



URGENT FIELD SAFETY NOTICE

Lifetech Cera™ Vascular Plug System

September 30th , 2018

Dear Customers:

The purpose of this letter is to inform you that Lifetech is initiating an Urgent Field Safety Notice for a sub-set of Lifetech Cera™ Vascular Plug System listed in the Appendix A. This Field Safety Notice is being initiated due to a potential risk that the size of the loader from a certain batch is too small and the matching delivery cable couldn't pass through. According to Lifetech's records, you have received the potentially affected devices.

This issue can be noticed during pre-operative preparation. A potential hazard would be a delay of the procedure and need to replace a new loader. To avoid recurrence of such issue, Lifetech initiates this voluntary recall. According to Lifetech's investigation, the cause of the issue is that the inner diameter of the loader of a certain batch didn't reach its lower limit, which was caused by the manufacturing process issue of the supplier. See Appendix A for affected Lot numbers and production identifiers.

Customer Advice/Actions:

For distributors:

- 1.) Please review your inventory for Cera™ Vascular Plug System, identify and quarantine the unused affected product with Lot numbers and production identifiers listed in Appendix A. Please share this notification with others in your organization as appropriate.
- 2.) If products within the scope of this notification have been forwarded to doctors/facilities, please notify them and retrieve all affected products. Lifetech will reach you for the ensuring replacement/reimbursement.
- 3.) After gathering all the unused affected products, please send them to address of Lifetech's designation listed below.

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Life Tech Scientific c/o Healthlink Europe
Burgemeester Burgerslaan 40A, 5245 NH Rosmalen
The Netherlands
Tel: +31-(0)73-3030584
Fax: +31-(0)13-5479301

Or you can reach marketing@lifetechmed.com and quality@lifetechmed.com for further details on the address and instruction of packaging.

For doctors:

Please review your inventory, identify and quarantine the unused affected product with Lot numbers and production identifiers listed in Appendix A. Your Lifetech representative will reach you to retrieve and replace/reimburse the product.

For questions related to this notification, please contact your representative. If you require assistance in contacting your representative, please contact Lifetech Scientific by phone or email.

Lifetech is committed to ensuring the products distributed meet the highest quality standards. We appreciate your cooperation and apologize for any inconvenience causing by the issue.

Sincerely,

Lily Shi

A handwritten signature in black ink that reads 'Lily Shi' in a cursive style.

RA Director

Lifetech Scientific (Shenzhen) Co., Ltd.

Tel: +86 755 8602 6250 ext. 6755

Email: shixiaoli@lifetechmed.com

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Appendix A:

Table. The Affected Products on The Markets of EEA, Switzerland and Turkey

Important Notes:

- The lot numbers are specified on the label;
- The Production Identifiers are specified in the second line of Barcode label.

NO.	Product Code	Lot #	Production Identifiers
1	LT-PLUG-04	180107	1721010410180107211801070372
2	LT-PLUG-04	180107	1721010410180107211801070373
3	LT-PLUG-04	180107	1721010410180107211801070374
4	LT-PLUG-04	180107	1721010410180107211801070375
5	LT-PLUG-04	180107	1721010410180107211801070376
6	LT-PLUG-04	180107	1721010410180107211801070377
7	LT-PLUG-04	180134	1721011810180134211801340251
8	LT-PLUG-04	180134	1721011810180134211801340252
9	LT-PLUG-04	180134	1721011810180134211801340253
10	LT-PLUG-04	180134	1721011810180134211801340254
11	LT-PLUG-04	180134	1721011810180134211801340255
12	LT-PLUG-04	180134	1721011810180134211801340256
13	LT-PLUG-04	180134	1721011810180134211801340258
14	LT-PLUG-04	180134	1721011810180134211801340259
15	LT-PLUG-04	180134	1721011810180134211801340260
16	LT-PLUG-06	171252	1720122710171252211712521320
17	LT-PLUG-06	171252	1720122710171252211712521321
18	LT-PLUG-06	171252	1720122710171252211712521322
19	LT-PLUG-06	171252	1720122710171252211712521323
20	LT-PLUG-06	171252	1720122710171252211712521327
21	LT-PLUG-06	171252	1720122710171252211712521328
22	LT-PLUG-06	171252	1720122710171252211712521329
23	LT-PLUG-06	171252	1720122710171252211712521330
24	LT-PLUG-06	180107	1721010410180107211801070384
25	LT-PLUG-06	180107	1721010410180107211801070385
26	LT-PLUG-06	180107	1721010410180107211801070386
27	LT-PLUG-06	180107	1721010410180107211801070387
28	LT-PLUG-06	180107	1721010410180107211801070388
29	LT-PLUG-06	180107	1721010410180107211801070389
30	LT-PLUG-06	180146	1721012410180146211801460777
31	LT-PLUG-06	180146	1721012410180146211801460778
32	LT-PLUG-06	180146	1721012410180146211801460779
33	LT-PLUG-06	171252	1720122710171252211712521325
34	LT-PLUG-06	171252	1720122710171252211712521324
35	LT-PLUG-06	180146	1721012410180146211801460780
36	LT-PLUG-06	180146	1721012410180146211801460781