OriGen
BIOMEDICAL

URGENT SAFETY NOTICE

O-Wrap, Tissue-Vault, and CryoStore Accessories,
FSCA: FA-2019-001
Device Correction

09.09.2019

Dear Distributor,

The devices listed below are subject to a field safety corrective action and as such, OriGen kindly requests your cooperation in carrying out the actions listed in this notice regarding the below-listed products.

Part/ Model #	Part Description	Lot(s)	Intended Use
CBS	DMSO-Resistant Bag Spike with Needle-Free Injection Port	U20617 U20646 U20683 U20711 U20725	Fluid transfer
SC-1	4-way stopcock, individually pouched	U20596	
OW 2436	O-Wrap 24x36cm pouch for LN freezing, packs of 5	U20595	Protection of other freezing bags in long term frozen storage
OW1330	O-Wrap, overwrap pouch for freezing, 13x30cm	U20662	
OW1430	O-Wrap, overwrap pouch for freezing, 14x30cm	U20630	
OW1430T	O-Wrap, overwrap 3-layer pouch for freezing, 14x30cm	U20706	
TV0909	TissueVault, Cell and Tissue Freezing 9x9cm bag	U20732	Freezing cells and tissues
TV0918	TissueVault, Cell and Tissue Freezing 9x18cm bag	U20592 U20759	
TV1430	TissueVault, Cell and Tissue Freezing 14x39cm bag	U20647 U20736	
TV1950	TissueVault, Cell and Tissue Freezing 19x50cm bag	U20731	

A field safety corrective action is being initiated for these products following one instance in the field and one instance on unreleased product of an unsealed sterile barrier pouch that shows no evidence of a seal ever being made. The complaint was made on a device that is packaged in a double sterile barrier system, thus there was not a breach of sterility and therefore, no patient harm; however, the in-house detection of an unsealed pouch was on a device packaged in a single sterile barrier system, and thus, reflects a breach in sterility.

A risk assessment and health hazard evaluation were performed on the failure mode of an unsealed pouch with results showing a high health risk for an unsealed pouch of a fully sterile device packed in a single-sterile barrier system (single pouch only). The resulting hazardous situation is contamination of

the device/ breach in sterility of the device, and the associated patient harm is a serious blood infection/ sepsis.

A fully unsealed pouch is very easily detectable by the user and thus, it is unlikely that there have been devices used in the field that have had this packaging issue.

OriGen requests that all distributors who have purchased the parts and lots listed in this notice, which may potentially be affected by this packaging issue, follow the instructions provided below. Please complete all inspection and acknowledgement actions by September 30, 2019.

Instructions for Inspection of Pouch Seals:

1. Identify and quarantine any devices from the lots listed in this notice.
2. Create an area free of clutter, debris, or other product, and large enough to allow segregation and sorting of product without risk of mix-up.
3. Move quarantined product to this work area.
4. Working with one carton at a time to prevent mix-ups, remove pouches from the carton.
5. Inspect each pouch for the sterile seal located on the opposite side of the chevron that is typically pealed to access product before use.
6. Visually verify the presence of a seal at this location.
    a. It should not be necessary to manipulate the product or pouch in any way in order to detect whether the seal is formed or not. A missing seal will be obvious by holding the pouch vertically upright at eye level.
7. If the seal is missing or incomplete set aside in a reject bin.
8. If the seal is complete and present then the pouched product may be placed back into its carton and the carton identified as accepted (by physical location placement or otherwise depending on quantity of product being inspected).
9. If reject product (unsealed pouch) is found, complete OriGen's Material Return Authorization form (RD36), attached as Annex I to this notice.
    a. Leave the 'RMA # (assigned by OriGen to Customer)' blank
    b. In 'Reason for Return:' section, please write 'FA.19.08.13'
10. Send the RD36 form to OriGen Customer Service (t.wilson@origenbio.com). OriGen Customer Service will provide a return label, an RMA# to enter on the RD36 form, and will issue a credit for the product.
11. Appropriately package the rejected product and return to OriGen using the supplied return label.

Instructions for Acknowledgement of Receipt and Actions:

1. Please complete the FSN Distributor Reply Form attached as Annex II to this notice, scan, and send to OriGen Customer Service (t.wilson@origenbio.com).

This information and instruction must be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred and remain unused.

Please note that the Competent Authority of your country has been informed about this communication to distributors.

If you should have any questions or concerns regarding this field notice, please contact Kiersten Soderman, Associate Director of Regulatory and Quality, at k.soderman@origenbio.com or at 512-615-7606.

Thank you for your attention to this notice and for your continued business with OriGen Biomedical.

Sincerely,

Kiersten Soderman
Associate Director of Regulatory and Quality
OriGen Biomedical