

## URGENT FIELD SAFETY NOTICE

### Lifetech Cera™ Vascular Plug System

May 15<sup>th</sup>, 2019

#### Attention: Risk Manager, Health Care Professional

This letter contains important information which requires your **immediate** attention.

#### Dear Customers,

The purpose of this letter is to inform you that Lifetech is initiating an advisory Field Safety Notice related to the Lifetech **Cera™ Vascular Plug System**. The Cera™ Vascular Plug system is composed of Cera™ Vascular Plug, loader, delivery cable and haemostatic valve.

This advisory Field Safety Notice is being initiated due to the potential risks of the delivery cable bending and delivery cable connection failure. Lifetech is the legal manufacturer of the Cera™ Vascular Plug System. According to Lifetech's records, you have received the potentially affected occluders. The affected catalogue codes and lot numbers are listed in Appendix 1.

#### Description of the Problem

Based on customer feedback, Lifetech has identified that there are two potential risks:

- 1) when advancing the plug into the sheath, the thinner part at the distal end of the delivery cable may twist if the physician holds the delivery cable far away from the haemostatic valve, thus, the Cera™ Vascular Plug may not be able to be advanced into the sheath;
- 2) the Cera™ Vascular Plug is pre-connected to the delivery cable after factory releasing, however, the plug may separate from the delivery cable during transportation if the screw connection is not tight, so that the users could not find it easily in the packaging especially for the smaller sized plugs.

A potential hazard for both problems would be a delay of the procedure, either need to replace a new delivery cable or need to take more time to find the plug.

There is no risk to the users, other persons or to patients who are previously treated.

#### Advice on action to be taken:

- 1) Please refer to the Lifetech provided tips and tricks on how to advance the Cera™ Plug device into the delivery sheath to prevent cable bending.
- 2) If find the Cera™ Plug disconnected with the cable prior to opening the sterile pouch, then make sure the opening of the pouch is upward when open the Tyvek pouch, carefully find out the plug in the pouch. After that, screw the plug to the delivery cable and continue to use per the instructions for use.



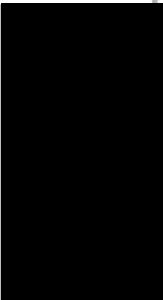
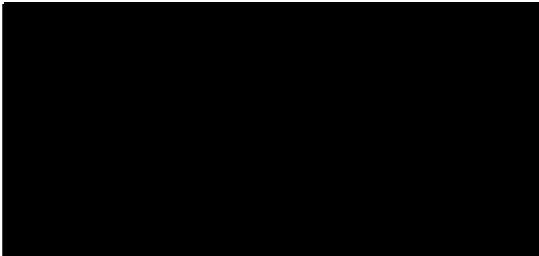
**There is no requirement for customers to return any Cera™ Vascular Plug System to Lifetech. These products can continue to be used in accordance with the Tips in this Safety Notice & the product instructions for use.**

Should you have any questions or require assistance relating to this notification, please contact your representative. If you require assistance in contacting your representative, please contact me.

We confirm that the appropriate Competent Authority have been informed of these actions. Meanwhile, Lifetech will add an action "screw the plug to the delivery cable tightly" in the Lifetech packaging SOP as an emergency method, and train Lifetech related personnel when assembling the components of the Cera™ vascular plug system to make sure that the plug is screwed tightly on the delivery cable. Also, Lifetech will start a packaging change to add more clips on the current scaleboard of inner packaging to keep the plug steadily fixed during transportation.

Please share this notification with others in your organization as appropriate. If product within the scope of this notification has been forwarded to another facility, please alert the facility of this notification. Lifetech is committed to ensuring the product distributed meets the highest quality standards. We appreciate your cooperation and apologize for any inconvenience this issue may cause.

Sincerely,



**Appendix 1:** Affected Catalogue Number , Date of manufacture and Lot Number of Cera™ Vascular Plug System



| Product Name                     | Catalogue Number | Date of manufacture                                | LOT Number |
|----------------------------------|------------------|--|------------|
| Cera™<br>Vascular Plug<br>System | LT-PLUG-04       | All devices manufactured in and after May 4th 2016 | All LOTs   |
|                                  | LT-PLUG-06       |  |            |
|                                  | LT-PLUG-08       |  |            |
|                                  | LT-PLUG-10       |  |            |
|                                  | LT-PLUG-12       |  |            |
|                                  | LT-PLUG-14       |  |            |
|                                  | LT-PLUG-16       |  |            |
|                                  | LT-PLUG-18       |  |            |
|                                  | LT-PLUG-20       |  |            |
|                                  | LT-PLUG-22       |  |            |
|                                  | LT-PLUG-24       |  |            |

