



Blood Cell Storage, Inc. (BCSI)
123 NW 36th St.
Suite 220
Seattle, WA 98107

23 October 2019

CSMP – Field Advisory Notice (FAN)

sv² sensor kit changes: expiration dating and packaging

231019SV20019

Identified Issue and Analysis:

The purpose of this notification is to inform you that Blood Cell Storage, Inc. (dba “BCSI,” “SAFE Sens”) recently implemented changes to its sv² sensor kits. These changes consist of an extension to the maximum expiration dating assigned during the sensor manufacturing calibration step, as well as a packaging update.

We are pleased to announce that the sensor kit expiration dating has been extended by an additional 6 months. Previously a 12-month expiration maximum, the kits will now carry a maximum of 18 months from date of sensor calibration.

The outer packaging has undergone a color change, and the sensor kit mylar bags are now black in color. As an appearance change, all other attributes including bag material, dimensions, form, and function will remain the same as with the original blue-colored bags.

Impact to Users:

From a product quality, performance/function, and customer use perspective, these changes will have no impact to customers. There will be no change to product descriptions or part numbers, and there will be no change to our Quality Release Criteria.

The longer expiration dating will allow for easier consumable management for vendors and end users alike. Under this new dating, BCSI’s vendor policy is to not ship kits with less than 12 months expiration remaining, unless previously approved by the customer. Before placing an order, we encourage vendors to inquire with our sales team at orders@safesens.com with any questions about product availability or expiration dating of BCSI’s inventory.

If you have any questions or require further documentation on these changes, please contact our support team at support@safesens.com.

Thank you for your continued interest in the SAFE Sens products!



Evan Rhead
Product Manager
Blood Cell Storage, Inc.
evan.rhead@safesens.com
1.425.654.8457

29 October 2019

Date

Transmittal& receipt acknowledged by CSMP

Signature

Date