AlloFuse Select @

STORAGE & PREPARATION GUIDE

Natural osteoconductive, osteoinductive and osteogenic properties with native, viable bone forming cells to help initiate and nurture bone growth delivering the benefits of autograft without the drawbacks.



INSTRUCTIONS

AlloFuse[®] Select CM must be stored at the proper temperature to maintain its integrity. Once the AlloFuse Select CM shipment has been received, remove the package from the shipping container. The bone graft must be stored as is, in its branded packaging, at $-80^{\circ}C \pm 5^{\circ}C$, $(-112^{\circ}F \pm 9^{\circ}F)$. When properly stored at $-80^{\circ}C \pm 5^{\circ}C$, AlloFuse Select CM has a five-year shelf life. The bone graft should remain at this temperature until it is ready to be used.

If AlloFuse Select CM is stored at temperatures between -45°C and -75°C (-49°F and -103°F), the bone graft must be used within 90 days. Within this 90 day period, AlloFuse Select CM may be returned to storage at -80°C + 5°C to maintain its five-year shelf life.



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READY TO USE IN A FEW SIMPLE STEPS

AlloFuse[®] Select CM is ready for use after thawing – no decanting or mixing required.

V

Remove inner tray from the box. Using aseptic technique, peel open the tray from the marked corner.



V

- Transfer the vial into the sterile field.
- Place the closed vial in a sterile saline bath that is between 35°C (95°F) and 39°C (102°F).



NOTE: It is recommended to keep the vial closed during thawing. Open the vial just prior to use to ensure the bone graft stays hydrated maintaining cell viability. WARNING: Do not use a bath at a temperature greater than 39°C (102°F).

AlloSource®, a non-profit organization, offers more than 200 types of precise bone, skin, soft-tissue and custom-machined allografts for use in an array of life-saving and life-enhancing medical procedures. Committed to honoring the gift of donation, the company delivers unparalleled expertise and customer service to its network of surgeons, partners and the country's most reputable organ procurement organizations.

AlloSource is a leader in live cell tissue processing including fresh skin allografts for severe burns, fresh cartilage tissue for joint repair and adult mesenchymal stem cells.

V

Thaw the AlloFuse Select CM for approximately 10 minutes (1 cc) to 25 minutes (5 to 10 cc). Note that the 10 cc vial might take longer to completely thaw.

NOTE: For increased operating room efficiency, AlloFuse Select CM has up to 6 hours of working time after it is thawed. It is recommended to thaw AlloFuse Select CM during the beginning of the case.

NOTE: If applicable, under New York law, all cellular allografts are limited to <u>5 hours</u> of working.

AlloFuse Select CM is now ready to use. Remove the graft from the vial and implant into place. Do not add any saline or other product to the bone graft. Discard any unused bone graft.



NOTE: Please refer to the AlloFuse Select CM package insert for more information.

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(VIA