

SOP 305-15 Rev. 04

CHANGE NOTIFICATION LETTER

Changes to Bags 91-200-84, 91-200-85, 91-200-86, and 91-200-87

January, 2016

Please note that this notification describes two modifications to the products:

- 1) External luer/tubing interface modification, and
- 2) Secondary product packaging.
- 1. External luer/tubing interface modification:

A cable tie will be added external to the fluid path to strengthen the overall connection between the bag and PVC tubing pieces. The addition of the cable tie improves tensile strength resulting in an overall stronger junction connecting the tubing to the bag. The cable tie modification is external only and thus there is no change to the product path (i.e. product contact). No other changes were made to the actual product.

2. Secondary product packaging:

Packaging of the products will be reduced from 3 pouches to 2 pouches to allow for easier handling by the end user. This change does not impact the function of the products in any manner.

If you have any questions regarding this change, please contact Corning Scientific Support (<u>Scientificsupport@corning.com</u> or (800) CELLGRO (235-5476)).

