

Technical Bulletin

1812

Subject: Update to the CryoStore IFU

Date: December 2018

To: All CryoStore Distributors and Customers

Products Affected: CryoStore Products

Related Documents (attached):

CryoStore Instructions for Use (LC33.12 (Not distributed) and LC33.13)

CryoStore Multi-Chamber Freezing Bag Supplemental IFU (LC184.03 (Not distributed) and LC184.04)

OriGen Biomedical has recently updated the CryoStore Instructions for Use (IFU). This update includes the addition of the recently FDA cleared OriGen Biomedical CryoStore Multi-Chamber Freezing Bag Product Codes and the deletion of the maximum fill capacity section of the product fill volume table (page 1 of the IFU). In addition, a supplemental IFU for the CryoStore Multi-Chamber Freezing Bag will be shipped with all orders of the relevant product codes. An update to OriGen's European Union Authorized Representative is included in the update as well.

OriGen Biomedical CryoStore Multi-Chamber Freezing Bag

OriGen has received FDA clearance for the CryoStore Multi-Chamber Freezing Bag (product code: CS24 and CS30). In addition to FDA clearance, CryoStore Multi-Chamber Freezing Bags hold a CE Mark and are licensed through Health Canada.

The CryoStore Multi-Chamber Freezing Bag is composed of distinct 4-6ml chambers that are filled simultaneously through the channel located at the bottom of the bag. The separation of the individual chambers allows for multiple post-thaw applications. The CryoStore Multi-Chamber Freezing Bag is composed of the same EVA film material as all other OriGen CryoStore bags.



Update to the Product Fill Volume Table

The Product Volume Table on the CryoStore IFU (LC33.12) includes validated maximum and minimum freeze volumes in milliliters. The updated table does not include the previous maximum capacity in milliliters section of the table. The freeze volume recommendation is based on horizontal freezing in a standard cassette [internal thickness of approximately 0.37 inches (0.9cm)]. If the bag is frozen in another manner, the optimum fill volume must be determined by the user.



European Union Authorized Representative Transition (LC33.13)

OriGen Biomedical is transitioning to a new European Union Authorized Representative (EU AR). This change will be reflected on the last page of the CryoStore IFU. Additional information about the EU AR can be found on TB 1812.19[00] European Union Authorized Representative Transition and TB1812.21[00] OriGen Removal of the EU Authorized Representative (EU AR) on Instructions for Use.

Ordering and Questions

The CryoStore Multi-Chamber Freezing Bag is available for sale in the EU, Canada, and the USA. For products in other geographies please contact your distributor. Please contact your Account Manager at OriGen to request samples.