Voluntary recall: esophageal and tracheobronchial stents
Ranges NES - NESA – EPW et NTS – Lots between 16050212 & 16070862

Bagnolet, August 22nd 2016

Hospital
To the attention of
Department
Street
City
Country

Dear Customer

Origin

We have recently been informed by the manufacturer of a quality problem on a components of stent delivery device mentioned below. Supplier warns of a potential risk to the catheter which could persist on introducers (but not on the stent itself). He therefore decided to implement a voluntary recall of concerned lots.

Cause analysis

Today, the investigations on the manufacture process of this product confirmed the product achieving compliance. It seems that the concern comes from one of the raw materials used.

Corrective and preventive actions

Although a visual inspection may identify non-compliant product, it was decided to establish a voluntary recall; all products will be replaced. In parallel, the raw material controls settings have been enhanced to detect all non-conformities.

Caution implement

Today the concerned lots are not sold any more.

If your institution has in stock a product concerned please return it for exchange.

If you received this product and it has been placed on a patient, there is no residual risk for the patient, no specific action is to be implemented.

Stents to return

If you have some balloon to return, you should contact your supplier, who will inform you of their return procedure:

- **Supplier name :**
  Life Partners Europe - Service qualité
  161 Avenue Gallieni, 93170 Bagnolet – France
  Tel : 01 49 88 85 62 ou 01 49 88 83 41 - Fax : 01 49 88 83 45

Please ensure all the health professionals in your hospital, who use these devices (and in particular the endoscopy operating room) are informed of this FSCA.

You will also find attached an 'acknowledgement of receipt' for this important FSCA, please complete and return as soon as possible.

The competent authority in France, the ANSM, has been informed of this safety notice.

For any additional information regarding this safety notice, please contact the Quality Control Department at Life Partners Europe. (email: a.merle@lifeurope.com).

We apologise for the inconvenience caused by this notice, although it is aimed at guaranteeing patient safety and customer satisfaction and we thank you for your co-operation and understanding in this matter.

Eric Morel d'Arleux — CEO

Amélie Merle — Quality Manager

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ACKNOWLEDGEMENT OF RECEIPT – to return by fax at: -----
I confirm that I have received the safety notice which has been communicated to the users in my centre.

Stents in consignment in your center :

Type de document	N° du document	date du document	Reference	N° Lot	Quantité	Quantité posée	Quantité à nous retourner

The prostheses shown in the table below have been billed to your center after a consignment. If they have been placed in a patient, there is no risk for him.

Type de document	N° du document	date du document	Reference	N° Lot	Quantité	Quantité posée	Quantité à nous retourner

Person in charge of this safety notice:

Surname-First Name: _____

Position: _____

Department: _____

E-mail address: _____

Direct phone: ___ ___ ___ ___ ___

Date: _____ Signature and stamp: