not used the **third time** after being brought to room temperature, it must be **used within 10 hours or discarded**.

Please contact me directly if further data is needed.

Sincerely,

**Brian Jacoby**

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