



Memorandum

To: AlloSource Customers

From: Donna Sinn, Vice President
Regulatory Affairs and Quality Assurance

Date: December 15, 2009

Re: Transport Storage Conditions

This information is being provided to customers who seek to better understand the methods employed to maintain temperature control during the transport and in the storage of allograft tissue provided by AlloSource.

AlloSource adheres to the American Association of Tissue Bank (AATB) Standards and the regulations established by the Food and Drug Administration (FDA) in its production and distribution of allograft tissue. Additionally, AlloSource provides information in its package insert that further describes the storage conditions for the various types of processes used to produce allograft tissue, and includes instructions for preparing the allograft prior to implantation.

Freeze-Dried or Lyophilized tissue

Freeze-dried tissues do not require any form of temperature maintenance during transport and can be stored without the need for refrigeration or freezing for a period of up to five years. While the recommended storage temperature for this type of allograft is between 15°C and 30°C, the most important consideration is package integrity. Graft packaging should be checked at the time of receipt to ensure that all seals are intact and that no damage to the packaging materials has occurred.

Refrigerated tissue

Tissue that requires refrigeration should not be frozen nor should it reach temperatures outside the range of 1°C – 10°C for storage. The shelf life of refrigerated tissue is specific to each graft type and should be reviewed by examining the individual package label.

Frozen or Cryopreserved tissue

Frozen tissue is aseptically processed and then frozen to -80°C for storage and distribution. Tissue should be maintained in the range of -80°C and -40°C as this qualifies for a shelf life of up to 5 years, but can be stored above -40°C and below -20°C for a period of six months. Graft packaging should be checked at the time of receipt to ensure that all the seals are intact and that no damage to the packaging materials has occurred.

Each of the containers that are used for transporting AlloSource allografts have been validated for temperature control and durability. The validations include calculation of sublimation rates, which are used to determine the expiration time of the transport container based on the amount of dry ice or wet ice placed in the container. These transport expiration times are posted on the shipping label on the outside of the container.

We hope this information is helpful.