Urgent Field Safety Notice

Commercial name/Model: Hemoclip AG-51044-2300-090-16
Lot No.510160625, 510160628
FSCA-identifier: FSCA-510-161201
Type of action: Recall

Dec.15, 2016

Dear Customer

Origin

We have recently been informed by the manufacturer of a quality problem involving hemoclips mentioned below. Supplier warns of a potential risk to the hemoclip during the release of the hemoclip in the patient. He therefore decided to implement a voluntary recall of concerned lots.

Cause analysis

Today, the investigations on this product confirmed the product achieving compliance. The root cause of the incidents has been identified and the manufacturer has set up actions so that this incident does not happen again.

Corrective and preventive actions

It was decided to establish a voluntary recall; all products will be replaced. In parallel, preventive actions has been set so to ensure product conformity.

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.

Hemoclip to return

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

Support Engineer – Alan Sheng

Organization:

Hangzhou AGS MedTech Co., Ltd.

Tel: 0086-571-87671223-8070

Fax: 0086-571-87671225

Please ensure all the health professionals in your hospital, who use these devices (and in particular the endoscopy operating room) are informed of this recall.
You will also find attached an 'acknowledgement of receipt' for this important recall, please complete and return as soon as possible.

This Notice has been notified the appropriate Regulatory Agency.

For any additional information regarding this safety notice, please contact the Quality Control Department at Hangzhou AGS MedTech Co., Ltd.(E-mail:shengyy@bioags.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.

(Closing paragraph)

Signature:

Alan Sheng

Alan Sheng
Quality Center

Building 6,Kangxin Road No.597,Qianjiang Economic
Development Area, Hangzhou, Zhejiang, 311106 , P.R.China
Tel: 0086-571-87671223-8070
Fax: 0086-571-87671225
Email: shengyy@bioags.com

Customer - City - Country

ACKNOWLEDGEMENT OF RECEIPT – to return by fax at: Lot No.510160625, 510160628
I confirm that I have received the safety notice which has been communicated to the users in my centre.

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

No.	Lot No.	Specification	Production quantity	delivery date	delivery quantity	**Distributor /Hospital**	**Contact person**	**Address**	**Telephone**	**Email**
1	510160625	AG-51044 -2300-090-16	2000	2016/7/7	2000	Life Partners Europe	Amélie Merle	161, Avenue Galliéni/ 93170 BAGNOLET France	+33 149 88 85 62	a.merle@lifeurope.com
2	510160628	AG-51044 -2300-090-16	2000	2016/7/12	2000	Life Partners Europe	Amélie Merle	161, Avenue Galliéni/ 93170 BAGNOLET France	+33 149 88 85 62	a.merle@lifeurope.com

Person in charge of this safety notice:

Surname-First Name: _____

Position: _____

Department: _____

E-mail address: _____

Direct phone: ___ ___ ___ ___ ___

Date: _____ Signature and stamp: