

**URGENT FIELD SAFETY NOTICE****Lifetech IrisFIT™ Patent Foramen Ovale (PFO) Occluders**

March 9<sup>th</sup>, 2017

Dear Risk Manager or Health Care Professional:

The purpose of this letter is to inform you that Lifetech is initiating an Urgent Field Safety Notice for Lifetech IrisFIT™ Patent Foramen Ovale (PFO) Occluders with product codes of LT-PFOs-18, LT-PFOs-25 and LT-PFOs-30, which is specified on the product labels. This Field Safety Notice is being initiated due to a risk of product wire fracture is identified. Lifetech is the legal manufacturer of the IrisFIT™ PFO Occluders. According to Lifetech's records, you have received the potentially affected occluders.

So far the cause of the incident is still under investigation. Lifetech initiates this voluntary recall so that there will not be more patient who may expose to this risk of device wire fracture.

For affected product that has been implanted, no extra action is necessary and patients should continue to be managed in accordance with your standard patient management protocol.

**Customer Advice/Actions:**

- 1.) Please review your inventory for IrisFIT™ PFO Occluders, identify the unused IrisFIT™ PFO Occluder in your inventory, with affected product models as below:  
LT-PFOs-18, LT-PFOs-25 and LT-PFOs-30, which is specified on the product labels.
- 2.) Return all identified IrisFIT™ PFO in your inventory to Lifetech by contacting Ms. Cherry Jing at +86 755 8602 6250 (ext.8807) or by email at [cherry.jing@lifetechmed.com](mailto:cherry.jing@lifetechmed.com). Your Lifetech representative can assist you in the return of affected product as necessary.

**Note** that the Lifetech SteerEase™ Introducer, which is used together with the IrisFIT™ PFO Occluder, is not impacted by this Field Safety Notice.

For questions related to this notification, please contact your representative. If you require assistance in contacting your representative, please contact me.

The Competent Authority of your country has been notified of this issue.

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,

Yanhong Zhang  
RA Specialist



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